

Patent Law and Policy: 2010-11 Supplement

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CHAPTER 1: INTRODUCTION

Insert on page 66, addendum to the latter portions of “Domestic Patent Reform Legislation”:

While the 109th Congress failed to enact either Smith or Hatch’s version of major reform legislation, the issue of patent reform continued to percolate throughout the 110th Congress (2007-2008). After reviving and carrying over many of the same proposals as in previous bills, the Smith legislation was passed by the House of Representatives on September 7, 2007. Unfortunately for proponents of major patent reform, the Senate failed to act on the pending legislation before the conclusion of the 110th session.

Undeterred, the 111th Congress (2009-) has now revived many of the same provisions of past patent reform measures, with three separate proposals introduced since March 2009. *See* “Patent Reform Act of 2009, S.515, Mar. 3, 2009 111th Cong., 1st Sess., available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d111:s.00515>: (Senator Leahy’s version); “Patent Reform Act of 2009, S.610, Mar. 17, 2009 111th Cong., 1st Sess., available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d111:s.00610> (Senator Kyl’s version); “Patent Reform Act of 2009, H.R. 1260, Mar. 17, 2009 111th Cong., 1st Sess., available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d111:h.01260>: (Representative Conyers’ version). Senator Leahy’s bill, S.515, has now been reported out of committee (from the Senate Judiciary Committee, which is chaired by Senator Leahy). Leahy’s bill is now seeking to enact an interesting compromise on patent damages. Rather than attempting to spell out an elaborate “apportionment” procedure for the calculation of patent damages, S.515 keeps the judiciary in charge of developing the law of damages. The key provision, set forth in a proposed new section 284(b) of the Patent Act, would require that the courts “identify the methodologies and factors that are relevant to the determination of damages, and the court or jury, shall consider only those methodologies and factors relevant to making such determination.” The whole text of that section is:

(b) Procedure for Determining Damages-

“(1) IN GENERAL- The court shall identify the methodologies and factors that are relevant to the determination of damages, and the court or jury, shall consider only those methodologies and factors relevant to making such determination.

“(2) DISCLOSURE OF CLAIMS- By no later than the entry of the final pretrial order, unless otherwise ordered by the court, the parties shall state, in writing and with particularity, the methodologies and factors the parties propose for instruction to the jury in determining damages under this section, specifying the relevant underlying legal and factual bases for their assertions.

“(3) SUFFICIENCY OF EVIDENCE- Prior to the introduction of any evidence concerning the determination of damages, upon motion of either party or sua sponte, the court shall consider whether one or more of a party's damages contentions lacks a legally sufficient evidentiary basis. After providing a nonmovant the opportunity to be heard, and after any further proffer of evidence, briefing, or argument that the court may deem

appropriate, the court shall identify on the record those methodologies and factors as to which there is a legally sufficient evidentiary basis, and the court or jury shall consider only those methodologies and factors in making the determination of damages under this section. The court shall only permit the introduction of evidence relating to the determination of damages that is relevant to the methodologies and factors that the court determines may be considered in making the damages determination.

The damages provision in S.515 highlights the shrinking ambitions of congressional patent reform. Though the patent reform legislation was originally supposed to be a comprehensive reworking of the statute, legislative ambitions have been repeatedly curtailed.

In many respects, the reduced scope of legislative patent reform has occurred because “judicial patent reform” has occurred so swiftly. While congressional action has stalled repeatedly, the courts have made major changes to the judicial doctrines governing patent injunctions (*eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)), the obviousness doctrine (*KSR v. Teleflex*, 550 U.S. 398 (2007)), damages for willful infringement (*In re Seagate*, 497 F.3d 1360 (Fed. Cir. 2007)), and the availability of declaratory judgments (*MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007)).

Indeed, even as the 111th Congress continued deliberating about the wisdom of legislative changes to the Patent Act, patent reform has continued in the courts. For example, one of the most important issues in the legislative arena has always been the calculation of patent damages, especially in the area where the patentee seeks “reasonable royalties” as the measure of damages. In June of 2009, the Chief Judge of the Federal Circuit commented during oral argument in *Lucent v. Gateway* that the Federal Circuit’s precedents contained “massive unclarity about how reasonable royalty damages are to be calculated.” Oral argument recording from *Lucent v. Gateway*, No. 2008-1485, available at <http://oralarguments.cafc.uscourts.gov/mp3/2008-1485.mp3> (time index = 27:10). In late 2009, the Federal Circuit issued its opinion in the *Lucent* case, which attempted to provide greater clarity as to the appropriate theories for assessing patent damages. (The decision in *Lucent* is covered more fully in Chapter 10 of this supplement.) In light of the continued judicial attention to the perceived weaknesses of current patent doctrine, the prospects for major legislative change seem to be diminishing.

CHAPTER 2: PATENTABLE SUBJECT MATTER**Add after page 78:**

On June 28, 2010—the very last day of the Supreme Court’s 2009 Term—the Court handed down its decision in *Bilski v. Kappos*. The case easily rivals *Diamond v. Chakrabarty* in importance to the law of patentable subject matter, and it is similar to *Chakrabarty* in other ways too. As in *Chakrabarty*, the *Bilski* Court emphasizes the importance of the broad statutory language in § 101 and rejects proposed rules that would have barred patents on entire categories of inventions. Yet *Bilski* also provides an excellent counterpoint to *Chakrabarty*, for in *Bilski* all of the patent claims at issue were held to be unpatentable abstract ideas. As you read through the *Bilski* decision, you should try to appreciate the similarities between it and *Chakrabarty* and also try to identify differences in the facts or methodology that account for the different outcomes.

BILSKI v. KAPPOS

___ U.S. ___, 130 S.Ct. 3218, 2010 U.S. LEXIS 5521 (June 28, 2010)

Justice KENNEDY delivered the opinion of the Court, except as to Parts II-B-2 and II-C-2. [Chief Justice ROBERTS and Justices ALITO and THOMAS joined the opinion in its entirety. Justice SCALIA joined the opinion except for Parts II-B-2 and II-C-2.]

The question in this case turns on whether a patent can be issued for a claimed invention designed for the business world. The patent application claims a procedure for instructing buyers and sellers how to protect against the risk of price fluctuations in a discrete section of the economy. Three arguments are advanced for the proposition that the claimed invention is outside the scope of patent law: (1) it is not tied to a machine and does not transform an article; (2) it involves a method of conducting business; and (3) it is merely an abstract idea. The Court of Appeals ruled that the first mentioned of these, the so-called machine-or-transformation test, was the sole test to be used for determining the patentability of a “process” under the Patent Act, 35 U.S.C. § 101.

I

Petitioners' application seeks patent protection for a claimed invention that explains how buyers and sellers of commodities in the energy market can protect, or hedge, against the risk of price changes. The key claims are claims 1 and 4. Claim 1 describes a series of steps instructing how to hedge risk. Claim 4 puts the concept articulated in claim 1 into a simple mathematical formula. Claim 1 consists of the following steps:

“(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumers;

“(b) identifying market participants for said commodity having a counter-risk position to said consumers; and

“(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.” App. 19-20.

The remaining claims explain how claims 1 and 4 can be applied to allow energy suppliers and consumers to minimize the risks resulting from fluctuations in market demand for energy. For example, claim 2 claims “[t]he method of claim 1 wherein said commodity is energy and said market participants are transmission distributors.” *Id.*, at 20. Some of these claims also suggest familiar statistical approaches to determine the inputs to use in claim 4’s equation. For example, claim 7 advises using well-known random analysis techniques to determine how much a seller will gain “from each transaction under each historical weather pattern.” *Id.*, at 21.

The patent examiner rejected petitioners’ application, explaining that it “‘is not implemented on a specific apparatus and merely manipulates [an] abstract idea and solves a purely mathematical problem without any limitation to a practical application, therefore, the invention is not directed to the technological arts.’” App. to Pet. for Cert. 148a. The Board of Patent Appeals and Interferences affirmed, concluding that the application involved only mental steps that do not transform physical matter and was directed to an abstract idea. *Id.*, at 181a-186a.

The United States Court of Appeals for the Federal Circuit heard the case en banc and affirmed. The case produced five different opinions. Students of patent law would be well advised to study these scholarly opinions.

Chief Judge Michel wrote the opinion of the court. The court rejected its prior test for determining whether a claimed invention was a patentable “process” under § 101—whether it produces a “‘useful, concrete, and tangible result’ ” — as articulated in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373 (1998), and *AT & T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 1357 (1999). See *In re Bilski*, 545 F.3d 943, 959-960, and n. 19 (C.A.Fed.2008) (en banc). The court held that “[a] claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” *Id.*, at 954. The court concluded this “machine-or-transformation test” is “the sole test governing § 101 analyses,” *id.*, at 955, and thus the “test for determining patent eligibility of a process under § 101,” *id.*, at 956. Applying the machine-or-transformation test, the court held that petitioners’ application was not patent eligible. *Id.*, at 963-966. Judge Dyk wrote a separate concurring opinion, providing historical support for the court’s approach. *Id.*, at 966-976.

Three judges wrote dissenting opinions. Judge Mayer argued that petitioners' application was "not eligible for patent protection because it is directed to a method of conducting business." *Id.*, at 998. He urged the adoption of a "technological standard for patentability." *Id.*, at 1010. Judge Rader would have found petitioners' claims were an unpatentable abstract idea. *Id.*, at 1011. Only Judge Newman disagreed with the court's conclusion that petitioners' application was outside of the reach of § 101. She did not say that the application should have been granted but only that the issue should be remanded for further proceedings to determine whether the application qualified as patentable under other provisions. *Id.*, at 997.

This Court granted certiorari. 556 U.S. ----, 129 S.Ct. 2735 (2009).

II

A

Section 101 defines the subject matter that may be patented under the Patent Act:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

Section 101 thus specifies four independent categories of inventions or discoveries that are eligible for protection: processes, machines, manufactures, and compositions of matter. "In choosing such expansive terms ... modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980). Congress took this permissive approach to patent eligibility to ensure that " 'ingenuity should receive a liberal encouragement.' " *Id.*, at 308-309, 100 S.Ct. 2204 (quoting 5 Writings of Thomas Jefferson 75-76 (H. Washington ed. 1871)).

The Court's precedents provide three specific exceptions to § 101's broad patent-eligibility principles: "laws of nature, physical phenomena, and abstract ideas." *Chakrabarty, supra*, at 309. While these exceptions are not required by the statutory text, they are consistent with the notion that a patentable process must be "new and useful." And, in any case, these exceptions have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years. See *Le Roy v. Tatham*, 14 How. 156, 174-175 (1853). The concepts covered by these exceptions are "part of the storehouse of knowledge of all men ... free to all men and reserved exclusively to none." *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

The § 101 patent-eligibility inquiry is only a threshold test. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the Patent Act's protection the claimed invention must also satisfy "the conditions and requirements of this title." § 101. Those requirements include that the invention be novel, see § 102, nonobvious, see § 103, and fully and particularly described, see § 112.

The present case involves an invention that is claimed to be a “process” under § 101. Section 100(b) defines “process” as:

“process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”

The Court first considers two proposed categorical limitations on “process” patents under § 101 that would, if adopted, bar petitioners' application in the present case: the machine-or-transformation test and the categorical exclusion of business method patents.

B
1

Under the Court of Appeals' formulation, an invention is a “process” only if: “(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” 545 F.3d, at 954. This Court has “more than once cautioned that courts ‘should not read into the patent laws limitations and conditions which the legislature has not expressed.’” *Diamond v. Diehr*, 450 U.S. 175 (1981) (quoting *Chakrabarty, supra*, at 308, 100 S.Ct. 2204; some internal quotation marks omitted). In patent law, as in all statutory construction, “[u]nless otherwise defined, ‘words will be interpreted as taking their ordinary, contemporary, common meaning.’” *Diehr, supra*, at 182. The Court has read the § 101 term “manufacture” in accordance with dictionary definitions, see *Chakrabarty, supra*, at 308, and approved a construction of the term “composition of matter” consistent with common usage, see *Chakrabarty, supra*, at 308.

Any suggestion in this Court's case law that the Patent Act's terms deviate from their ordinary meaning has only been an explanation for the exceptions for laws of nature, physical phenomena, and abstract ideas. See *Parker v. Flook*, 437 U.S. 584, 588-589 (1978). This Court has not indicated that the existence of these well-established exceptions gives the Judiciary *carte blanche* to impose other limitations that are inconsistent with the text and the statute's purpose and design. Concerns about attempts to call any form of human activity a “process” can be met by making sure the claim meets the requirements of § 101.

Adopting the machine-or-transformation test as the sole test for what constitutes a “process” (as opposed to just an important and useful clue) violates these statutory interpretation principles. Section 100(b) provides that “[t]he term ‘process’ means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.” The Court is unaware of any “‘ordinary, contemporary, common meaning.’” *Diehr, supra*, at 182, of the definitional terms “process, art or method” that would require these terms to be tied to a machine or to transform an article. Respondent urges the Court to look to the other patentable categories in § 101—machines, manufactures, and compositions of matter—to confine the meaning of “process” to a machine or transformation, under the doctrine of *noscitur a*

sociis. Under this canon, “an ambiguous term may be given more precise content by the neighboring words with which it is associated.” *United States v. Stevens*, 559 U.S. ----, ---, 130 S.Ct. 1577, 1587 (2010) (internal quotation marks omitted). This canon is inapplicable here, for § 100(b) already explicitly defines the term “process.” See *Burgess v. United States*, 553 U.S. 124, 130 (2008) (“When a statute includes an explicit definition, we must follow that definition” (internal quotation marks omitted)).

The Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-transformation test as the exclusive test. It is true that *Cochrane v. Deener*, 94 U.S. 780, 788 (1877), explained that a “process” is “an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.” More recent cases, however, have rejected the broad implications of this dictum; and, in all events, later authority shows that it was not intended to be an exhaustive or exclusive test. *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972), noted that “[t]ransformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.” At the same time, it explicitly declined to “hold that no process patent could ever qualify if it did not meet [machine or transformation] requirements.” *Id.*, at 71. *Flook* took a similar approach, “assum[ing] that a valid process patent may issue even if it does not meet [the machine-or-transformation test].” 437 U.S., at 588, n. 9.

This Court's precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible “process.”

2

[Part B.2 is an opinion for Justice Kennedy and three other Justices.]

It is true that patents for inventions that did not satisfy the machine-or-transformation test were rarely granted in earlier eras, especially in the Industrial Age, as explained by Judge Dyk's thoughtful historical review. See 545 F.3d, at 966-976 (concurring opinion). But times change. Technology and other innovations progress in unexpected ways. For example, it was once forcefully argued that until recent times, “well-established principles of patent law probably would have prevented the issuance of a valid patent on almost any conceivable computer program.” *Diehr*, 450 U.S., at 195 (STEVENS, J., dissenting). But this fact does not mean that unforeseen innovations such as computer programs are always unpatentable. See *id.*, at 192-193 (majority opinion) (holding a procedure for molding rubber that included a computer program is within patentable subject matter). Section 101 is a “dynamic provision designed to encompass new and unforeseen inventions.” *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 135 (2001). A categorical rule denying patent protection for “inventions in areas not contemplated by Congress ... would frustrate the purposes of the patent law.” *Chakrabarty*, 447 U.S., at 315.

The machine-or-transformation test may well provide a sufficient basis for evaluating processes similar to those in the Industrial Age—for example, inventions grounded in a physical or other tangible form. But there are reasons to doubt whether the test should be the sole criterion for determining the patentability of inventions in the Information Age. As numerous *amicus* briefs argue, the machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals. See, *e.g.*, Brief for Business Software Alliance 24-25; Brief for Biotechnology Industry Organization et al. 14-27; Brief for Boston Patent Law Association 8-15; Brief for Houston Intellectual Property Law Association 17-22; Brief for Dolby Labs., Inc., et al. 9-10.

In the course of applying the machine-or-transformation test to emerging technologies, courts may pose questions of such intricacy and refinement that they risk obscuring the larger object of securing patents for valuable inventions without transgressing the public domain. The dissent by Judge Rader refers to some of these difficulties. 545 F.3d, at 1015. As a result, in deciding whether previously unforeseen inventions qualify as patentable “process[es],” it may not make sense to require courts to confine themselves to asking the questions posed by the machine-or-transformation test. Section 101’s terms suggest that new technologies may call for new inquiries. See *Benson, supra*, at 71 (to “freeze process patents to old technologies, leaving no room for the revelations of the new, onrushing technology[,] ... is not our purpose”).

It is important to emphasize that the Court today is not commenting on the patentability of any particular invention, let alone holding that any of the above-mentioned technologies from the Information Age should or should not receive patent protection. This Age puts the possibility of innovation in the hands of more people and raises new difficulties for the patent law. With ever more people trying to innovate and thus seeking patent protections for their inventions, the patent law faces a great challenge in striking the balance between protecting inventors and not granting monopolies over procedures that others would discover by independent, creative application of general principles. Nothing in this opinion should be read to take a position on where that balance ought to be struck.

C
1

Section 101 similarly precludes the broad contention that the term “process” categorically excludes business methods. The term “method,” which is within § 100(b)’s definition of “process,” at least as a textual matter and before consulting other limitations in the Patent Act and this Court’s precedents, may include at least some methods of doing business. See, *e.g.*, Webster’s New International Dictionary 1548 (2d ed.1954) (defining “method” as “[a]n orderly procedure or process ... regular way or manner of doing anything; hence, a set form of procedure adopted in investigation or instruction”). The Court is unaware of any argument that the “ ‘ordinary, contemporary, common meaning,’ ” *Diehr, supra*, at 182, of “method” excludes business methods. Nor is it clear how far a

prohibition on business method patents would reach, and whether it would exclude technologies for conducting a business more efficiently. See, e.g., Hall, Business and Financial Method Patents, Innovation, and Policy, 56 *Scottish J. Pol. Econ.* 443, 445 (2009) (“There is no precise definition of ... business method patents”).

The argument that business methods are categorically outside of § 101's scope is further undermined by the fact that federal law explicitly contemplates the existence of at least some business method patents. Under 35 U.S.C. § 273(b)(1), if a patent-holder claims infringement based on “a method in [a] patent,” the alleged infringer can assert a defense of prior use. For purposes of this defense alone, “method” is defined as “a method of doing or conducting business.” § 273(a)(3). In other words, by allowing this defense the statute itself acknowledges that there may be business method patents. Section 273's definition of “method,” to be sure, cannot change the meaning of a prior-enacted statute. But what § 273 does is clarify the understanding that a business method is simply one kind of “method” that is, at least in some circumstances, eligible for patenting under § 101.

A conclusion that business methods are not patentable in any circumstances would render § 273 meaningless. This would violate the canon against interpreting any statutory provision in a manner that would render another provision superfluous. See *Corley v. United States*, 556 U.S. ----, ----, 129 S.Ct. 1558 (2009). This principle, of course, applies to interpreting any two provisions in the U.S.Code, even when Congress enacted the provisions at different times. See, e.g., *Hague v. Committee for Industrial Organization*, 307 U.S. 496, 529-530 (1939) (opinion of Stone, J.). This established rule of statutory interpretation cannot be overcome by judicial speculation as to the subjective intent of various legislators in enacting the subsequent provision. Finally, while § 273 appears to leave open the possibility of some business method patents, it does not suggest broad patentability of such claimed inventions.

2

[Part C.2 is an opinion for Justice Kennedy and three other Justices.]

Interpreting § 101 to exclude all business methods simply because business method patents were rarely issued until modern times revives many of the previously discussed difficulties. See *supra*, at ---- - ----. At the same time, some business method patents raise special problems in terms of vagueness and suspect validity. See *eBay Inc. v. MercExchange, L.L. C.*, 547 U.S. 388, 397 (2006) (KENNEDY, J., concurring). The Information Age empowers people with new capacities to perform statistical analyses and mathematical calculations with a speed and sophistication that enable the design of protocols for more efficient performance of a vast number of business tasks. If a high enough bar is not set when considering patent applications of this sort, patent examiners and courts could be flooded with claims that would put a chill on creative endeavor and dynamic change.

In searching for a limiting principle, this Court's precedents on the unpatentability of abstract ideas provide useful tools. See *infra*, at ---- - ----. Indeed, if the Court of Appeals were to succeed in defining a narrower category or class of patent applications that claim to instruct how business should be conducted, and then rule that the category is unpatentable because, for instance, it represents an attempt to patent abstract ideas, this conclusion might well be in accord with controlling precedent. See *ibid*. But beyond this or some other limitation consistent with the statutory text, the Patent Act leaves open the possibility that there are at least some processes that can be fairly described as business methods that are within patentable subject matter under § 101.

Finally, even if a particular business method fits into the statutory definition of a “process,” that does not mean that the application claiming that method should be granted. In order to receive patent protection, any claimed invention must be novel, § 102, nonobvious, § 103, and fully and particularly described, § 112. These limitations serve a critical role in adjusting the tension, ever present in patent law, between stimulating innovation by protecting inventors and impeding progress by granting patents when not justified by the statutory design.

III

Even though petitioners' application is not categorically outside of § 101 under the two broad and atextual approaches the Court rejects today, that does not mean it is a “process” under § 101. Petitioners seek to patent both the concept of hedging risk and the application of that concept to energy markets. App. 19-20. Rather than adopting categorical rules that might have wide-ranging and unforeseen impacts, the Court resolves this case narrowly on the basis of this Court's decisions in *Benson*, *Flook*, and *Diehr*, which show that petitioners' claims are not patentable processes because they are attempts to patent abstract ideas. Indeed, all members of the Court agree that the patent application at issue here falls outside of § 101 because it claims an abstract idea.

In *Benson*, the Court considered whether a patent application for an algorithm to convert binary-coded decimal numerals into pure binary code was a “process” under § 101. 409 U.S., at 64-67. The Court first explained that “[a] principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.” *Id.*, at 67, 93 S.Ct. 253 (quoting *Le Roy*, 14 How., at 175). The Court then held the application at issue was not a “process,” but an unpatentable abstract idea. “It is conceded that one may not patent an idea. But in practical effect that would be the result if the formula for converting ... numerals to pure binary numerals were patented in this case.” 409 U.S., at 71, 93 S.Ct. 253. A contrary holding “would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.” *Id.*, at 72.

In *Flook*, the Court considered the next logical step after *Benson*. The applicant there attempted to patent a procedure for monitoring the conditions during the catalytic conversion process in the petrochemical and oil-refining industries. The application's

only innovation was reliance on a mathematical algorithm. 437 U.S., at 585-586. *Flook* held the invention was not a patentable “process.” The Court conceded the invention at issue, unlike the algorithm in *Benson*, had been limited so that it could still be freely used outside the petrochemical and oil-refining industries. 437 U.S., at 589-590. Nevertheless, *Flook* rejected “[t]he notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process.” *Id.*, at 590. The Court concluded that the process at issue there was “unpatentable under § 101, not because it contain[ed] a mathematical algorithm as one component, but because once that algorithm [wa]s assumed to be within the prior art, the application, considered as a whole, contain[ed] no patentable invention.” *Id.*, at 594. As the Court later explained, *Flook* stands for the proposition that the prohibition against patenting abstract ideas “cannot be circumvented by attempting to limit the use of the formula to a particular technological environment” or adding “insignificant postsolution activity.” *Diehr*, 450 U.S., at 191-192.

Finally, in *Diehr*, the Court established a limitation on the principles articulated in *Benson* and *Flook*. The application in *Diehr* claimed a previously unknown method for “molding raw, uncured synthetic rubber into cured precision products,” using a mathematical formula to complete some of its several steps by way of a computer. 450 U.S., at 177. *Diehr* explained that while an abstract idea, law of nature, or mathematical formula could not be patented, “an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” *Id.*, at 187. *Diehr* emphasized the need to consider the invention as a whole, rather than “dissect[ing] the claims into old and new elements and then ... ignor[ing] the presence of the old elements in the analysis.” *Id.*, at 188. Finally, the Court concluded that because the claim was not “an attempt to patent a mathematical formula, but rather [was] an industrial process for the molding of rubber products,” it fell within § 101's patentable subject matter. *Id.*, at 192-193.

In light of these precedents, it is clear that petitioners' application is not a patentable “process.” Claims 1 and 4 in petitioners' application explain the basic concept of hedging, or protecting against risk: “Hedging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class.” 545 F.3d, at 1013 (Rader, J., dissenting); see, e.g., D. Chorafas, *Introduction to Derivative Financial Instruments* 75-94 (2008); C. Stickney, R. Weil, K. Schipper, & J. Francis, *Financial Accounting: An Introduction to Concepts, Methods, and Uses* 581-582 (13th ed.2010); S. Ross, R. Westerfield, & B. Jordan, *Fundamentals of Corporate Finance* 743-744 (8th ed.2008). The concept of hedging, described in claim 1 and reduced to a mathematical formula in claim 4, is an unpatentable abstract idea, just like the algorithms at issue in *Benson* and *Flook*. Allowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.

Petitioners' remaining claims are broad examples of how hedging can be used in commodities and energy markets. *Flook* established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept

patentable. That is exactly what the remaining claims in petitioners' application do. These claims attempt to patent the use of the abstract idea of hedging risk in the energy market and then instruct the use of well-known random analysis techniques to help establish some of the inputs into the equation. Indeed, these claims add even less to the underlying abstract principle than the invention in *Flook* did, for the *Flook* invention was at least directed to the narrower domain of signaling dangers in operating a catalytic converter.

* * *

Today, the Court once again declines to impose limitations on the Patent Act that are inconsistent with the Act's text. The patent application here can be rejected under our precedents on the unpatentability of abstract ideas. The Court, therefore, need not define further what constitutes a patentable "process," beyond pointing to the definition of that term provided in § 100(b) and looking to the guideposts in *Benson*, *Flook*, and *Diehr*.

And nothing in today's opinion should be read as endorsing interpretations of § 101 that the Court of Appeals for the Federal Circuit has used in the past. See, e.g., *State Street*, 149 F.3d, at 1373; *AT & T Corp.*, 172 F.3d, at 1357. It may be that the Court of Appeals thought it needed to make the machine-or-transformation test exclusive precisely because its case law had not adequately identified less extreme means of restricting business method patents, including (but not limited to) application of our opinions in *Benson*, *Flook*, and *Diehr*. In disapproving an exclusive machine-or-transformation test, we by no means foreclose the Federal Circuit's development of other limiting criteria that further the purposes of the Patent Act and are not inconsistent with its text.

The judgment of the Court of Appeals is affirmed.

It is so ordered.

Justice STEVENS, with whom Justice GINSBURG, Justice BREYER, and Justice SOTOMAYOR join, concurring in the judgment.

In the area of patents, it is especially important that the law remain stable and clear. The only question presented in this case is whether the so-called machine-or-transformation test is the exclusive test for what constitutes a patentable "process" under 35 U.S.C. § 101. It would be possible to answer that question simply by holding, as the entire Court agrees, that although the machine-or-transformation test is reliable in most cases, it is not the *exclusive* test.

I agree with the Court that, in light of the uncertainty that currently pervades this field, it is prudent to provide further guidance. But I would take a different approach. Rather than making any broad statements about how to define the term "process" in § 101 or tinkering with the bounds of the category of unpatentable, abstract ideas, I would restore patent law to its historical and constitutional moorings.

For centuries, it was considered well established that a series of steps for conducting business was not, in itself, patentable. In the late 1990's, the Federal Circuit and others called this proposition into question. Congress quickly responded to a Federal Circuit decision with a stopgap measure designed to limit a potentially significant new problem for the business community. It passed the First Inventors Defense Act of 1999 (1999 Act), 113 Stat. 1501A-555 (codified at 35 U.S.C. § 273), which provides a limited defense to claims of patent infringement, see § 273(b), for “method[s] of doing or conducting business,” § 273(a)(3). Following several more years of confusion, the Federal Circuit changed course, overruling recent decisions and holding that a series of steps may constitute a patentable process only if it is tied to a machine or transforms an article into a different state or thing. This “machine-or-transformation test” excluded general methods of doing business as well as, potentially, a variety of other subjects that could be called processes.

The Court correctly holds that the machine-or-transformation test is not the sole test for what constitutes a patentable process; rather, it is a critical clue.¹ But the Court is quite wrong, in my view, to suggest that any series of steps that is not itself an abstract idea or law of nature may constitute a “process” within the meaning of § 101. The language in the Court's opinion to this effect can only cause mischief. The wiser course would have been to hold that petitioners' method is not a “process” because it describes only a general method of engaging in business transactions-and business methods are not patentable. More precisely, although a process is not patent-ineligible simply because it is useful for conducting business, a claim that merely describes a method of doing business does not qualify as a “process” under § 101.

I.

[In Part I of his concurrence, Justice Stevens restated the facts and procedural history of the case.]

II

Before explaining in more detail how I would decide this case, I will comment briefly on the Court's opinion. The opinion is less than pellucid in more than one respect, and, if misunderstood, could result in confusion or upset settled areas of the law. Three preliminary observations may be clarifying.

First, the Court suggests that the terms in the Patent Act must be read as lay speakers use those terms, and not as they have traditionally been understood in the context of patent law. See, *e.g.*, *ante*, at ---- (terms in § 101 must be viewed in light of their “ ‘ordinary, contemporary, common meaning’ ”); *ante*, at ---- (patentable “method”

¹ Even if the machine-or-transformation test may not define the scope of a patentable process, it would be a grave mistake to assume that anything with a “ ‘useful, concrete and tangible result,’ ” *State Street Bank & Trust v. Signature Financial Group, Inc.*, 149 F. 3d 1368, 1373 (CA Fed. 1998), may be patented.

is any “orderly procedure or process,” “regular way or manner of doing anything,” or “set form of procedure adopted in investigation or instruction” (internal quotation marks omitted)). As I will explain at more length in Part III, *infra*, if this portion of the Court's opinion were taken literally, the results would be absurd: Anything that constitutes a series of steps would be patentable so long as it is novel, nonobvious, and described with specificity. But the opinion cannot be taken literally on this point. The Court makes this clear when it accepts that the “atextual” machine-or-transformation test, *ante*, at ----, is “useful and important,” *ante*, at ----, even though it “violates” the stated “statutory interpretation principles,” *ante*, at ----; and when the Court excludes processes that tend to pre-empt commonly used ideas, see *ante*, at ---- - ----.

Second, in the process of addressing the sole issue presented to us, the opinion uses some language that seems inconsistent with our centuries-old reliance on the machine-or-transformation criteria as clues to patentability. Most notably, the opinion for a plurality suggests that these criteria may operate differently when addressing technologies of a recent vintage. See *ante*, at ---- - ---- (machine-or-transformation test is useful “for evaluating processes similar to those in the Industrial Age,” but is less useful “for determining the patentability of inventions in the Information Age”). In moments of caution, however, the opinion for the Court explains – correctly – that the Court is merely restoring the law to its historical state of rest. See *ante*, at ---- (“This Court's precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101”). Notwithstanding this internal tension, I understand the Court's opinion to hold only that the machine-or-transformation test remains an important test for patentability. Few, if any, processes cannot effectively be evaluated using these criteria.

Third, in its discussion of an issue not contained in the questions presented – whether the particular series of steps in petitioners' application is an abstract idea – the Court uses language that could suggest a shift in our approach to that issue. Although I happen to agree that petitioners seek to patent an abstract idea, the Court does not show how this conclusion follows “clear[ly],” *ante*, at ----, from our case law. The patent now before us is not for “[a] principle, in the abstract,” or a “fundamental truth.” *Parker v. Flook*, 437 U.S. 584, 589 (1978) (internal quotation marks omitted). Nor does it claim the sort of phenomenon of nature or abstract idea that was embodied by the mathematical formula at issue in *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972), and in *Flook*.

The Court construes petitioners' claims on processes for pricing as claims on “the basic concept of hedging, or protecting against risk,” *ante*, at ----, and thus discounts the application's discussion of what sorts of data to use, and how to analyze those data, as mere “token postsolution components,” *ante*, at ----. In other words, the Court artificially limits petitioners' claims to hedging, and then concludes that hedging is an abstract idea rather than a term that describes a category of processes including petitioners' claims. Why the Court does this is never made clear. One might think that the Court's analysis means that any process that utilizes an abstract idea is *itself* an unpatentable, abstract idea. But we have never suggested any such rule, which would undermine a host of

patentable processes. It is true, as the Court observes, that petitioners' application is phrased broadly. See *ante*, at ---- - ----. But claim specification is covered by § 112, not § 101; and if a series of steps constituted an unpatentable idea merely because it was described without sufficient specificity, the Court could be calling into question some of our own prior decisions.² At points, the opinion suggests that novelty is the clue. See *ante*, at ----. But the fact that hedging is “ ‘long prevalent in our system of commerce,’ ” *ibid.*, cannot justify the Court's conclusion, as “the proper construction of § 101 ... does not involve the familiar issu[e] of novelty” that arises under § 102. *Flook*, 437 U.S., at 588. At other points, the opinion for a plurality suggests that the analysis turns on the category of patent involved. See, *e.g.*, *ante*, at ---- (courts should use the abstract-idea rule as a “too [1]” to set “a high enough bar” “when considering patent applications of this sort”). But we have never in the past suggested that the inquiry varies by subject matter.

The Court, in sum, never provides a satisfying account of what constitutes an unpatentable abstract idea. Indeed, the Court does not even explain if it is using the machine-or-transformation criteria. The Court essentially asserts its conclusion that petitioners' application claims an abstract idea. This mode of analysis (or lack thereof) may have led to the correct outcome in this case, but it also means that the Court's musings on this issue stand for very little.

III

I agree with the Court that the text of § 101 must be the starting point of our analysis. As I shall explain, however, the text must not be the end point as well.

Section 101 undoubtedly defines in “expansive terms” the subject matter eligible for patent protection, as the statute was meant to ensure that “ ‘ingenuit[ies] receive a liberal encouragement.’ ” *Diamond v. Chakrabarty*, 447 U.S. 303, 308-309 (1980). Nonetheless, not every new invention or discovery may be patented. Certain things are “free for all to use.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989).

The text of the Patent Act does not on its face give much guidance about what constitutes a patentable process. The statute defines the term “process” as a “process, art or method [that] includes a new use of a known process, machine, manufacture, composition of matter, or material.” § 100(b). But, this definition is not especially helpful, given that it also uses the term “process” and is therefore somewhat circular.

² For example, a rule that broadly-phrased claims cannot constitute patentable processes could call into question our approval of Alexander Graham Bell's famous fifth claim on “ ‘[t]he method of, and apparatus for, transmitting vocal or other sounds telegraphically, as herein described, by causing electrical undulations, similar in form to the vibrations of the air accompanying the said vocal or other sounds, substantially as set forth,’ ” *The Telephone Cases*, 126 U.S. 1, 531 (1888).

As lay speakers use the word “process,” it constitutes any series of steps. But it has always been clear that, as used in § 101, the term does not refer to a “ ‘process’ in the ordinary sense of the word,” *Flook*, 437 U.S., at 588; see also *Corning v. Burden*, 15 How. 252, 268 (1854) (“[T]he term process is often used in a more vague sense, in which it cannot be the subject of a patent”). Rather, as discussed in some detail in Part IV, *infra*, the term “process” (along with the definitions given to that term) has long accumulated a distinctive meaning in patent law. When the term was used in the 1952 Patent Act, it was neither intended nor understood to encompass *any* series of steps or any *way* to do any *thing*.

With that understanding in mind, the Government has argued that because “a word” in a statute “is given more precise content by the neighboring words with which it” associates, *United States v. Williams*, 553 U.S. 285, 294 (2008), we may draw inferences from the fact that “[t]he other three statutory categories of patent-eligible subject matter identified in Section 101 – ‘machine, manufacture, or composition of matter’ – all ‘are things made by man, and involve technology.’ ” Brief for Respondent 26. Specifically, the Government submits, we may infer “that the term ‘process’ is limited to technological and industrial methods.” *Ibid*. The Court rejects this submission categorically, on the ground that “§ 100(b) already explicitly defines the term ‘process.’ ” *Ante*, at ----. But § 100(b) defines the term “process” by using the term “process,” as well as several other general terms. This is not a case, then, in which we must *either* “follow” a definition, *ante*, at ----, *or* rely on neighboring words to understand the scope of an ambiguous term. The definition itself contains the very ambiguous term that we must define.

In my view, the answer lies in between the Government's and the Court's positions: The terms adjacent to “process” in § 101 provide a clue as to its meaning, although not a very strong clue. Section 101's list of categories of patentable subject matter is phrased in the disjunctive, suggesting that the term “process” has content distinct from the other items in the list. It would therefore be illogical to “rob” the word “process” of all independent meaning. Moreover, to the extent we can draw inferences about what is a “process” from common attributes in § 101, it is a dangerous endeavor to do so on the basis of a perceived overarching theme. Given the many moving parts at work in the Patent Act, there is a risk of merely confirming our preconceived notions of what should be patentable or of seeing common attributes that track “the familiar issues of novelty and obviousness” that arise under other sections of the statute but are not relevant to § 101, *Flook*, 437 U.S., at 588. The placement of “process” next to other items thus cannot prove that the term is limited to any particular categories; it does, however, give reason to be skeptical that the scope of a patentable “process” extends to cover any series of steps at all.

The Court makes a more serious interpretive error. As briefly discussed in Part II, *supra*, the Court at points appears to reject the well-settled proposition that the term “process” in § 101 is not a “ ‘process’ in the ordinary sense of the word,” *Flook*, 437 U.S., at 588. Instead, the Court posits that the word “process” must be understood in light of its

“ordinary, contemporary, common meaning,” *ante*, at ---- (internal quotation marks omitted). Although this is a fine approach to statutory interpretation in general, it is a deeply flawed approach to a statute that relies on complex terms of art developed against a particular historical background.³ Indeed, the approach would render § 101 almost comical. A process for training a dog, a series of dance steps, a method of shooting a basketball, maybe even words, stories, or songs if framed as the steps of typing letters or uttering sounds – all would be patent-eligible. I am confident that the term “process” in § 101 is not nearly so capacious.

So is the Court, perhaps. What is particularly incredible about the Court's stated method of interpreting § 101 (other than that the method itself may be patent-eligible under the Court's theory of § 101) is that the Court deviates from its own professed commitment to “ordinary, contemporary, common meaning.” As noted earlier, the Court accepts a role for the “atextual” machine-or-transformation “clue.” *Ante*, at ----, ----. The Court also accepts that we have “foreclose[d] a purely literal reading of § 101,” *Flook*, 437 U.S., at 589, by holding that claims that are close to “laws of nature, natural phenomena, and abstract ideas,” *Diamond v. Diehr*, 450 U.S. 175, 185 (1981), do not count as “processes” under § 101, even if they can be colloquially described as such. The Court attempts to justify this latter exception to § 101 as “a matter of statutory *stare decisis*.” *Ante*, at ----. But it is strange to think that the very same term must be interpreted literally on some occasions, and in light of its historical usage on others.

In fact, the Court's understanding of § 101 is even more remarkable because its willingness to *exclude* general principles from the provision's reach is in tension with its apparent willingness to *include* steps for conducting business. The history of patent law contains strong norms against patenting these two categories of subject matter. Both norms were presumably incorporated by Congress into the Patent Act in 1952.

IV

Because the text of § 101 does not on its face convey the scope of patentable processes, it is necessary, in my view, to review the history of our patent law in some detail. This approach yields a much more straightforward answer to this case than the Court's. As I read the history, it strongly supports the conclusion that a method of doing business is not a “process” under § 101.

I am, of course, mindful of the fact that § 101 “is a dynamic provision designed to encompass new and unforeseen inventions,” and that one must therefore view historical conceptions of patent-eligible subject matter at an appropriately high level of generality. *J.E.M. Ag Supply*, 534 U.S., at 135. But it is nonetheless significant that while people have long innovated in fields of business, methods of doing business fall outside of the

³ For example, if this Court were to interpret the Sherman Act according to the Act's plain text, it could prohibit “the entire body of private contract,” *National Soc. of Professional Engineers v. United States*, 435 U.S. 679, 688 (1978).

subject matter that has “historically been eligible to receive the protection of our patent laws,” *Diehr*, 450 U.S., at 184, and likely go beyond what the modern patent “statute was enacted to protect,” *Flook*, 437 U.S., at 593. It is also significant that when Congress enacted the latest Patent Act, it did so against the background of a well-settled understanding that a series of steps for conducting business cannot be patented. These considerations ought to guide our analysis. As Justice Holmes noted long ago, sometimes, “a page of history is worth a volume of logic.” *New York Trust Co. v. Eisner*, 256 U.S. 345, 349 (1921).

English Backdrop

The Constitution's Patent Clause was written against the “backdrop” of English patent practices, *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 5 (1966), and early American patent law was “largely based on and incorporated” features of the English patent system, E. Walterscheid, *To Promote the Progress of Useful Arts: American Patent Law and Administration, 1789-1836*, p. 109 (1998) (hereinafter Walterscheid, *To Promote the Progress*). The governing English law, the Statute of Monopolies, responded to abuses whereby the Crown would issue letters patent, “granting monopolies to court favorites in goods or businesses which had long before been enjoyed by the public.” *Graham*, 383 U.S., at 5.

Although it is difficult to derive a precise understanding of what sorts of methods were patentable under English law, there is no basis in the text of the Statute of Monopolies, nor in pre-1790 English precedent, to infer that business methods could qualify. There was some debate throughout the relevant time period about what processes could be patented. But it does not appear that anyone seriously believed that one could patent “a method for organizing human activity.” 545 F.3d, at 970 (Dyk, J., concurring). [From footnote: See also Pollack, *The Multiple Unconstitutionality of Business Method Patents: Common Sense, Congressional Consideration, and Constitutional History*, 28 *Rutgers Computer & Tech. L.J.* 61, 94-96 (2002) (hereinafter Pollack) (describing English practice).].

There were a small number of patents issued between 1623 and 1790 relating to banking or lotteries and one for a method of life insurance, but these did not constitute the “prevail[ing]” “principles and practice” in England on which our patent law was based, *Pennock v. Dialogue*, 2 Pet. 1, 18 (1829). Such patents were exceedingly rare, and some of them probably were viewed not as inventions or discoveries but rather as special state privileges that until the mid-1800's were recorded alongside inventions in the patent records, see [C. MacLeod, *Inventing the Industrial Revolution: The English Patent System, 1660-1800* (1988), at pp. 1-2] (explaining that various types of patents were listed together). It appears that the only English patent of the time that can fairly be described as a business method patent was one issued in 1778 on a “Plan for assurances on lives of persons from 10 to 80 years of Age.” Woodcroft 324. And “[t]here is no indication” that this patent “was ever enforced or its validity tested,” 545 F.3d, at 974

(Dyk, J., concurring); the patent may thus have represented little more than the whim – or error – of a single patent clerk.

In any event, these patents (or patent) were probably not known to the Framers of early patent law. In an era before computerized databases, organized case law, and treatises, the American drafters probably would have known about particular patents only if they were well publicized or subject to reported litigation. So far as I am aware, no published cases pertained to patents on business methods.

Also noteworthy is what was *not* patented under the English system. During the 17th and 18th centuries, Great Britain saw innovations in business organization, business models, management techniques, and novel solutions to the challenges of operating global firms in which subordinate managers could be reached only by a long sea voyage. Few if any of these methods of conducting business were patented. [citing Pollack 97-100 and other sources, including Ronald Harris, *The Bubble Act: Its Passage and its Effects on Business Organization*, 54 *J. Econ. Hist.* 610, 624-625 (1994)].

Early American Patent Law

At the Constitutional Convention, the Founders decided to give Congress a patent power so that it might “promote the Progress of ... useful Arts.” Art. I, § 8, cl. 8. There is little known history of that Clause. We do know that the Clause passed without objection or debate. This is striking because other proposed powers, such as a power to grant charters of incorporation, generated discussion about the fear that they might breed “monopolies.” Indeed, at the ratification conventions, some States recommended amendments that would have prohibited Congress from granting “ ‘exclusive advantages of commerce.’ ” If the original understanding of the Patent Clause included the authority to patent methods of doing business, it might not have passed so quietly.

In 1790, Congress passed the first Patent Act. . . . [W]e know that the term “useful arts” was used in the founding era to refer to manufacturing and similar applied trades. See . . . Thomas, *The Patenting of the Liberal Professions*, 40 *Boston College L.Rev.* 1139, 1164 (1999) (“[The Framers of the Constitution] undoubtedly contemplated the industrial, mechanical and manual arts of the late eighteenth Century, in contrast to the seven ‘liberal arts’ and the four ‘fine arts’ of classical learning”). Indeed, just days before the Constitutional Convention, one delegate listed examples of American progress in “manufactures and the useful arts,” all of which involved the creation or transformation of physical substances. See T. Coxe, *An Address to an Assembly of the Friends of American Manufactures* 17-18 (1787) (listing, *inter alia*, meal, ships, liquors, potash, gunpowder, paper, starch, articles of iron, stone work, carriages, and harnesses). Numerous scholars have suggested that the term “useful arts” was widely understood to encompass the fields that we would now describe as relating to technology or “technological arts.” [Citing, *inter alia*, Samuelson, *Benson Revisited: The Case Against Patent Protection for Algorithms and Other Computer-Related Inventions*, 39 *Emory L.J.* 1025, 1033, n. 24 (1990).]

Thus, fields such as business and finance were not generally considered part of the “useful arts” in the founding Era. See, *e.g.*, The Federalist No. 8, p. 69 (C. Rossiter ed. 1961) (A. Hamilton) (distinguishing between “the arts of industry, and the science of finance”); 30 The Writings of George Washington 1745-1799, p. 186 (J. Fitzpatrick ed. 1939) (writing in a letter that “our commerce has been considerably curtailed,” but “the useful arts have been almost imperceptible pushed to a considerable degree of perfection”). Indeed, the same delegate to the Constitutional Convention who gave an address in which he listed triumphs in the useful arts distinguished between those arts and the conduct of business. He explained that investors were now attracted to the “manufactures and the useful arts,” much as they had long invested in “commerce, navigation, stocks, banks, and insurance companies.” T. Coxe, A Statement of the Arts and Manufactures of the United States of America for the Year 1810, (1814), in 2 American State Papers, Finance 666, 688 (1832).

Some scholars have remarked, as did Thomas Jefferson, that early patent statutes neither included nor reflected any serious debate about the precise scope of patentable subject matter. See, *e.g.*, *Graham*, 383 U.S., at 9-10, 86 S.Ct. 684 (discussing Thomas Jefferson's observations). It has been suggested, however, that “[p]erhaps this was in part a function of an understanding – shared widely among legislators, courts, patent office officials, and inventors – about what patents were meant to protect. Everyone knew that manufactures and machines were at the core of the patent system.” Merges, Property Rights for Business Concepts and Patent System Reform, 14 Berkeley Tech. L.J. 577, 585 (1999) (hereinafter Merges). Thus, although certain processes, such as those related to the technology of the time, might have been considered patentable, it is possible that “[a]gainst this background, it would have been seen as absurd for an entrepreneur to file a patent” on methods of conducting business. *Ibid.*

Development of American Patent Law

During the first years of the patent system, no patents were issued on methods of doing business. Indeed, for some time, there were serious doubts as to “the patentability of processes per se,” as distinct from the physical end product or the tools used to perform a process. *Id.*, at 581-582.

Although courts occasionally struggled with defining what was a patentable “art” during those 160 years, they consistently rejected patents on methods of doing business. The rationales for those decisions sometimes varied. But there was an overarching theme, at least in dicta: Business methods are not patentable arts. See, *e.g.*, *United States Credit Sys. Co. v. American Credit Indem. Co.*, 53 F. 818, 819 (CCSDNY 1893) (“method of insuring against loss by bad debts” could not be patented “as an art”); *Hotel Security Checking Co. v. Lorraine Co.*, 160 F. 467, 469 (C.A.2 1908) (“A system of transacting business disconnected from the means for carrying out the system is not, within the most liberal interpretation of the term, an art”); *Guthrie v. Curlett*, 10 F.2d 725, 726 (C.A.2 1926) (method of abbreviating rail tariff schedules, “if it be novel, is not the kind of art

protected by the patent acts”); *In re Patton*, 127 F.2d 324, 327-328 (CCPA 1942) (holding that novel “ ‘interstate and national fire-fighting system’ ” was not patentable because, *inter alia*, “a system of transacting business, apart from the means for carrying out such system is not” an art within the meaning of the patent law, “nor is an abstract idea or theory, regardless of its importance or ... ingenuity”); *Loew's Drive-in Theatres, Inc. v. Park-in Theatres, Inc.*, 174 F.2d 547, 552 (C.A.1 1949) (“[A] system for the transaction of business, such, for example, as the cafeteria system for transacting the restaurant business ... however novel, useful, or commercially successful is not patentable apart from the means for making the system practically useful, or carrying it out”); *Joseph E. Seagram & Sons, Inc. v. Marzall*, 180 F.2d 26, 28 (C.A.D.C.1950) (method of focus-group testing for beverages is not patentable subject matter); see also *In re Howard*, 55 C.C.P.A. 1121, 394 F.2d 869, 872 (CCPA 1968) (Kirkpatrick, J., concurring) (explaining that a “method of doing business” cannot be patented). Between 1790 and 1952, this Court never addressed the patentability of business methods. But we consistently focused the inquiry on whether an “art” was connected to a machine or physical transformation, an inquiry that would have excluded methods of doing business.

By the early 20th century, it was widely understood that a series of steps for conducting business could not be patented. A leading treatise, for example, listed “ ‘systems' of business” as an “unpatentable subjec[t].” 1 A. Deller, Walker on Patents § 18, p. 62 (1937) [and citing other sources].

Modern American Patent Law

[I]n 1952, when Congress updated the patent laws as part of its ongoing project to revise the United States Code, it changed the operative language in § 101, replacing the term “art” with “process” and adding a definition of “process” as a “process, art or method,” § 100(b).

That change was made for clarity and did not alter the scope of a patentable “process.” See *Diehr*, 450 U.S., at 184. The new terminology was added only in recognition of the fact that courts had been interpreting the category “art” by using the terms “process or method”; Congress thus wanted to avoid “the necessity of explanation that the word ‘art’ as used in this place means ‘process or method.’ ” S.Rep. No.1979, 82d Cong., 2d Sess., 5 (1952) (hereinafter S. Rep.1979); accord, H.R.Rep. No.1923, 82d Cong., 2d Sess., 6 (1952) (hereinafter H.R. Rep.1923).

It appears that when Congress changed the language in § 101 to incorporate the prevailing judicial terminology, it merely codified the prevailing judicial interpretation of that category of subject matter. Indeed, one of the main drafters of the Act explained that the definition of the term “process” in § 100(b) reflects “how the courts have construed the term ‘art.’” Tr. of address by Judge Giles S. Rich to the New York Patent Law Association 7-8 (Nov. 6, 1952).

“Anything Under the Sun”

Despite strong evidence that Congress has consistently authorized patents for a limited class of subject matter and that the 1952 Act did not alter the nature of the then-existing limits, petitioners and their *amici* emphasize a single phrase in the Act's legislative history, which suggests that the statutory subject matter “ ‘include[s] anything under the sun that is made by man.’ ” Brief for Petitioners 19 (quoting *Chakrabarty*, 447 U.S., at 309, in turn quoting S. Rep.1979, at 5). Similarly, the Court relies on language from our opinion in *Chakrabarty* that was based in part on this piece of legislative history. See *ante*, at ----, ----.

This reliance is misplaced. We have never understood that piece of legislative history to mean that any series of steps is a patentable process. Indeed, if that were so, then our many opinions analyzing what is a patentable process were simply wastes of pages in the U.S. Reports. And to accept that errant piece of legislative history as widening the scope of the patent law would contradict other evidence in the congressional record, as well as our presumption that the 1952 Act merely codified the meaning of “process” and did not expand it, see *Diehr*, 450 U.S., at 184.

Taken in context, it is apparent that the quoted language has a far less expansive meaning. The full sentence in the Committee Reports reads: “A person may have ‘invented’ a machine or a manufacture, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of [this] title are fulfilled.” S.Rep.1979, at 5; H.R. Rep.1923, at 6. Viewed as a whole, it seems clear that this language does not purport to explain that “anything under the sun” is patentable. Indeed, the language may be understood to state the exact opposite: that “[a] person may have ‘invented’ ... anything under the sun,” but that thing “is not necessarily patentable under section 101.” Thus, even in the *Chakrabarty* opinion, which relied on this quote, we cautioned that the 1952 Reports did not “suggest that § 101 has no limits or that it embraces every discovery.” 447 U.S., at 309.

Moreover, even if the language in the Committee Reports was meant to flesh out the meaning of any portion of § 101, it did not purport to define the term “process.” The language refers only to “manufacture[s]” and “machine[s],” tangible objects “made by man.” It does not reference the “process” category of subject matter (nor could a process be comfortably described as something “*made* by man”). The language may also be understood merely as defining the term “invents” in § 101.

The 1952 Act, in short, cannot be understood as expanding the scope of patentable subject matter by suggesting that any series of steps may be patented as a “process” under § 101. If anything, the Act appears to have codified the conclusion that subject matter which was understood not to be patentable in 1952 was to remain unpatentable.

* * *

Since at least the days of Assyrian merchants, people have devised better and better ways to conduct business. Yet it appears that neither the Patent Clause, nor early patent law, nor the current § 101 contemplated or was publicly understood to mean that such innovations are patentable. Although it may be difficult to define with precision what is a patentable “process” under § 101, the historical clues converge on one conclusion: A business method is not a “process.” And to the extent that there is ambiguity, we should be mindful of our judicial role. “[W]e must proceed cautiously when we are asked to extend patent rights” into an area that the Patent Act likely was not “enacted to protect,” *Flook*, 437 U.S., at 596, 593, lest we create a legal regime that Congress never would have endorsed, and that can be repaired only by disturbing settled property rights.

V

Despite the strong historical evidence that a method of doing business does not constitute a “process” under § 101, petitioners nonetheless argue – and the Court suggests in dicta, *ante*, at ---- – that a subsequent law, the First Inventor Defense Act of 1999, “must be read together” with § 101 to make business methods patentable. Brief for Petitioners 29. This argument utilizes a flawed method of statutory interpretation and ignores the motivation for the 1999 Act.

In 1999, following a Federal Circuit decision that intimated business methods could be patented, see *State Street*, 149 F.3d 1368, Congress moved quickly to limit the potential fallout. Congress passed the 1999 Act, codified at 35 U.S.C. § 273, which provides a limited defense to claims of patent infringement, see § 273(b), regarding certain “method[s] of doing or conducting business,” § 273(a)(3).

It is apparent, both from the content and history of the Act, that Congress did not in any way ratify *State Street* (or, as petitioners contend, the broadest possible reading of *State Street*). The Act merely limited one potential effect of that decision: that businesses might suddenly find themselves liable for innocently using methods they assumed could not be patented. The Act did not purport to amend the limitations in § 101 on eligible subject matter. Indeed, Congress placed the statute in Part III of Title 35, which addresses “Patents and Protection of Patent Rights,” rather than in Part II, which contains § 101 and addresses “Patentability of Inventions and Grant of Patents.” Particularly because petitioners' reading of the 1999 Act would expand § 101 to cover a category of processes that have not “historically been eligible” for patents, *Diehr*, 450 U.S., at 184, 101 S.Ct. 1048, we should be loathe to conclude that Congress effectively amended § 101 without saying so clearly. We generally presume that Congress “does not, one might say, hide elephants in mouseholes.” *Whitman v. American Trucking Assns., Inc.*, 531 U.S. 457, 468 (2001).

The Act therefore is, at best, merely evidence of 1999 legislative views on the meaning of the earlier, 1952 Act. “[T]he views of a subsequent Congress,” however, “form a hazardous basis for inferring the intent of an earlier one.” *United States v. Price*, 361 U.S. 304, 313 (1960). When a later statute is offered as “an expression of how the ...

Congress interpreted a statute passed by another Congress ... a half century before,” “such interpretation has very little, if any, significance.” *Rainwater v. United States*, 356 U.S. 590, 593 (1958).

Furthermore, even assuming that Congress' views at the turn of the 21st century could potentially serve as a valid basis for interpreting a statute passed in the mid-20th century, the First Inventor Defense Act does not aid petitioners because it does not show that the later Congress itself understood § 101 to cover business methods. If anything, it shows that a few judges on the Federal Circuit understood § 101 in that manner and that Congress understood what those judges had done. The Act appears to reflect surprise and perhaps even dismay that business methods might be patented. Thus, in the months following *State Street*, congressional authorities lamented that “business methods and processes ... until recently were thought not to be patentable,” H.R.Rep. No. 106-464, p. 121 (1999); accord, H.R.Rep. No. 106-287, pt. 1, p. 31 (1999). The fact that Congress decided it was appropriate to create a new *defense* to claims that business method patents were being infringed merely demonstrates recognition that such claims could create a significant new problem for the business community.

The Court nonetheless states that the 1999 Act “acknowledges that there may be business method patents,” thereby “clarify[ing]” its “understanding” of § 101. *Ante*, at --- -. More specifically, the Court worries that if we were to interpret the 1952 Act to exclude business methods, our interpretation “would render § 273 meaningless.” *Ibid*. I agree that “[a] statute should be construed so that effect is given to all its provisions.” *Corley v. United States*, 556 U.S. ----, ----, 129 S.Ct. 1558, 1566 (2009) (internal quotation marks omitted). But it is a different matter altogether when the Court construes one statute, the 1952 Act, to give effect to a different statute, the 1999 Act.

Put another way, we ordinarily assume, quite sensibly, that Congress would not in one statute include two provisions that are at odds with each other. But as this case shows, that sensible reasoning can break down when applied to different statutes. The 1999 Act was passed to limit the impact of the Federal Circuit's then-recent statements on the 1952 Act. Although repudiating that judicial dictum (as we should) might effectively render the 1999 Act a nullity going forward, such a holding would not mean that it was a nullity when Congress enacted it. Section 273 may have been a technically unnecessary response to confusion about patentable subject matter, but it appeared necessary in 1999 in light of what was being discussed in legal circles at the time.

In light of its history and purpose, I think it obvious that the 1999 Congress would never have enacted § 273 if it had foreseen that this Court would rely on the provision as a basis for concluding that business methods are patentable. Section 273 is a red herring; we should be focusing our attention on § 101 itself.

VI

The constitutionally mandated purpose and function of the patent laws bolster the conclusion that methods of doing business are not “processes” under § 101.

The Constitution allows Congress to issue patents “[t]o promote the Progress of ... useful Arts,” Art. I, § 8, cl. 8. This clause “is both a grant of power and a limitation.” *Graham*, 383 U.S., at 5. It “reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’ ” *Bonito Boats*, 489 U.S., at 146. Thus, although it is for Congress to “implement the stated purpose of the Framers by selecting the policy which in its judgment best effectuates the constitutional aim,” *Graham*, 383 U.S., at 6, we interpret ambiguous patent laws as a set of rules that “wee[d] out those inventions which would not be disclosed or devised but for the inducement of a patent,” *id.*, at 11, and that “embod[y]” the “careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy,” *Bonito Boats*, 489 U.S., at 146.

Although there is certainly disagreement about the need for patents, scholars generally agree that when innovation is expensive, risky, and easily copied, inventors are less likely to undertake the guaranteed costs of innovation in order to obtain the mere possibility of an invention that others can copy. Both common sense and recent economic scholarship suggest that these dynamics of cost, risk, and reward vary by the type of thing being patented. [See, *e.g.*, Burk & Lemley, Policy Levers in Patent Law, 89 Va. L.Rev. 1575, 1577-1589 (2003) (hereinafter Burk & Lemley).]

Many have expressed serious doubts about whether patents are necessary to encourage business innovation. [See, *e.g.*, Burk & Lemley 1618;); Dreyfuss, Are Business Methods Patents Bad for Business? 16 Santa Clara Computer & High Tech. L.J. 263, 274-277 (2000); Posner, The Law and Economics of Intellectual Property, 131 Daedalus 5 (Spring 2002).]. Although counterfactuals are a dubious form of analysis, I find it hard to believe that many of our entrepreneurs forwent business innovation because they could not claim a patent on their new methods.

“[C]ompanies have ample incentives to develop business methods even without patent protection, because the competitive marketplace rewards companies that use more efficient business methods.” Burk & Lemley 1618. Innovators often capture advantages from new business methods notwithstanding the risk of others copying their innovation. Some business methods occur in secret and therefore can be protected with trade secrecy. And for those methods that occur in public, firms that innovate often capture long-term benefits from doing so, thanks to various first mover advantages, including lockins, branding, and networking effects. [See Burk & Lemley 1618; Dreyfuss 275. Concededly, there may some methods of doing business that do not confer sufficient first-mover advantages. See Abramowicz & Duffy, Intellectual Property for Market Experimentation, 83 N.Y.U. L.Rev. 337, 340-342 (2008).]

The primary concern is that patents on business methods may prohibit a wide swath of legitimate competition and innovation. As one scholar explains, “it is useful to conceptualize knowledge as a pyramid: the big ideas are on top; specific applications are at the bottom.” Dreyfuss 275. The higher up a patent is on the pyramid, the greater the social cost and the greater the hindrance to further innovation. [See Merges & Nelson, On the Complex Economics of Patent Scope, 90 Colum. L. Rev. 839, 873-878 (1990).]

If business methods could be patented, then many business decisions, no matter how small, could be *potential* patent violations. Businesses would either live in constant fear of litigation or would need to undertake the costs of searching through patents that describe methods of doing business, attempting to decide whether their innovation is one that remains in the public domain. See Long, Information Costs in Patent and Copyright, 90 Va. L.Rev. 465, 487-488 (2004) [See also P. Menell & S. Scotchmer, Intellectual Property Law, in 2 Handbook of Law and Economics 1500-1501, 1506 (M. Polinsky & S. Shavell eds.2007).]

* * *

The constitutional standard for patentability is difficult to apply with any precision, and Congress has significant discretion to “implement the stated purpose of the Framers by selecting the policy which in its judgment best effectuates the constitutional aim,” *Graham*, 383 U.S., at 6, 86 S.Ct. 684. But Congress has not, either explicitly or implicitly, determined that patents on methods of doing business would effectuate this aim. And as I understand their practical consequences, it is hard to see how they would.

VII

The Constitution grants to Congress an important power to promote innovation. In its exercise of that power, Congress has established an intricate system of intellectual property. The scope of patentable subject matter under that system is broad. But it is not endless. In the absence of any clear guidance from Congress, we have only limited textual, historical, and functional clues on which to rely. Those clues all point toward the same conclusion: that petitioners' claim is not a “process” within the meaning of § 101 because methods of doing business are not, in themselves, covered by the statute. In my view, acknowledging as much would be a far more sensible and restrained way to resolve this case. Accordingly, while I concur in the judgment, I strongly disagree with the Court's disposition of this case.

Justice BREYER, with whom Justice SCALIA joins as to Part II, concurring in the judgment.

I

I agree with Justice STEVENS that a “general method of engaging in business transactions” is not a patentable “process” within the meaning of 35 U.S.C. § 101. *Ante*, at ---- (STEVENS, J., concurring in judgment). This Court has never before held that so-called “business methods” are patentable, and, in my view, the text, history, and purposes of the Patent Act make clear that they are not. *Ante*, at ---- - ----. I would therefore decide this case on that ground, and I join Justice STEVENS' opinion in full.

I write separately, however, in order to highlight the substantial *agreement* among many Members of the Court on many of the fundamental issues of patent law raised by this case. In light of the need for clarity and settled law in this highly technical area, I think it appropriate to do so.

II

In addition to the Court's unanimous agreement that the claims at issue here are unpatentable abstract ideas, it is my view that the following four points are consistent with both the opinion of the Court and Justice STEVENS' opinion concurring in the judgment:

First, although the text of § 101 is broad, it is not without limit. See *ante*, at ---- - ---- - (opinion of the Court); *ante*, at ---- (STEVENS, J., concurring in judgment). “[T]he underlying policy of the patent system [is] that ‘the things which are worth to the public the embarrassment of an exclusive patent,’ ... must outweigh the restrictive effect of the limited patent monopoly.” *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 10-11 (1966) (quoting Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in 6 Writings of Thomas Jefferson 181 (H. Washington ed.)). The Court has thus been careful in interpreting the Patent Act to “determine not only what is protected, but also what is free for all to use.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151. In particular, the Court has long held that “[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable” under § 101, since allowing individuals to patent these fundamental principles would “wholly pre-empt” the public's access to the “basic tools of scientific and technological work.” *Gottschalk v. Benson*, 409 U.S. 63, 67, 72.

Second, in a series of cases that extend back over a century, the Court has stated that “[t]ransformation and reduction of an article to a different state or thing is *the clue* to the patentability of a process claim that does not include particular machines.” *Diehr, supra*, at 184 (emphasis added; internal quotation marks omitted). Application of this test, the so-called “machine-or-transformation test,” has thus repeatedly helped the Court to determine what is “a patentable ‘process.’ ” *Flook, supra*, at 589.

Third, while the machine-or-transformation test has always been a “useful and important clue,” it has never been the “sole test” for determining patentability. *Ante*, at ---; see also *ante*, at ---- (STEVENS, J., concurring in judgment); *Benson, supra*, at 71 (rejecting the argument that “no process patent could ever qualify” for protection under § 101 “if it did not meet the [machine-or-transformation] requirements”). Rather, the Court has emphasized that a process claim meets the requirements of § 101 when, “considered as a whole,” it “is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing).” *Diehr, supra*, at 192. The machine-or-transformation test is thus an *important example* of how a court can determine patentability under § 101, but the Federal Circuit erred in this case by treating it as the *exclusive test*.

Fourth, although the machine-or-transformation test is not the only test for patentability, this by no means indicates that anything which produces a “ ‘useful, concrete, and tangible result,’ ” *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373 (C.A.Fed.1998), is patentable. “[T]his Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary.” *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124, 136 (2006) (BREYER, J., dissenting from dismissal of certiorari as improvidently granted). Indeed, the introduction of the “useful, concrete, and tangible result” approach to patentability, associated with the Federal Circuit’s *State Street* decision, preceded the granting of patents that “ranged from the somewhat ridiculous to the truly absurd.” *In re Bilski*, 545 F.3d 943, 1004 (C.A.Fed.2008) (Mayer, J., dissenting) (citing patents on, *inter alia*, a “method of training janitors to dust and vacuum using video displays,” a “system for toilet reservations,” and a “method of using color-coded bracelets to designate dating status in order to limit ‘the embarrassment of rejection’”).

In sum, it is my view that, in reemphasizing that the “machine-or-transformation” test is not necessarily the *sole* test of patentability, the Court intends neither to de-emphasize the test’s usefulness nor to suggest that many patentable processes lie beyond its reach.

III

With these observations, I concur in the Court’s judgment.

NOTES AND QUESTIONS ON *BILSKI*

1. Justice Stevens’s Lost Majority? Many observers of Supreme Court practice believe that Justice Stevens had originally been assigned to write the majority opinion in the case and that his opinion was first drafted as a majority opinion rather than as a concurrence. Part I of Justice Stevens’ opinion is one strong hint that he did lose the majority in the case, for concurrences and dissents typically do not repeat the recitation of the facts already stated in the majority opinion. At some point after the drafting of the opinion, Justice Stevens probably did “lose the Court,” possibly by losing the vote of

Justice Scalia. Thus, the Court came extremely close to ruling that business methods are never patentable. What factors do you think swayed the majority to agree with Justice Kennedy's opinion?

2. Textualism vs. A Common-Law Approach to Statutory Interpretation. As noted on page 78 of the casebook (note 4), the proper approach to statutory interpretation has long been one of the most important sub-issues in the case law on patentable subject matter. In *Bilski*, disagreements about statutory interpretation are once again hugely important. Two points, however, are new in the *Bilski* opinions. First, in footnote 3 of his opinion, Justice Stevens cites the Sherman Antitrust Act to demonstrate that using the ordinary meanings of words is “a deeply flawed approach to a statute that relies on complex terms of art developed against a particular historical background.” Stevens' citation to the Sherman Act was a brilliant gambit, for that statute is a celebrated instance in which even conservative textualist judges have been willing to read a statute as authorizing the courts to develop a judge-made common law unconstrained by the statutory text. See, e.g., Frank H. Easterbrook, *Statutes' Domains*, 50 U. Chi. L. Rev. 533, 544 (1983) (recognizing the Sherman Act as an example where Congress has authorized courts to create judge-made federal law). Furthermore, many areas of patent law—especially patentable subject matter—have historically been dominated by judge-made case law, even in areas where in theory the cases are grounded on some statutory text. Nevertheless, the majority rejects taking the Patent Act down the path of the Sherman Act. Why?

A second major development in *Bilski* comes in how the majority opinion addresses the relationship between the statutory text and the three “atextual” exceptions (“laws of nature, physical phenomena, and abstract ideas”) that prior Supreme Court precedents have read into the statute. Prior to *Bilski*, Court majorities in cases such as *Chakrabarty* had simultaneously (i) embraced a broad, textualist interpretation of § 101, and (ii) recognized the traditional exceptions, but the Court had failed to explain how the exceptions could be reconciled with textualism. The majority in *Bilski* finally attempts to provide an answer. Although acknowledging that the atextual “exceptions are not required by the statutory text,” the Court's tied those exceptions to the statutory text of § 101, noting that the exceptions are “consistent with the notion that a patentable process must be ‘new and useful.’” Thus, the Justices in the majority finally felt the need to justify the judge-made exceptions to patentability and they did so by bringing (or by attempting to bring) the exceptions into the framework of textualism. Were they successful? If the three exceptions are grounded in the language “new and useful,” does that statutory basis provide some clue as to how the Court will apply the three exceptions in the future?

3. Section 273 and the Entrenching of Business Method Patents. Earlier editions of this casebook have noted that the enactment of § 273 had the effect of entrenching the patentability of business methods (see the casebook page 173, note 4.c). That effect can be seen quite clearly in the majority opinion, and it might have been crucial in winning over Justice Scalia's vote. Justice Stevens points out (quite correctly) that, in enacting § 273, Congress did not have the “motivation” to ratify business method patents. Stevens even quotes an earlier Supreme Court opinion—one authored by Scalia

himself—to support the point that Congress “does not, one might say, hide elephants in mouseholes.” *Whitman v. American Trucking Assns., Inc.*, 531 U.S. 457, 468 (2001) (Scalia, J.). Why did Justice Stevens lose on this point? Shouldn’t Congress’s motivation in enacting § 273 be relevant?

4. Rules vs. Standards. Scholars frequently note that legal norms can be established either through more hard-edged rules or through more general standards that require the consideration and balancing of several factors. In *Chakrabarty* and *Bilski*, the Court rejected opportunities to impose *per se* rules limiting the scope of patentable subject matter and instead opted to evaluate patentable subject matter by more open-ended standards. *Chakrabarty* emphasizes the degree of “human ingenuity” needed to make the claimed invention; *Bilski* looks to the degree to which the claims are “abstract.” Are these more general standards better for the development of patent law? Does a “standards-based” approach breed the very uncertainty that all the Justices seem to decry?

5. The Demise (?) of *State Street*. All of the Justices who authored opinions in *Bilski* seem to go out of their way to disavow or at least to distance themselves from the Federal Circuit’s ruling in *Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (1998). That case has an interesting history. It became famous (or infamous) for holding in quite clear terms that there was no business method exception to patentable subject matter. Yet the case was not so dramatic an event as its fame might suggest. The specific patent in the case had been issued years earlier. Moreover, the PTO had been issuing similar business method patents for several years, and three years prior *State Street*, the agency had also removed from the Manual of Patent Examining Procedure (the agency’s “Bible” on patent law) any suggestion that patent law contained a “business method exception” to patentability. Finally, the specific legal test employed in *State Street*—the “useful, concrete and tangible” test—had been introduced in an earlier en banc Federal Circuit decision.

In the *Bilski* litigation, the *State Street* decision met its demise. Or did it? The en banc Federal Circuit opinion below expressly overruled the legal test applied in *State Street*, but it reaffirmed the view that business methods are patentable. So too at the Court, the majority decided that business methods are patentable, even though none of the Justices have a kind word for the Federal Circuit most famous case on business methods. Does the Court’s hostility toward *State Street* indicate that business method patents are likely to have a dim future?

In assessing the future of business method patents, you may find of use the following charts, which provide the number of business method and finance patents issued per year in the last decade:

Patents in PTO Class 705 (Inventions concerning “Financial, Business Practice, Management, or Cost/Price Determination”) ⁴			
Year	Total	Number with “method” in a Patent Claim	Number with “Method” in the Patent Title
2010 (six months)	2463 (six months)	2185 (six months)	1166 (six months)
2009	3007	2629	1507
2008	2642	2336	1404
2007	2050	1788	1064
2006	2201	1884	1145
2005	1434	1248	769
2004	990	835	531
2003	950	791	471
2002	860	704	443
2001	868	734	429
2000	1058	888	531

Number of Patents in Class 705 / Subclass 35 (Inventions concerning “Finance (e.g., banking, investment or credit)” ⁵)			
Year	Total	Number with “method” in a Patent Claim	Number with “Method” in the Patent Title
2010 (six months)	454 (six months)	410 (six months)	234 (six months)
2009	503	454	252
2008	365	336	198
2007	213	200	109
2006	243	210	114
2005	78	71	38
2004	46	40	21
2003	48	42	18
2002	50	41	27
2001	57	45	26
2000	95	77	43

⁴ This is the title the PTO gives to this class of invention. For the complete description of the class and its title, see <http://www.uspto.gov/web/patents/classification/uspc705/defs705.htm>.

⁵ For the title and description of subclass 35, see <http://www.uspto.gov/web/patents/classification/uspc705/defs705.htm#C705S035000>.

6. The Constitutional Issue. Justice Stevens spends many pages attempting to prove that business method patents are outside the Congress's constitutional power to grant patents. Why does the majority not respond on this constitutional point? One standard canon of statutory construction is the so-called canon of constitutional avoidance, which provides that an ambiguous "statute is to be construed where fairly possible so as to avoid substantial constitutional questions." *United States v. X-Citement Video*, 513 U.S. 64, 69 (1994). Should the majority's ruling be construed as deciding (i) that there are no *substantial* constitutional questions as to whether Congress could authorize the patenting of business methods, or (ii) that the statute is not ambiguous? Given the definition of "process" in section 100(b), is section 101 the Patent Act ambiguous as to the scope of patentable process or is the statute simply broad? Does statutory breadth necessarily imply statutory ambiguity?

7. The Need for Business Method Patents. Pages 177-81 of the casebook discuss the lively policy debate about whether business method patents are wise economic policy. While the *Bilski* decision appears to settle the issue whether current statutory law permits such patents, Congress could always amend the Patent Act to exclude business methods. Should it do so? Should more narrow categories of business methods (e.g., tax planning methods) be excluded?

Add after page 117 (after *Parke-Davis* and *Funk Brothers*):

**Association for Molecular Pathology v. United States PTO
(The "Myriad" Case)**

2010 U.S. Dist. LEXIS 35418 (Apr. 5, 2010)

Sweet, J.:

[This suit concerns patents to isolated DNA sequences or "genes" known as the Breast Cancer Susceptibility Genes 1 and 2, or BRCA1 and BRCA2. As the name suggests, the BRCA1/2 genes are important because they have certain "alleles" or forms causing susceptibility to cancer, in particular breast and ovarian cancer. The isolated DNA sequence can be used in genetic testing to determine whether a person carries certain alleles of the BRCA 1 or 2 gene and is thus at higher risk for breast or ovarian cancer. The isolated sequences can also be used in research.

The plaintiff individual researchers and associations, including the American Civil Liberties Union, brought suit against the PTO and the patent co-owners, Myriad Genetics, Inc., and the University of Utah Research Foundation. The plaintiff researchers and associations sought a declaratory judgment that the patents on the isolated BRCA1 and BRCA2 DNA sequences were invalid as beyond the scope of patentable subject matter. (The case also involved certain process claims, but the discussion of those claims is omitted here.) Claim 1 of U.S. Pat. No. 5,747,282 (issued 1998) was found by the district court to be a good representative of the group of composition claims:

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO: 2.

Note that the “SEQ ID NO: 2” is defined in the patent specification to mean a particular sequence of amino acids (the second sequence, or no. 2, defined in the patent) that is 1863 amino acids long. The precise sequence of amino acids is set forth in several pages of text in the patent, with each of the 1863 amino acids listed in the order defined to be “SEQ ID NO: 2.”

Judge Sweet’s opinion is lengthy and provides numerous details about the technology at issue and the posture of the case. Below is the crucial legal analysis determining that claims to “isolated DNA” sequences are invalid.]

IV.C. The Composition Claims Are Invalid Under 35 U.S.C. § 101

[T]he issue presented by the instant motions with respect to the composition claims is whether or not claims directed to isolated DNA containing naturally-occurring sequences fall within the products of nature exception to § 101. Based upon the reasons set forth below, it is concluded that the composition claims-in-suit are excepted.

1. Consideration of the merits of Plaintiffs’ challenge is appropriate.

[Omitted.]

2. Patentable subject matter must be "markedly different" from a product of nature.

Supreme Court precedent has established that products of nature do not constitute patentable subject matter absent a change that results in the creation of a fundamentally new product. In *American Fruit Growers* [*v. Brodget Co.*, 283 U.S. 1 (1931)], the Supreme Court rejected patent claims covering fruit whose skin had been treated with mold-resistant borax. Acknowledging that the "complete article is not found in nature," and "treatment, labor and manipulation" went into producing the fruit, the Court nonetheless held that the fruit did not become an "article of manufacture" unless it "possesses a new or distinctive form, quality, or property" compared to the naturally-occurring article."⁶ 283 U.S. at 11. The Court went on to observe:

Manufacture implies a change, but every change is not manufacture, and yet every change in an article is the result of treatment, labor, and manipulation. But something more is necessary . . . There must be transformation; a new and different article must emerge having a distinctive name, character, or use.

⁶ Myriad argues that *American Fruit Growers* was decided on novelty grounds, rather than subject matter patentability. See Myriad Br. at 26. However, the Court’s novelty discussion was restricted to its analysis of the process claims. *Am. Fruit Growers*, 283 U.S. at 13-14 (“If it be assumed that the process claims under consideration cover an invention, we think this lacked novelty when application was made for the patent August 13, 1923”). In contrast, its rejection of the composition claims was based on an analysis of subject matter patentability. See *id.* at 11 (“Is an orange, the rind of which has become impregnated with borax, through immersion in a solution, and thereby resistant to blue mold decay, a ‘manufacture,’ or manufactured article, within the meaning of section 31, title 35, U.S. Code?”).

Id. at 12-13 (quoting *Anheuser-Busch Brewing Ass'n v. United States*, 207 U.S. 556, 562 (1908)) (internal citation and quotation marks omitted).

Similarly, in *Funk Brothers*, the Supreme Court considered whether a mixture of several naturally-occurring species of bacteria was patentable.⁷ 333 U.S. at 128-31. Each species of bacteria in the mixture could extract nitrogen from the air for plant usage. While the patent holder had created a mixture by selecting and testing for strains of bacteria that did not mutually inhibit one another, the Court concluded that the patent holder "did not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable." *Id.* at 130.

Most recently, the Supreme Court addressed the application of § 101 to product claims in *Diamond v. Chakrabarty*, 447 U.S. 303. In *Chakrabarty*, the Court considered whether a "live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101." *Id.* at 305. The microorganism in question was a bacterium that had been genetically engineered to break down multiple components of crude oil and possessed considerable utility in the treatment of oil spills. *Id.* In concluding that the man-made bacterial strain was patentable, the Court observed that the claim "is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter - a product of human ingenuity 'having a distinctive name, character [and] use.'" *Id.* at 309-10 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)). The Court went on to contrast the *Chakrabarty* bacterium with the bacterial mixture at issue in *Funk Brothers*, stating that in *Chakrabarty's* case, "the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own" *Id.* at 310. This requirement that an invention possess "markedly different characteristics" for purposes of § 101 reflects the oft-repeated requirement that an invention have "a new or distinctive form, quality, or property" from a product of nature. *Am. Fruit Growers*, 283 U.S. at 11; *In re Merz*, 97 F.2d 599, 601, 25 C.C.P.A. 1314, 1938 Dec. Comm'r Pat. 728 (C.C.P.A. 1935) ("[M]ere purification of known materials does not result in a patentable product," unless "the product obtained in such a case had properties and characteristics which were different in kind from those of the known product rather than in degree.").

Courts have also specifically held that "purification" of a natural compound, without more, is insufficient to render a product of nature patentable. In *The American Wood-Paper Co. v. The Fibre Disintegrating Co.*, 90 U.S. (23 Wall.) 566, 23 L. Ed. 31 (1874), the Supreme Court held that refined cellulose, consisting of purified pulp derived from wood and vegetable, was unpatentable because it was "an extract obtained by the decomposition or disintegration of material substance." *Id.* at 593. As the Court observed:

There are many things well known and valuable in medicine or in the arts which may be extracted from divers[e] substances. But the extract is the same, no matter

⁷ Myriad suggests that the Supreme Court's holding in *Funk Brothers* was premised on an obviousness determination, rather than patentable subject matter. Subsequent Supreme Court opinions, however, have treated the holding in *Funk Brothers* as a statement of patentable subject matter. See *Chakrabarty*, 447 U.S. at 309-10; *Flook*, 437 U.S. at 591-92; *Benson*, 409 U.S. at 67-68.

from what it has been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture.

Id. at 593-94. Similarly, in *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884), the Court rejected a patent on an artificial version of a natural red dye called alizarine that was produced by manipulating another compound through acid, heat, water or distillation. See generally, *id.* Although the artificial version of the dye was of a brighter hue than the naturally occurring dye, the Court concluded that "[c]hanging it artificial alizarine did not make it a new composition of matter, and patentable as such" *Id.* at 311 (citing *Am. Wood-Paper*, 90 U.S. (23 Wall.) at 593).

In *General Electric [v. De Forest Radio Co.]*, 28 F.2d 641, 642 (3d Cir. 1928), the Third Circuit Court of Appeals considered the patentability of purified tungsten, which possessed superior characteristics and utility over its brittle, naturally-occurring form. The court first noted that "[i]f it is a natural thing then clearly, even if [the patentee] was the first to uncover it and bring it into view, he cannot have a patent for it because a patent cannot be awarded for a discovery or for a product of nature, or for a chemical element." *Id.* The court went on to state:

Naturally we inquire who created pure tungsten. Coolidge? No. It existed in nature and doubtless has existed there for centuries. The fact that no one before Coolidge found it there does not negative its origin or existence.

The second part of the claim reads: "Having ductility and high tensile strength." Did Coolidge give those qualities to "substantially pure tungsten"? We think not for it is now conceded that tungsten pure is ductile cold. If it possess that quality now it is certain that it possessed it always.

Id. at 643. The Court of Customs and Patent Appeals ("C.C.P.A."), the precursor to the Federal Circuit Court of Appeals, subsequently relied on *General Electric* in rejecting patents claiming purified uranium and vanadium. See *In re Marden*, 47 F.2d 957, 957-58, 18 C.C.P.A. 1046, 1931 Dec. Comm'r Pat. 329 (C.C.P.A. 1931) ("*Marden I*"); *In re Marden*, 47 F.2d 958, 18 C.C.P.A. 1057, 1059, 1931 Dec. Comm'r Pat. 352 (C.C.P.A. 1931) ("*Marden II*") ("The quality of purity of vanadium or its ductility is a quality of a natural product and as such is not patentable."). Similarly, in *Ex Parte Latimer*, the Patent Commissioner refused to allow a patent on pine needle fibers that were better suited for textile production, even though it was necessary to remove the needle from its sheath and other resinous material. 1889 Dec. Comm'r Pat. 123, 125 (1889) ("Nature made them so and not the process by which they are taken from the leaf or needle.").

Myriad argues that purification of "naturally occurring" compounds that "do not exist in nature in pure form" renders such compounds patent-eligible." Myriad Br. at 21 (quoting *In re Bergstrom*, 427 F.2d 1394, 1401, 57 C.C.P.A. 1240 (C.C.P.A. 1970)). However, Myriad cites no Supreme Court authority that would rebut the authorities presented by Plaintiffs, nor do the cited cases support Myriad's position.

Myriad has relied heavily on the holding of the Honorable Learned Hand in *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911).⁸ In *Parke-Davis*, Judge Hand considered a challenge to the validity of a patent claiming an adrenaline compound that had been isolated and purified from animal suprarenal glands. *Id.* at 97. It had been known that suprarenal glands in powdered form had hemostatic, blood-pressure-raising and astringent properties, but could not be used for those purposes in gross form. The isolated adrenaline, however, possessed the desired therapeutic properties and could be administered to humans.

Although Myriad argues that the holding in *Parke-Davis* establishes that the purification of a natural product necessarily renders it patentable, the opinion, read closely, fails to support such a conclusion. The question before the court in *Parke-Davis* was one of novelty (a modern-day § 102 question), not of patentable subject matter (the § 101 question before this Court). In framing the issue, Judge Hand observed that, "[the validity of the claims] is attacked, first, because they are anticipated in the art; and second, for a number of technical grounds which I shall take up in turn." *Id.* at 101 (emphasis added). He went on to conclude that the patented purified extract was not, in fact, different from the prior art "only for a degree of purity," but rather was a different chemical substance from that found in the prior art. *Id.* at 103 (observing that "no one had ever isolated a substance [adrenaline] which was not in salt form" and that "the [claimed] base [form of adrenaline] was an original production of [the patentee's]"). Thus, Judge Hand held that the purified adrenaline was not anticipated by the prior art, namely, the ground suprarenal gland that was known to possess certain beneficial properties. See *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 162 (4th Cir. 1958) ("It was further held [in *Parke-Davis*] that the invention was not anticipated, though the principle was known to exist in the suprarenal glands.").

Only after concluding that the claimed purified adrenaline was novel over the prior art did Judge Hand offer, as dicta, the statement to which Myriad cites: "But, even if it were merely an extracted product without change, there is no rule that such products are not patentable." *Id.* at 103. While the accuracy of this statement at the time was written is dubious in light of *American Wood-Paper* (to which Judge Hand did not cite) it is certainly no longer good law in light of subsequent Supreme Court cases, which, as

⁸ The invocation of Judge Hand is frequently practiced in this Circuit. [Citing numerous cases.] See also, Remarks of the Honorable John M. Walker, Jr. Upon Receiving the Learned Hand Medal for Excellence in Federal Jurisprudence, 76 St. John's L. Rev. 595, 596 (2002) ("Judge Hand is widely considered to have been one of the four greatest judges of the first half of the twentieth century."); James L. Oakes, Personal Reflections on Learned Hand and the Second Circuit, 47 Stan. L. Rev. 387 (1995); Gerald Gunther, Learned Hand: the Man and the Judge (1994); Kathryn Griffin, Judge Learned Hand and the Role of the Federal Judiciary (1973); Marvin Schick, Learned Hand's Court (1970); Marcia Nelson, ed., The Remarkable Hands: An Affectionate Portrait (1983); Hershel Shanks, ed., The Art and Craft of Judging: The Decisions of Judge Learned Hand (1968). Although Judge Hand once turned his back on the author of this opinion arguing before him on behalf of the Government, his opinion in *Parke-Davis* deserves careful review but brings to mind that oft repeated adage "Quote Learned, but follow Gus." See Oakes, 47 Stan. L. Rev. at 389 n.175. [The reference is to Augustus or "Gus" Hand, Learned Hand's cousin who was also a very well regarded judge on the Second Circuit.] This author, confronted by genomics and molecular biology, also emphatically empathizes with Judge Hand's complaint in *Parke-Davis* about his lack of knowledge of the rudiments of chemistry. See *Parke-Davis*, 189 F. at 114.

noted above, require that a claimed invention possess "markedly different characteristics" over products existing in nature in order for it to constitute patentable subject matter.⁹ *Chakrabarty*, 447 U.S. at 310; see also *Funk Bros.*, 333 U.S. at 130-32. By the same token, Judge Hand's suggestion that a claimed invention was patentable since it was a "new thing commercially and therapeutically," *Parke-Davis*, 189 F. at 103, is firmly contradicted by subsequent case law establishing that "it is improper to consider whether a claimed element or step in a process is novel or nonobvious, since such considerations are separate requirements" when evaluating whether a claim is patent-eligible subject matter. *Prometheus [Labs. v. Mayo Collaborative Servs.]*, 581 F.3d 1336, 1343 (Fed. Cir. 2009)], see also *In re Bergy*, 596 F.2d 952, 960-61 (C.C.P.A. 1979). Such an approach would also be inconsistent with the Supreme Court's rejection of the patentability of the commercially useful mixture of bacteria in *Funk Brothers*, the refined cellulose in *American Wood-Paper*, and the electromagnetic communication devices in *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 14 L. Ed. 601 (1853).

* * *

Finally, *Merck & Co., Inc. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, cited by *Myriad*, is entirely consistent with the principle set forth in *Funk Brothers* and *American Fruit Growers* that something derived from a product of nature must "possess a new or distinctive form, quality, or property" in order to become patentable subject matter. *Am. Fruit Growers*, 283 U.S. at 11. In *Merck*, the Fourth Circuit considered the validity of a patent claiming a Vitamin B12 composition useful for treating pernicious anemia. *Id.* at 157. Although naturally occurring Vitamin B[12] produced in cows had known therapeutic properties and was commercially available, the court found the purified B[12] composition, which was obtained from a microorganism, patentable. In upholding the validity of the patent, the court held:

Every slight step in purification does not produce a new product. What is gained may be the old product, but with a greater degree of purity. Alpha alumina purified is still alpha alumina, *In re Ridgway*, 76 F.2d 602, 22 C.C.P.A. 1169, 1935 Dec. Comm'r Pat. 533,[] and ultramarine from which floatable impurities have been removed is still ultramarine, *In re Merz*, 97 F.2d 599, 25 C.C.P.A. 1314, 1938 Dec. Comm'r Pat. 728 . . .

Id. at 163. Because the court concluded that the purified B[12] was more than a "mere advance in the degree of purity of a known product," it determined that the claimed invention was entitled to patent protection. *Id.* at 164.

In sum, the clear line of Supreme Court precedent and accompanying lower court authorities, stretching from *American Wood-Paper* through to *Chakrabarty*, establishes that purification of a product of nature, without more, cannot transform it into patentable subject matter. Rather, the purified product must possess "markedly different characteristics" in order to satisfy the requirements of § 101.

⁹ Notwithstanding Judge Hand's reputation, see *supra* note 46, his opinion in *Parke-Davis* was one of a district court judge and does not supersede contrary statements of the law by the C.C.P.A. or the Supreme Court.

3. The claimed isolated DNA is not "markedly different" from native DNA

The question thus presented by Plaintiffs' challenge to the composition claims is whether the isolated DNA claimed by Myriad possesses "markedly different characteristics" from a product of nature. *Chakrabarty*, 447 U.S. at 310. In support of its position, Myriad cites several differences between the isolated DNA claimed in the patents and the native DNA found within human cells. None, however, establish the subject matter patentability of isolated BRCA1/2 DNA.

The central premise of Myriad's argument that the claimed DNA is "markedly different" from DNA found in nature is the assertion that "[i]solated DNA molecules should be treated no differently than other chemical compounds for patent eligibility," Myriad Br. at 26, and that the alleged "difference in the structural and functional properties of isolated DNA" render the claimed DNA patentable subject matter, Myriad Br. at 31.

Myriad's focus on the chemical nature of DNA, however, fails to acknowledge the unique characteristics of DNA that differentiate it from other chemical compounds. As Myriad's expert Dr. Joseph Straus observed: "Genes are of double nature: On the one hand, they are chemical substances or molecules. On the other hand, they are physical carriers of information, i.e., where the actual biological function of this information is coding for proteins. Thus, inherently genes are multifunctional." Straus Decl. P 20; see also *The Cell* at 98, 104 ("Today the idea that DNA carries genetic information in its long chain-of nucleotides is so fundamental to biological thought that it is sometimes difficult to realize the enormous intellectual gap that it filled. . . . DNA is relatively inert chemically."); Kevin Davies & Michael White, *Breakthrough: The Race to Find the Breast Cancer Gene 166* (1996) (noting that Myriad Genetics' April 1994 press release described itself as a "genetic information business"). This informational quality is unique among the chemical compounds found in our bodies, and it would be erroneous to view DNA as "no different[]" than other chemicals previously the subject of patents.¹⁰

Myriad's argument that all chemical compounds, such as the adrenaline at issue in *Parke-Davis*, necessarily conveys some information ignores the biological realities of DNA in comparison to other chemical compounds in the body. The information encoded in DNA is not information about its own molecular structure incidental to its biological function, as is the case with adrenaline or other chemicals found in the body. Rather, the information encoded by DNA reflects its primary biological function: directing the synthesis of other molecules in the body -- namely, proteins, "biological molecules of enormous importance" which "catalyze biochemical reactions" and constitute the "major structural materials of the animal body." *O'Farrell*, 853 F.3d at 895-96. DNA, and in

¹⁰ Myriad and many of the amici suggest that the invalidation of the patents-in-suit will result in the decimation of the biotechnology industry. See, e.g., Myriad Br. at 28-29 (suggesting that a finding that DNA is unpatentable subject matter will invalidate patents to important chemical compounds such as the anticancer drug Taxol (paclitaxel) and leave "little to nothing" of the United States biotechnology industry). The conclusions reached in this opinion concerning the subject matter patentability of isolated DNA, however, are based on the unique properties of DNA that distinguish it from all other chemicals and biological molecules found in nature. As a result, Myriad's predictions for the future of the U.S. biotechnology industry are unfounded.

particular the ordering of its nucleotides, therefore serves as the 'physical embodiment of laws of nature - those that define the construction of the human body. Any "information" that may be embodied by adrenaline and similar molecules serves no comparable function, and none of the declarations submitted by Myriad support such a conclusion. Consequently, the use of simple analogies comparing DNA with chemical compounds previously the subject of patents cannot replace consideration of the distinctive characteristics of DNA.

In light of DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad between native BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed in the patents-in-suit render the claimed DNA "markedly different." This conclusion is driven by the overriding importance of DNA's nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated" form. The preservation of this defining characteristic of DNA in its native and isolated forms mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature.

Myriad argues that the § 101 inquiry into the subject matter patentability of isolated DNA should focus exclusively on the differences alleged to exist between native and isolated DNA, rather than considering the similarities that exist between the two forms of DNA. See, e.g., Myriad Reply at 8-9 ("[T]he observation that isolated DNA and native DNA share this single property [i.e. the same protein coding sequences] is irrelevant to the critical issue of whether there are differences in their properties. It is the differences that are legally relevant to the novelty inquiry under Section 101, not the properties held in common." (emphasis in original)); Myriad Br. at 8. Setting aside the fact that considerations such as novelty are irrelevant for § 101 purposes, see Bergy, 596 F.2d at 960-61, Myriad offers no authorities supporting such an approach. To the contrary, the Supreme Court has held that "[i]n determining the eligibility of [a] claimed process for patent protection under § 101, [the] claims must be considered as a whole." *Diehr*, 450 U.S. at 188. Similarly, the Federal Circuit has expressly held that "[i]n the final analysis under § 101, the claimed invention, as a whole, must be evaluated for what it is." *In re Grams*, 888 F.2d 835, 839 (Fed. Cir. 1989) (quoting *In re Abele*, 684 F.2d 902, 907 (C.C.P.A. 1982)).

Were Myriad's approach the law, it is difficult to discern how any invention could fail the test. For example, the bacterial mixture in *Funk Brothers* was unquestionably different from any preexisting bacterial mixture; yet the Supreme Court recognized that a patent directed to the mixture, considered as a whole, did no more than patent "the handiwork of nature." 333 U.S. at 131. There will almost inevitably be some identifiable differences between a claimed invention and a product of nature; the appropriate § 101 inquiry is whether, considering the claimed invention as a whole, it is sufficiently distinct in its fundamental characteristics from natural phenomena to possess the required "distinctive name, character, [and] use." *Chakrabarty*, 447 U.S. at 309-10.

None of Myriad's arguments establish the distinctive nature of the claimed DNA. Myriad's argument that association of chromosomal proteins with native DNA establishes the existence of "structural differences" between native and isolated DNA relies on an

incorrect comparison between isolated DNA and chromatin, which are indeed different insofar as chromatin includes chromosomal proteins normally associated with DNA. The proper comparison is between the claimed isolated DNA and the corresponding native DNA, and the presence or absence of chromosomal proteins merely constitutes a difference in purity that cannot serve to establish subject matter patentability. See *Gen. Elec.*, 28 F.2d at 642-43; *Marden I*, 47 F.2d at 957-58; *Marden II*, 18 C.C.P.A. at 1059.

* * *

Myriad's argument that the functional differences between native and isolated DNA demonstrates that they are "markedly different" relies on the fact that isolated DNA may be used in applications for which native DNA is unsuitable, namely, in "molecular diagnostic tests (e.g., as probes, primers, templates for sequencing reactions), in biotechnological processes (e.g. production of pure BRCA1 and BRCA2 protein), and even in medical treatments (e.g. gene therapy)." Myriad Reply at 9; see also Myriad Br. at 30-32.

Isolated DNA's utility as a primer or a molecular probe (for example, for Southern blots) arises from its ability to "target and interact with other DNA molecules," that is, the ability of a given DNA molecule to bind exclusively to a specific DNA target sequence. Myriad Br. at 33; see Kay Decl. P 138. Thus, for example, a 24 nucleotide segment of isolated BRCA1 DNA can be used as a primer because it will bind only to its corresponding location in the BRCA1 gene. However, the basis for this utility is the fact that the isolated DNA possesses the identical nucleotide sequence as the target DNA sequence, 54 thus allowing target specific hybridization between the DNA primer and the portion of the target DNA molecule possessing the corresponding sequence. Kay Decl. HSI 135-36, 138. In contrast, another 24 nucleotide segment of DNA possessing the same nucleotide composition but a different nucleotide sequence would not have the same utility because it would be unable to hybridize to the proper location in the BRCA1 gene. 55 Indeed, Myriad implicitly acknowledges this fact when it states that the usefulness of isolated DNA molecules "is based on their ability to target and interact with other DNA molecules, which is a function of their own individual structure and chemistry." Myriad Br. at 33 (emphasis added). Therefore, the cited utility of the isolated DNA as a primer or probe is primarily a function of the nucleotide sequence identity between native and isolated BRCA1/2 DNA.

Similarly, the utility of isolated DNA as a sequencing target relies on the preservation of native DNA's nucleotide sequence. Indeed, one need look no further than Myriad's BRAC Analysis testing, which relies on the sequencing of isolated DNA (i.e. the PCR amplified exons of BRCA1/2), to determine the sequence of the corresponding DNA coding sequences found in the cell. The entire premise behind Myriad's genetic testing is that the claimed isolated DNA retains, in all relevant respects, the identical nucleotide sequence found in native DNA. The use of isolated BRCA1/2 DNA in the production of BRCA1/2 proteins or in gene therapy also relies on the identity between the native DNA sequences and the sequences contained in the isolated DNA molecule. Were the isolated BRCA1/2 sequences different in any significant way, the entire point of their use - the production of BRCA1/2 proteins - would be undermined.

While the absence of proteins and other nucleotide sequences is currently required for DNA to be useful for the cited purposes, the purification of native DNA does not alter its essential characteristic - its nucleotide sequence - that is defined by nature and central to both its biological function within the cell and its utility as a research tool in the lab. The requirement that the DNA used be "isolated" is ultimately a technological limitation to the use of DNA in this fashion, and a time may come when the use of DNA for molecular and diagnostic purposes may not require such purification. The nucleotide sequence, however, is the defining characteristic of the isolated DNA that will always be required to provide the sequence-specific targeting and protein coding ability that allows isolated DNA to be used for the various applications cited by Myriad. For these reasons, the use of isolated DNA for the various purposes cited by Myriad does not establish the existence of differences "in kind" between native and isolated DNA that would establish the subject matter patentability of what is otherwise a product of nature. See *Am. Fruit Growers*, 283 U.S. at 11.

Finally, the isolated BRCA1/2 DNA claimed in Myriad's patents bears comparison to the bacterial mixture in *Funk Brothers*. In explaining why the claimed mixture of bacteria did not constitute an invention, the Court observed that the first part of the claimed invention was the "[d]iscovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either" which was "a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable." 333 U.S. at 131. The Court went on to observe that the second part of the claimed invention was "[t]he aggregation of select strains of the several species into one product[,] an application of that newly-discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants." *Id.*

According to Myriad, the invention claimed in its patents required the identification of the specific segments of chromosomes 17 and 13 that correlated with breast and ovarian cancer (BRCA1 and BRCA2) followed by the isolation of these sequences away from other genomic DNA and cellular components. Myriad Reply at 6 ("By identifying these particular BRCA DNAs and isolating them away from other genomic DNA and other cellular components, the inventors created the claimed isolated BRCA DNA molecules."). Like the discovery of the mutual non-inhibition of the bacteria in *Funk Brothers*, discovery of this important correlation was a discovery of the handiwork of nature - the natural effect of certain mutations in a particular segment of the human genome. And like the aggregation of bacteria in *Funk Brothers*, the isolation of the BRCA1 and BRCA2 DNA, while requiring technical skill and considerable labor, was simply the application of techniques well-known to those skilled in the art. See Parthasarathy Decl. P 19. The identification of the BRCA1 and BRCA2 gene sequences is unquestionably a valuable scientific achievement for which Myriad deserves recognition, but that is not the same as concluding that it is something for which they are entitled to a patent. See *Funk Bros.*, 333 U.S. at 132 ("[O]nce nature's secret of the non-inhibitive quality of certain strains of the [nitrogen-fixing bacteria] was discovered, the

state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention.").

Because the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under 35 U.S.C. § 101.

[The court issued summary judgment for the Plaintiffs.]

NOTES AND QUESTIONS ON *MYRIAD*

1. Learned Hand vs. Robert Sweet. In *Myriad*, Judge Robert Sweet provides an excellent counterpoint to Learned Hand's famous opinion in *Parke-Davis*. These two judges are sufficiently long-lived that their careers overlapped, with Judge Sweet vividly remembering that Learned Hand (by then a highly respected Second Circuit judge) turned his back on a much younger Robert Sweet as he was arguing a case for the government. Who gets the better of the argument here? Which judge's opinion will prevail on appeal? Is Hand's position in *Parke-Davis* really incompatible with Sweet's opinion here?

2. Legal Realism. Judge Hand's *Parke-Davis* opinion seems to be influenced by the early legal realist movement which, roughly speaking, rejected reliance on formalisms and logic and instead looked to social and industrial facts and policies in crafting and applying legal principles. Thus, for example, Learned Hand thought the result in *Parke-Davis* should "be drawn rather from the common usages of men than from nice considerations of dialectic." Because artificially purified adrenaline was widely recognized as "a new thing commercially and therapeutically," Hand was willing to recognize it as a new thing (not a natural thing) for purposes of the law. If the "common usages" of today were applied in *Myriad*, how should the case come out? Would your opinion change if, as Judge Sweet found, at least some "scientists in the fields of molecular biology and genomics" consider the practice of patenting isolated DNA sequences to be "a 'lawyer's trick' that circumvents the prohibitions on the direct patenting of the DNA in our bodies but which, in practice, reaches the same result"?

3. The PTO's Position. The PTO has now been issuing patents on isolated or purified naturally occurring substances for many years. The agency has also expressly endorsed Judge Hand's *Parke-Davis* opinion. See U.S. Patent and Trademark Office, *Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (relying on Hand's *Parke-Davis* opinion to support the view that an isolated DNA sequence is patentable subject matter "because that DNA molecule does not occur in that isolated form in nature"). Should the courts give some deference to this administrative practice?

4. The Inevitable Appeal(s). The *Myriad* decision is being appealed to the Federal Circuit, and it may eventually wind up going to the Supreme Court, which would then have an opportunity to rule on the validity of Judge Hand's *Parke-Davis* position. Stay tuned.

On pages 166-170, replace *State Street Bank* with the following:

As discussed earlier, *Bilski v. Kappos* has now decided that business method patents are not categorically excluded from patentable subject matter. Yet *Bilski* also decided that all claims in the case were unpatentable as abstract ideas. As a result of *Bilski*'s holding, the most important issue in the patenting of business methods is not whether business methods can ever be patented but whether the particular business methods at issue in any particular patent application or patent litigation are sufficiently non-abstract so as to be patentable. The *Bilski* decision itself provides some guidance on this point, but the PTO provided more guidance one month after the Court's decision in *Bilski*. The following are the agency's proposed "guidelines" for applying *Bilski* to the thousands of business method patent applications now pending in the Office. The guidelines are worth reviewing in part because they provide a very nice outline of all the relevant factors that have been identified in prior caselaw. The guidelines can be helpful for an examiner in ruling on an application (their primary intended use), for a court in deciding a case, or even for a student taking a patent law exam.

**Interim Guidance for Determining Subject Matter Eligibility for
Process Claims in View of *Bilski v. Kappos***

75 FR 43922 (USPTO July 27, 2010)

[After setting forth some preliminary material (such as a summary of the *Bilski* litigation, the PTO sets forth its view of how process and method claims should be evaluated in Parts IV and V of the guidance document:]

IV. Evaluating Method Claims for Eligibility:

Where the claim is written in the form of a method and is potentially a patentable process, as defined in 35 U.S.C. 100(b), the claim is patent-eligible so long as it is not disqualified as one of the exceptions to § 101's broad patent-eligibility principles; i.e., laws of nature, physical phenomena, and abstract ideas.

Taking into account the following factors, the examiner should determine whether the claimed invention, viewed as a whole, is disqualified as being a claim to an abstract idea. Relevant factors--both those in favor of patent-eligibility and those against such a finding--should be weighed in making the determination. Factors that weigh in favor of patent-eligibility satisfy the criteria of the machine-or-transformation test or provide evidence that the abstract idea has been practically applied. Factors that weigh against patent-eligibility neither satisfy the criteria of the machine-or-transformation test nor provide evidence that the abstract idea has been practically applied. Each case will present different factors, and it is likely that only some of the factors will be present in each application. It would be improper to make a conclusion based on one factor while ignoring other factors. ...

Factors To Be Considered in an Abstract Idea Determination of a Method Claim

A. Whether the method involves or is executed by a particular machine or apparatus. If so, the claims are less likely to be drawn to an abstract idea; if not, they are

more likely to be so drawn. Where a machine or apparatus is recited or inherent in a patent claim, the following factors are relevant:

(1) The particularity or generality of the elements of the machine or apparatus; i.e., the degree to which the machine in the claim can be specifically identified (not any and all machines). Incorporation of a particular machine or apparatus into the claimed method steps weighs toward eligibility.

(2) Whether the machine or apparatus implements the steps of the method. Integral use of a machine or apparatus to achieve performance of the method weighs toward eligibility, as compared to where the machine or apparatus is merely an object on which the method operates, which weighs against eligibility.

(3) Whether its involvement is extrasolution activity or a field-of-use, i.e., the extent to which (or how) the machine or apparatus imposes meaningful limits on the execution of the claimed method steps. Use of a machine or apparatus that contributes only nominally or insignificantly to the execution of the claimed method (e.g., in a data gathering step or in a field-of-use limitation) would weigh against eligibility.

B. Whether performance of the claimed method results in or otherwise involves a transformation of a particular article. If such a transformation exists, the claims are less likely to be drawn to an abstract idea; if not, they are more likely to be so drawn. Where a transformation occurs, the following factors are relevant:

(1) The particularity or generality of the transformation. A more particular transformation would weigh in favor of eligibility.

(2) The degree to which the recited article is particular; i.e., can be specifically identified (not any and all articles). A transformation applied to a generically recited article would weigh against eligibility.

(3) The nature of the transformation in terms of the type or extent of change in state or thing, for instance by having a different function or use, which would weigh toward eligibility, compared to merely having a different location, which would weigh against eligibility.

(4) The nature of the article transformed, i.e., whether it is an object or substance, weighing toward eligibility, compared to a concept such as a contractual obligation or mental judgment, which would weigh against eligibility.

(5) Whether its involvement is extrasolution activity or a field-of-use, i.e., the extent to which (or how) the transformation imposes meaningful limits on the execution of the claimed method steps. A transformation that contributes only nominally or insignificantly to the execution of the claimed method (e.g., in a data gathering step or in a field-of-use limitation) would weigh against eligibility.

C. Whether performance of the claimed method involves an application of a law of nature, even in the absence of a particular machine, apparatus, or transformation. If such an application exists, the claims are less likely to be drawn to an abstract idea; if not, they are more likely to be so drawn. Where such an application is present, the following factors are relevant:

(1) The particularity or generality of the application. Application of a law of nature having broad applicability across many fields of endeavor weighs against eligibility, such as where the claim generically recites an effect of the law of nature or claims every mode of accomplishing that effect, such that the claim would monopolize a natural force or patent a scientific fact. (As an example, claiming "the use of electromagnetism for transmitting signals at a distance.")

(2) Whether the claimed method recites an application of a law of nature solely involving subjective determinations; e.g., ways to think about the law of nature. Application of a law of nature to a particular way of thinking about, or reacting to, a law of nature would weigh against eligibility.

(3) Whether its involvement is extrasolution activity or a field-of-use, i.e., the extent to which (or how) the application imposes meaningful limits on the execution of the claimed method steps. An application of the law of nature that contributes only nominally or insignificantly to the execution of the claimed method (e.g., in a data gathering step or in a field-of-use limitation) would weigh against eligibility.

D. Whether a general concept (which could also be recognized in such terms as a principle, theory, plan or scheme) is involved in executing the steps of the method. The presence of such a general concept can be a clue that the claim is drawn to an abstract idea. Where a general concept is present, the following factors are relevant:

(1) The extent to which use of the concept, as expressed in the method, would preempt its use in other fields; i.e., that the claim would effectively grant a monopoly over the concept.

(2) The extent to which the claim is so abstract and sweeping as to cover both known and unknown uses of the concept, and be performed through any existing or future-devised machinery, or even without any apparatus.

(3) The extent to which the claim would effectively cover all possible solutions to a particular problem; i.e., that the claim is a statement of the problem versus a description of a particular solution to the problem.

(4) Whether the concept is disembodied or whether it is instantiated; i.e., implemented, in some tangible way. Note, however, that limiting an abstract idea to one field of use or adding token postsolution components does not make the concept patentable. A concept that is well-instantiated weighs in favor of eligibility.

(5) The mechanism(s) by which the steps are implemented; e.g., whether the performance of the process is observable and verifiable rather than subjective or imperceptible. Steps that are observable and verifiable weigh in favor of eligibility.

(6) Examples of general concepts include, but are not limited to:

. Basic economic practices or theories (e.g., hedging, insurance, financial transactions, marketing);

. Basic legal theories (e.g., contracts, dispute resolution, rules of law);

. Mathematical concepts (e.g., algorithms, spatial relationships, geometry);

- . Mental activity (e.g., forming a judgment, observation, evaluation, or opinion);
- . Interpersonal interactions or relationships (e.g., conversing, dating);
- . Teaching concepts (e.g., memorization, repetition);
- . Human behavior (e.g., exercising, wearing clothing, following rules or instructions);
- . Instructing "how business should be conducted," *Bilski*, slip op. at 12.

V. Making the Determination of Eligibility:

Each of the factors relevant to the particular patent application should be weighed to determine whether the method is claiming an abstract idea by covering a general concept, or combination of concepts, or whether the method is limited to a particular practical application of the concept. The presence or absence of a single factor will not be determinative as the relevant factors need to be considered and weighed to make a proper determination as to whether the claim as a whole is drawn to an abstract idea such that the claim would effectively grant a monopoly over an abstract idea and be ineligible for patent protection.

If the factors indicate that the method claim is not merely covering an abstract idea, the claim is eligible for patent protection under § 101 and must be further evaluated for patentability under all of the statutory requirements, including utility and double patenting (§ 101); novelty (§ 102); non-obviousness (§ 103); and definiteness and adequate description, enablement, and best mode (§ 112). Section 101 is merely a coarse filter and thus a determination of eligibility under § 101 is only a threshold question for patentability. Sections 102, 103, and 112 are typically the primary tools for evaluating patentability unless the claim is truly abstract, see, e.g., *Bilski*, slip op. at 12 ("[S]ome business method patents raise special problems in terms of vagueness and suspect validity.").

If the factors indicate that the method claim is attempting to cover an abstract idea, the examiner will reject the claim under § 101, providing clear rationale supporting the determination that an abstract idea has been claimed, such that the examiner establishes a prima facie case of patent-ineligibility. The conclusion made by the examiner must be based on the evidence as a whole. In making a rejection or if presenting reasons for allowance when appropriate, the examiner should specifically point out the factors that are relied upon in making the determination. If a claim is rejected under § 101 on the basis that it is drawn to an abstract idea, the applicant then has the opportunity to explain why the claimed method is not drawn to an abstract idea. Specifically identifying the factors used in the analysis will allow the applicant to make specific arguments in response to the rejection if the applicant believes that the conclusion that the claim is directed to an abstract idea is in error.

QUESTION ON THE PTO'S GUIDANCE

Prior to the Supreme Court's decision in *Bilski*, the PTO had been taking a more "rule-based" approach to deciding whether a process or method was patentable: If the process satisfied the machine-or-transformation test, then it was likely a patentable process. If not, then it was almost certainly unpatentable. The PTO's Interim Guidance takes a "standards-based" approach that lists many factors but does not give any clear rule as to how those factors should be balanced. The benefit of that approach is that no unusual invention is categorically denied the chance for a patent; the cost is that individual examiners may make widely divergent decisions as they weigh all of these factors. How are these factors to be "weighed"? What metrics of abstraction should be used for assessing how much weight to give each factor? Is this enough "guidance" to produce consistent outcomes?

CHAPTER 4: DISCLOSURE AND ENABLEMENT

Add at page 290 after *In re Strahilevitz*, the following case on Prophetic Examples:

JANSSEN PHARMACEUTICA V. TEVA

583 F.3d 1317 (Fed. Cir. 2009)

DYK, J.:

Janssen Pharmaceutica N.V., Janssen L.P., and Synaptech, Inc. (“Janssen”), appeal from a final judgment of the United States District Court for the District of Delaware. After a bench trial, the district court determined that the claims of U.S. Patent No. 4,663,318 (“the ‘318 patent”) were invalid for lack of enablement. *In re ‘318 Patent Infringement Litig.*, 578 F.Supp.2d 711, 737 (D.Del. 2008). We affirm.

BACKGROUND

Janssen's '318 patent claims a method for treating Alzheimer's disease with galanthamine. Claim 1 is representative. It claims “[a] method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof.” '318 patent col.3 ll.6-10. The application for the '318 patent was filed on January 15, 1986, by Dr. Bonnie Davis, the claimed inventor.

Alzheimer's disease is a form of progressive dementia in which memory and mental abilities steadily decline. At the time of the '318 patent's application in early 1986, researchers had observed a correlation between Alzheimer's disease symptoms and a reduced level of the neurotransmitter acetylcholine in the brain. During neurotransmission, acetylcholine is released by a transmitting neuron and binds to receptors on a receiving neuron. The two main types of acetylcholine receptors are nicotinic receptors and muscarinic receptors. Nicotinic and muscarinic receptors are present in neurons in both the central nervous system (which includes the brain and spinal cord) and the peripheral nervous system (which connects the central nervous system to muscles and organs).

In early 1986, many researchers focused primarily on the importance of central nervous system muscarinic receptors in developing treatments for Alzheimer's disease. At that time, galanthamine (also spelled “galantamine”), a small molecule compound, was known to inhibit acetylcholinesterase, an enzyme that breaks down acetylcholine. Acetylcholinesterase inhibitors like galantamine increase the amount of acetylcholine available for binding to muscarinic or nicotinic receptors.

The specification for the '318 patent was only just over one page in length, and it provided almost no basis for its stated conclusion that it was possible to administer “an effective Alzheimer's disease cognitively-enhancing amount of galanthamine.” *Id.* col.1 ll.47-48. The specification provided short summaries of six scientific papers in which galantamine had been administered to humans or animals. The specification summarized the first paper as showing that administering galantamine with the drug atropine to

humans under anesthesia raised blood levels of the hormone cortisol, and the second paper as showing that administering galantamine and atropine together during anesthesia also raised levels of adrenocorticotrophic hormone (“ACTH”) in humans. *See id.* col.1 ll.13-21. There was no explanation of the significance of increasing cortisol or ACTH levels, but it was known to those skilled in the art in early 1986 that the production of cortisol and ACTH was controlled by the central nervous system rather than the peripheral nervous system, and that the studies thus suggested that galantamine was able to cross the blood-brain barrier and have effects within the brain.

The specification then provided brief summaries of four scientific papers reporting brain effects and positive effects on memory from administering galantamine to animals. *See id.* col.1 ll.22-33. The first paper concluded that galantamine intravenously administered to rabbits affected brain wave activity. The second paper concluded that galantamine increased short-term memory in dogs. The third and fourth papers concluded that galantamine reversed amnesia in rats that had been induced by administering the drug scopolamine. The specification did not suggest that such scopolamine-induced amnesia was similar to Alzheimer's disease. The specification did not provide analysis or insight connecting the results of any of these six studies to galantamine's potential to treat Alzheimer's disease in humans.

The specification noted that another prior art scientific paper described an animal testing model for replicating in animals the acetylcholine deficit and other effects of Alzheimer's disease. The specification agreed that acetylcholine deficiency in animals is a “good animal model for Alzheimer's disease in humans” because the deficiency produces “[n]umerous behavioral deficits, including the inability to learn and retain new information.” *Id.* col.2 ll.50-52. The specification cited the prior art for the conclusion that “[d]rugs that can normalize these abnormalities would have a reasonable expectation of efficacy in Alzheimer's disease.” *Id.* col.2 ll.52-54. However, the specification did not refer to any then-existing animal test results involving the administration of galantamine in connection with this animal model of Alzheimer's disease.

In April 1986 an examiner at the United States Patent and Trademark Office (“PTO”) rejected the claims in the '318 patent's application for indefiniteness and obviousness. The examiner found the patent application's claim of a method of “diagnosing” Alzheimer's disease to be indefinite, because diagnosing “has nothing to do with treating” and because the claims thus “fail[ed] to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” J.A. 4108. The examiner also found the patent application's claim of a method of treating Alzheimer's disease obvious-in light of the animal studies cited in the specification describing the use of galantamine to treat scopolamine-induced amnesia and in improving short-term memory. The examiner did not reject the application for lack of enablement.

In September 1986 the applicant, Dr. Davis, responded to the examiner's indefiniteness rejection by narrowing the claim language, deleting the words “and diagnosing” from the original application's claim of “[a] method of treating and diagnosing Alzheimer's disease.” Dr. Davis responded to the obviousness rejection by explaining that, because the brains of the animals in the studies cited in the specification

were “normal” (rather than having “physiological changes” similar to Alzheimer's disease), the studies were conducted under “circumstances having no relevance to Alzheimer's disease,” and that it thus would be “baseless” to predict from such studies that galantamine would be useful to treat Alzheimer's disease. J.A. 4407.

In addition, Dr. Davis responded by stating that “experiments [are] underway using animal models which are expected to show that treatment with galanthamine does result in an improvement in the condition of those suffering from Alzheimer's disease,” and that it was “expected that data from this experimental work will be available in two to three months and will be submitted to the Examiner promptly thereafter.” J.A. 4405. The '318 patent issued on May 5, 1987. Dr. Davis did not learn the results of the animal testing experiments—which suggested that galantamine could be a promising Alzheimer's disease treatment—until July 1987, after the '318 patent had issued. These studies required several months and considerable effort by researchers at the Johns Hopkins University under the supervision of Dr. Joseph T. Coyle. No such testing results were ever submitted to the PTO.

After the '318 patent issued in May 1987, Dr. Davis licensed the patent in November 1995 to Janssen. In February 2001 Janssen received approval from the Food and Drug Administration (“FDA”) for using galantamine to treat mild to moderate Alzheimer's disease.

In February 2005 several generic drug manufacturers filed abbreviated new drug applications (“ANDAs”), and Janssen sued each manufacturer for infringing the '318 patent. The actions were consolidated, the defendants conceded infringement of claims 1 and 4 of the '318 patent, and a bench trial was held in May 2007 on the invalidity issues of anticipation, obviousness, and enablement.

The district court found that the '318 patent was neither anticipated nor obvious. However, the district court concluded that the '318 patent was invalid for lack of enablement on two distinct grounds. The district court found that the specification did not demonstrate utility because relevant animal testing experiments were “not finished ... by the time the '318 patent was allowed” and the specification provided only “minimal disclosure” of utility. *'318 Patent Infringement Litig.*, 578 F.Supp.2d at 723, 735; *see also id.* at 736-37 & n. 39. The district court alternatively found that the specification and claims did not “teach one of skill in the art how to use the claimed method” because the application “only surmise[d] how the claimed method could be used” without providing sufficient galantamine dosage information. *Id.* at 736. The district court entered judgment in favor of the defendants that the '318 patent was invalid for lack of enablement.

Janssen timely appealed. We have jurisdiction under 28 U.S.C. §§ 1291 and 1295(a)(1).

DISCUSSION

Enablement is a question of law we review without deference. *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1070 (Fed.Cir. 2005). We review the factual issues underlying enablement for clear error. *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1369 (Fed.Cir. 1999).

Enablement is closely related to the requirement for utility. As we noted in *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed.Cir.1999),

The enablement requirement of 35 U.S.C. § 112, ¶ 1 requires that the specification adequately discloses to one skilled in the relevant art how to make, or in the case of a process, how to carry out, the claimed invention without undue experimentation. The utility requirement of 35 U.S.C. § 101 mandates that any patentable invention be useful and, accordingly, the subject matter of the claim must be operable. *If a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement.*

(emphasis added, citations and footnote omitted). *See also* 3 Donald A. Chisum, *Chisum on Patents* § 7.03(6) (2007). The Supreme Court in *Brenner v. Manson*, 383 U.S. 519 (1966), discussing the utility requirement, stated that inventions must have “substantial utility” and “specific benefit exist[ing] in currently available form.” *Id.* at 534-35.

The utility requirement prevents mere ideas from being patented. As we noted in *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed.Cir. 1997), “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.... Tossing out the mere germ of an idea does not constitute enabling disclosure.” *See also In re Fisher*, 421 F.3d 1365, 1373 (Fed.Cir. 2005) (inventions fail to meet the utility requirement if their “asserted uses represent merely hypothetical possibilities, objectives which the claimed [inventions] ... *could* possibly achieve, but none for which they have been used in the real world”).

The utility requirement also prevents the patenting of a mere research proposal or an invention that is simply an object of research. Again as the Supreme Court stated in *Brenner*, “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” 383 U.S. at 536. A process or product “which either has no known use or is useful only in the sense that it may be an object of scientific research” is not patentable. *Id.* at 535. As we observed in *Fisher*, inventions do not meet the utility requirement if they are “objects upon which scientific research could be performed with no assurance that anything useful will be discovered in the end.” 421 F.3d at 1373. Allowing ideas, research proposals, or objects only of research to be patented has the potential to give priority to the wrong party and to “confer power to block off whole areas of scientific development, without compensating benefit to the public.” *Brenner*, 383 U.S. at 534 (footnote omitted).

Typically, patent applications claiming new methods of treatment are supported by test results. But it is clear that testing need not be conducted by the inventor. In addition, human trials are not required for a therapeutic invention to be patentable. Our predecessor court, the United States Court of Customs and Patent Appeals, held in *In re Krimmel* that patent applications need not “prove that compounds or other materials which [the applicant] is claiming, and which [the applicant] has stated are useful for

'pharmaceutical applications' are safe, effective, and reliable for use with humans." 48 C.C.P.A. 1116, 292 F.2d 948, 954 (Cust. & Pat.App.1961).

We have held that results from animal tests or in vitro experiments ^{FN7} may be sufficient to satisfy the utility requirement. Our predecessor court held in *Krimmel* that animal tests showing that a new nonobvious compound "exhibits some useful pharmaceutical property" are sufficient to demonstrate utility. 292 F.2d at 953. We noted in *Cross v. Iizuka* that "[w]e perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the [pharmaceutical] compound in question" in order for a patent to issue. 753 F.2d 1040, 1051 (Fed.Cir.1985). We concluded that in vitro test results for a claimed pharmaceutical compound, combined with animal test results for a structurally similar compound, showed "a reasonable correlation between the disclosed *in vitro* utility and an in vivo activity, and therefore a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the probative evidence." *Id.* at 1050.

In this case, however, neither in vitro test results nor animal test results involving the use of galantamine to treat Alzheimer's-like conditions were provided. The results from the '318 patent's proposed animal tests of galantamine for treating symptoms of Alzheimer's disease were not available at the time of the application, and the district court properly held that they could not be used to establish enablement.

Nor does Janssen contend that the prior art animal testing summarized in the '318 patent application's specification established utility. Indeed, both in responding to the examiner's obviousness rejection and in responding to the obviousness defense at trial, the inventor (Dr. Davis) and Janssen's witnesses explicitly stated that the utility of the invention could not be inferred from the prior art testing described in the application. The response of the inventor, Dr. Davis, to the examiner's obviousness rejection stated, with regard to studies cited in the specification showing galantamine's ability to reverse scopolamine-induced amnesia in normal rats, that "[n]othing in this teaching leads to an expectation of utility against Alzheimer's disease." J.A. 4409. The response of Dr. Davis also stated that "predict[ing] that galanthamine would be useful in treating Alzheimer's disease just because it has been reported [in the prior art studies cited in the specification] to have an effect on memory in circumstances having no relevance to Alzheimer's disease" would be "as baseless as a prediction that impaired eyesight due to diabetes would respond to devices (eyeglasses) or treatments (eye exercises) known to improve the vision of normal persons." J.A. 4407. Janssen's other expert Dr. Raskind testified that studying a compound's effects on scopolamine-induced amnesia "ignores the whole other [nicotinic] part that's damaged in Alzheimer's disease" and thus "doesn't mimic Alzheimer's disease." J.A. 9301-02. The district court agreed, finding, for example, that the utility of galantamine in treating scopolamine-induced amnesia did not establish galantamine's utility in treating Alzheimer's disease. *See '318 Patent Infringement Litig.*, 578 F.Supp.2d at 731 ("[S]copolamine [']s ... usefulness as a model for [Alzheimer's disease] research has limitations.... [A] person of skill in the art would not have a reasonable expectation of success for using a drug that worked for scopolamine-induced delirium to treat [Alzheimer's disease].").

However, Janssen argues that in some circumstances utility may be established without testing the proposed treatment in the claimed environment or a sufficiently similar or predictive environment; that is, Janssen argues that utility may be established by analytic reasoning. Although no case has been called to our attention where utility was established simply by analytic reasoning, the PTO's Manual of Patent Examining Procedure ("MPEP") has recognized that "arguments or reasoning" may be used to establish an invention's therapeutic utility.

Janssen goes on to argue that the specification here establishes utility by analytic reasoning. Relying on trial testimony, Janssen reasons that the selection and description of the prior art tests, while not directly pertinent, "set[] forth the evidence from existing studies demonstrating galantamine's effects on central nicotinic as well as muscarinic receptors and connect[ed] it to a model for Alzheimer's therapy rendering those effects therapeutically relevant." Janssen Reply Br. 17 n. 2. Janssen asserts that the prior art tests summarized in the specification would lead one skilled in the art to infer that galantamine affected the ability of acetylcholine to bind to both nicotinic and muscarinic receptors in the brain. Janssen also asserts that the animal tests proposed in the specification as a model for Alzheimer's disease would further lead one skilled in the art to infer that the model's method of impairing brain acetylcholine availability would allow both muscarinic and nicotinic effects to be observed. Janssen thus argues that because nicotinic receptors in the brain are involved with the ability to learn, the specification suggested that galantamine could have beneficial effects on learning (unlike prior art treatments, which had primarily affected muscarinic receptors). These insights, however, are nowhere described in the specification. Nor was there evidence that someone skilled in the art would infer galantamine's utility from the specification, even if such inferences could substitute for an explicit description of utility.

Janssen relies on the testimony of its expert Dr. Coyle, the scientist who later supervised the performance of the animal studies suggested in the specification. He testified that the specification "connected the dots" for galantamine as a potential Alzheimer's disease treatment, listing the "dots" as "[g]alanthamine in humans safe and well tolerated [,][c]holinesterase inhibitor, selective nicotinic effects, and very modest muscarinic receptor side effects." J.A. 9057-58. This testimony of Dr. Coyle on which Janssen relies, however, characterized the use of galantamine to treat Alzheimer's disease as "a *proposal* that connected the dots that raised very interesting questions and *worth the effort to check it out* in a model in which ... both nicotinic and muscarinic receptors would come into play." *Id.* (emphases added). Similarly, agreement by another of Janssen's expert witnesses, Dr. Raskind, that a person of ordinary skill in the art in early 1986 would have viewed the "invention as set forth in the patent as scientifically grounded" falls far short of demonstrating that a person of ordinary skill in the art would have recognized that the specification conveyed the required assertion of a credible utility. J.A. 9305. In fact, the inventor's own testimony reveals that an ordinarily skilled artisan would not have viewed the patent's disclosure as describing the utility of galantamine as a treatment for Alzheimer's disease: "[W]hen I submitted this patent, I certainly wasn't sure, and a lot of other people weren't sure that cholinesterase inhibitors[,"

a category of agents that includes galantamine,] would ever work.” J.A. 8747; *see* '318 *Patent Infringement Litig.*, 578 F.Supp.2d at 736.

Thus, at the end of the day, the specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis. That is not sufficient. *See Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed.Cir. 2005) (“If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to ‘inventions’ consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the ‘inventor’ would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis.”).

The '318 patent's description of using galantamine to treat Alzheimer's disease thus does not satisfy the enablement requirement because the '318 patent's application did not establish utility.

CONCLUSION

For the foregoing reasons, the decision of the district court is affirmed.

AFFIRMED

NOTE ON JANSSEN

It is very rare for a patent to be invalidated on grounds of utility during litigation. A recent article argues that utility is underutilized as a patent policy lever, and that there are good reasons to ramp up application of this doctrine to better effectuate the goals of the patent system. See Michael Risch, *Reinventing Usefulness*, forthcoming 2010 B.Y.U. L. Rev. , avail. at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1568063. See also the summary and review of this article: John F. Duffy, *The Utility Requirement Reduxit*, JOTWELL, May 5, 2010, available at <http://ip.jotwell.com/patent-utility-reduxit/>.

C. THE WRITTEN DESCRIPTION REQUIREMENT

Add at the end of the Notes following *Gentry Gallery*, on page 309:

7. Sophisticated Application. *Rambus, Inc. v. Hynix Semiconductor, Inc.*, 2008 WL 2754805 (N.D. Cal., July 10, 2008), provides a sophisticated treatment of written description doctrine in action at the trial court level. The opinion, by the eminent district court judge Ronald M. Whyte (a noted expert on patent law) is especially interesting for its discussion of a specification that excludes or distinguishes certain non-described species from those that *are* explicitly described. The district court worked hard to reconcile cases of this type – call them “denigrated species” cases – from other cases in which written description is really focused on the traditional problem of undue claim breadth (i.e., lack of commensurateness between the specification and the claims). Relying on cases such as *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed.Cir.2008), the defendants – referred to by the court as “the manufacturers” – moved for summary judgment of invalidity. In considering the motion, the court dealt with the troublesome problem of reconciling “denigrated species” and “undue breadth” cases under the written description doctrine:

[T]he court interprets the *Tronzo* [*v. Biomet, Inc.*, 156 F.3d 1154 (Fed.Cir.1998)] line of the Federal Circuit's written description case law as invalidating claims to a genus where the written description specifically distinguished its embodiment from the genus or expressly disclaims other members of the genus. These clear limits on the *Tronzo* line of authority take into account that *Tronzo* is an outlier in the Federal Circuit's jurisprudence. The touchstone of the written description requirement is that the specification must demonstrate to a person of ordinary skill that the patentee possessed what it claimed. *Pandrol USA, LP v. Airboss Ry. Products, Inc.*, 424 F.3d 1161, 1165 (Fed.Cir.2005). The court in *Lizardtech* applied the same standard, noting that after reading the specification, a person of ordinary skill would have only understood Lizardtech as possessing the specific method described. 424 F.3d at 1345. The *Tronzo* decision, however, does not accord with this principle. By suggesting that claims covering generic shapes did not satisfy the written description requirement because the patentee specifically distinguished them, it seems inescapable that the patentee *actually did, in fact, possess* devices of other shapes. *See Tronzo*, 156 F.3d at 1159. How else could the patentee have denigrated the other shapes if it did not possess them? It seems that the patentee simply did not consider the other shapes its invention. By contrast, the other lines of cases recognized in *Bilstad*—those involving unpredictable arts—support the thrust of the other written description jurisprudence because if an art is unpredictable, it is unlikely that the patentee possessed all of the variants within the art simply because it possessed one of them. Whether a specification like the one in *Tronzo* should invalidate a claim under the written description requirement or not is beside the point; *Tronzo* sets forth a principle that has been repeatedly cited by the Federal Circuit. The court points out the inconsistency between *Tronzo* and other written description cases only to attempt to cabin a

divergent and confusing doctrine and provide structure for this court's review of the Manufacturers' motion.

Rambus v. Hynix, supra, 2008 WL 2754805 (N.D. Cal., July 10, 2008), slip op. at 43. The court concludes:

Accordingly, the court denies the Manufacturers' motion for summary judgment of invalidity based on want of written description under *Tronzo*. By this holding, the court does not foreclose further inquiry into the written description support of the various claims in the . . . patents [at issue] including what was known by one skilled in the art at the time the original application was filed.

Id., at 48.

Add at the end of Note 2 in the Notes after *Eli Lilly*, page 313:

2A. PTO Training Materials. The PTO's Guidelines have now been supplemented with examiner training materials that further flesh out the PTO's views on written description issues. See USPTO, "Written Description Training Materials," Revision 1, March 25, 2008, avail. at www.uspto.gov/web/menu/written.pdf ("Training Materials"). Many of the examples and problems discussed relate closely to biotechnology; it is safe to say that written description is now developing special subdoctrines to deal with this important field. For example, the guidelines include discussions of (1) claims to expressed sequence tags, as in the case of *In re Fisher* in Chapter 3 (see pages 13-16 of the Training Materials); (2) disclosure of and claims to partial protein structures (pages 17-20); (3) DNA hybridization claims (pages 21-24); (4) allelic variants, pages 25-28); (5) Bioinformatics (29-30); and Protein Variants (pages 31-32).

Despite the tight focus on biotechnology, some aspects of the Training Materials should be of interest to all students of patent law. In particular, three issues stand out: (1) the discussion of written description with respect to claim; (2) the Material's treatment of written description and amended claims; and (3) examples pertaining to claims covering a genus with "widely varying species".

Priority Claims

Example One of the Training Materials includes a hypothetical based on *Tronzo v. BioMet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998). As in *Tronzo*, the example describes a fact pattern similar in many respects to *Gentry Gallery*. The patent application in question describes a replacement hip socket. The original specification, the parent, describes only one acceptable shape for the "cup" part of the hip socket device – a conical shape. During prosecution, the applicant amended the specification (by filing a CIP) to broaden the description of the cup portion of the hip socket. The CIP specification says the shape of the cup is not important; so long as the cup works well, many shapes will do. After the parent specification, but before the CIP, a prior art reference became available that describes a non-conical cup for a hip socket replacement. This raises a question of priority: can the applicant obtain the benefit of the original specification filing date, and

thus pre-date the reference, or does that reference invalidate the claims of the patent, because it comes before the CIP filing date?

The Training Materials state:

[T]here is nothing in the earlier-filed application to suggest that shapes other than conical are part of the disclosure. In fact, the earlier-filed application teaches the advantages of conical cups versus other shapes of cups. Accordingly, a person of ordinary skill in the art would not view the applicant to have been in possession of the generic subject matter claimed based on the single species disclosed in the earlier-filed application.

Conclusion:

The parent application fails to adequately describe the full scope of the genus of claim 1. Thus, claim 1 is not entitled to the benefit of the parent application filing date. Accordingly, a rejection should be made under the appropriate section(s) of 35 U.S.C.102 over the intervening prior art.

Training Materials, at p. 4. Although this example does not discuss the applicant's motivation for making the amendment, it does suggest the unfairness of permitting an applicant to expand the original description to include embodiments that he or she only later realizes are valuable. Perhaps there is a latent presumption, then, that a CIP like the one in the example could be motivated by someone else's disclosure, or a competitor's new product – an example of what is referred to in the Introduction to this section as “misappropriation by amendment.” See Introduction, *supra*; Robert P. Merges, Software and Patent Scope: A Report from the Middle Innings, 85 Tex. L. Rev. 1528, 1652-1656 (2007) (describing in detail written description case law as a response to cases where a patentee incorporates via patent application amendment technology first disclosed or commercialized by a third party). A good discussion of the issues raised by this example can be found on the Patently-O Blog, <http://www.patentlyo.com/patent/2008/04/pto-written-des.html>.

Amended Claims

Example 2 of the Training Materials closely tracks the *Gentry Gallery* case in the casebook. The interesting feature of the discussion is use of a “decision tree” aimed at examiners, which is said to be a useful summary of caselaw in this area. See Training Materials, as Appendix B, page B-1.

The key question in the decision tree relates to the “missing limitation” in cases such as *Gentry Gallery* – the limitation in the original claim that is omitted in the later, broader, version of the claim. (Recall the limitation omitted in *Gentry Gallery* relates to the location of the chair controls.) The key question in the Training Materials is stated this way: “Is the missing limitation described by applicant as being a critical feature of the claim as a whole?” If the answer is yes, according to the decision tree, the examiner should issue a written description rejection. If the answer is yes, the applicant must still show that there is “express, inherent or implicit support for the claim as a whole,” in order to avoid such a rejection.

Based on this guidance, what is the best way for a patent drafter to avoid a future written description rejection when filing an original application? What trends would you expect to see in post-*Gentry Gallery* patent drafting techniques?

Broad Genus Claims

The introduction Example 15, which deals with genus claims, reads as follows:

The specification discloses a working example in which a full-length cDNA was isolated from a mouse cDNA library. The complete cDNA sequence (SEQ ID NO: 1) and predicted amino acid sequence (SEQ ID NO: 2) are disclosed. The specification states that the cDNA encodes a novel protein that the specification refers to as the murine “Squeaker” protein. The specification discloses a method for isolating human and other mammalian Squeaker cDNA sequences. However, the specification does not disclose any working examples showing isolation of other Squeaker cDNAs, and does not disclose any cDNA sequences other than the mouse sequence. There is no evidence in the record of allelic variants of the mouse Squeaker protein or gene. However, the art recognized that homologous genes in different species tend to differ in sequence, and that the amount and type of sequence variation is unpredictable.

Training Materials at 50. The Materials then go on to present a number of claims based on this hypothetical disclosure, to pose difficult questions of patentability under the written description requirement. For example, consider the discussion of hypothetical claims 3 and 5, set out below:

Claim 3 is directed to a nucleic acid comprising a sequence that encodes the amino acid sequence of SEQ ID NO: 2 [the Materials do not provide an actual sequence, just this standard reference, found in claims such as claim 3.]. The specification provides an actual reduction to practice and the full structure of one nucleic acid sequence (SEQ ID NO: 1) that encodes SEQ ID NO: 2. The specification discloses that the function of the cDNA of SEQ ID NO: 1 is to encode SEQ ID NO: 2. Therefore . . . those of ordinary skill in the art could readily envisage, by applying the genetic code, a variety of nucleic acids that encode mouse Squeaker protein (SEQ ID NO: 2). Methods of making nucleic acid sequences of any desired sequence are routine in the art. Based on the level of knowledge in the art and the correlation between structure and function provided by the genetic code, those skilled in the art would have recognized that the description of SEQ ID NO: 2 would have put the applicant in possession of the nucleic acid sequences encoding SEQ ID NO: 2 at the time of filing.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 3.

* * *

Claim 5 is directed to a nucleic acid comprising a sequence that encodes human

Squeaker protein. The specification describes a method of isolating the claimed nucleic acids, but does not provide an actual reduction to practice of the claimed nucleic acid or the protein encoded by it. The specification does not describe the complete structure of the claimed nucleic acid or the encoded protein in drawings or by chemical formula. The specification does not describe any partial structure of the claimed nucleic acid (e.g., by nucleotide sequence or restriction sites) or of the encoded protein. The specification does not describe any physical or chemical properties of the claimed nucleic acid (e.g., length, molecular weight, or hybridization to DNAs of known structure), nor are any such properties taught in the prior art. The specification does not describe the function of the claimed nucleic acid in terms of encoding a specified amino acid sequence, such that its function could be correlated to specific structure by operation of the genetic code.

The level of knowledge and skill in the art does not allow those skilled in the art to structurally envisage or recognize a nucleic acid encoding human Squeaker protein because it is known that a gene in one species will tend to differ unpredictably from the corresponding gene in other species (e.g., the human insulin gene will differ in unpredictable ways from the rat insulin

gene). Therefore, those skilled in the art would have recognized that the specification's description of the mouse Squeaker cDNA and protein would not have put the applicant in possession of nucleic acids encoding the human Squeaker protein at the time of filing. Thus, the specification does not describe sufficiently detailed, relevant characteristics to show that the applicant was in possession of the claimed nucleic acid encoding human Squeaker protein.

Conclusion:

The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 5.

Training Materials at 52-53.

The example as stated seems to reach the proper conclusion, given the facts assumed. The major question it raises, however, is why a case such as this could not be as easily resolved with the traditional enablement doctrine, since the essence of the problem described falls comfortably within traditional enablement doctrine, dating all the way back to *The Incandescent Lamp Patent* earlier in this Chapter.

Add to the Note after the *Lizardtech* case, page 327:

2. PTO Practice and Court Review. In the important case of *Hyatt v. Dudas*, 492 F.3d 1365 (Fed. Cir. 2007), the Federal Circuit held that (1) it had jurisdiction to review PTO standards for establishing a prima facie case of unpatentability under the written description requirement, as that practice was set forth in the PTO's Manual of Patent Examination Procedure, or MPEP; and (2) the examiner supported the written description rejection in this case with adequate factual information, and therefore successfully shifted the burden to the applicant to provide more factual information.

Add to page 327 after Note on Written Description and Infringement, the following new case:

ARIAD PHARMACEUTICALS, INC. v. ELI LILLY & CO.,
598 F.3d 1336 (Fed. Cir. 2010) (en banc)

Opinion for the court filed by Circuit Judge LOURIE, in which Chief Judge MICHEL and Circuit Judges NEWMAN, MAYER, BRYSON, GAJARSA, DYK, PROST, and MOORE join. Additional views filed by Circuit Judge NEWMAN. Concurring opinion filed by Circuit Judge GAJARSA. Dissenting-in-part, concurring-in-part opinion filed by Circuit Judge RADER, in which Circuit Judge LINN joins. Dissenting-in-part, concurring-in-part opinion filed by Circuit Judge LINN, in which Circuit Judge RADER joins.

LOURIE, Circuit Judge.

Ariad Pharmaceuticals, Inc., Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College (collectively, “Ariad”) brought suit against Eli Lilly & Company (“Lilly”) in the United States District Court for the District of Massachusetts, alleging infringement of U.S. Patent 6,410,516 (“the '516 patent”). After trial, at which a jury found infringement, but found none of the asserted claims invalid, a panel of this court reversed the district court's denial of Lilly's motion for judgment as a matter of law (“JMOL”) and held the asserted claims invalid for lack of written description. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. 2009).

Ariad petitioned for rehearing *en banc*, challenging this court's interpretation of 35 U.S.C. § 112, first paragraph, as containing a separate written description requirement. Because of the importance of the issue, we granted Ariad's petition and directed the parties to address whether § 112, first paragraph, contains a written description requirement separate from the enablement requirement and, if so, the scope and purpose of that requirement. We now reaffirm that § 112, first paragraph, contains a written description requirement separate from enablement, and we again reverse the district court's denial of JMOL and hold the asserted claims of the '516 patent invalid for failure to meet the statutory written description requirement.

BACKGROUND

The '516 patent relates to the regulation of gene expression by the transcription factor NF-κB. The inventors of the '516 patent were the first to identify NF-κB and to uncover the mechanism by which NF-κB activates gene expression underlying the body's immune responses to infection. The inventors discovered that NF-κB normally exists in cells as an inactive complex with a protein inhibitor, named “IκB” (“Inhibitor of kappa B”), and is activated by extracellular stimuli, such as bacterial-produced lipopolysaccharides, through a series of biochemical reactions that release it from IκB. Once free of its inhibitor, NF-κB travels into the cell nucleus where it binds to and activates the transcription of genes containing a NF-κB recognition site. The activated

genes (*e.g.*, certain cytokines), in turn help the body to counteract the extracellular assault. The production of cytokines can, however, be harmful in excess. Thus the inventors recognized that artificially interfering with NF-kB activity could reduce the harmful symptoms of certain diseases, and they filed a patent application on April 21, 1989, disclosing their discoveries and claiming methods for regulating cellular responses to external stimuli by reducing NF-kB activity in a cell.

Ariad brought suit against Lilly on June 25, 2002, the day the '516 patent issued. Ariad alleged infringement of claims 80, 95, 144, and 145 by Lilly's Evista® and Xigris® pharmaceutical products. The asserted claims, rewritten to include the claims from which they depend, are as follows:

80. [A method for modifying effects of external influences on a eukaryotic cell, which external influences induce NF-kB-mediated intracellular signaling, the method comprising altering NF-kB activity in the cells such that NF-kB-mediated effects of external influences are modified, wherein NF-kB activity in the cell is reduced] wherein reducing NF-kB activity comprises reducing binding of NF-kB to NF-kB recognition sites on genes which are transcriptionally regulated by NF-kB.

95. [A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF-kB mediated intracellular signaling, the method comprising reducing NF-kB activity in the cells such that expression of said genes is reduced], carried out on human cells.

144. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-kB activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells] wherein reducing NF-kB activity comprises reducing binding of NF-kB to NF-kB recognition sites on genes which are transcriptionally regulated by NF-kB.

145. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-kB activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells], carried out on human cells.

The claims are thus genus claims, encompassing the use of all substances that achieve the desired result of reducing the binding of NF-kB to NF-kB recognition sites. Furthermore, the claims, although amended during prosecution, use language that corresponds to language present in the priority application. . . . The specification also hypothesizes three types of molecules with the potential to reduce NF-kB activity in cells: decoy, dominantly interfering, and specific inhibitor molecules.

In April 2006, the district court held a fourteen-day jury trial on the issues of infringement and validity. The jury rendered a special verdict finding infringement of claims 80 and 95 with respect to Evista® and claims 144 and 145 with respect to Xigris®. The jury also found that the asserted claims were not invalid for anticipation,

lack of enablement, or lack of written description. The court denied without opinion Lilly's motions for JMOL and, in the alternative, a new trial. In August 2006, the court conducted a four-day bench trial on Lilly's additional defenses of unpatentable subject matter, inequitable conduct, and prosecution laches, ruling in favor of Ariad on all three issues. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 529 F.Supp.2d 106 (D.Mass. 2007).

Lilly timely appealed to this court, and on April 3, 2009, a panel affirmed in part and reversed in part. *Ariad*, 560 F.3d at 1369. The panel upheld the district court's finding of no inequitable conduct, *id.* at 1380, but reversed the jury's verdict on written description, holding the asserted claims invalid for lack of an adequate written description as required by 35 U.S.C. § 112, first paragraph, *id.* at 1376. Ariad petitioned for rehearing *en banc*, challenging the existence of a written description requirement in § 112, first paragraph, separate from the enablement requirement. Although not a new question, *see In re Barker*, 559 F.2d 588, 591-93 (CCPA 1977), its prominence has increased in recent years In light of the controversy concerning the distinctness and proper role of the written description requirement, we granted Ariad's petition, vacating the prior panel opinion and directing the parties to brief two questions:

(1) Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?

(2) If a separate written description requirement is set forth in the statute, what is the scope and purpose of that requirement?

DISCUSSION

I.

Although the parties differ in their answers to the court's questions, their positions converge more than they first appear. Ariad, in answering the court's first question, argues that § 112, first paragraph, does *not* contain a written description requirement separate from enablement. Yet, in response to this court's second question on the scope and purpose of a written description requirement, Ariad argues that the statute contains two description requirements: "Properly interpreted, the statute requires the specification to describe (i) what the invention is, and (ii) how to make and use it. . . . Ariad reconciles this apparent contradiction by arguing that the legal sufficiency of its two-prong description requirement is judged by whether it enables one of skill in the art to make and use the claimed invention. Thus, according to Ariad, in order to enable the invention, the specification must first identify "*what* the invention is, for otherwise it fails to inform a person of skill in the art what to make and use. Yet Ariad argues that this first step of "identifying" the invention applies only in the context of priority (*i.e.*, claims amended during prosecution; priority under 35 U.S.C. §§ 119, 120; and interferences) because original claims "constitute their own description."

Lilly, in contrast, answers the court's first question in the affirmative, arguing that two hundred years of precedent support the existence of a statutory written description requirement separate from enablement. Thus, Lilly argues that the statute requires, first, a written description of the invention and, second, a written description of how to make and use the invention so as to enable one of skill in the art to make and use it. Finally, Lilly

asserts that this separate written description requirement applies to all claims – both original and amended – to ensure that inventors have actually invented the subject matter claimed.

Thus, although the parties take diametrically opposed positions on the existence of a written description requirement separate from enablement, both agree that the specification must contain a written description of the invention to establish what the invention is. The dispute, therefore, centers on the standard to be applied and whether it applies to original claim language.

A.

As in any case involving statutory interpretation, we begin with the language of the statute itself. Section 112, first paragraph, reads as follows:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

According to Ariad, a plain reading of the statute reveals two components: a written description (i) of the invention, and (ii) of the manner and process of making and using it. Yet those two components, goes Ariad's argument, must be judged by the final prepositional phrase; both written descriptions must be “in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same.” Specifically, Ariad parses the statute as follows:

The specification shall contain

[A] a written description

[i] of the invention, and

[ii] of the manner and process of making and using it,

[B] in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same ...

Ariad argues that its interpretation best follows the rule of English grammar that prepositional phrases (here, “of the invention,” “of the manner and process of making and using it,” and “in such full, clear, concise, and exact terms”) modify another word in the sentence (here, “written description”), and that it does not inexplicably ignore the comma after “making and using it” or sever the “description of the invention” from the requirement that it be in “full, clear, concise, and exact terms,” leaving the description without a legal standard.

Ariad also argues that earlier versions of the Patent Act support its interpretation. Specifically, Ariad contends that the first Patent Act, adopted in 1790, and its immediate successor, adopted in 1793, required a written description of the invention that accomplished two purposes: (i) to distinguish the invention from the prior art, and (ii) to

enable a person skilled in the art to make and use the invention. Ariad then asserts that when Congress assigned the function of defining the invention to the claims in 1836, Congress amended the written description requirement so that it served a single purpose: enablement.

Lilly disagrees, arguing that § 112, first paragraph, contains three separate requirements. Specifically, Lilly parses the statute as follows:

(1) “The specification shall contain a written description of the invention, *and*”

(2) “The specification shall contain a written description ... of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, *and*”

(3) “The specification ... shall set forth the best mode contemplated by the inventor of carrying out the invention.”

Lilly argues that Ariad's construction ignores a long line of judicial precedent interpreting the statute's predecessors to contain a separate written description requirement, an interpretation Congress adopted by reenacting the current language of § 112, first paragraph, without significant amendment.

We agree with Lilly and read the statute to give effect to its language that the specification “shall contain a written description of the invention” and hold that § 112, first paragraph, contains two separate description requirements: a “written description [i] of the invention, *and* [ii] of the manner and process of making and using [the invention]”. 35 U.S.C. § 112, ¶ 1 (emphasis added). On this point, we do not read Ariad's position to be in disagreement as Ariad concedes the existence of a written description requirement. . . . Instead Ariad contends that the written description requirement exists, not for its own sake as an independent statutory requirement, but only to identify the invention that must comply with the enablement requirement.

But, unlike Ariad, we see nothing in the statute's language or grammar that unambiguously dictates that the adequacy of the “written description of the invention” must be determined solely by whether that description identifies the invention so as to enable one of skill in the art to make and use it. The prepositional phrase “in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same” modifies only “the written description ... of the manner and process of making and using [the invention],” as Lilly argues, without violating the rules of grammar. That the adequacy of the description of the manner and process of *making* and *using* the invention is judged by whether that description enables one skilled in the art to *make* and *use* the same follows from the parallelism of the language.

While Ariad agrees there is a requirement to describe the invention, a few amici appear to suggest that the only description requirement is a requirement to describe enablement. If Congress had intended enablement to be the sole description requirement of § 112, first paragraph, the statute would have been written differently. Specifically,

Congress could have written the statute to read, “The specification shall contain a written description of the invention, in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same,” or “The specification shall contain a written description of the manner and process of making and using the invention, in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same.” Under the amici's construction a portion of the statute – either “and of the manner and process of making and using it” or “[a written description] of the invention” – becomes surplusage, violating the rule of statutory construction that Congress does not use unnecessary words.

Furthermore, since 1793, the Patent Act has expressly stated that an applicant must provide a written description of the invention, and after the 1836 Act added the requirement for claims, the Supreme Court applied this description requirement separate from enablement. *See infra* Section I.B. Congress recodified this language in the 1952 Act, and nothing in the legislative history indicates that Congress intended to rid the Act of this requirement.

Finally, a separate requirement to describe one's invention is basic to patent law. Every patent must describe an invention. It is part of the *quid pro quo* of a patent; one describes an invention, and, if the law's other requirements are met, one obtains a patent. The specification must then, of course, describe how to make and use the invention (*i.e.*, enable it), but that is a different task. A description of the claimed invention allows the United States Patent and Trademark Office (“PTO”) to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights.

B.

Ariad argues that Supreme Court precedent comports with its reading of the statute and provides no support for a written description requirement separate from enablement. Specifically, Ariad asserts that in *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-34, 5 L.Ed. 472 (1822), the Supreme Court recognized just two requirements under § 3 of the 1793 Act, the requirements “to enable” the invention and “to distinguish” it from all things previously known. And, goes Ariad's argument, since the 1836 Act, which removed the latter language and added the requirement for claims, the Court has consistently held that a patent applicant need fulfill but a single “written description” requirement, the measure of which is enablement.

Lilly disagrees and reads *Evans* as acknowledging a written description requirement separate from enablement. Lilly further contends that the Court has continually confirmed the existence of a separate written description requirement, including in *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853) under the 1836 Act; *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47 (1938), under the 1870 Act; and more recently in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002).

Like Lilly, we also read Supreme Court precedent as recognizing a written description requirement separate from an enablement requirement even after the introduction of claims. Specifically, in *Schriber-Schroth*, the Court held that a patent directed to pistons for a gas engine with “extremely rigid” webs did not adequately describe amended claims that recited flexible webs under the then-in-force version of § 112, first paragraph. 305 U.S. at 56-57, 59. The Court ascribed two purposes to this portion of the statute, only the first of which involved enablement:

[1] to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent and [2] to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.

Id. at 57. The Court then concluded that even if the original specification enabled the use of a flexible web, the claim could derive no benefit from it because “that was not the invention which [the patentee] *described* by his references to an extremely rigid web.” *Id.* at 58-59 (emphasis added); *see also MacKay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 98-102 (1939) (holding invalid claims amended to include structures “not within the invention described in the application” even though the variations were small). Although the Court did not expressly state that it was applying a description of the invention requirement separate from enablement, that is exactly what the Court did.

Further, both before and after *Schriber-Schroth*, the Court has stated that the statute serves a purpose other than enablement. In *Gill v. Wells*, 89 U.S. (22 Wall.) 1 (1874), the Court held invalid a reissue patent for claiming a combination not described in the original application, but the Court also emphasized the need for all patents to meet the “three great ends” of § 26, only one of which was enablement. Specifically, the Court stated:

(1) That the government may know what they have granted and what will become public property when the term of the monopoly expires. (2.) That licensed persons desiring to practice the invention may know, during the term, how to make, construct, and use the invention.(3.) That other inventors may know what part of the field of invention is unoccupied.

Id. at 25-26. Finally, most recently in *Festo*, the Court recited three requirements for § 112, first paragraph, and noted a written description requirement separate from the others:

[T]he patent application must *describe, enable, and set forth the best mode* of carrying out the invention. These latter requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public. What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue. The patent also should not issue if the other requirements of § 112 are not satisfied....

535 U.S. at 736 (emphasis added) (internal citations omitted). As a subordinate federal court, we may not so easily dismiss such statements as dicta but are bound to follow them.

A separate written description requirement also does not conflict with the function of the claims. 35 U.S.C. § 112, ¶ 2. Claims define the subject matter that, after examination, has been found to meet the statutory requirements for a patent. Their principal function, therefore, is to provide notice of the boundaries of the right to exclude and to define limits; it is not to describe the invention, although their original language contributes to the description and in certain cases satisfies it. Claims define and circumscribe, the written description discloses and teaches.

C.

In addition to the statutory language and Supreme Court precedent supporting the existence of a written description requirement separate from enablement, *stare decisis* impels us to uphold it now. Ariad acknowledges that this has been the law for over forty years, and to change course now would disrupt the settled expectations of the inventing community, which has relied on it in drafting and prosecuting patents, concluding licensing agreements, and rendering validity and infringement opinions. . . . If the law of written description is to be changed, contrary to sound policy and the uniform holdings of this court, the settled expectations of the inventing and investing communities, and PTO practice, such a decision would require good reason and would rest with Congress.

D.

Ariad next argues that an incorrect reading of *In re Ruschig*, 54 C.C.P.A. 1551, 379 F.2d 990 (1967), by our predecessor court, the Court of Customs and Patent Appeals (“CCPA”), and then by this court, created the first written description requirement separate from enablement. Yet Ariad also asserts, in response to Lilly’s argument that *In re Moore*, 33 C.C.P.A. 1083, 155 F.2d 379 (1946); *In re Sus*, 49 C.C.P.A. 1301, 306 F.2d 494 (1962); and *Jepson v. Coleman*, 50 C.C.P.A. 1051, 314 F.2d 533 (1963), applied a separate written description requirement pre-*Ruschig*, that those cases “merely tested whether the specification *identified* the same invention that was defined by later-added or amended claims – which is an aspect of enablement – and did not interpret § 112, ¶ 1 as containing an independent description-possession requirement.” Appellee Br. 22-23. Thus, according to Ariad, a written description of the invention is required but is not separate from enablement because it identifies the invention that must be enabled, and this, in Ariad’s view, differs from first requiring the invention to be described and then separately requiring it to be enabled.

We view this argument as a distinction without a practical difference insofar as both approaches require a written description of the invention in the specification. In either case the analysis compares the claims with the invention disclosed in the specification, and if the claimed invention does not appear in the specification, both Ariad and Lilly agree that the claim – whether in *Schriber-Schroth* or *Ruschig* – fails regardless whether one of skill in the art could make or use the claimed invention. *Ruschig* involved a claim amended during prosecution to recite a specific chemical

compound, chlorpropamide. 379 F.2d at 991. The specification as filed disclosed a genus encompassing about “half a million possible compounds,” but it did not disclose chlorpropamide specifically. *Id.* at 993. The CCPA affirmed the PTO's rejection of the compound claim because the specification provided no guides or “blaze marks” to single out chlorpropamide from all the other compounds, and thus did not support the later-added claim. *Id.* at 994-95. The court also rejected the argument that one of skill in the art would be enabled to make chlorpropamide as “beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented,” which, the court held, it did not. *Id.* at 995-96.

According to Ariad, the court properly rejected Ruschig's claim based on enablement because the specification did not identify the later-claimed compound, leaving the skilled artisan with no guide to select that compound from the myriad of other compounds encompassed by the broad disclosure. According to Lilly, the court properly rejected the claim under a written description requirement separate from enablement because the specification did not disclose the later-claimed compound to one of skill in the art as something the inventors actually invented out of the myriad of other compounds encompassed by the broad disclosure. Again, this difference amounts to little more than semantics as the parties agree that the court properly affirmed the rejection because the original application did not disclose the specific claimed invention, chlorpropamide, even if one of skill in the art could, based on the disclosure with respect to related compounds, make and use it.

Ariad also argues that the court properly rejected Ruschig's claim as violating 35 U.S.C. § 132's prohibition on “new matter.” But § 132 is an examiner's instruction, and unlike § 282 of the Patent Act, which makes the failure to comply with § 112 a defense to infringement, § 132 provides no statutory penalty for a breach. Express statutory invalidity defenses carry more weight than examiner's instructions, and prohibiting adding new matter to the claims has properly been held enforceable under § 112, first paragraph. *See In re Rasmussen*, 650 F.2d 1212, 1214-15 (CCPA 1981). Regardless, one can fail to meet the requirements of the statute in more than one manner, and the prohibition on new matter does not negate the need to provide a written description of one's invention.

E.

In contrast to amended claims, the parties have more divergent views on the application of a written description requirement to original claims. Ariad argues that *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), extended the requirement beyond its proper role of policing priority as part of enablement and transformed it into a heightened and unpredictable general disclosure requirement in place of enablement. Rather, Ariad argues, the requirement to describe what the invention is does not apply to original claims because original claims, as part of the original disclosure, constitute their own written description of the invention. Thus, according to Ariad, as long as the claim language appears *in ipsius verbis* in the specification as filed,

the applicant has satisfied the requirement to provide a written description of the invention.

Lilly responds that the written description requirement applies to all claims and requires that the specification objectively demonstrate that the applicant actually invented – was in possession of – the claimed subject matter. Lilly argues that § 112 contains no basis for applying a different standard to amended versus original claims and that applying a separate written description requirement to original claims keeps inventors from claiming beyond their inventions and thus encourages innovation in new technological areas by preserving patent protection for actual inventions.

Again we agree with Lilly. If it is correct to read § 112, first paragraph, as containing a requirement to provide a separate written description of the invention, as we hold here, Ariad provides no principled basis for restricting that requirement to establishing priority. Certainly nothing in the language of § 112 supports such a restriction; the statute does not say “The specification shall contain a written description of the invention *for purposes of determining priority.*” And although the issue arises primarily in cases involving priority, Congress has not so limited the statute, and neither will we.

Furthermore, while it is true that original claims are part of the original specification, that truism fails to address the question whether original claim language necessarily discloses the subject matter that it claims. Ariad believes so, arguing that original claims identify whatever they state, *e.g.*, a perpetual motion machine, leaving only the question whether the applicant has enabled anyone to make and use such an invention. We disagree that this is always the case. Although many original claims will satisfy the written description requirement, certain claims may not. For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.

We held [in *Eli Lilly*] that a sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can “visualize or recognize” the members of the genus. *Id.* at 1568-69. We explained that an adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials. We have also held that functional claim language can meet the written description requirement when the art has established a correlation between structure and function. But merely drawing a fence around the outer limits of a purported genus is not an adequate substitute

for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species.

In fact, this case similarly illustrates the problem of generic claims. The claims here recite methods encompassing a genus of materials achieving a stated useful result, i.e., reducing NF-kB binding to NF-kB recognition sites in response to external influences. But the specification does not disclose a variety of species that accomplish the result.

F.

Since its inception, this court has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement, and we have articulated a “fairly uniform standard,” which we now affirm. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562-63 (Fed. Cir. 1991). Specifically, the description must “clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.” *Id.* at 1563 (citing *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.

The term “possession,” however, has never been very enlightening. It implies that as long as one can produce records documenting a written description of a claimed invention, one can show possession. But the hallmark of written description is disclosure. Thus, “possession as shown in the disclosure” is a more complete formulation. Yet whatever the specific articulation, the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.

This inquiry, as we have long held, is a question of fact. Thus, we have recognized that determining whether a patent complies with the written description requirement will necessarily vary depending on the context. Specifically, the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.

The law must be applied to each invention at the time it enters the patent process, for each patented advance has a novel relationship with the state of the art from which it emerges. Thus, we do not try here to predict and adjudicate all the factual scenarios to which the written description requirement could be applied. Nor do we set out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field. *Compare Eli Lilly*, 119 F.3d at 1567 (holding an amino acid sequence did not describe the DNA sequence encoding it), *with In re Wallach*, 378 F.3d 1330, 1334 (Fed. Cir. 2004) (discussing how it is now a “routine matter” to convert an amino acid sequence into all the DNA sequences that can encode it). Thus, whatever inconsistencies may appear to some to exist in the application of the law, those

inconsistencies rest not with the legal standard but with the different facts and arguments presented to the courts.

There are, however, a few broad principles that hold true across all cases. We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366-67 (Fed. Cir. 2006). Conversely, we have repeatedly stated that actual “possession” or reduction to practice outside of the specification is not enough. Rather, as stated above, it is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement, *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997).

We also reject the characterization, cited by Ariad, of the court's written description doctrine as a “super enablement” standard for chemical and biotechnology inventions. The doctrine never created a heightened requirement to provide a nucleotide-by-nucleotide recitation of the entire genus of claimed genetic material; it has always expressly permitted the disclosure of structural features common to the members of the genus. It also has not just been applied to chemical and biological inventions. See *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1343-47 (Fed.Cir.2005).

Perhaps there is little difference in some fields between describing an invention and enabling one to make and use it, but that is not always true of certain inventions, including chemical and chemical-like inventions. Thus, although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described. For example, a propyl or butyl compound may be made by a process analogous to a disclosed methyl compound, but, in the absence of a statement that the inventor invented propyl and butyl compounds, such compounds have not been described and are not entitled to a patent. See *In re DiLeone*, 58 C.C.P.A. 925, 436 F.2d 1404, 1405 n. 1 (1971) (“[C]onsider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described.”).

The written description requirement also ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function – a problem that is particularly acute in the biological arts. This situation arose not only in *Eli Lilly* but again in *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004). In *Rochester*, we held invalid claims directed to a method of selectively inhibiting the COX-2 enzyme by administering a non-steroidal compound that selectively inhibits the COX-2 enzyme. *Id.* at 918. We reasoned that because the specification did not describe any specific compound capable of performing the claimed

method and the skilled artisan would not be able to identify any such compound based on the specification's function description, the specification did not provide an adequate written description of the claimed invention. *Id.* at 927-28. Such claims merely recite a description of the problem to be solved while claiming all solutions to it and, as in *Eli Lilly and Ariad's* claims, cover any compound later actually invented and determined to fall within the claim's functional boundaries-leaving it to the pharmaceutical industry to complete an unfinished invention.

Ariad complains that the doctrine disadvantages universities to the extent that basic research cannot be patented. But the patent law has always been directed to the “useful Arts,” U.S. Const. art. I, § 8, cl. 8, meaning inventions with a practical use, *see Brenner v. Manson*, 383 U.S. 519, 532-36, 86 S.Ct. 1033, 16 L.Ed.2d 69 (1966). Much university research relates to basic research, including research into scientific principles and mechanisms of action, *see, e.g., Rochester*, 358 F.3d 916, and universities may not have the resources or inclination to work out the practical implications of all such research, i.e., finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law's interpretation, but its intention. Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others. “[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” *Id.* at 930 n. 10 (quoting *Brenner*, 383 U.S. at 536, 86 S.Ct. 1033). Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of “invention”—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public.

That research hypotheses do not qualify for patent protection possibly results in some loss of incentive, although Ariad presents no evidence of any discernable impact on the pace of innovation or the number of patents obtained by universities. But claims to research plans also impose costs on downstream research, discouraging later invention. The goal is to get the right balance, and the written description doctrine does so by giving the incentive to actual invention and not “attempt[s] to preempt the future before it has arrived.” *Fiers*, 984 F.2d at 1171. It is part of the *quid pro quo* of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time.

II.

Because we reaffirm our written description doctrine, we see no reason to deviate from the panel's application of that requirement to the facts of this case. As such, we adopt that analysis, as follows, as the decision of the *en banc* court.

A.

We review the denial of Lilly's motion for JMOL without deference.

Ariad explains that developing the subject matter of the '516 patent “required years of hard work, great skill, and extraordinary creativity – so much so that the inventors first needed to discover, give names to, and describe previously unknown cellular components as a necessary predicate for their inventions.” Thus, this invention

was made in a new and unpredictable field where the existing knowledge and prior art was scant.

B.

Ariad claims methods comprising the single step of reducing NF-kB activity. Lilly argues that the asserted claims are not supported by a written description because the specification of the '516 patent fails to adequately disclose how the claimed reduction of NF-kB activity is achieved. The parties agree that the specification of the '516 patent hypothesizes three classes of molecules potentially capable of reducing NF-kB activity: specific inhibitors, dominantly interfering molecules, and decoy molecules. Lilly contends that this disclosure amounts to little more than a research plan, and does not satisfy the patentee's *quid pro quo* as described in *Rochester*. Ariad responds that Lilly's arguments fail as a matter of law because Ariad did not actually claim the molecules. According to Ariad, because there is no term in the asserted claims that corresponds to the molecules, it is entitled to claim the methods without describing the molecules. Ariad's legal assertion, however, is flawed.

In *Rochester*, as discussed above, we held very similar method claims invalid for lack of written description. 358 F.3d at 918-19 (holding the patent invalid because “Rochester did not present any evidence that the ordinarily skilled artisan would be able to identify any compound based on [the specification's] vague functional description”) Ariad attempts to categorically distinguish *Rochester*, *Fiers*, and *Eli Lilly*, because in those cases, the claims explicitly included the non-described compositions. For example, in *Rochester*, the method claims recited a broad type of compound that we held was inadequately described in the specification of the patent:

1. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment.

Id. at 918. Ariad's attempt to distinguish these cases is unavailing. Regardless whether the asserted claims recite a compound, Ariad still must describe some way of performing the claimed methods, and Ariad admits that the specification suggests only the use of the three classes of molecules to achieve NF-kB reduction. Thus, to satisfy the written description requirement for the asserted claims, the specification must demonstrate that Ariad possessed the claimed methods by sufficiently disclosing molecules capable of reducing NF-kB activity

C.

Alternatively, Ariad argues that the specification of the '516 patent and the expert testimony of Tom Kadesch provided the jury with substantial evidence of adequate written description of the claimed methods.

Specific inhibitors are molecules that are “able to block (reduce or eliminate) NF-kB binding” to DNA in the nucleus. '516 patent col. The only example of a specific inhibitor given in the specification is I-kB, a naturally occurring molecule whose function is to hold NF-kB in an inactive state until the cell receives certain external influences.

Nearly all of Ariad's evidence regarding the disclosure of I-kB relies upon figure 43. Ariad's expert, Dr. Kadesch, testified that figure 43 discloses the sequence of DNA that encodes I-kB and relied on this disclosure with regard to his opinion that the written description requirement was satisfied by disclosure of specific inhibitor molecules. But as Ariad admits, figure 43 was not disclosed until 1991. Because figure 43 was not in the 1989 application, neither it nor Dr. Kadesch's testimony regarding it can offer substantial evidence for the jury determination. The only other testimony of Dr. Kadesch with regard to I-kB was that it existed in 1989 and that one of ordinary skill could through experimentation isolate natural I-kB. In the context of this invention, a vague functional description and an invitation for further research does not constitute written disclosure of a specific inhibitor.

Dominantly interfering molecules are “a truncated form of the NF-kB molecule.” The truncation would “retain[] the DNA binding domain, but lack[] the RNA polymerase activating domain.” As such, the dominantly interfering molecule “would recognize and bind to the NF-KB binding site [on nuclear DNA], however, the binding would be unproductive.” In other words, the dominantly interfering molecules would block natural NF-kB from inducing the expression of its target genes. The specification provides no example molecules of this class. Moreover, the specification acknowledges that dominantly interfering molecules can work only “*if* the DNA binding domain and the DNA polymerase domain of NF-kB are spatially distinct in the molecule.” The jury also heard Dr. Kadesch's testimony that “it is a fair representation” that “the '516 patent itself doesn't disclose in its text that the DNA binding domain and the RNA preliminary activating domain of NF-kB are, in fact, separable or spatially distinct.” Considering that the inventors of the '516 patent discovered NF-kB, if they did not know whether the two domains are distinct, one of ordinary skill in the art was at best equally ignorant.

Decoy molecules are “designed to mimic a region of the gene whose expression would normally be induced by NF-êB. In this case, NF-êB would bind the decoy, and thus, not be available to bind its natural target.” Like the other two classes of molecules, decoy molecules are presented hypothetically, but unlike the other two classes of molecules, the specification proposes example structures for decoy molecules. As Dr. Kadesch explained, decoy molecules are DNA oligonucleotides, and because the specification discloses specific example sequences, there is little doubt that the specification adequately described the actual molecules to one of ordinary skill in the art. Yet this does not answer the question whether the specification adequately describes using those molecules to reduce NF-kB activity. The full extent of the specification's disclosure of a method that reduces NF-kB activity using decoy molecules is that NF-kB “would bind the decoy” and thereby, “negative regulation can be effected.” Prophetic examples are routinely used in the chemical arts, and they certainly can be sufficient to satisfy the written description requirement. But this disclosure is not so much an “example” as it is a mere mention of a desired outcome. As Dr. Latchman pointed out, there is no descriptive link between the table of decoy molecules and reducing NF-KB activity.

CONCLUSION

For the foregoing reasons, we hold that the asserted claims of the '516 patent are invalid for lack of written description, and we do not address the other validity issues that were before the panel.

REVERSED IN PART AND AFFIRMED IN PART

NEWMAN, Circuit Judge, additional views.

I join the court's opinion. However, I write separately because the real issue of this case is too important to be submerged in rhetoric. The issue was recognized by Ariad, who complained that the written description requirement “has severe adverse consequences for research universities” because it prevents the patenting of “the type of discoveries that universities make,” that is, it prevents the patenting of basic scientific research.

Basic scientific principles are not the subject matter of patents, while their application is the focus of this law of commercial incentive. The role of the patent system is to encourage and enable the practical applications of scientific advances, through investment and commerce. Although Ariad points out that “basic patents” of broad scope are well recognized, several amici point out that in no case has an invention of basic science been patented with not even one embodiment demonstrating its application and illustrating its breadth. Lilly points out that the specification herein demonstrates none of the three methods that are suggested for possible use to reduce NF-kB activity in cells.

GAJARSA, Circuit Judge, concurring.

I join the opinion of the court, but write separately to explain my reasons for doing so. In my judgment, the text of § 112, ¶ 1 is a model of legislative ambiguity. The interpretation of the statute, therefore, is one over which reasonable people can disagree, and indeed, reasonable people have so disagreed for the better part of a decade. While not entirely free from doubt, the majority's interpretation of § 112, ¶ 1 is reasonable, and for the need to provide some clarity to this otherwise conflicting area of our law, I concur with the majority's opinion that the statute may be interpreted to set forth an independent written description requirement.

I disagree, however, with those who view an independent written description requirement as a necessity of patent law. . . . Empirical evidence demonstrates that outside the priority context the written description doctrine seldom serves as a separate vehicle for invalidating claims. *See, e.g.,* Dennis Crouch, *An Empirical Study of the Role of the Written Description Requirement in Patent Prosecution* 12 (Univ. of Mo. Sch. Of Law Legal Studies Research Paper No.2010-06, 2000), available at <http://ssrn.com/abstract=1554949> (analyzing 2858 Board of Patent Appeals and Interference patent opinions decided between January and June 2009 and finding “none of the outcomes of those decisions would have been impacted by a hypothetical change that eliminated the written description requirement so long as new matter rejections were still allowed under the same standard available today”); Christopher Holman, *Is Lilly Written Description a*

Paper Tiger?: A Comprehensive Assessment of the Impact of Eli Lilly and its Progeny in the Courts and PTO, 17 Alb. L.J. Sci. & Tech. 1, 26-78 (2007) (analyzing Federal Circuit, district court, and BPAI cases since *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), and finding only a small number of cases that invalidated a claim for failure to satisfy the written description requirement).

The empirical evidence confirms my belief that written description serves little practical purpose as an independent invalidity device and better serves the goals of the Patent Act when confined to the priority context. As a matter of statutory interpretation, however, we cannot limit the written description only to priority cases, but Congress could establish such a limit by statute. Confining written description to the priority context would provide greater clarity to district courts and practitioners, both of whom are currently left to trudge through a thicket of written description jurisprudence that provides no conclusive answers and encourages a shotgun approach to litigation. Yet, this thicket is the result of our best efforts to construe an ambiguous statute; only Congress wields the machete to clear it.

RADER, Circuit Judge, with whom LINN, Circuit Judge, joins, dissenting-in-part and concurring-in-part.

The Constitution of the United States gives Congress, not the courts, the power to promote the progress of the useful arts by securing exclusive rights to inventors for limited times. Art. I, § 8, cl. 8. Yet this court proclaims itself the body responsible for achieving the “right balance” between upstream and downstream innovation. Ante at 1353. The Patent Act, however, has already established the balance by requiring that a patent application contain “a written description of the invention, and of the manner and process of making and using it, *in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same.*” 35 U.S.C. § 112, ¶ 1 (emphasis added). In rejecting that statutory balance in favor of an undefined “written description” doctrine, this court ignores the problems of standardless decision making and serious conflicts with other areas of patent law. Because the Patent Act already supplies a better test, I respectfully dissent.

I.

The frailties of this court's “written description” doctrine have been exhaustively documented in previous opinions. These earlier writings document the embarrassingly thin (perhaps even mistaken) justifications for the minting of this new description doctrine in 1997 and the extensive academic criticism of this product of judicial imagination. For present purposes I will only recount those frailties of this court's relatively recent justifications for a doctrine of its own making.

First and foremost, the separate written description requirement that the court petrifies today has no statutory support. As noted, § 112, first paragraph . . . says that the written descriptions of the invention and of the manner and process of making and using the invention are both judged by whether they are in such full, clear, concise, and exact terms as to enable a person skilled in the art to make and use the invention. The reason

for a description doctrine is clear: to ensure that the inventor fully discloses the invention in exchange for an exclusive right. The test for the adequacy of the specification that describes the invention is also clear: Is the description sufficient to enable a person of ordinary skill in the art to make and use the claimed invention? Nowhere does the paragraph require that the inventor satisfy some quixotic possession requirement.

This court, however, calves the “written description of the invention” language out of its context in the rest of the paragraph. In this court's strained reading, the prepositional phrases that follow apply only to a “written description ... of the manner and process of making and using” the invention, not to a “written description of the invention.” The practical effect of the court's interpretation is that the written description of the invention contained in the specification need not be full. It need not be clear. It need not be concise. It need not be exact. And, of course, it need not enable. Instead, it must satisfy a vague possession notion.

If Congress had intended enablement to test only the sufficiency of the written description of the manner and process of making and using the invention, then it would have simply required “a written description ... of the manner and process of making and using it in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to *do so*.” Note also that the comma after “it” in the statute as written is meaningless under the court's interpretation.

In reality, the court simply sidesteps the conflict between its position and the language of the statute by suggesting that Supreme Court precedent has settled this issue. *Ante* at 1344-45. Of course, that is a question for the Supreme Court to answer, but reading the statute as it is written is in fact fully consistent with cases like *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 59 S.Ct. 8, 83 L.Ed. 34 (1938).

Specifically, the description doctrine under a correct reading of the statute shows that a specification satisfies the “written description of the invention” requirement when it tells a person of skill in the art what the invention is. In other words, a proper reading of the statutory description requirement recognizes that the enablement requirement identifies the invention and tells a person of ordinary skill *what* to make and use. The [Supreme Court] cases stand only for the unremarkable proposition that an applicant cannot add new matter to an original disclosure.

[T]his court's new creation offers the public nothing more in exchange for a patent than the statutory enablement requirement already ensures. As the Supreme Court explains, the “*quid pro quo* [for a patent monopoly] is disclosure of a process or device in sufficient detail *to enable one skilled in the art to practice the invention once the period of the monopoly has expired.*” *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944) (emphasis added). What “teaching function,” *Ariad*, 560 F.3d at 1370 (quoting *Univ. of Rochester*, 358 F.3d at 922), does the court propagate by telling an inventor that a patent application must show “possession as shown in the disclosure,” whatever that means? Inventors, to my knowledge, are always quite certain that they possess their invention.

II.

“A ‘blocking patent’ is an earlier patent that must be licensed in order to practice a later patent. This often occurs, for instance, between a pioneer patent and an improvement patent.” *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1379 n. 2 (Fed. Cir. 2000). The Supreme Court has long acknowledged the “well established” rule that “an improver cannot appropriate the basic patent of another and that the improver without a license is an infringer and may be sued as such.” *Temco Elec. Motor Co. v. Apco Mfg. Co.*, 275 U.S. 319, 328 (1928). This blocking condition can exist even where the original patentee “failed to contemplate” an additional element found in the improvement patent. *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703 (Fed. Cir. 1983).

Blocking conditions conceivably occur often where a pioneering patent claims a genus and an improvement patent later claims a species of that genus. These blocking patents often serve the market well by pressuring both inventors to license their innovations to each other and beyond.

After *Eli Lilly*, however, the value of these blocking situations will disappear unless the pioneering patentee “possessed,” yet for some reason chose not to claim, the improvement. That situation, of course, would rarely, if ever, happen. Unfortunately the new *Eli Lilly* doctrine effectively prevents this long-standing precept of patent law. For example, although “[i]mprovement and selection inventions are ubiquitous in patent law; such developments do not cast doubt on enablement of the original invention,” *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1340 (Fed. Cir. 2003), they apparently do cast doubt on the written description of the original invention. Without this new rule, downstream and upstream innovators in this case would have benefited from the ability to cross license. Under the new regime, mere improvements will likely invalidate genus patents. The principle of unintended consequences once again counsels against judicial adventurism.

III.

Under this new doctrine, patent applicants will face a difficult burden in discerning proper claiming procedure under this court's unpredictable written description of the invention requirement. The court talks out of both sides of its mouth as it lays out the test. On the one hand, the test seems to require the fact finder to make a subjective inquiry about what the inventor possessed. *Ante* at 1350-51. On the other, the court states that the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. But a test becomes no less subjective merely because it asks a fact finder to answer the subjective question objectively. This court still asks the fact finder to imagine what a person of skill in the art would have understood the inventor to have subjectively possessed based on the description in the specification (which of course by definition describes the exact same invention according to this court's claim construction rules).

B. The Majority's Proposed Written Description Test

I credit the majority for acknowledging that the “possession” test “has never been very enlightening” and for attempting to clarify that “possession as shown in the disclosure” should be an “objective inquiry into the four-corners of the specification.”

Maj. Op. at 1351. Yet, given the court's concern for public notice, the opinion fails to set the boundaries for compliance with its separate written description test.

The language that the majority uses to explain “possession as shown in the disclosure” not only fails to justify a separate test, it also fails to distinguish the test for written description from the requirements for enablement. “[T]he level of detail required to satisfy the written description requirement,” according to the majority, “varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.” *Maj. Op.* at 1351. These considerations, however, mirror the *Wands* factors for enablement, which include “the nature of the invention,” “the breadth of the claims,” and “the predictability or unpredictability of the art.” 858 F.2d at 737. The court attempts to distinguish enablement by observing that “although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that *have not been invented*, and thus cannot be described.” *Maj. Op.* at 1352 (emphasis added). Yet, if a person of ordinary skill is enabled to make and use a novel and nonobvious invention clearly recited in the claims, I fail to see how that invention can be said to “have not been invented” or be in need of some undefined level of additional description.

In my view, the question before the en banc court should have been answered in the negative and the appeal returned to the panel for resolution of the enablement question and Lilly's remaining invalidity and noninfringement defenses.

NOTES ON *ARIAD*

1. Description vs. Teaching. The basic issue resolved in *Ariad* is the difference between describing an invention and teaching about it. There *is* a difference, the majority holds, and the difference has its basis in the Patent Act. The long-running dispute between a minority faction of the Federal Court, which had resisted a separate written description requirement, and the majority, appears to be over. Unless the Supreme Court intervenes, the written description requirement is and will remain a fixture in U.S. patent law.

2. Chemical Cases. While there is nothing in the opinion stating that the written description requirement applies only to some types of inventions (e.g., biotechnology and chemistry), the court hints at the origins of the recent written description cases in the following terms:

For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a

generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.

Ariad, 598 F.3d 1336, 1349. The conflict in this area may stem in part at least from the very liberal enablement standard in chemical cases (which is implicit in this passage), coupled with aggressive claims to functional entities, such as the mechanism claimed in the *Ariad* case itself.

CHAPTER 7: NONOBVIOUSNESS**B. SUBTESTS OF OBVIOUSNESS**

Add to page 685, a new note:

OBVIOUSNESS AFTER KSR

1. Continued Vitality of the “Teaching, Suggestion, or Motivation” Test? The two years since the Supreme Court’s decision in *KSR v. Teleflex* have produced many Federal Circuit cases applying the decision. Though the very first sentence in the Supreme Court’s legal analysis in *KSR* sets forth a seemingly clear rejection of the Federal Circuit’s prior doctrine (“We begin by rejecting the rigid approach of the Court of Appeals.”), various Federal Circuit panels have made statements that seemingly adopt an extraordinarily narrow of the Supreme Court’s opinion. These decisions tend to assert that the TSM test is not at all dead and that the Supreme Court in *KSR* disapproved of only the “rigid” applications of the test.

Thus, for example, the panel in *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358 (Fed. Cir. 2008) stated that “a flexible TSM test remains the *primary guarantor* against a non-statutory hindsight analysis such as occurred in this case.” *Id.* at 1365 (emphasis added). The court elaborated that “[t]he TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence—teachings, suggestions (a tellingly broad term), or motivations (an equally broad term)—that arise before the time of invention as the statute requires.” Similarly, in *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007), the court instructed:

While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation (“TSM”) test in an obviousness inquiry, the Court acknowledged the importance of identifying ‘a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does’ in an obviousness determination...Moreover, the Court indicated that there is “no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis.”... As long as the test is not applied as a “rigid and mandatory” formula, that test can provide “helpful insight” to an obviousness inquiry.

The Federal Circuit views were summarized in one unpublished opinion as being “that the teaching, suggestion, motivation test remains good law for obviousness, only a rigid application of that test is problematic.” *Black & Decker, Inc. v. Robert Bosch Tool Corp.*, 260 Fed. Appx. 284 (Fed. Cir. 2008) (*unpublished opinion*).

Are these opinions consistent with the Supreme Court’s opinion in *KSR*? Are these statements likely to attract the Supreme Court’s attention back to the area of obviousness? In the petition seeking certiorari in *KSR*, the petitioner argued that the Federal Circuit had departed from the Supreme Court’s teachings on obviousness. Is the Federal Circuit paving the way for future petitioners on the obviousness issue to make similar arguments?

More fundamentally, what is a “flexible” TSM test? Does such a test mean that the test must be satisfied to hold a patent obvious, but that the court will be more generous in finding implicit suggestions or motivations in the prior art? Or does a “flexible” approach mean merely that the TSM test *may* be used to invalidate a patent but other tests may be used as well? Under either view, how helpful is a “flexible” TSM test to a court or patent examiner trying to evaluate whether a patent claim is obvious? For example, consider a case where an accused infringer maintains that, in light of the availability of prior art pieces a, b and c, there is an implicit motivation to combine those pieces of prior art to make the invention. Does the flexible TSM test assist in evaluating that assertion of obviousness? The court in *Ortho-McNeil* emphasized that, under the reformed TSM test, the relevant “teachings, suggestions, or motivations need not always be written references but may be found within the knowledge and creativity of ordinarily skilled artisans.” 520 F.3d at 1365. When should a court or patent examiner hold that the unwritten creativity of the ordinary artisan provides the necessary motivation to make the claimed invention? When it would be obvious?

Despite the claims that *KSR* made only a modest change to Federal Circuit law, the actual results of cases suggest quite a significant shift. Since *KSR* was decided, the Federal Circuit has not once relied on the TSM test to reverse either a district court or PTO ruling that had been adverse to the patentee or patent applicant. In fact, since the Supreme Court’s decision, the Federal Circuit’s reversals of district court obviousness decisions have generally been *against* the validity of the patent. The court has overturned a few obviousness holdings of the PTO, but in those cases, the reversal was generally based more on procedural grounds and not on a misapplication of substantive obviousness law. *In re Reuning*, 2008 U.S. App. LEXIS 8940 (Fed. Cir. Apr. 25, 2008) (unpublished) (accepting the suggestion of the PTO Solicitor that an obviousness decision of the PTO Board of Patent Appeal should be vacated and remanded because the Board had failed to consider the obviousness arguments related to several claims at issue); *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007) (reversing an obviousness decision by the PTO Board because it failed to consider expert testimony offered to rebut an obviousness holding).

A new empirical survey of the Federal Circuit’s decisions after *KSR* provides rigorous evidence of the extent to which the Supreme Court’s decision has changed the actual practice of the law in the field. See Jennifer Phend Nock and Sreekar Gadde, *Raising the Bar for Nonobviousness: An Empirical Study of Federal Circuit Case Law Following KSR*, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1612052. Through “an empirical study of all Federal Circuit decisions on obviousness in the two and a half years following *KSR*,” the paper “documents a remarkable shift in the Federal Circuit’s willingness to uphold findings of obvious below.” *Id.* (abstract). The paper finds that, after *KSR*, “[t]he Federal Circuit is now much less likely to reverse a lower-tribunal finding that a patent is obvious than a finding that a patent is nonobvious,” and that “[d]uring the two and a half year post-*KSR* period studied, the Federal Circuit did not reverse a single lower-tribunal determination [that a patent was obvious and thus invalid].” *Id.*

As the TSM test recedes in importance, new doctrinal themes are emerging, at least three of which are significant. Each of these themes is discussed in the main text of the casebook, and now new case law shows that each is growing in importance.

2. Predictability. As emphasized in the casebook, predictability of an art—always a significant variable in obviousness analysis—has taken on additional importance as a means by which patentees can demonstrate the nonobviousness of their inventions. Consider, for example, the Federal Circuit’s analysis in *Eisai Co. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. July 21, 2008), where the court (in an opinion by Judge Rader) affirmed a district court decision that had sustained the validity of a pharmaceutical patent:

In *KSR*, the Supreme Court noted that an invention may have been obvious “[w]hen there [was] . . . a design need or market pressure to solve a problem and there [were] . . . a finite number of identified, predictable solutions.” 127 S. Ct. at 1742 (tense changes supplied to clarify, as the Court stated and as per 35 U.S.C. § 103, that the obviousness inquiry must rely on evidence available “at the time” of the invention, see *Takeda*, 492 F.3d at 1356 n.2). The Supreme Court’s analysis in *KSR* thus relies on several assumptions about the prior art landscape. First, *KSR* assumes a starting reference point or points in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions. Second, *KSR* presupposes that the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound. See *Takeda*, 492 F.3d at 1357 (“Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.”). Third, the Supreme Court’s analysis in *KSR* presumes that the record before the time of invention would supply some reasons for narrowing the prior art universe to a “finite number of identified, predictable solutions,” 127 S. Ct. at 1742. In *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008), this court further explained that this “easily traversed, small and finite number of alternatives . . . might support an inference of obviousness.” To the extent an art is unpredictable, as the chemical arts often are, *KSR*’s focus on these “identified, predictable solutions” may present a difficult hurdle because potential solutions are less likely to be genuinely predictable.

Id. at 1359. Because of analyses like the one above, *KSR* has had less practical impact in the pharmaceutical industry, in which patents often involve the generally unpredictable interactions of various chemicals.

3. Mere Updating Is Typically Obvious. As discussed in the casebook, *KSR* involved a patent covering an electronically updated version of prior art technology. Shortly after *KSR* was decided, the Federal Circuit decided *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157 (Fed. Cir. 2007), which also invalidated a patent

covering an innovation that required little more than the updating prior technology to take account of modern electronic and computer technology.

The “mere updating” line of cases continued in 2008 with the Federal Circuit’s decision in *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008), which involved a patent for municipal bond auctions conducted over an electronic network, such as the Internet, *using a web browser*. As of the May 29, 1998, filing date of the patent application, the prior art already included (1) software that enabled municipal bond auctions to be conducted over an electronic network, and (2) web browser software. The patented improvement was the combination of the two. Adhering to *KSR*, the Federal Circuit asked “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 1325. The Federal Circuit relied on both *KSR* and *Leapfrog* to invalidate the patent claims at issue:

[W]e note that the use of the internet and web browser technology to conduct electronic auctions was well-established at the time the '099 patent application was filed. For example, U.S. Patent No. 5,794,219, filed on February 20, 1996, 1 discloses an online auction wherein bids are submitted using internet browsers such as Netscape. '219 patent Fig. 1, col.5 ll.14-30. Similarly, U.S. Patent No. 5,835,896, filed on March 29, 1996, 2 also discloses the use of the World Wide Web and a web browser to conduct an electronic auction. '896 patent Fig. 3, col.6 ll.23-38. Although neither the '219 patent nor the '896 patent specifically address original issuer auctions of financial instruments, “[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one.” *KSR*, 127 S. Ct. at 1740. With regard to this case, a speech given in May of 1996 at a meeting of the Government Finance Officer's Association (“GFOA”) explicitly addressed the desirability of using World Wide Web technology to distribute debt issue to consumers. Girard Miller, Technical Servs. Dir., GFOA, Speech at the 1996 General Session of the GFOA Conference (May 18-22, 1996). At a minimum, this speech suggests “the effects of demands known to the design community or present in the marketplace,” *KSR*, 127 S. Ct. at 1740, thereby indicating the obviousness of the claimed combination.

Finally, the combination of known elements present in this case is quite similar to that in *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157 (Fed. Cir. 2007). In *Leapfrog*, the court ruled that “[a]ccommodating a prior art mechanical device that accomplishes [the goal of teaching a child to read phonetically] to modern electronics would have been reasonably obvious to one of ordinary skill in designing children's learning devices.” 485 F.3d at 1161. The court reached this result based in part on its reasoning that “[a]pplying modern electronics to older mechanical devices has been commonplace in recent years.” *Id.* The record in this case demonstrates that adapting existing electronic processes to incorporate modern internet and web browser technology was similarly commonplace at the time the '099 patent application was filed.

Id. at 1326-27.

KSR, *Leapfrog* and *Muniauction* appear to involve disparate industries—auto parts, children’s toys, and financial products software. Yet in fact all three cases involve the effects that one industry—the electronics and computer industry—is having across other industries. As the price, reliability and communications capability of computers fell dramatically during the computer revolution of the late twentieth century, new applications of computers and computer networks emerged quickly, and many of these new applications were obvious adaptations of old technology to the new computer technologies.

4. Objective (Secondary) Considerations. The demise of the TSM test has also led to increased emphasis on objective considerations of obviousness. Thus, for example, the Federal Circuit’s decision in *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007)—which is one of the few post-*KSR* circuit decisions in which the court has reversed a holding of obviousness by a lower adjudicator—concerned the PTO Board’s failure to consider expert testimony on, *inter alia*, objective secondary considerations tending to support nonobviousness. Not only are patentees placing more reliance on such considerations, but also objective, historical factors are also being woven into the obviousness analysis. *Muniauction*, for example, takes a broad historical view of the industrial conditions of the mid-1990’s, when the internet was just emerging as powerful new channel of commerce. For an argument that such historical considerations, especially considerations of an invention’s timing in relation to the emergence of the prior art, should play a central role in obviousness decisions, see John F. Duffy, *A Timing Approach To Patentability*, 12 Lewis & Clark L. Rev. 343 (2008).

5. Academic Commentary. *KSR* has also lead to a renaissance of scholarly commentary on obviousness and its role in the patent system. For excellent symposium on the topic, see *Nonobviousness—The Shape of Things to Come*, 12 Lewis & Clark L. Rev. 323-598 (Summer Issue 2008).

6. Routine Experimentation. A recent decision authored by Judge Richard Posner sitting by designation on the Federal Circuit provides a highly interesting example where a patent was held invalid because supposedly “routine experimentation” would lead to the patented invention.

The case, *Ritchie v. Vast Res., Inc.*, 563 F.3d 1334 (Fed. Cir. 2009), involved a risqué invention—a sexual toy made from “borosilicate glass,” which is a type of glass known for its smoothness as well as its resistance to heat, chemicals, electricity and bacterial absorption. (Pyrex™ products are made from such glass.) It was conceded that, before long before time of the alleged invention, similar forms of sexual toys had been made, but those prior art toys had been made with soda-lime glass, the most common form of glass. It was also conceded that borosilicate glass was known for about a century prior to the time of the alleged invention.

Judge Posner begins his analysis with what seems to be a solid instinct:

Given that [the invention] has commercial value, as heavily emphasized by the plaintiffs, and given that Pyrex, made originally as we said from borosilicate glass, has been sold by Corning for almost a century (and it was sold under other

names beginning in 1893, when borosilicate glass was first invented), to call its use in a sexual device "obvious" may seem the triumph of hindsight over insight. Commercial value is indeed one of the indicia of nonobviousness, *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575-76 (Fed. Cir. 1984), because an invention that has commercial value is likely to come on the market very shortly after the idea constituting the invention (in this case the use of borosilicate glass in a sexual device) became obvious; if the invention did not appear so soon despite its value in the market, this is some evidence that it wasn't obvious after all.

Id. at 1336. Judge Posner's reasoning in this paragraph links up with what our casebook describes as one of the most important questions to ask in evaluating obviousness, which is a question of *timing*: "If a valuable idea is so obvious that people in the field would develop it without much effort, then why didn't other people develop it prior to the person who is seeking patent rights on it?" Merges & Duffy Casebook, at 615. One significant flaw in *Ritchie* analysis is that Judge Posner conflates this timing issue with commercial success. Commercial success need not be linked necessarily with *timing* evidence that suggests nonobviousness. Thus, for example, if borosilicate glass had been invented in 1993 and this alleged invention had been made in 1994, the commercial success of the product might have been the same, but relevant timing evidence would not at all support a conclusion of nonobviousness.

Overlooking the slight error in describing this evidence as merely evidence of commercial success, Judge Posner appears to have the right instinct when he asserts that the timing evidence generally supports nonobviousness. Yet he nonetheless holds the invention obvious:

Among the inventions that the law deems obvious are those modest, routine, everyday, incremental improvements of an existing product or process that confer commercial value (otherwise they would not be undertaken) but do not involve sufficient inventiveness to merit patent protection. This class of inventions is well illustrated by efforts at routine experimentation with different standard grades of a material used in a product—standard in the sense that their properties, composition, and method of creation are well known, making successful results of the experimentation predictable. This is such a case.

...

This case thus exemplifies the Supreme Court's analysis in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705 (2007). "When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Id.* at 417 (emphasis added). (The last sentence describes our case to a tee.) There was, the Court continued, no need

for the district court to "seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418.

Id. at 1337. How is it possible that, although this commercially successful innovation was obvious to people of ordinary skill in the art and could have been achieved with routine and predictable experimentation, it nonetheless took more than a century to do it? Are there some inventions that are simply too trivial to protect by patent? Judge Posner also relies on *Hotchkiss v. Greenwood* to suggest that inventions involving the mere substitution of one material for another should be viewed as obvious. Should the law adopt such a *per se* rule? Would such a rule violate *KSR* by creating an overly rigid rule against patentability?

7. Procedural Differences: Expert Testimony and Common Sense. As emphasized in the casebook, *KSR* signaled a change in procedure as much as a change in substance, as the Supreme Court's holding indicated that obviousness issues could be resolved more frequently as a matter of law through summary judgment or similar procedural devices. In a recent opinion authored by Judge Dyk and joined by judges Lourie and Linn, see *Wyers v. Master Lock Co.*, 2010 U.S. App. LEXIS 15271 (July 22, 2010), the Federal Circuit elaborated on the procedural change:

[*KSR*] instructs courts to take a more "expansive and flexible approach" in determining whether a patented invention was obvious at the time it was made. 550 U.S. at 415. In particular, the Court emphasized the role of "common sense": "[r]igid preventative rules that deny factfinders recourse to common sense . . . are neither necessary under our case law nor consistent with it." *Id.* at 421.

Before *KSR*, we had also consistently treated the question of motivation to combine prior art references as a question of fact. See, e.g., *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006); *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). While *KSR* did not change this rule, *KSR* and our later cases establish that the question of motivation to combine may nonetheless be addressed on summary judgment or JMOL in appropriate circumstances. . . .

The Court [in *KSR*] also made clear that expert testimony concerning motivation to combine may be unnecessary and, even if present, will not necessarily create a genuine issue of material fact. We had held that the district court erred in granting summary judgment, as the affidavits of Teleflex's two experts stating their opinion that the invention was non-obvious created a material issue of fact. We had noted that "[a]t the summary judgment stage of a proceeding, it is improper for a district court to make credibility determinations." *Teleflex*, 119 F. App'x. at 290. The Supreme Court disagreed:

In considering summary judgment on that question the district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact. That is not the end of the issue, however. The ultimate judgment of obviousness is a legal determination. . . . *Where, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material*

dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate. Nothing in the declarations proffered by Teleflex prevented the District Court from reaching the careful conclusions underlying its order for summary judgment in this case.

KSR, 550 U.S. at 427 (emphasis added).

KSR and our later cases establish that the legal determination of obviousness may include recourse to logic, judgment, and common sense, in lieu of expert testimony. *See, e.g., Perfect Web*, 587 F.3d at 1329; *Ball Aerosol*, 555 F.3d at 993. In *Perfect Web*, the patented technology involved a method of managing bulk e-mail comprising essentially the steps of targeting a group of recipients, sending e-mail to those recipients, calculating the number of successfully delivered e-mails, and repeating the first three steps until reaching the desired quantity. It was undisputed that the first three steps were disclosed in the prior art. With respect to the last step, the district court explained: "If 100 email deliveries were ordered, and the first transmission delivered only 95, common sense dictates that one should try again. One could do little else." *Perfect Web*, 587 F.3d at 1330. We affirmed the district court's obviousness determination and endorsed its "common sense" reasoning. *Id.* We furthermore concluded that no expert opinion was required to support the obviousness determination, because the technology was "easily understandable." *Id.* at 1329-30 (quoting *Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1369 (Fed. Cir. 2004)); *see also Sundance*, 550 F.3d at 1365.

Thus, in appropriate cases, the ultimate inference as to the existence of a motivation to combine references may boil down to a question of "common sense," appropriate for resolution on summary judgment or JMOL. *See Perfect Web*, 587 F.3d at 1330. Other recent cases have confirmed the appropriateness of this approach. [Discussion of other Federal Circuit cases omitted.]

Id. at *15-*19. If a novel combination of parts required nothing more than "common sense," why did the PTO ever issue a patent on it? Why was the common sense combination not tried previously? Should the application of a court's "common sense" be limited to certain circumstances, such as where the PTO lacked certain pieces of relevant prior art or where the agency was applying pre-*KSR* law (which may have made the agency too generous in issuing patent)? Resorting to common sense can economize on the costs of litigation and expert witnesses. What are the risks of common sense?

8. Obviousness in Biotechnology. One extremely important effect of *KSR* has been the overruling by the Federal Circuit of its prior decision in *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995). *Deuel* had held that a prior art reference disclosing a partial amino acid sequence of a protein was *not* sufficient to render obvious the DNA molecules encoding the protein even though known methods of gene cloning could isolate the DNA molecules encoding a protein once the amino acid sequence of the protein were known. *Deuel* reasoned that "a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would

have been obvious, in the absence of other prior art that suggests the claimed DNAs.” *Deuel* had relied in part on prior Federal Circuit law rejecting the use of “obvious to try” as a factor in obviousness analysis, and that circuit law was obviously undermined by the Supreme Court in *KSR*.

In reading the decision below, you should be aware of two crucial dates that were in the record of the case, but are not recited in the opinion. First, the patent on the relevant protein (the patent to Valiante) was issued on November 18, 1997, from an application filed in September of 1994. Second, Kubin’s application on the DNA sequence encoding the protein was filed on September 20, 2000. Thus, a little less than three years separated the public disclosure of the Valiante prior art and the filing of the application on Kubin’s claimed invention. Consider whether that three year separation makes the claimed invention seem obvious (because of the relatively short period it took to make this obvious advance) or nonobvious (because three years is a long time in a fast-paced industry like biotech).

Add after the new note on Obviousness After *KSR* (p. 685), the following new case:

IN RE KUBIN

561 F.3d 1351 (Fed. Cir. 2009)

Before RADER, FRIEDMAN, and LINN, Circuit Judges

RADER, Circuit Judge

Marek Kubin and Raymond Goodwin (“appellants”) appeal from a decision of the Board of Patent Appeals and Interferences (the “Board”) rejecting the claims of U.S. Patent Application Serial No. 09/667,859 (“859 Application”) as obvious under 35 *U.S.C.* § 103(a) ... Because the Board correctly determined that appellants’ claims are unpatentably obvious, this court affirms.

I.

This case presents a claim to a classic biotechnology invention -- the isolation and sequencing of a human gene that encodes a particular domain of a protein. This court provided a primer on the basics of this technology in *In re O’Farrell*, 853 F.2d 894, 895-99 (Fed. Cir. 1988). Specifically, appellants claim DNA molecules (“polynucleotides”) encoding a protein (“polypeptide”) known as the Natural Killer Cell Activation Inducing Ligand (“NAIL”).

Natural Killer (“NK”) cells, thought to originate in the bone marrow, are a class of cytotoxic lymphocytes that play a major role in fighting tumors and viruses. NK cells express a number of surface molecules which, when stimulated, can activate cytotoxic mechanisms. NAIL is a specific receptor protein on the cell surface that plays a role in activating the NK cells.

The specification of the claimed invention recites an amino acid sequence of a NAIL polypeptide. The invention further isolates and sequences a polynucleotide that encodes a NAIL polypeptide. Moreover, the inventors trumpet their alleged discovery of a binding

relationship between NAIL and a protein known as CD48. The NAIL-CD48 interaction has important biological consequences for NK cells, including an increase in cell cytotoxicity and in production of interferon. Representative claim 73 of appellants' application claims the DNA that encodes the CD48-binding region of NAIL proteins:

73. An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds CD48.

In other words, appellants claim a genus of isolated polynucleotides encoding a protein that binds CD48 and is at least 80% identical to amino acids 22-221 of SEQ ID NO:2 -- the disclosed amino acid sequence for the CD48-binding region of NAIL.

Appellants' specification discloses nucleotide sequences for two polynucleotides falling within the scope of the claimed genus, namely SEQ ID NO:1 and SEQ ID NO:3. SEQ ID NO: 1 recites the specific coding sequence of NAIL, whereas SEQ ID NO: 3 recites the full NAIL gene, including upstream and downstream non-coding sequences. The specification also contemplates variants of NAIL that retain the same binding properties. ... However, the specification does not indicate any example variants of NAIL that make these conservative amino acid substitutions.

...

II.

[The Federal Circuit recounted the reasoning of the Board of Patent Appeals and Interferences decision that affirmed the rejection of Kubin's claims. It was undisputed that prior art references discussed and taught essentially the same methodology that the appellants' employed in isolating DNA encoding the NAIL protein. The court also discussed the 1997 Valiante patent, which disclosed the NAIL protein:]

[U.S. Patent No. 5,688,690 ("Valiante")] discloses a receptor protein called "p38" that is found on the surface of human NK cells. ... The Board found (and appellants do not dispute) that Valiante's p38 protein is the same protein as NAIL. ...

Valiante teaches that "[t]he DNA and protein sequences for the receptor p38 may be obtained by resort to conventional methodologies known to one of skill in the art." '690 Patent col.7 ll.49-51. ... Example 12 of Valiante's patent further describes a five-step cloning protocol for "isolating and identifying the p38 receptor." Id. at col.18 l.6-col.19 l.28.

[The] Board found that

Valiante's disclosure of the polypeptide p38, and a detailed method of isolating its DNA, including disclosure of a specific probe to do so, i.e., mAb C1.7, established Valiante's possession of p38's amino acid sequence and provided a reasonable expectation of success in obtaining a polynucleotide encoding p38, a polynucleotide within the scope of Appellants' claim 73. (See Valiante, col.7, l.48 to col.8, l.7.)

Because of NAIL's important role in the human immune response, the Board further found that "one of ordinary skill in the art would have recognized the value of isolating NAIL cDNA, and would have been motivated to apply conventional methodologies, such as those disclosed in Sambrook and utilized in Valiante, to do so." *Id.* at 6-7.

...

III.

...

The instant case also requires this court to consider the Board's application of this court's early assessment of obviousness in the context of classical biotechnological inventions, specifically *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995). In *Deuel*, this court reversed the Board's conclusion that a prior art reference teaching a method of gene cloning, together with a reference disclosing a partial amino acid sequence of a protein, rendered DNA molecules encoding the protein obvious. *Id.* at 1559. In reversing the Board, this court in *Deuel* held that "knowledge of a protein does not give one a conception of a particular DNA encoding it." *Id.* Further, this court stated that "obvious to try" is an inappropriate test for obviousness.

[T]he existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs. . . . "Obvious to try" has long been held not to constitute obviousness. A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out.

Id. (internal citations omitted) (emphases added). Thus, this court must examine *Deuel's* effect on the Board's conclusion that Valiante's teaching of the NAIL protein, combined with Valiante's/Sambrook's teaching of a method to isolate the gene sequence that codes for NAIL, renders claim 73 obvious.

With regard to *Deuel*, the Board addressed directly its application in this case. In particular, the Board observed that the Supreme Court in *KSR* cast doubts on this court's application of the "obvious to try" doctrine:

To the extent *Deuel* is considered relevant to this case, we note the Supreme Court recently cast doubt on the viability of *Deuel* to the extent the Federal Circuit rejected an "obvious to try" test. *See KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739, 167 L. Ed. 2d 705, 82 U.S.P.Q. 2d 1385, 1394, 1396, 550 U.S. 398 (2007) (citing *Deuel*, 51 F.3d at 1559). Under *KSR*, it's now apparent "obvious to try" may be an appropriate test in more situations than we previously contemplated.

Board Decision at 8. Insofar as *Deuel* implies the obviousness inquiry cannot consider that the combination of the claim's constituent elements was "obvious to try," the Supreme Court in *KSR* unambiguously discredited that holding. In fact, the Supreme Court expressly invoked *Deuel* as a source of the discredited "obvious to try" doctrine.

The *KSR* Court reviewed this court's rejection, based on *Deuel*, of evidence showing that a particular combination of prior art elements was obvious because it would have been obvious to one of ordinary skill in the art to attempt such a combination:

The only declaration offered by KSR--a declaration by its Vice President of Design Engineering, Larry Willemsen--did not go to the ultimate issue of motivation to combine prior art, i.e. whether one of ordinary skill in the art would have been motivated to attach an electronic control to the support bracket of the assembly disclosed by Asano. Mr. Willemsen did state that an electronic control "could have been" mounted on the support bracket of a pedal assembly. (Willemsen Decl. at P33, 36, 39.) Such testimony is not sufficient to support a finding of obviousness, however. *See, e.g., In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995) ("'Obvious to try' has long been held not to constitute obviousness.").

Teleflex, Inc. v. KSR Int'l Co., 119 F. App'x 282, 289 (Fed. Cir. 2005). The Supreme Court repudiated as "error" the *Deuel* restriction on the ability of a skilled artisan to combine elements within the scope of the prior art:

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance *the fact that a combination was obvious to try might show that it was obvious under § 103*.

KSR, 550 U.S. at 421 (internal citation omitted) (emphasis added).

The Supreme Court's admonition against a formalistic approach to obviousness in this context actually resurrects this court's own wisdom in *In re O'Farrell*, which predates the *Deuel* decision by some seven years. This court in *O'Farrell* cautioned that "obvious to try" is an incantation whose meaning is often misunderstood:

It is true that this court and its predecessors have repeatedly emphasized that "obvious to try" is not the standard under § 103. However, the meaning of this maxim is sometimes lost. Any invention that would in fact have been obvious under § 103 would also have been, in a sense, obvious to try. The question is: when is an invention that was obvious to try nevertheless nonobvious?

In re O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988). To differentiate between proper and improper applications of "obvious to try," this court outlined two classes of situations where "obvious to try" is erroneously equated with obviousness under § 103. In the first class of cases,

what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.

Id. In such circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness. The inverse of this proposition is succinctly encapsulated by the Supreme Court's statement in *KSR* that where a skilled artisan merely pursues "known options" from a "finite number of identified, predictable solutions," obviousness under § 103 arises. *550 U.S. at 421.*

The second class of *O'Farrell's* impermissible "obvious to try" situations occurs where

what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

853 F.2d at 903. Again, *KSR* affirmed the logical inverse of this statement by stating that § 103 bars patentability unless "the improvement is more than the predictable use of prior art elements according to their established functions." *550 U.S. at 417.*

This court in *O'Farrell* found the patentee's claims obvious because the Board's rejection of the patentee's claims had not presented either of the two common "obvious to try" pitfalls. Specifically, this court observed that an obviousness finding was appropriate where the prior art "contained *detailed enabling methodology* for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful." *853 F.2d at 902* (emphasis added). Responding to concerns about uncertainty in the prior art influencing the purported success of the claimed combination, this court stated: "[o]bviousness does not require absolute predictability of success . . . *all that is required is a reasonable expectation of success.*" *Id. at 903-04* (emphasis added). The Supreme Court in *KSR* reinvigorated this perceptive analysis.

KSR and *O'Farrell* directly implicate the instant case. Appellants' claim 73 recites a genus of isolated nucleic acid molecules encoding the NAIL protein. As found by the Board, the Valiante reference discloses the very protein of appellants' interest -- "p38" as per Valiante. *Board Decision at 4.* Valiante discloses a monoclonal antibody mAb C1.7 that is specific for p38/NAIL, and further teaches a five-step protocol for cloning nucleic acid molecules encoding p38/NAIL using mAb C1.7. *Id.* In fact, while stating that "[t]he DNA and protein sequences for the receptor p38 may be obtained by resort to conventional methodologies known to one of skill in the art," '690 *Patent* at col.7 ll.49-51, Valiante cites to the *very same* cloning manual, Sambrook, cited by Kubin and Goodwin for their proposition that the gene sequence is identified and recovered "by standard biochemical methods." '859 *Application* at 16. Moreover, the record strongly

reinforces (and appellants apparently find no room to dispute) the Board's factual finding that one of ordinary skill would have been motivated to isolate NAIL cDNA, given Valiante's teaching that p38 is "expressed by virtually all human NK cells and thus plays a role in the immune response." *Board Decision at 6*. The record shows that the prior art teaches a protein of interest, a motivation to isolate the gene coding for that protein, and illustrative instructions to use a monoclonal antibody specific to the protein for cloning this gene. Therefore, the claimed invention is "the product not of innovation but of ordinary skill and common sense." *KSR, 550 U.S. at 421*. Or stated in the familiar terms of this court's longstanding case law, the record shows that a skilled artisan would have had a resoundingly "reasonable expectation of success" in deriving the claimed invention in light of the teachings of the prior art. *See O'Farrell, 853 F.2d at 904*.

This court also declines to cabin *KSR* to the "predictable arts" (as opposed to the "unpredictable art" of biotechnology). In fact, this record shows that one of skill in this advanced art would find these claimed "results" profoundly "predictable." The record shows the well-known and reliable nature of the cloning and sequencing techniques in the prior art, not to mention the readily knowable and obtainable structure of an identified protein. Therefore this court cannot deem irrelevant the ease and predictability of cloning the gene that codes for that protein. This court cannot, in the face of *KSR*, cling to formalistic rules for obviousness, customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area of art. *See In re Durden, 763 F.2d 1406, 1411 (Fed. Cir. 1985)* ("Our function is to apply, in each case, § 103 as written to the facts of disputed issues, not to generalize or make rules for other cases which are unforeseeable."). As this court's predecessor stated in *In re Papesch*, "[t]he problem of 'obviousness' under section 103 in determining the patentability of new and useful chemical compounds . . . is not really a problem in chemistry or pharmacology or in any other related field of science such as biology, biochemistry, pharmacodynamics, ecology, or others yet to be conceived. It is a problem of patent law." *315 F.2d 381, 386, 50 C.C.P.A. 1084, 1963 Dec. Comm'r Pat. 334 (CCPA 1963)*.

The record in this case shows that Valiante did not explicitly supply an amino acid sequence for NAIL or a polynucleotide sequence for the NAIL gene. In that sense, Kubin and Goodwin's disclosure represents some minor advance in the art. But "[g]ranted patent protection to advances that would occur in the ordinary course without real innovation retards progress." *KSR, 550 U.S. at 419*. "Were it otherwise patents might stifle, rather than promote, the progress of useful arts." *Id. at 427*. In light of the concrete, specific teachings of Sambrook and Valiante, artisans in this field, as found by the Board in its expertise, had every motivation to seek and every reasonable expectation of success in achieving the sequence of the claimed invention. In that sense, the claimed invention was reasonably expected in light of the prior art and "obvious to try." *See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1364 (Fed. Cir. 2008)* ("*KSR* posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness."). These references, which together teach a protein identical to NAIL, a commercially available monoclonal antibody specific for NAIL, and explicit instructions for obtaining the DNA

sequence for NAIL, are not analogous to prior art that gives "no direction as to which of many possible choices is likely to be successful" or "only general guidance as to the particular form of the claimed invention or how to achieve it." *O'Farrell*, 853 F.2d at 903. As the Board found, the prior art here provides a "reasonable expectation of success" for obtaining a polynucleotide within the scope of claim 73, *Board Decision at 6*, which, "[f]or obviousness under § 103 [is] all that is required." *O'Farrell*, 853 F.2d at 903. Thus, this court affirms the Board's conclusion as to obviousness.

IV.

For the reasons stated above, the Board did not err in finding appellants' claims obvious as a matter of law. ...

AFFIRMED

CHAPTER 8: INFRINGEMENT**B. INTERPRETING CLAIMS**

Add to page 820, the following new case:

1A. INTERPRETING PRODUCT-BY-PROCESS CLAIMS**ABBOTT LABORATORIES V. SANDOZ, INC.**

566 F.3d 1282 (Fed. Cir. 2009) (en banc)

Before RADER, PLAGER, and BRYSON, Circuit Judges. MICHEL, Chief Judge, and RADER, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, Circuit Judges, have joined Section III.A.2 of the opinion. Dissenting opinion as to Section III.A.2 filed by NEWMAN, Circuit Judge, in which MAYER and LOURIE, Circuit Judges, join. Dissenting opinion filed by LOURIE, Circuit Judge. SCHALL, Circuit Judge, did not participate as a member of the en banc court.

RADER, Circuit Judge.

[Abbott Laboratories, the exclusive licensee of U.S. Patent No. 4,935,507 (the '507 patent), markets the product of the '507 patent under the trade name Omnicef. Generic drug manufacturers filed Abbreviated New Drug Applications to market generic versions of Omnicef. In the district court for the Eastern District of Virginia, one generic drug manufacturer filed suit against Abbott for a declaratory judgment of noninfringement of the '507 patent. In a separately filed case in the Northern District of Illinois, Abbott sued several other generic drug manufacturers for infringement of the '507 patent. The Federal Circuit consolidated the two appeals over the '507 patent, to determine a number of issues, including whether the district courts properly construed the patent claims at issue.]

II.

The '507 *patent* has five claims, all of which Abbott asserts against Lupin as well as Sandoz and Teva. Claim 1 claims crystalline cefdinir, using its chemical name, and defining its unique characteristics with powder X-ray diffraction (PXRD) angle peaks:

1. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem.-4-carboxylic acid (syn isomer) which shows the peaks at the diffraction angles shown in the following table in its powder X-ray diffraction pattern:

diffraction angle [degree]

about 14.7 [degrees]

about 17.8 [degrees]

about 21.5 [degrees]

about 22.0 [degrees]

about 23.4 [degrees]

about 24.5 [degrees]

about 28.1 [degrees]

'507 *patent*, col.16 ll.13-27. In contrast, claims 2-5 claim crystalline cefdinir, without any PXRD peak limitations, but with descriptions of processes used to obtain the crystalline cefdinir. Claims 2 and 5 are independent:

2. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) which is obtainable by acidifying a solution containing 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) at room temperature or under warming.

5. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) which is obtainable by dissolving 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room temperature and allowing the solution to stand.

Id. at col.16 ll.29-34, 43-50.

These claims use PXRD as a way to claim the structure and characteristics of the unique crystalline form. PXRD is a method for identifying and distinguishing different crystalline compounds. The method beams X-rays toward a powdered chemical. The method then measures the ways the rays reflect or bend upon contact with the chemical. The diffraction angles and intensities vary with the type and purity of the test compound. A graph then plots the diffraction angle on one axis and the intensity on another. These graphs yield a unique "fingerprint" for each crystalline form of a chemical. ...

The '507 *patent* was not the first cefdinir patent. Rather, Astellas' prior art *U.S. Patent No. 4,559,334* (the '334 *patent*) describes the discovery of cefdinir as a compound demonstrating high antimicrobial activity. '334 *patent*, col.11 ll.18-24. The '334 *patent* expired on May 6, 2007. ...

The Eastern District of Virginia ...concluded that claims 2-5 were product-by-process claims. *Id.* Later the district court concluded that the process terms of claims 2-5, indicated by the phrase "obtainable by," limit the claims to the specified processes and process steps. In reaching that conclusion, the trial court followed this court's opinion in *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992). *Lupin SJ Order*, 491 F. Supp. 2d at 567-68; *Lupin Ltd. v. Abbott Labs.*, No. 3:06-CV-400 (E.D. Va. May 10, 2007) (*Lupin PbyP Order*). [Because Abbott was unable to prove that the generic versions of cenfdenir had the relevant X-ray finger print described in claim 1 or that they were produced by the processes set forth in claims 2-5, Abbott suffered a summary judgment that the accused products did not infringe the relevant patent claims. Abbott appealed.]

III.

Evaluation of a summary judgment of noninfringement requires two steps: claim construction, which this court reviews without deference, *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1451 (Fed. Cir. 1998) (en banc), and comparison of the properly construed claims to the accused product, process, or composition of matter, which in the context of summary judgment also occurs without deference, *see Ormco Corp. v. Align Technologies, Inc.*, 498 F.3d 1307, 1312 (Fed. Cir. 2007). ...

A. Claim Construction

Because the claims define the patent right, *see Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004), naturally "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). But the claims "must be read in view of the specification, of which they are a part." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). A patent's specification provides necessary context for understanding the claims, and "is always highly relevant to the claim construction analysis." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). While equally true in a general sense, sometimes the specification offers practically incontrovertible directions about claim meaning. For example, inventors may act as their own lexicographers and give a specialized definition of claim terms. *See id.* at 1316. Likewise, inventors and applicants may intentionally disclaim, or disavow, subject matter that would otherwise fall within the scope of the claim. *See id.*

When consulting the specification to clarify the meaning of claim terms, courts must take care not to import limitations into the claims from the specification. This court has recognized the "fine line between" the encouraged and the prohibited use of the specification. *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). When the specification describes a single embodiment to enable the invention, this court will not limit broader claim language to that single application "unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting *Teleflex, Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002)). By the same token, the claims cannot "enlarge what is patented beyond what the inventor has described as the invention." *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1140 (Fed. Cir. 2003) (quoting *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001)). Thus this court may reach a narrower construction, limited to the embodiment(s) disclosed in the specification, when the claims themselves, the specification, or the prosecution history clearly indicate that the invention encompasses no more than that confined structure or method. *See Liebel-Flarsheim*, 358 F.3d at 908.

...

2. proper interpretation of product-by process claims¹

¹ This court, *sua sponte*, took en banc Section III.A.2 before issuing a panel opinion. The following judges join this section of the opinion: Chief Judge Michel and Judges Rader, Bryson, Gajarsa, Linn, Dyk,

This court addresses Part III.A.2 of this opinion en banc, which addresses the proper interpretation of product-by-process claims in determining infringement.

Claims 2-5 of the '507 *patent* begin by reciting a product, crystalline cefdinir, and then recite a series of steps by which this product is "obtainable." The Eastern District of Virginia correctly categorized claims 2-5 as product-by-process claims. On appeal, Abbott argues that the Eastern District erred in construing the process steps of claims 2-5 under the rule in *Atlantic Thermoplastics*, 970 F.2d at 846-47, that "process terms in product-by-process claims serve as limitations in determining infringement," rather than in accordance with *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991) ("[T]he correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims."). This court takes this opportunity to clarify en banc the scope of product-by-process claims by adopting the rule in *Atlantic Thermoplastics*.

In *Atlantic Thermoplastics*, this court considered the scope of product-by-process claim 26 in the patent at issue: "[t]he molded innersole produced by the method of claim 1." 970 F.2d at 836. The patentee urged that competing, indistinguishable innersoles made by a different method nonetheless infringed claim 26. *Id.* at 838. This court rejected the patentee's position. This court in *Atlantic Thermoplastics* construed product-by-process claims as limited by the process. *Id.* at 846-7.

This rule finds extensive support in Supreme Court opinions that have addressed the proper reading of product-by-process claims. See *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 493, 23 L. Ed. 952, 1877 Dec. Comm'r Pat. 171 (1877) ("The process detailed is thereby made as much a part of the invention as are the materials of which the product is composed."); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 224, 26 L. Ed. 149, 1881 Dec. Comm'r Pat. 131 (1880) ("[T]o constitute infringement of the patent, both the material of which the dental plate is made . . . and the process of constructing the plate . . . must be employed."); *Merrill v. Yeomans*, 94 U.S. 568, 24 L. Ed. 235, 1877 Dec. Comm'r Pat. 279 (1877); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 4 S. Ct. 455, 28 L. Ed. 433, 1884 Dec. Comm'r Pat. 230 (1884) (BASF); *The Wood-Paper Patent*, 90 U.S. 566, 596, 23 L. Ed. 31 (1874); *Plummer v. Sargent*, 120 U.S. 442, 7 S. Ct. 640, 30 L. Ed. 737 (1887); *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 58 S. Ct. 899, 82 L. Ed. 1402, 1938 Dec. Comm'r Pat. 813 (1938); see also *Atl. Thermoplastics*, 970 F.2d at 839-42 (discussing each of these cases). In these cases, the Supreme Court consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations. In addition, the binding case law of this court's predecessor courts, the United States Court of Customs and Patent Appeals (see *In re Hughes*, 496 F.2d 1216, 1219 (CCPA 1974) (acknowledging that "true product claims" are "broader" in scope than product-by-process claims)), and the United States Court of Claims (see *Tri-Wall Containers v. United States*, 408 F.2d 748, 751, 187 Ct. Cl. 326 (Ct. Cl. 1969)), followed the same rule.

Prost, and Moore. Judges Newman and Lourie dissent in separate opinions. Judges Mayer and Lourie join in Judge Newman's dissent. Judge Schall did not participate as a member of the en banc court.

This court's sister circuits also followed the general rule that the defining process terms limit product-by-process claims. *See, e.g., Hide-It Leather v. Fiber Prods.*, 226 F. 3d, 36 (1st Cir. 1915) ("It is also a well-recognized rule that, although a product has definite characteristics by which it may be identified apart from the process, still, if in a claim for the product it is not so described, but is set forth in the terms of the process, nothing can be held to infringe the claim which is not made by the process."); *Paeco, Inc. v. Applied Moldings, Inc.*, 562 F.2d 870, 876 (3d Cir. 1977) ("A patent granted on a product claim describing one process grants no monopoly as to identical products manufactured by a different process."). Indeed, this court itself had articulated that rule: "For this reason, even though *product-by-process claims are limited by and defined by the process*, determination of patentability is based on the product itself." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (emphasis added).

The Supreme Court has long emphasized the limiting requirement of process steps in product-by-process claims. In *BASF*, the Court considered a patent relating to artificial alizarine. Specifically, the patent claimed "[a]rtificial alizarine, produced from anthracine or its derivatives by either of the methods herein described, or by any other method which will produce a like result." 111 U.S. at 296 (quoting *U.S. Patent Reissue No. RE 4,321*). In turn, the specification generally described a method for making artificial alizarine involving anthracine or its derivatives. Alizarine had been in use for thousands of years as a red textile dye, traditionally extracted from madder root. Pure alizarine has the chemical formula C₁₄H₈O₄, but "artificial alizarines" available in the market at the time of the litigation varied from almost completely pure alizarine, to combinations of alizarine and anthrapurpurine, to pure purpurine containing no alizarine whatsoever. *Id.* at 309-10. The defendant's product contained approximately sixty percent anthrapurpurine. Thus both alizarine and artificial alizarines were known in the prior art. The Supreme Court clearly articulated some of the scope and validity problems that arise when process limitations of product-by-process claims are ignored:

[The defendant's product] is claimed by the plaintiff to be the artificial alizarine described in No. 4,321, and to be physically, chemically, and in coloring properties similar to that. But what that is is not defined in No. 4,321, except that it is the product of the process described in No. 4,321. Therefore, unless it is shown that the process of No. 4,321 was followed to produce the defendant's article, or unless it is shown that that article could not be produced by any other process, the defendant's article cannot be identified as the product of the process of No. 4,321. Nothing of the kind is shown.

...

If the words of the claim are to be construed to cover all artificial alizarine, whatever its ingredients, produced from anthracine or its derivatives by methods invented since Graebe and Liebermann invented the bromine process, we then have a patent for a product or composition of matter which gives no information as to how it is to be identified. *Every patent for a product or composition of matter must identify it so that it can*

be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.

Id. at 310 (emphasis added).

After *BASF*, the Supreme Court continued to emphasize the importance of process steps in evaluating the infringement of product-by-process claims. *See, e.g., Plummer, 120 U.S. at 448* ("[W]hatever likeness that may appear between the product of the process described in the patent and the article made by the defendants, their identity is not established unless it is shown that they are made by the same process."); *Gen. Elec. Co., 304 U.S. at 373* ("[A] patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced." (footnote omitted)).

Thus, based on Supreme Court precedent and the treatment of product-by-process claims throughout the years by the PTO and other binding court decisions, this court now restates that "process terms in product-by-process claims serve as limitations in determining infringement." *Atl. Thermoplastics, 970 F.2d at 846-47*. As noted earlier, this holding follows this court's clear statement in *In re Thorpe* that "product by process claims are limited by and defined by the process." *777 F.2d at 697*.

More recently, the Supreme Court has reiterated the broad principle that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." *Warner-Jenkinson, 520 U.S. at 19*. Although *Warner-Jenkinson* specifically addressed the doctrine of equivalents, this rule applies to claim construction overall. As applied to product-by-process claims, *Warner-Jenkinson* thus reinforces the basic rule that the process terms limit product-by-process claims. To the extent that *Scripps Clinic* is inconsistent with this rule, this court hereby expressly overrules *Scripps Clinic*.

The dissenting opinions lament the loss of a "right" that has never existed in practice or precedent -- the right to assert a product-by-process claim against a defendant who does not practice the express limitations of the claim. This court's en banc decision in no way abridges an inventor's right to stake claims in product-by-process terms. Instead this decision merely restates the rule that the defining limitations of a claim -- in this case process terms -- are also the terms that show infringement.

Thus this court does not question at all whether product-by-process claims are legitimate as a matter of form. The legitimacy of this claim form was indeed a relevant issue in the nineteenth century when *Ex parte Painter, 1891 C.D. 200, 200-01 (Comm'r Pat. 1891)*, and some later cases were before the Commissioner of Patents. However, this court need not address that settled issue. The issue here is only whether such a claim is infringed by products made by processes other than the one claimed. This court holds that it is not.

The jurisprudence of the Court of Customs and Patent Appeals -- a court with virtually no jurisdiction to address infringement litigation -- can shed little light on the enforcement of the only claim limitations that an applicant chooses to define the

invention. Indeed, this court's venerable predecessor expressed its ambivalence towards the relevant infringement analysis:

The policy of the Patent Office in permitting product-by-process type claims to define a patentable product, where necessary, has developed with full cognizance of the fact that in infringement suits some courts have construed such claims as covering only a product made by the particular process set forth in the claim and not to the product per se.

In re Bridgeford, 357 F.2d 679, 683 n.5, 53 C.C.P.A. 1182 (CCPA 1966). The reference to "some courts" in this prior citation, as this court notes en banc, includes the United States Supreme Court and every circuit court to consider the question, including this circuit. See also Jon S. Saxe & Julian S. Levitt, *Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice*, 42 J. Pat. Off. Soc'y 528, 530 (1960) ("[P]roduct-by-process claims have met with a most strict interpretation in the courts in infringement proceedings [T]he courts uniformly hold that only a product produced by the claim-designated process may be held to infringe the claim.") (citing *Gen. Elec. Co.*, 304 U.S. 364, 58 S. Ct. 899, 82 L. Ed. 1402, 1938 Dec. Comm'r Pat. 813 and *BASF*, 111 U.S. at 310).

Product-by-process claims, especially for those rare situations when products were difficult or impossible to describe, historically presented a concern that the Patent Office might deny *all* product protection to such claims. See *In re Butler*, 37 F.2d 623, 17 C.C.P.A. 810, 813, 1930 Dec. Comm'r Pat. 187 (CCPA 1930) ("Process claims are valuable, and appellant thinks he is entitled to them; but it is submitted that he should not be limited to control of the process when the article which that process produces is new and useful."). In the modern context, however, if an inventor invents a product whose structure is either not fully known or too complex to analyze (the subject of this case -- a product defined by sophisticated PXR technology -- suggests that these concerns may no longer in reality exist), this court clarifies that the inventor is absolutely free to use process steps to define this product. The patent will issue subject to the ordinary requirements of patentability. The inventor will not be denied protection. Because the inventor chose to claim the product in terms of its process, however, that definition also governs the enforcement of the bounds of the patent right. This court cannot simply ignore as verbiage the only definition supplied by the inventor.

This court's rule regarding the proper treatment of product-by-process claims in infringement litigation carries its own simple logic. Assume a hypothetical chemical compound defined by process terms. The inventor declines to state any structures or characteristics of this compound. The inventor of this compound obtains a product-by-process claim: "Compound X, obtained by process Y." Enforcing this claim without reference to its defining terms would mean that an alleged infringer who produces compound X by process Z is still liable for infringement. But how would the courts ascertain that the alleged infringer's compound is really the same as the patented compound? After all, the patent holder has just informed the public and claimed the new product solely in terms of a single process. Furthermore, what analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a

comparison of the claimed and accused infringing processes? If the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed. Why also would the courts deny others the right to freely practice process Z that may produce a better product in a better way?

In sum, it is both unnecessary and logically unsound to create a rule that the process limitations of a product-by-process claim should not be enforced in some exceptional instance when the structure of the claimed product is unknown and the product can be defined only by reference to a process by which it can be made. Such a rule would expand the protection of the patent beyond the subject matter that the inventor has "particularly point[ed] out and distinctly claim[ed]" as his invention, 35 U.S.C. § 112 P 6.

Thus, the Eastern District of Virginia correctly applied the rule that the recited process steps limit the product-by-process claims 2-5 for any infringement analysis.

3. "obtainable by"

In this case, Abbott's plain language argument, that "obtainable by" introduces an optional process, even if "obtained by" would introduce limiting process steps, is also unavailing. The *BASF* case, an analogous situation to this case, controls. As noted above, the Supreme Court in *BASF* considered the following claim language: "Artificial alizarine, produced from anthracine or its derivatives by either of the methods herein described, *or by any other method which will produce a like result.*" 111 U.S. at 296 (emphasis added). The patentee argued that even though the defendant did not make artificial alizarine by "either of the methods herein described," the claim should capture the product because of the "or by another method" language. *Id.* at 309. The Supreme Court refused to attach importance to those expansive words: "No. 4,321 furnishes no test by which to identify the product it covers, except that such product is to be the result of the process it describes." *Id.* at 305. Abbott's claims 2-5, like those in *BASF* and like product-by-process claims in general, do not furnish any test by which to identify the cefdinir crystals except that they are the result of their respectively claimed processes. As per *BASF*, Abbott's claim cannot capture a product obtained by or obtainable by processes other than those explicitly recited in the claims.

If this court were to strip the process elements from the claims, as Abbott would urge, for infringement purposes, there would then be nothing to differentiate independent claim 2 from independent claim 5. After all, if those claims are not bound by the process terms but only "define" the basic cefdinir compound, then each of the claims recite the same thing, over and over again. Though Abbott argues that it merely intends to give meaning to the word "obtainable," it instead seeks to have this court render meaningless the explicit process limitations that the applicant chose to define its invention.

The intrinsic evidence in this case further rebuts Abbott's contention that its claims are not limited to those products actually obtained by the processes recited. In column 2 of the '507 patent, under the title heading "The Process for Preparing Crystal A of the Compound (I)," the patentee used specific language to describe the very two processes that are mirrored in claims 2 and 5. '507 patent col.2 ll.13-51. This language is not open-ended, nor does it constitute a mere description of the product by reference to the manner

in which it can be made, as Abbott argues. By drafting claims 2 and 5 to incorporate these specific processes, Abbott made a conscious choice to place process requirements on its claimed product. If Abbott had wanted to obtain broader coverage for crystalline cefdinir devoid of any process limitations, as it seeks to do here, it could have simply done so (if indeed, as it argues, it is really the product that is the heart of the invention, not the process). But it did not. The crystals of claims 2 and 5 are simply not identifiable other than by the processes disclosed in column 2. This court must enforce the ways and terms that a party chooses to define its invention.

The prosecution history also does not support Abbott's contention that "obtainable by" offers merely an optional set of definitional process conditions. During prosecution, Abbott faced obviousness rejections based on application claims 6-9, which were process claims that mirrored the *very* process limitations of issued claims 2-5. The PTO refused to issue the claims until one set of duplicates was cancelled. Abbott's action in cancelling claims 6-9 demonstrates its acquiescence to the PTO's view that the process elements of claims 2-5 are critical parts of those claims. In addition, in a response to the PTO's office action, Abbott chose to differentiate a cited § 103 reference, Takaya, on the basis that Abbott's claimed processes are different. For these reasons, the applicant's statement in the file wrapper that "the method of preparation . . . is not considered the heart of the present invention" should not be afforded undue gravitas. The process limitations cannot be haphazardly jettisoned for an infringement analysis when they were so important in the patentability analysis.

In sum, a patentee's use of the word "obtainable" rather than "obtained by" cannot give it a free pass to escape the ambit of the product-by-process claiming doctrine. Claims that include such ambiguous language should be viewed extremely narrowly. If this court does not require, as a precondition for infringement, that an accused infringer actually use a recited process, simply because of the patentee's choice of the probabilistic suffix "able," the very recitation of that process becomes redundant. This would widen the scope of the patentee's claims beyond that which is actually invented--a windfall to the inventor at the expense of future innovation and proper notice to the public of the scope of the claimed invention. For all the above reasons, the Eastern District of Virginia correctly construed the process limitations beginning with "obtainable by" in claims 2-5 as limiting the asserted claims to products made by those process steps.

AFFIRMED.

NOTES ON ABBOTT V. SANDOZ

1. Why the Limitations? Why did Abbott include process limitations in its claims? (Note that there is a very specific and clear answer to this question.)

2. Is the Rule Fair? The en banc majority states that it is "unnecessary and logically unsound to create a rule that the process limitations of a product-by-process claim should not be enforced in some exceptional instance when the structure of the claimed product is unknown and the product can be defined only by reference to a process by which it can be made." Is this a rule of claim interpretation? Or is it a

substantive rule limiting the scope of inventors' claims where they create a new substance but cannot describe it other than through the process used in creating it?

Add to page 849, the following new subchapter:

4. JOINT AND DIVIDED INFRINGEMENT

BMC RESOURCES, INC. v. PAYMENTECH, L.P.

498 F.3d 1373 (Fed. Cir. 2007)

Before RADER, GAJARSA, and PROST, Circuit Judges

RADER, Circuit Judge

[BMC is the assignee of a pair of patents covering a method for processing debit transactions without the use of a personal identification number code. The accused infringer Paymentech processes banking transactions and offered to provide similar services to its customers, leading BMC to sue for patent infringement. Claim 1 of BMC's patent reads:

1. A method of paying bills using a telephone connectable to at least one remote payment card network via a payee's agent's system, wherein a caller places a call using said telephone to initiate a spontaneous payment transaction that does not require pre-registration, to a payee, the method comprising the steps of:

prompting the caller to enter an account number using the telephone, the account number identifying an account of a payor with the payee in connection with the payment transaction;

responsive to entry of an account number, determining whether the entered account number is valid;

prompting the caller to enter a payment number using the telephone, the payment number being selected at the discretion of the caller from any one of a number of credit or debit forms of payment;

responsive to entry of the payment, determining whether the entered payment number is valid;

prompting the caller to enter a payment amount for the payment transaction using the telephone;

responsive to a determination that a payment amount has been entered and further responsive to a determination that the entered account number and payment number are valid, and during the call;

accessing a remote payment network associated with the entered payment number, the accessed remote payment network determining, during the call, the account associated with the entered payment number to complete the payment transaction; accessing a remote payment network associated with the entered payment number, the accessed remote payment network determining, during the

call, whether sufficient available credit or funds exist in an account associated with the entered payment number to complete the payment transaction;

responsive to a determination that sufficient available credit or funds exist in the associated account, charging the entered payment amount against the account associated with the entered payment number, adding the entered payment amount to an account associated with the entered account number, informing the caller that the payment transaction has been authorized, and storing the account number, payment number and payment amount in a transaction log file of the system during the call; and

responsive to determination that sufficient available credit or funds do not exist in the associated account, informing the caller during the call that the current payment transaction has been declined and terminating the current payment transaction.

Paymentech argued that it did not perform the steps under the patent either by itself, or in conjunction with others. The District Court found no evidence of direct infringement, and granted Paymentech's motion for summary judgment.]

The case presents the issue of the proper standard for joint infringement by multiple parties of a single claim. As the parties agree, Paymentech does not perform every step of the method at issue in this case. With other parties performing some claimed method steps, this court must determine if Paymentech may nonetheless be liable for direct infringement under 35 U.S.C. § 271(a) (2000). ...

Direct infringement requires a party to perform or use each and every step or element of a claimed method or product. *Warner-Jenkinson Corp. v. Hilton Davis Corp.*, 520 U.S. 17 (1997) (holding that the doctrine of equivalents, like literal infringement, must be tested element by element)... For process patent or method patent claims, infringement occurs when a party performs all of the steps of the process. *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993).

When a defendant participates in or encourages infringement but does not directly infringe a patent, the normal recourse under the law is for the court to apply the standards for liability under indirect infringement. Indirect infringement requires, as a predicate, a finding that some party amongst the accused actors has committed the entire act of direct infringement. *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004).

These rules for vicarious liability might seem to provide a loophole for a party to escape infringement by having a third party carry out one or more of the claimed steps on its behalf. *Cross Med. Prods. v. Medtronic Sofamor Danek*, 424 F.3d 1293, 1311 (Fed. Cir. 2005). To the contrary, the law imposes vicarious liability on a party for the acts of another in circumstances showing that the liable party controlled the conduct of the acting party. *Engle v. Dinehart*, 213 F.3d 639 (5th Cir. 2000) (unpublished decision) (citing Restatement (Second) of Agency § 220 cmt. d). In the context of patent infringement, a defendant cannot thus avoid liability for direct infringement by having someone else carry out one or more of the claimed steps on its behalf. ...

On appeal, BMC argues that the district court erred in dismissing its argument that this court's recent opinion in *On Demand* sanctioned a finding of infringement by a party who performs some steps of a claim in cases where a patent claims a new and useful invention that cannot be performed by one person. BMC argues that the district court's decision is contrary to *On Demand* and urges this court to vacate and remand this decision.

On Demand dealt with a patent covering systems and methods for manufacturing a single copy of a book. 442 F.3d at 1333. In *On Demand*, the plaintiff argued that a district court verdict could still stand, even under a corrected claim construction. The district court instructed the jury as follows:

It is not necessary for the acts that constitute infringement to be performed by one person or entity. When infringement results from the participation and combined action(s) of more than one person or entity, they are all joint infringers and jointly liable for patent infringement. Infringement of a patented process or method cannot be avoided by having another perform one step of the process or method. Where the infringement is the result of the participation and combined action(s) of one or more persons or entities, they are joint infringers and are jointly liable for the infringement.

Id. at 1344-45.

This court stated that it “discern[ed] no flaw in this instruction as a statement of law,” *id.*, but it did so without any analysis of the issues presented relating to divided infringement. Instead, *On Demand* primarily addressed the claim construction issue that governed the outcome of that case. BMC argues that *On Demand* adopted a “participation and combined action” standard as the type of “connection” a plaintiff must show to prove joint infringement.

The district court considered *On Demand* and determined that it did not change the traditional standard requiring a single party to perform all steps of a claimed method. It further noted that the *On Demand* decision did not in any way rely on the relationship between the parties. As such, the district court concluded that “[b]ecause the district court’s definition of ‘connection’ was not relied on in the panel’s conclusion, the Court refuses to read the panel’s dictum that it found ‘no flaw’ as a wholesale adoption of the district court’s jury instruction.” *Order*, slip op. at 7.

The district court properly analyzed the law and this court’s cases. As Paymentech succinctly noted in its brief, “[i]t is unlikely the Court intended to make a major change in its jurisprudence in the *On Demand* [statement] that was not even directly necessary to its decision in the case.” (Appellee’s Br. 32.) In other words, BMC’s interpretation of *On Demand* goes beyond settled law. *On Demand* did not change this court’s precedent with regard to joint infringement.

Infringement requires, as it always has, a showing that a defendant has practiced each and every element of the claimed invention. *Warner-Jenkinson*, 520 U.S. at 40 (element-by-element analysis for doctrine of equivalents). This holding derives from the statute itself, which states “whoever without authority makes, uses, offers to sell, or sells

any patented invention within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a) (2000). Thus, liability for infringement requires a party to make, use, sell, or offer to sell the patented invention, meaning the entire patented invention.

Where a defendant participates in infringement but does not directly infringe the patent, the law provides remedies under principles of indirect infringement. However, this court has held that inducement of infringement requires a predicate finding of direct infringement. *Dynacore*, 363 F.3d at 1272.

Two such cases that have found that a party cannot be liable for direct infringement because the party did not perform all the steps are *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1568 (Fed. Cir. 1985) (finding no direct infringement by manufacturer who performed the first step of a process claim even where its customer performed the other step of the claim) and *Cross Medical Products*, 424 F.3d at 1311 (rejecting patentees’ efforts to combine the acts of surgeons with those of a medical device manufacturer to find direct infringement of an apparatus claim).

Courts faced with a divided infringement theory have also generally refused to find liability where one party did not control or direct each step of the patented process. See *BMC Resources, Inc. v. Paymentech, L.P.*, (N.D. Tex. Feb. 9, 2006) (“No court has ever found direct infringement based on the type of arms-length business transaction presented here.”); *Faroudja Labs v. Dwin Elecs., Inc.*, 1999 U.S. Dist. LEXIS 22987 (N.D. Cal. Feb. 24, 1999); *Mobil Oil Corp. v. Filtrrol Corp.*, 501 F.2d 282, 291-92 (9th Cir. 1974) (expressing doubt over the possibility of divided infringement liability).

A party cannot avoid infringement, however, simply by contracting out steps of a patented process to another entity. In those cases, the party in control would be liable for direct infringement. It would be unfair indeed for the mastermind in such situations to escape liability. District courts in those cases have held a party liable for infringement. See *Shields v. Halliburton Co.*, 493 F. Supp. 1376, 1389 (W.D. La. 1980).

This court acknowledges that the standard requiring control or direction for a finding of joint infringement may in some circumstances allow parties to enter into arms-length agreements to avoid infringement. Nonetheless, this concern does not outweigh concerns over expanding the rules governing direct infringement. For example, expanding the rules governing direct infringement to reach independent conduct of multiple actors would subvert the statutory scheme for indirect infringement. Direct infringement is a strict-liability offense, but it is limited to those who practice each and every element of the claimed invention. By contrast, indirect liability requires evidence of “specific intent” to induce infringement. Another form of indirect infringement, contributory infringement under § 271(c), also requires a mens rea (knowledge) and is limited to sales of components or materials without substantial noninfringing uses. Under BMC’s proposed approach, a patentee would rarely, if ever, need to bring a claim for indirect infringement.

The concerns over a party avoiding infringement by arms-length cooperation can usually be offset by proper claim drafting. A patentee can usually structure a claim to

capture infringement by a single party. *See* Mark A. Lemley et al., *Divided Infringement Claims*, 33 AIPLA Q.J. 255, 272-75 (2005). In this case, for example, BMC could have drafted its claims to focus on one entity. The steps of the claim might have featured references to a single party's supplying or receiving each element of the claimed process. However, BMC chose instead to have four different parties perform different acts within one claim. BMC correctly notes the difficulty of proving infringement of this claim format. Nonetheless, this court will not unilaterally restructure the claim or the standards for joint infringement to remedy these ill-conceived claims. *See Sage Prods. Inc. v. Devon Indus. Inc.*, 126 F.3d 1420, 1425 (Fed. Cir. 1997) (“[A]s between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed structure.”) ...

AFFIRMED

NOTES ON PAYMENTECH

1. Divide and Conquer. As the court's opinion noted, the existing standards for divided infringement may lead parties to engage in “arms-length agreements to avoid infringement.” 498 F.3d at 1381. Does this standard encourage parties to divide up processes so that, if they later discover the process to be patented, they can all avoid liability? Is this approach sensible?

2. “Use.” Paymentech may not be performing all the steps in the patented claim, but isn't it still “using” the process in the sense that it is deriving benefit from the process. Why isn't that use sufficient to trigger section 271(a)'s prohibition against any unauthorized “use” of a patent? Note that, as a result of the court's ruling in *Paymentech*, the patented process is being performed but no one is using it. Consider the following three hypotheticals:

(a) Computer user Anne wants to have a large amount of data processed. She goes to BigProcessor, which is a company that has large computers capable of running fast and sophisticated data processing programs. BigProcessor sells Anne time on the computer, and Anne sits down and runs the data processing algorithm. Though Anne does not know it, the computer is using a patented process to do her data processing job. Is Anne liable for infringing the process?

(b) Computer user Betty also wants to have a large amount of data processed. She emails all of her data BigProcessor.com and asks the company to process the data. BigProcessor.com completes the job and emails the result back to Betty. Though Betty did not know it, BigProcessor.com's computers were using a patented process to do her data processing job. Is Betty liable for infringing the process?

(c) Computer user Charles also wants to have a large amount of data processed. He emails his data to LittleProcessor.com, which is a company that has smaller computers. LittleProcessor.com's computers are not capable of running fast and sophisticated data processing programs, but their computers can be linked up to OtherCo's computers. Together the two companies' linked computers can perform the process. Though Charles doesn't not know it, his data was processed by a patented

process, which was being jointly carried out by the linked computers of LittleProcessor.com and OtherCo. Is Charles, LittleProcessor.com or OtherCo liable for infringing the process? Who used the process?

3. Claim Drafting. The court notes that good patent prosecutors may be able to draft claims which cover divided infringement situations. What would such claims look like? Is there any reason that the law should encourage the drafting of such cumbersome claims? Would any patentee want to claim a process when performed by one party but not when it is performed by multiple parties?

4. Evidentiary Standard. The court in *Paymentech* cited the lack of a contractual relationship between Paymentech and its financial institutions as evidence of a lack of the control necessary to support a conclusion of joint infringement. Even though Paymentech provided information for processing debit transactions, and profited from the marketing of these services, the Federal Circuit nonetheless refused to find liability. Is the court's standard too high of an evidentiary standard for a patentee to establish? How much control and direction must be shown before a patentee can establish joint infringement?

A number of courts have attempted to address this question in the wake of the *Paymentech* decision. See *SIRF Technology, Inc. v. ITC*, 601 F.3d 1319 (Fed. Cir. 2019) (steps of "communicating" and "transmitting" to a user-device were interpreted as steps that did not require end-user action even though the actual process involves end-user devices downloading the transmitted data; therefore, the claims avoid the problem of divided infringement and are infringed by a single party, the defendant); *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329-1330 (Fed. Cir. 2008) (finding no infringement where there was no proof that the alleged infringer directed another party to perform the steps of the claims); *Global Patent Holdings, LLC v. Panthers BRHC LLC*, 586 F. Supp. 2d 1331, 1335 (S.D. Fla. 2008) (no joint infringement where the accused infringer did not establish a contractual or agency relationship sufficient that the accused infringer would be held vicariously liable for the actions of the third party).

CHAPTER 9: REMEDIES

In Chapter 9.B “Reasonable Royalty Damages,” add the following new case at page 985:

LUCENT TECHNOLOGIES, INC. v. GATEWAY, INC.
580 F.3d 1301 (Fed. Cir. 2009)

Before MICHEL, Chief Judge, NEWMAN and LOURIE, Circuit Judges.

MICHEL, Chief Judge.

[Defendant] Microsoft Corporation appeals the denial of post-trial motions concerning a jury verdict that U.S. Patent No. 4,763,356 (the “Day patent”) was not invalid and that Microsoft indirectly infringed the Day patent. Microsoft also appeals the \$357,693,056.18 jury award to Lucent Technologies, Inc. for Microsoft's infringement of the Day patent. Because the validity and infringement decisions were not contrary to law and supported by substantial evidence, we affirm. Because the damages calculation lacked sufficient evidentiary support, we vacate and remand that portion of the case to the district court for further proceedings.

BACKGROUND

In December 1986, three computer engineers at AT & T filed a patent application, which eventually issued as the Day patent. The patent is generally directed to a method of entering information into fields on a computer screen without using a keyboard. A user fills in the displayed fields by choosing concurrently displayed, predefined tools adapted to facilitate the inputting of the information in a particular field, wherein the predefined tools include an on-screen graphical keyboard, a menu, and a calculator. The system may display menus of information for filling in a particular field and may also be adapted to communicate with a host computer to obtain the information that is inserted into the fields. In addition, one of the displayed fields can be a bit-mapped graphics field, which the user fills in by writing on the touch screen using a stylus.

In 2002, Lucent initiated the present action against Gateway, and Microsoft subsequently intervened. At trial, Lucent charged infringement by Microsoft of claims 19 and 21, among others, of the Day patent. Lucent alleged indirect infringement of claim 19 based on the sales and use of Microsoft Money, Microsoft Outlook, and Windows Mobile. As to claim 21, Lucent asserted that the use of Windows Mobile infringed. Lucent also alleged infringement by Dell and asserted claims of the other patents as well, but those issues are not on appeal. Microsoft challenged Lucent's infringement contentions, contending among other defenses that the Day patent was invalid for being anticipated or obvious and, even if valid, Microsoft's sales of its products did not infringe the Day patent.

The jury found Microsoft liable on claim 19 as to all three products and on claim 21 as to Windows Mobile but returned a finding of no infringement by Dell as to those two claims. The verdict, without distinguishing among the three products or between inducement and contributory infringement, awarded a single lump-sum against Microsoft for all products involved. The jury awarded \$357,693,056.18 for Microsoft's infringement of the Day patent, excluding prejudgment interest.

The district court held that neither judgment as a matter of law nor a new trial was appropriate on the jury's finding that Lucent had proven damages in the amount of approximately \$358 million. The district court granted only the post-trial motion setting aside the obviousness verdict concerning U.S. Patent No. 4,958,226 but denied all other post-trial motions, including those for the Day patent. *See Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.Supp.2d 1016 (S.D.Cal. 2008). Microsoft has timely appealed the district court's decision.

ANALYSIS

I. Standards of Review

When reviewing the denial of a motion for judgment as a matter of law (“JMOL”) after a jury verdict, we “ ‘appl[y] the same standard of review as that applied by the trial court.’ ” *Wechsler v. Macke Int'l Trade, Inc.*, 486 F.3d 1286, 1290 (Fed.Cir. 2007) (quoting *nCube Corp. v. SeaChange Int'l, Inc.*, 436 F.3d 1317, 1319 (Fed.Cir. 2006)). Furthermore, “[t]he grant or denial of a motion for judgment as a matter of law is a procedural issue not unique to patent law, reviewed under the law of the regional circuit in which the appeal from the district court would usually lie.” *Summit Tech., Inc. v. Nidek Co.*, 363 F.3d 1219, 1223 (Fed.Cir. 2004). In the Ninth Circuit, a district court grants JMOL only “if the evidence, construed in the light most favorable to the nonmoving party, permits only one reasonable conclusion, and that conclusion is contrary to the jury's verdict.” *Pavao v. Pagay*, 307 F.3d 915, 918 (9th Cir. 2002). Similarly, a district court in the Ninth Circuit “may grant a new trial only if the verdict is against the clear weight of the evidence.” *Id.*

We review for an abuse of discretion a district court's decision concerning the methodology for calculating damages. *Unisplay, S.A. v. Am. Elec. Sign Co.*, 69 F.3d 512, 517 n. 8 (Fed.Cir.1995); *see also State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1576-77 (Fed.Cir.1989) (noting that the precise methodology used in “assessing and computing damages is committed to the sound discretion of the district court”). We review the jury's determination of the amount of damages, an issue of fact, for substantial evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1164 n. 2 (Fed.Cir. 1991). “A jury's decision with respect to an award of damages ‘must be upheld unless the amount is grossly excessive or monstrous, clearly not supported by the evidence, or based only on speculation or guesswork.’ ” *State Contracting & Eng'g Corp. v. Condotte Am., Inc.*, 346 F.3d 1057, 1072 (Fed.Cir. 2003) (quoting *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1580 (Fed.Cir.1992)).

Independent claim 19 is directed to a method of inputting data using certain predefined “tools” and entering that information into particular fields displayed in a computer form.

Claim 21 depends from claim 19 and further specifies that the information field is displayed as “a bit-mapped-graphics field.” Claims 19 and 21 read in full as follows.

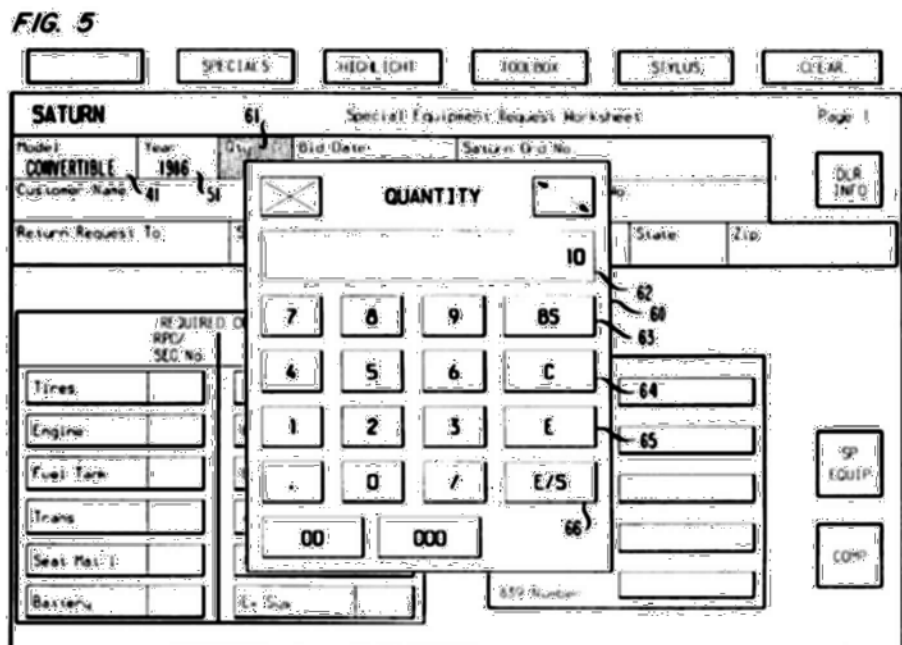
19. A method for use in a computer having a display comprising the steps of displaying on said display a plurality of information fields, identifying for each field a kind of information to be inserted therein, indicating a particular one of said information fields into which information is to be inserted and for concurrently displaying a predefined tool associated with said one of said fields, said predefined tool being operable to supply information of the kind identified for said one field, said tool being selected from a group of predefined tools including a tool adapted to supply an individual entry from a menu of alternatives and at least a tool adapted to allow said user to compose said information, and inserting in said one field information that is derived as a result of said user operating said displayed tool.

* * *

21. The method set forth in claim 19 wherein the step of displaying said pattern includes the step of displaying one or more of said information fields as a bit-mapped-graphics field.

The '356 patent, col.17 l.27 to col.18 l.22. Figure 5 of the Day patent, shown below, illustrates an embodiment of the invention in which a graphical calculator overlays the form having multiple fields, one of which—“Quantity” (Qty 61)—is highlighted.

FIG. 5



III. Infringement

The jury found indirect infringement by Microsoft. Claims 19 and 21 are method claims; thus, Microsoft's sales of its software alone cannot infringe the patent. Infringement occurs only when someone performs the method using a computer running the necessary software. Thus, Microsoft can only be liable for infringement of claims 19 and 21 as a contributor and/or an inducer.

Microsoft makes the following arguments concerning indirect infringement. First, Lucent didn't prove direct infringement, a necessary predicate for proving indirect infringement. Second, Lucent didn't prove contributory infringement because the products have substantial noninfringing uses. Third, Lucent can't prove inducement because the products are merely capable of inducing and Microsoft wasn't shown to have the requisite intent to induce. We address each argument in turn.

A. Direct Infringement

To infringe a method claim, a person must have practiced all steps of the claimed method. *See Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed.Cir.1993) (“A method claim is *directly* infringed only by one practicing the patented method.”); *see also* 35 U.S.C. § 271 (2006). Just as anticipation can be found by a single prior art use, a finding of infringement can rest on as little as one instance of the claimed method being performed during the pertinent time period.

Lucent asserts that certain features of Outlook, Money, and Windows Mobile, when used, practice the methods of claims 19 and 21. For instance, Outlook includes a calendar tool that allows the user to enter dates in a form when preparing a record of an appointment. The tool displays a monthly calendar as a grid of numbered dates, along with graphical controls that allow the user to scroll to adjacent months or skip directly to a different month and year. Once the user defines a date with the tool, the software enters the numerical day, month, and year into the corresponding field in the appointment form. Similar to the number pad tool illustrated in the Day patent, Outlook's calendar date-picker tool enables the user to select a series of numbers, corresponding to the day, month, and year, using graphical controls. This date-picker calendar tool is incorporated in a few of Outlook's features. Microsoft Money and Windows Mobile have similar functionalities.

According to Microsoft, Lucent failed to introduce any evidence that any customer actually used the claimed method in any of the Microsoft products. Noting that “each accused product has numerous uses that do not involve forms with onscreen composition tools” and that “the specific narrow function of the patented method-filling in a form-can be performed without using the asserted ‘composition tool’ features,” Microsoft urges that “infringement is not inevitable.” The only evidence of direct infringement, in Microsoft's view, is the testimony of Lucent's expert.

We agree with Microsoft that there was little, if any, direct evidence of infringement. Microsoft correctly points out that Lucent's direct evidence of infringement was limited. Nevertheless, circumstantial evidence was just adequate to permit a jury to find that at least one other person within the United States during the relevant time

period, other than the expert, had performed the claimed method. Lucent's expert testified that “[i]t's hard to imagine that we're the only two people in the world that ever used it.” J.A. 07517. As Lucent notes “Microsoft not only designed the accused products to practice the claimed invention, but also instructed its customers to use the accused products in an infringing way.”

Without doubt, Lucent would have been on much firmer ground had it introduced some direct evidence of using the claimed method. Nevertheless, Lucent's circumstantial evidence of infringement was “something less than the weight of the evidence,” *Consolo v. Fed. Maritime Comm'n*, 383 U.S. 607, 620 (1966), yet it was just “more than a mere scintilla,” *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). Accordingly and for these reasons, we are not convinced that the district court erred in denying Microsoft's JMOL motion with respect to infringement. For similar reasons, substantial evidence supports the jury's finding as it relates to direct infringement by the use of Microsoft Money and Windows Mobile.

B. Contributory Infringement

Under 35 U.S.C. § 271(c), a party is liable for infringement if he “offers to sell or sells within the United States or imports into the United States ... a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.” “In order to succeed on a claim of contributory infringement, in addition to proving an act of direct infringement, plaintiff must show that defendant ‘knew that the combination for which its components were especially made was both patented and infringing’ and that defendant's components have ‘no substantial non-infringing uses.’ ” *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1312 (Fed.Cir. 2005) (quoting *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed.Cir. 2004)).

According to Microsoft, Lucent did not prove contributory infringement because the products have substantial noninfringing uses. Lucent counters that the date-picker tool does not have any noninfringing uses. Thus, as framed by the parties, the main issue reduces to whether the “material or apparatus” is the entire software package or just the particular tool (e.g., the calendar date-picker) that performs the claimed method. If the former, then Microsoft prevails because the entire software package has substantial noninfringing uses. If the material or apparatus is the specific date-picker tool, then Lucent wins because that tool was “especially made or especially adapted for” practicing the claimed method.

Here, the infringing feature for completing the forms, i.e., the date-picker tool, is suitable only for an infringing use. Inclusion of the date-picker feature within a larger program does not change the date-picker's ability to infringe. Because Microsoft included the date-picker tool in Outlook, the jury could reasonably conclude, based on the evidence presented, that Microsoft intended computer users to use the tool—perhaps not frequently—and the only intended use of the tool infringed the Day patent.

C. Inducing Infringement

A party who “actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. § 271(b). Under this provision, “[t]he plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements.” *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed.Cir. 1990).

Having perused the evidence, we agree with Microsoft that the evidence is not strong, but we are not persuaded that the jury was unreasonable in finding that Microsoft possessed the requisite intent to induce at least one user of its products to infringe the claimed methods.

IV. Damages

Based on the evidence of record, Microsoft (and Dell) sold approximately 110 million units of the three software products capable of practicing the methods of the asserted claims. The total dollar value of the sales was approximately \$8 billion. At trial, Lucent's theory of damages was based on 8% of sales revenue for the accused software products, and it asked the jury to award \$561.9 million based on Microsoft's infringing sales. Microsoft countered that a lump-sum payment of \$6.5 million would have been the correct amount for licensing the protected technology. *See Lucent Techs.*, 580 F.Supp.2d at 1042 & n. 7.

Microsoft challenges the jury's damages award on several bases. First, Microsoft argues that the jury should not have applied the entire market value rule to the value of its three software products. Microsoft's second argument for reversing the damages award is that, for method claims, *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263 (Fed.Cir. 2004), requires that damages be limited to the proven number of instances of actual infringing use. Microsoft states that, “[u]nder *Dynacore*, Lucent had to tie its damages claim to demonstrated instances of direct infringement.” For the reasons stated below, we reject both arguments as presented by Microsoft. We agree, nevertheless, with Microsoft's argument that substantial evidence does not support the jury's verdict of a lump-sum royalty payment of \$357,693,056.18. Further, to the extent the jury relied on an entire market value calculation to arrive at the lump-sum damages amount, that award is not supported by substantial evidence and is against the clear weight of the evidence.

A. Reasonable Royalty

“Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.” 35 U.S.C. § 284. As the Supreme Court has framed the general issue of determining damages, at least for competitors, a court must ask, “[H]ad the Infringer not infringed, what would [the] Patent Holder[] have made?” *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964; *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 536, 552 (1886)).

The burden of proving damages falls on the patentee. *Dow Chem. Co. v. Mee Indus., Inc.*, 341 F.3d 1370, 1381 (Fed.Cir. 2003); *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1551 (Fed.Cir. 1994). Two alternative categories of infringement compensation are the patentee's lost profits and the reasonable royalty he would have received through arms-length bargaining. See *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1157 (6th Cir. 1978) (Markey, J.). Lost profits are not at issue in the present case. A reasonable royalty is, of course, "merely the floor below which damages shall not fall." *Bandag, Inc. v. Gerrard Tire Co.*, 704 F.2d 1578, 1583 (Fed.Cir. 1983).

Litigants routinely adopt several approaches for calculating a reasonable royalty. The first, the analytical method, focuses on the infringer's projections of profit for the infringing product. See *TWM Mfg. Co. v. Dura Corp.*, 789 F.2d 895, 899 (Fed.Cir. 1986) (describing the analytical method as "subtract[ing] the infringer's usual or acceptable net profit from its anticipated net profit realized from sales of infringing devices"). The second, more common approach, called the hypothetical negotiation or the "willing licensor-willing licensee" approach, attempts to ascertain the royalty upon which the parties would have agreed had they successfully negotiated an agreement just before infringement began. See *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F.Supp. 1116, 1120 (S.D.N.Y. 1970); see also *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1554 n. 13 (Fed.Cir.1995) (en banc); *Radio Steel & Mfg. Co. v. MTD Prods., Inc.*, 788 F.2d 1554, 1557 (Fed.Cir. 1986) ("The determination of a reasonable royalty, however, is based not on the infringer's profit, but on the royalty to which a willing licensor and a willing licensee would have agreed at the time the infringement began."). The hypothetical negotiation tries, as best as possible, to recreate the *ex ante* licensing negotiation scenario and to describe the resulting agreement. In other words, if infringement had not occurred, willing parties would have executed a license agreement specifying a certain royalty payment scheme. The hypothetical negotiation also assumes that the asserted patent claims are valid and infringed.

In the present appeal, the parties, in offering the damages evidence, each adopted the hypothetical negotiation approach, without objection. Both Microsoft and Lucent must therefore accept that any reasonable royalty analysis "necessarily involves an element of approximation and uncertainty." *Unisplay*, 69 F.3d at 517. We review the damages award within the *Georgia-Pacific* framework.

Before the district court, Lucent asked for a damages award based only on a running royalty. Microsoft, on the other hand, told the jury that the damages should be a lump-sum royalty payment of \$6.5 million. Based on the verdict form, the jury decided on a lump-sum award, not a running royalty. The verdict form notes a lump-sum damages amount and no amount (i.e., zero or "N/A") on the lines for a running royalty. Faced with the jury's selection, our task is to determine whether substantial evidence supports a lump-sum, paid-in-full royalty of approximately \$358 million for Microsoft's indirect infringement of the Day patent. To do this, we must decide whether substantial evidence supports the jury's implicit finding that Microsoft would have agreed to, at the time of the hypothetical negotiation, a lump-sum, paid-in-full royalty of about \$358 million. In performing this analysis, we focus mainly on the damages case as it applies to Microsoft Outlook, as infringement by the use of Outlook apparently constituted the vast majority

of the award. We focus also on the relevant *Georgia-Pacific* factors, as presented to the jury through all the evidence and particularly the experts' testimony.

We also note the following at the outset of our analysis. Microsoft does not argue on appeal that any of the evidence relevant to the damages award was improperly before the jury. At times, Microsoft's briefs seem to suggest that the district court judge "abdicated" her role as a gatekeeper. The responsibility for objecting to evidence, however, remains firmly with the parties. Here, the record reveals that, at trial, Microsoft objected neither to the introduction of any of the licenses discussed below nor to the testimony of Lucent's expert as it related to those licenses. In this instance, the district court judge had no independent mandate to exclude any of that evidence. Therefore, we must accept that the licensing agreements and other evidence were properly before the jury. Any implicit objection on appeal is deemed waived by failing to object at trial.

1. Factor 2

The second *Georgia-Pacific* factor is "[t]he rates paid by the licensee for the use of other patents comparable to the patent in suit." 318 F.Supp. at 1120. This factor examines whether the licenses relied on by the patentee in proving damages are sufficiently comparable to the hypothetical license at issue in suit. *See* Russell L. Parr, *Royalty Rates for Licensing Intellectual Property* 64 (2007) ("For similar license agreements to be used as a proxy for derivation of a fair market royalty, the form of license compensation should be on a like-kind basis."). Subsumed within this factor is the question of whether the licensor and licensee would have agreed to a lump-sum payment or instead to a running royalty based on ongoing sales or usage.

Significant differences exist between a running royalty license and a lump-sum license. In a standard running royalty license, the amount of money payable by the licensee to the patentee is tied directly to how often the licensed invention is later used or incorporated into products by the licensee. A running royalty structure shifts many licensing risks to the licensor because he does not receive a guaranteed payment. Royalties are dependent on the level of sales or usage by the licensee, which the licensee can often control.

Lucent's licensing expert, Roger Smith, argued for damages based solely on a running royalty rate. Smith emphasized his choice of a running royalty over a lump-sum payment.

On appeal, however, Lucent defends the damages award, contending that substantial evidence supports the lump-sum award of about \$358 million. This is problematic for several reasons. First, no evidence of record establishes the parties' expectations about how often the patented method would be used by consumers. Second, the jury heard little factual testimony explaining how a license agreement structured as a running royalty agreement is probative of a lump-sum payment to which the parties would have agreed. Third, the license agreements for other groups of patents, invoked by Lucent, were created from events far different from a license negotiation to avoid infringement of the one patent here, the Day patent.

Parties agreeing to a lump-sum royalty agreement may, during the license negotiation, consider the expected or estimated usage (or, for devices, production) of a given invention, assuming proof is presented to support the expectation, because the more frequently most inventions are used, the more valuable they generally are and therefore the larger the lump-sum payment. Conversely, a minimally used feature, with all else being equal, will usually command a lower lump-sum payment. In this case, Lucent identifies no documentary evidence or testimony showing the parties' expectations as to usage of the claimed method. Lucent submitted no evidence upon which a jury could reasonably conclude that Microsoft and Lucent would have estimated, at the time of the negotiation, that the patented date-picker feature would have been so frequently used or valued as to command a lump-sum payment that amounts to approximately 8% of the sale price of Outlook.

Lucent's expert Mr. Smith did try to explain how one would calculate what an acceptable lump-sum would be.

Q: Well, when one is considering what the magnitude of a lump-sum payment might be, does one ever look at what the expected royalty-total royalty would be produced by a running royalty based on the available information at that time?

A: That generally is the way a lump sum would be determined, by looking at what the running royalty-what the value of each use of the patent might be and *then speculating as to the extent of the future use.*

J.A. 07805 (emphasis added). But an explanation urging jurors to rely on speculation, without more, is often insufficient. Smith repeated his "lump-sum speculation theory" when he told the jury that parties "speculate" as to what they expect the future to be like when negotiating a lump-sum payment for a patent license. In short, Smith's testimony could be interpreted as suggesting to the jury that it was proper to "speculate" as to the proper lump-sum damages amount even though he may have intended the word "speculate" to mean "estimate."

Despite this shortcoming in its evidence, Lucent relies on eight varied license agreements which purportedly support the jury's lump-sum damages award. When we examine these license agreements, along with the relevant testimony, we are left with two strong conclusions. First, some of the license agreements are radically different from the hypothetical agreement under consideration for the Day patent. Second, with the other agreements, we are simply unable to ascertain from the evidence presented the subject matter of the agreements, and we therefore cannot understand how the jury could have adequately evaluated the probative value of those agreements.

Only four of the eight agreements purport to be lump-sum agreements: (1) a 1993 agreement between Dell and IBM for \$290 million; (2) a 1996 agreement between Microsoft and Hewlett-Packard for \$80 million; (3) a 1997 agreement between Microsoft and Apple Computer for \$93 million; and (4) a 1999 agreement between Microsoft and Inprise for \$100 million. Lucent's brief characterizes the four agreements as covering "PC-related patents," as if personal computer kinship imparts enough comparability to support the damages award. For the latter three, it is impossible for us, based on the

record, to determine whether the agreements are at all comparable to the hypothetical agreement of the present suit. For the first agreement, what little explanation there is only underscores the differences between it and any hypothetical agreement for the Day patent.

The 1993 agreement between IBM and Dell appears to be a modification of their 1988 agreement. These two IBM-Dell agreements are vastly different from any agreement Microsoft and Lucent would have struck for the Day patent at the time of infringement. As best as we can discern, the 1988 agreement appears to govern IBM's licensing of its entire patent portfolio protecting its one-time dominance in the personal computer market. *See* J.A. 08193 (witness testimony explaining in cursory fashion the Dell-IBM agreement). At the time, conventional wisdom instructed that selling IBM clones required a license to IBM's patent portfolio. Dell's business was built around selling IBM clones. From this information, a reasonable juror could only conclude that the IBM-Dell license agreement for multiple patents to broad, PC-related technologies is directed to a vastly different situation than the hypothetical licensing scenario of the present case involving only one patent, the Day patent, directed to a narrower method of using a graphical user interface tool known as the date-picker. Of course, without more information about the IBM-Dell agreement, one can only speculate about how the Dell-IBM agreement could be compared to any licensing agreement involving the Day patent.

For the other three lump-sum agreements, Lucent's expert supplied no explanation to the jury about the subject matter or patents covered by those agreements. For example, the entire substance of Lucent's expert's testimony about the Microsoft-Apple agreement amounted to the following colloquy:

Q: What did you ascertain or what is Plaintiff's Exhibit 5150?

A: Plaintiff's Exhibit 5150 is a patent cross-license agreement between Microsoft and Apple.

Q: And what did you find significant about this cross-license agreement between Microsoft and Apple?

A: The slide that's on the screen shows that this is a cross-license in which Hewlett-in which Microsoft gave to Apple in addition to a license under its patents a royalty payment or a balancing payment of some \$93,000,000.

J.A. 07746. Counsel for Lucent immediately followed this exchange with an equally scant inquiry into the Microsoft-Inprise agreement.

Q: And could you turn in your evidence binder to Plaintiff's Exhibit 5151 and tell us what that is?

A: 5151 is a patent cross-license agreement between Microsoft and a company known as Inprise.

Q: And if you could turn to slide 41, would that assist the presentation of your testimony in connection with that agreement?

A: It would.

Lucent candidly admits in its brief that “none of the real world licenses introduced at trial arose from circumstances identical to those presumed to prevail in the hypothetical royalty negotiation.” Appellee’s Br. 50. Moreover, the testimony excerpted above belies Lucent’s claim of “present[ing] particularized expert testimony explaining how various differences between the real and hypothetical license negotiations ... would factor into the appropriate royalty for Microsoft’s infringement.” *Id.* The testimony provides no analysis of those license agreements, other than, for example, noting the agreement was a cross-license of a large patent portfolio and the amount paid. Lucent had the burden to prove that the licenses were sufficiently comparable to support the lump-sum damages award. The law does not require an expert to convey all his knowledge to the jury about each license agreement in evidence, but a lump-sum damages award cannot stand solely on evidence which amounts to little more than a recitation of royalty numbers, one of which is arguably in the ballpark of the jury’s award, particularly when it is doubtful that the technology of those license agreements is in any way similar to the technology being litigated here.

Lucent also cites four running-royalty license agreements which purportedly provide substantial evidence supporting a lump-sum damages award of approximately \$358 million. A significant shortcoming of these agreements is their “running-royalty” nature, however. As we noted above, certain fundamental differences exist between lump-sum agreements and running-royalty agreements. This is not to say that a running-royalty license agreement cannot be relevant to a lump-sum damages award, and vice versa. For a jury to use a running-royalty agreement as a basis to award lump-sum damages, however, some basis for comparison must exist in the evidence presented to the jury. In the present case, the jury had almost no testimony with which to recalculate in a meaningful way the value of any of the running royalty agreements to arrive at the lump-sum damages award.

Furthermore, the running royalty agreements put into evidence, as with the lump-sum agreements, differ substantially from the hypothetical negotiation scenario involving the Day patent. The four running royalty agreements upon which Lucent relies are agreements between itself and Vox Communications (“Vox agreement”); between itself and Kenwood (“Kenwood agreement”); between itself and Acer (“Acer agreement”); and between Microsoft and MPEG-LA (“MPEG agreement”).

The Vox agreement covered five Lucent patents, which, as explained by Lucent’s expert, are directed to PC graphics boards manufactured by Vox. In addition to a lump-sum payment of \$50,000, Vox agreed to pay a per-unit rate of \$2.00 for each licensed product. But no testimony described how the patented technology of the Vox agreement relates to the licensed graphics boards. Lucent’s expert never explained to the jury whether the patented technology is essential to the licensed product being sold, or whether the patented invention is only a small component or feature of the licensed product (as is the case here). The jury also had no information about the price of Vox’s PC graphics boards and thus was unable to assess the magnitude of the \$2.00 rate, which seems particularly relevant given Lucent’s defense of an award amounting to about 8% of the market value of Outlook. In the absence of the price of graphics boards, the \$2.00 value is difficult, if not impossible, to evaluate. The testimony of Lucent’s expert relating

to the Vox agreement was confined essentially to the fact that the agreement is a cross-licensing agreement in which the rights granted to Lucent were royalty-free and that the royalty rate is structured as a commuted rate.

The Kenwood agreement, covering two Lucent patents directed to DVD player products, is a hybrid lump-sum/running royalty cross-license agreement. Kenwood agreed to pay Lucent an up-front payment of \$3 million along with a per-unit royalty of \$1.50 for each product in excess of 300,000 units. Lucent's expert told the jury that the Kenwood agreement was a cross-license, conveying rights to Lucent to practice Kenwood's patents, but the jury never learned anything about those patent rights and how valuable or essential those rights were. Even if we were to apply the \$1.50 per unit rate of the Kenwood agreement to the number of infringing units that could be used to infringe in the present case, this would yield only about \$165 million, substantially less than the \$358 million awarded by the jury.

The Acer agreement, executed in 1998, involved eight patents and various commercial products. Lucent refers to the Acer agreement as one involving PC-related patents. During his testimony, Lucent's expert focused almost exclusively on the per-unit royalty rate of \$2.50 and the lump-sum payment of \$14.5 million. But the jury again did not hear any explanation of the types of products covered by the agreement or the various royalty rates set forth in the agreement. Specifically, the agreement calls for different royalties for different products. For so-called "reportable products," the rate is not a fixed dollar amount but set at 2%, while the royalty rates for "semiconductive devices" is in the range of 1%. Furthermore, Lucent did not explain how the fact that the Acer agreement involved eight patents affects how probative it is of the Microsoft-Lucent hypothetical negotiation over one patent. Nor is there any document or testimony upon which a jury could have considered how similar or dissimilar the patented technology of the Acer agreement is to the invention of using the date-picker. Nor is there any evidence or testimony about how the \$2.50 per unit rate corresponds to a percentage of the cost of the "personal computers" sold under the license agreement. It is not implausible that the average price of the computers subject to the Acer agreement was close to \$1000. *See* Larry Armstrong, *How Did Santa Carry All Those Computers*, Business Week, Jan. 11, 1999, at 46, 46 (noting that, in November 1999, "the average selling price of a PC without monitor dropped below \$1,000 for the first time"). Such an average price would mean the \$2.50 per-unit rate of the Acer agreement equates to approximately one-quarter of one percent of the value of the computer, which is about one-thirtieth the constructive rate awarded to Lucent.

Finally, the MPEG agreement on its face supports a higher royalty rate of \$4 per unit. But, as with the other running royalty agreements, the structure of the MPEG agreement is more complicated, and the jury had little to no testimony explaining how such complexity would have affected the hypothetical negotiation analysis. Specifically, the 31-page agreement contains numerous provisions covering various MPEG-related products (e.g., decoding products, distribution encoding products, program stream products, etc.). Moreover, the various products appear to have different royalty rates, some as low as a penny per unit.

We now consider what Microsoft advocated, namely that the hypothetical negotiation would have yielded a lump-sum licensing agreement for \$6.5 million. For whatever reason, Microsoft urged the jury to accept its theory based on a proffer of a single license Microsoft had executed for a graphical user interface technology. Thus, at a minimum, a reasonable jury could have awarded \$6.5 million, or some larger amount as permitted by the evidence. *See Rite-Hite*, 56 F.3d at 1555 (“[W]hat an infringer would prefer to pay is not the test for damages.”).

But we see little evidentiary basis under *Georgia-Pacific* Factor 2 for awarding roughly three to four times the average amount in the lump-sum agreements in evidence. Here the award was \$358 million; there, the amounts were \$80, 93, 100, and 290 million. That some licenses were cross-licenses or commuted-rate licenses—which may warrant a higher damages award—does not fill the evidentiary lacunae. Again, it was Lucent's burden to prove that the licenses relied on were sufficiently comparable to sustain a lump-sum damages award of \$358 million. For the reasons stated, Factor 2 weighs strongly against the jury's award.

2. Factors 10 and 13

Factor 10 is “[t]he nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.” *Georgia-Pacific*, 318 F.Supp. at 1120. Factor 13 is “[t]he portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.” *Id.* These two factors, at least as applied to the facts of this case, both aim to elucidate how the parties would have valued the patented feature during the hypothetical negotiation.

The evidence can support only a finding that the infringing feature contained in Microsoft Outlook is but a tiny feature of one part of a much larger software program. Microsoft's expert explained that Outlook's e-mail component is “the part of Outlook that's most commonly used by our customers.” Microsoft's witness also explained that, in addition to sending and receiving e-mails, a user can create electronic tasks and notes. Additionally, Outlook can be used as an electronic Rolodex™, storing contact information, such as phone numbers, addresses, and the like. It also has a fully functional calendar system, in which a user can record appointments, meetings, and other items on one's schedule. As Lucent's own expert testified, Outlook is a “personal organizer” that is “an integrated suite of abilities to do e-mail, to set up contacts, to arrange meetings, to maintain your personal calendar, et cetera.” In short, Outlook is an enormously complex software program comprising hundreds, if not thousands or even more, features. We find it inconceivable to conclude, based on the present record, that the use of one small feature, the date-picker, constitutes a substantial portion of the value of Outlook.

The parties presented little evidence relating to Factor 13. Nonetheless, the only reasonable conclusion is that most of the realizable profit must be credited to non-patented elements, such as “the manufacturing process, business risks, or significant features or improvements added by [Microsoft].” As explained by Microsoft's expert Mr. Kennedy, Outlook consists of millions of lines of code, only a tiny fraction of which

encodes the date-picker feature. Although the weighing of Factor 13 cannot be reduced to a mere counting of lines of code, the glaring imbalance between infringing and non-infringing features must impact the analysis of how much profit can properly be attributed to the use of the date-picker compared to non-patented elements and other features of Outlook. Here, numerous features other than the date-picker appear to account for the overwhelming majority of the consumer demand and therefore significant profit.

The only reasonable conclusion that can be drawn from this evidence is that the infringing use of Outlook's date-picker feature is a minor aspect of a much larger software program and that the portion of the profit that can be credited to the infringing use of the date-picker tool is exceedingly small. For these reasons, Factors 10 and 13 of *Georgia-Pacific* provide little support for the jury's lump-sum damages award of \$357,693,056.18.

3. Factor 11

Factor 11 is “[t]he extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.” *Georgia-Pacific*, 318 F.Supp. at 1120. As with Factors 10 and 13, the eleventh factor informs the court and jury about how the parties would have valued the patented feature during the hypothetical negotiation. In doing so, Factor 11 relies on evidence about how much the patented invention has been used. Implicit in this factor is the premise that an invention used frequently is generally more valuable than a comparable invention used infrequently.

During oral argument, Microsoft characterized as irrelevant information about how often the date-picker tool has in fact been used by consumers of Microsoft products. That is so, according to Microsoft, because such facts postdate the time of the hypothetical negotiation. *See Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1081 (Fed.Cir. 1983) (“The issue of the infringer's profit is to be determined not on the basis of a hindsight evaluation of what actually happened, but on the basis of what the parties to the hypothetical license negotiations would have considered at the time of the negotiations.”). But neither precedent nor economic logic requires us to ignore information about how often a patented invention has been used by infringers. Nor could they since frequency of expected use and predicted value are related.

In *Sinclair Refining Co. v. Jenkins Petroleum Process Co.*, 289 U.S. 689, 698 (1933), the Supreme Court recognized that factual developments occurring after the date of the hypothetical negotiation can inform the damages calculation:

[A] different situation is presented if years have gone by before the evidence is offered. Experience is then available to correct uncertain prophecy. Here is a book of wisdom that courts may not neglect. We find no rule of law that sets a clasp upon its pages, and forbids us to look within.

Consideration of evidence of usage after infringement started can, under appropriate circumstances, be helpful to the jury and the court in assessing whether a royalty is reasonable. Usage (or similar) data may provide information that the parties would frequently have estimated during the negotiation. Such data might, depending on the case, come from sales projections based on past sales, consumer surveys, focus group

testing, and other sources. Even though parties to a license negotiation will usually not have precise data about future usage, they often have rough estimates as to the expected frequency of use. This quantitative information, assuming it meets admissibility requirements, ought to be given its proper weight, as determined by the circumstances of each case.

On the other hand, we have never laid down any rigid requirement that damages in all circumstances be limited to specific instances of infringement proven with direct evidence. Such a strict requirement could create a hypothetical negotiation far-removed from what parties regularly do during real-world licensing negotiations. As shown by the evidence in this case, companies in the high-tech computer industry often strike licensing deals in which the amount paid for a particular technology is not necessarily limited to the number of times a patented feature is used by a consumer. A company licensing a patented method often has strong reasons not to tie the royalty amount strictly to usage. The administrative cost of monitoring usage can be prohibitively expensive. Furthermore, with some inventions, say for example a method of detecting fires, value is added simply by having the patented invention available for use. Thus, potential licensors and licensees routinely agree to royalty payments regardless of whether the invention is used frequently or infrequently by the consumer.

No evidence describes how many Microsoft Outlook users had ever performed the patented method or how many times. Lucent had the burden to prove that the extent to which the infringing method has been used supports the lump-sum damages award.

5. Conclusion on Lump-Sum Reasonable Royalty

Having examined the relevant *Georgia-Pacific* factors, we are left with the unmistakable conclusion that the jury's damages award is not supported by substantial evidence, but is based mainly on speculation or guesswork. When the evidence is viewed *in toto*, the jury's award of a lump-sum payment of about \$358 million does not rest on substantial evidence and is likewise against the clear weight of the evidence. The evidence does not sustain a finding that, at the time of infringement, Microsoft and Lucent would have agreed to a lump-sum royalty payment subsequently amounting to approximately 8% of Microsoft's revenues for the sale of Outlook (and necessarily a larger percentage of Outlook's profits). We need not identify any particular *Georgia-Pacific* factor as being dispositive. Rather, the flexible analysis of all applicable *Georgia-Pacific* factors provides a useful and legally-required framework for assessing the damages award in this case. Furthermore, we do not conclude that the aforementioned license agreements (or other evidence) cannot, as a matter of law, support the damages award in this case. Instead, the evidence as presented did not reach the "substantial evidence" threshold and therefore no reasonable jury could have found that Lucent carried its burden of proving that the evidence, under the relevant *Georgia-Pacific* factors, supported a lump-sum damages award of \$357,693,056.18.

We admit that the above analysis focuses on Microsoft Outlook, not the other two software programs. Because the damages award with respect to infringement by Outlook

is not supported by the evidence but is against the clear weight of the evidence, a new trial on damages is necessary. We therefore need not specifically address the evidence as it relates to Microsoft Money and Windows Mobile. We leave that to the jury or court to assess on remand. We acknowledge that the factual findings based on the pertinent *Georgia-Pacific* factors may not be identical for all three products. For example, the tools that practice the infringing method may be incorporated more (or less) extensively throughout Windows Mobile and Microsoft Money than in Outlook.

B. Entire Market Value Analysis

Microsoft argues that the damages award must be reversed because the jury erroneously applied the entire market value rule. Despite the jury's indication on the verdict form that it was awarding a lump-sum reasonable royalty, Microsoft believes that the only way the jury could have calculated a figure of \$357,693,056.18 was by applying a royalty percentage to a total sales figure of the infringing software products. Indeed, it is difficult to understand how the jury could have chosen its lump-sum figure down to the penny unless it used a running royalty calculation. Furthermore, as Microsoft explains in its brief, working the math backwards strongly suggests that the jury must have used some calculation of a rate applied to the entire market value of the software. Assuming that the jury did apply the entire market value rule, such application would amount to legal error for two reasons.

In one sense, our law on the entire market value rule is quite clear. For the entire market value rule to apply, the patentee must prove that “the patent-related feature is the ‘basis for customer demand.’ ” *Rite-Hite*, 56 F.3d at 1549 (quoting *State Indus.*, 883 F.2d at 1580).

In the distant past, before a contemporary appreciation of the economics of infringement damages, the Supreme Court seemingly set forth rigid rules concerning the entire market value rule. Shortly before the Civil War, in *Seymour v. McCormick*, 57 U.S. (16 How.) 480, 491 (1853), a case involving one of Cyrus McCormick's famous reaping machine inventions, the Court warned that it would be “a very grave error to instruct a jury ‘that as to the measure of damages the same rule is to govern, whether the patent covers an entire machine or an improvement on a machine.’ ” About a century and a quarter ago, in *Garretson v. Clark*, the Court expressed further concern about basing damages on the value of the entire product:

When a patent is for an improvement, and not for an entirely new machine or contrivance, the patentee must show in what particulars his improvement has added to the usefulness of the machine or contrivance. He must separate its results distinctly from those of the other parts, so that the benefits derived from it may be distinctly seen and appreciated.... The patentee ... must in every case give evidence tending to separate or apportion the defendant's profits and the patentee's damages between the patented feature and the unpatented features, and such evidence must be reliable and tangible, and not conjectural or speculative; or he must show, by equally reliable and satisfactory evidence, that the profits and damages are to be calculated on the whole machine, for

the reason that the entire value of the whole machine, as a marketable article, is properly and legally attributable to the patented feature.

111 U.S. 120, 121 (1884) (quotation marks omitted). And early last century, the Court elaborated on this theme:

[An] invention may have been used in combination with valuable improvements made, or other patents appropriated by the infringer, and each may have jointly, but unequally, contributed to the profits. In such case, if plaintiff's patent only created a part of the profits, he is only entitled to recover that part of the net gains.

Westinghouse Elec. & Mfg. Co. v. Wagner Elec. & Mfg. Co., 225 U.S. 604, 614-15 (1912).

Translating the Court's early stylistic description into a precise, contemporary, economic paradigm presents a challenge. Notwithstanding this obstacle, the objective of the Court's concern has been two-fold: determining the correct (or at least approximately correct) value of the patented invention, when it is but one part or feature among many, and ascertaining what the parties would have agreed to in the context of a patent license negotiation. Litigants must realize that the two objectives do not always meet at the same precise number. Furthermore, licensors of patented technology often license an invention for more or less than its true "economic value." Such is the inherent risk in licensing intangible assets that may have no established market value.

The first flaw with any application of the entire market value rule in the present case is the lack of evidence demonstrating the patented method of the Day patent as the basis-or even a substantial basis-of the consumer demand for Outlook. As explained above, the only reasonable conclusion supported by the evidence is that the infringing use of the date-picker tool in Outlook is but a very small component of a much larger software program. The vast majority of the features, when used, do not infringe. The date-picker tool's minor role in the overall program is further confirmed when one considers the relative importance of certain other features, e.g., e-mail. Consistent with this description of Outlook, Lucent did not carry its evidentiary burden of proving that anyone purchased Outlook because of the patented method. Indeed, Lucent's damages expert conceded that there was no "evidence that anybody anywhere at any time ever bought Outlook, be it an equipment manufacturer or an individual consumer, ... because it had a date picker." J.A 07821-22.

As for Windows Mobile and Microsoft Money, a jury's conclusion might possibly be different. At this point in the litigation, we again need not decide these issues. Because the damages award based on the infringing date-picker feature of Outlook is not supported by substantial evidence and is contrary to the clear weight of the evidence, the damages award must be vacated. When the case is remanded to the trial court for further proceedings consistent with this opinion, it may be helpful to analyze the three infringing software products independently.

The second flaw with any application of the entire market value rule in this case lies in the approach adopted by Lucent's licensing expert. He had first tried to apply the entire market value rule to the sale of the "infringing" computers loaded with the

software, opining that Microsoft and Lucent would have agreed to a 1% royalty based on the entire price of the computer containing Outlook. In response, Microsoft filed a motion *in limine* to exclude such testimony, which the district court granted. At trial, Lucent's expert changed his opinion, contending that the royalty base should be the price of the software (and not the entire computer) but also that the royalty rate should be increased to 8% (from 1%). This opinion contrasted starkly to the rates he proposed for the other patents in suit, which were in the 1% range. In choosing 8%, he reasoned that, "in a typical situation, if one applied a royalty to a smaller patented portion in a computer as opposed to the entire computer using typically infringed patents, 8-percent ... of the fair market value of the patented portion would equate to 1-percent of the fair market value of the entire computer."

What Lucent's licensing expert proposed here does not comport with the purpose of damages law or the entire market value rule. Lucent's expert tried to reach the damages number he would have obtained had he used the price of the entire computer as a royalty base. Being precluded from using the computer as the royalty base, he used the price of the software, but inflated the royalty rate accordingly. This cannot be an acceptable way to conduct an analysis of what the parties would have agreed to in the hypothetical licensing context. The approach of Lucent's expert ignores what the district court's evidentiary ruling tried to accomplish. The district court implicitly recognized that any damages computation based on the value of the entire computer using common royalty rates (e.g., 1-5%) would be excessive.

Although our law states certain mandatory conditions for applying the entire market value rule, courts must nevertheless be cognizant of a fundamental relationship between the entire market value rule and the calculation of a running royalty damages award. Simply put, the base used in a running royalty calculation can always be the value of the entire commercial embodiment, as long as the magnitude of the rate is within an acceptable range (as determined by the evidence). Microsoft surely would have little reason to complain about the supposed application of the entire market value rule had the jury applied a royalty rate of 0.1% (instead of 8%) to the market price of the infringing programs. Such a rate would have likely yielded a damages award of less than Microsoft's proposed \$6.5 million. Thus, even when the patented invention is a small component of a much larger commercial product, awarding a reasonable royalty based on either sale price or number of units sold can be economically justified. *See, e.g., Kearns*, 32 F.3d at 1544 (awarding a reasonable royalty of 90 cents per vehicle that had the infringing intermittent windshield wipers, when the average car price was approximately \$4000 to \$6000).

Some commentators suggest that the entire market value rule should have little role in reasonable royalty law. *See, e.g., Mark A. Lemley, Distinguishing Lost Profits From Reasonable Royalties*, 51 Wm. & Mary L.Rev. (forthcoming 2009) (manuscript at 2), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1133173 (suggesting that "courts have distorted the reasonable royalty measure" by "importing inapposite concepts like the 'entire market value rule' in an effort to compensate patent owners whose real remedy probably should have been in the lost profits category"). But such general propositions ignore the realities of patent licensing and the flexibility needed in

transferring intellectual property rights. The evidence of record in the present dispute illustrates the importance the entire market value may have in reasonable royalty cases. The license agreements admitted into evidence (without objection from Microsoft, we note) highlight how sophisticated parties routinely enter into license agreements that base the value of the patented inventions as a percentage of the commercial products' sales price. There is nothing inherently wrong with using the market value of the entire product, especially when there is no established market value for the infringing component or feature, so long as the multiplier accounts for the proportion of the base represented by the infringing component or feature.

CONCLUSION

For the foregoing reasons, we affirm the district court's denial of Microsoft's JMOL motion for non-infringement. We reverse the district court's denial of Microsoft's JMOL regarding the damages award, vacate the award, and remand for a new trial on damages.

AFFIRMED IN PART, VACATED IN PART, and REMANDED

NOTES ON *LUCENT*

1. Comparability. Though the opinion in *Lucent* in many ways breaks no new ground – note the reliance on Supreme Court cases from the 19th century, for example – it surely signifies a tightening of attitudes regarding the admissibility and persuasiveness of evidence pertaining to “comparable” licensing agreement for purposes of determining damages in cases of patent infringement. See, e.g., *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010) (“The majority of the licenses on which ResQNet relied in this case are problematic for the same reasons that doomed the damage award in *Lucent*.”).

2. Overdeterrence of Infringement. Some commentators have argued that reasonable royalty case law had over time tended toward inflated damage awards, in part due to the courts’ desire to deter infringement—a policy that receives explicit recognition in the *Panduit* case. From this perspective, cases such as *Lucent* represent an opportunity to push back against this trend by bringing down reasonable royalty damages through the mechanism of more restrictive evidentiary requirements. See Brian Love, *The Misuse of Reasonable Royalty Damages as a Patent Infringement Deterrent*, 74 Missouri L. Rev. 909 (2009).

Add to page 1035, the following new case:

IN RE SEAGATE TECHNOLOGY, LLC

497 F.3d 1360 (Fed. Cir. 2007) (en banc)

Before NEWMAN, MAYER, LOURIE, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, and PROST, Circuit Judges

MAYER, Circuit Judge.

Seagate Technology, LLC ("Seagate") petitions for a writ of mandamus directing the United States District Court for the Southern District of New York to vacate its orders compelling disclosure of materials and testimony that Seagate claims is covered by the attorney-client privilege and work product protection. We ordered en banc review, and now grant the petition. We overrule *Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (1983), and we clarify the scope of the waiver of attorney-client privilege and work product protection that results when an accused patent infringer asserts an advice of counsel defense to a charge of willful infringement.

Background

Convolve, Inc. and the Massachusetts Institute of Technology (collectively "Convolve") sued Seagate on July 13, 2000, alleging infringement of *U.S. Patent Nos. 4,916,635* ("the '635 patent") and *5,638,267* ("the '267 patent"). Subsequently, *U.S. Patent No. 6,314,473* ("the '473 patent") issued on November 6, 2001, and Convolve amended its complaint on January 25, 2002, to assert infringement of the '473 patent. Convolve also alleged that Seagate willfully infringed the patents.

[Prior to the lawsuit, Seagate retained Gerald Sekimura to provide opinions concerning Convolve's patents. In three opinions, he concluded that many of the claims in the patents at issue were invalid and that Seagate's products did not infringe. After the infringement suit was filed, Seagate informed Convolve of its intention to rely on Sekimura's opinions to defend against willful infringement, and it subsequently disclosed Sekimura's entire work product to Convolve. Convolve then sought discovery of any communications and work product of Seagate's other counsel, which the district court granted. The court held that Seagate had waived any protection to the work product concerning the reasonableness of their reliance on Sekimura's opinions. Seagate sought a writ of mandamus to prevent the discovery.]

We stayed the discovery orders and, recognizing the functional relationship between our willfulness jurisprudence and the practical dilemmas faced in the areas of attorney-client privilege and work product protection, sua sponte ordered en banc review of the petition. The en banc order set out the following questions:

Should a party's assertion of the advice of counsel defense to willful infringement extend waiver of the attorney-client privilege to communications with that party's trial counsel? See *In re EchoStar Commc'n Corp.*, 448 F.3d 1294 (Fed. Cir. 2006).

What is the effect of any such waiver on work-product immunity?

Given the impact of the statutory duty of care standard announced in *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (Fed. Cir. 1983), on the issue of waiver of attorney-client privilege, should this court reconsider the decision in *Underwater Devices* and the duty of care standard itself?

In re Seagate Tech., LLC, 214 Fed. Appx. 997 (Fed. Cir. 2007). ...

Discussion

Because patent infringement is a strict liability offense, the nature of the offense is only relevant in determining whether enhanced damages are warranted. Although a trial court's discretion in awarding enhanced damages has a long lineage in patent law, the current statute, similar to its predecessors, is devoid of any standard for awarding them.⁴ Absent a statutory guide, we have held that an award of enhanced damages requires a showing of willful infringement. *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 923 F.2d 1576, 1578 (Fed. Cir. 1991); see also *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1570 (Fed. Cir. 1996) (holding that bad faith infringement, which is a type of willful infringement, is required for enhanced damages). This well-established standard accords with Supreme Court precedent. See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 479, 508, 84 S. Ct. 1526, 12 L. Ed. 2d 457, 1964 Dec. Comm'r Pat. 760 (1961) (enhanced damages were available for willful or bad faith infringement); see also *Dowling v. United States*, 473 U.S. 207, 227 n.19, 105 S. Ct. 3127, 87 L. Ed. 2d 152 (1985) (enhanced damages are available for "willful infringement"); *Seymour v. McCormick*, 57 U.S. 480, 489, 14 L. Ed. 1024 (1853) ("wanton or malicious" injury could result in exemplary damages). But, a finding of willfulness does not require an award of enhanced damages; it merely permits it. See 35 U.S.C. § 284; *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1274 (Fed. Cir. 1999); *Jurgens*, 80 F.3d at 1570.

This court fashioned a standard for evaluating willful infringement in *Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1389-90 (Fed. Cir. 1983): "Where . . . a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing. Such an affirmative duty includes, inter alia, the duty to seek and obtain competent legal advice from counsel before the initiation of any possible infringing activity." (citations omitted). This standard was announced shortly after the creation of the court, and at a time "when widespread disregard of patent rights was undermining the national innovation

⁴ The current statute, enacted in 1952 and codified at 35 U.S.C. § 284, provides:

In finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title.

The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

incentive." *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1343 (Fed. Cir. 2004) (en banc) (citing Advisory Committee on Industrial Innovation Final Report, Dep't of Commerce (Sep. 1979)). Indeed, in *Underwater Devices*, an attorney had advised the infringer that "[c]ourts, in recent years, have--in patent infringement cases--found [asserted patents] invalid in approximately 80% of the cases," and on that basis the attorney concluded that the patentee would not likely sue for infringement. 717 F.2d at 1385. Over time, our cases evolved to evaluate willfulness and its duty of due care under the totality of the circumstances, and we enumerated factors informing the inquiry. E.g., *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826-27 (Fed. Cir. 1992); *Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101, 1110 (Fed. Cir. 1986).

In light of the duty of due care, accused willful infringers commonly assert an advice of counsel defense. Under this defense, an accused willful infringer aims to establish that due to reasonable reliance on advice from counsel, its continued accused activities were done in good faith. Typically, counsel's opinion concludes that the patent is invalid, unenforceable, and/or not infringed. Although an infringer's reliance on favorable advice of counsel, or conversely his failure to proffer any favorable advice, is not dispositive of the willfulness inquiry, it is crucial to the analysis. E.g., *Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048, 1056 (Fed. Cir. 1994) ("Possession of a favorable opinion of counsel is not essential to avoid a willfulness determination; it is only one factor to be considered, albeit an important one.").

Since *Underwater Devices*, we have recognized the practical concerns stemming from our willfulness doctrine, particularly as related to the attorney-client privilege and work product doctrine. For instance, *Quantum Corp. v. Tandon Corp.*, 940 F.2d 642, 643 (Fed. Cir. 1991), observed that "[p]roper resolution of the dilemma of an accused infringer who must choose between the lawful assertion of the attorney-client privilege and avoidance of a willfulness finding if infringement is found, is of great importance not only to the parties but to the fundamental values sought to be preserved by the attorney-client privilege." We cautioned there that an accused infringer "should not, without the trial court's careful consideration, be forced to choose between waiving the privilege in order to protect itself from a willfulness finding, in which case it may risk prejudicing itself on the question of liability, and maintaining the privilege, in which case it may risk being found to be a willful infringer if liability is found." *Id.* at 643-44. We advised that in camera review and bifurcating trials in appropriate cases would alleviate these concerns. *Id.* However, such procedures are often considered too onerous to be regularly employed.

Recently, in *Knorr-Bremse*, we addressed another outgrowth of our willfulness doctrine. Over the years, we had held that an accused infringer's failure to produce advice from counsel "would warrant the conclusion that it either obtained no advice of counsel or did so and was advised that its [activities] would be an infringement of valid U.S. Patents." *Knorr-Bremse*, 383 F.3d at 1343 (quoting *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1580 (Fed. Cir. 1986)). Recognizing that this inference imposed "inappropriate burdens on the attorney-client relationship," *id.*, we held that invoking the attorney-client privilege or work product protection does not give rise to an adverse inference, *id.* at 1344-45. We further held that an accused infringer's failure to obtain

legal advice does not give rise to an adverse inference with respect to willfulness. *Id. at 1345-46.*

More recently, in *Echostar* we addressed the scope of waiver resulting from the advice of counsel defense. First, we concluded that relying on in-house counsel's advice to refute a charge of willfulness triggers waiver of the attorney-client privilege. *Echostar*, 448 F.3d at 1299. Second, we held that asserting the advice of counsel defense waives work product protection and the attorney-client privilege for all communications on the same subject matter, as well as any documents memorializing attorney-client communications. *Id. at 1299, 1302-03.* However, we held that waiver did not extend to work product that was not communicated to an accused infringer. *Id. at 1303-04.* *Echostar* did not consider waiver of the advice of counsel defense as it relates to trial counsel.

In this case, we confront the willfulness scheme and its functional relationship to the attorney-client privilege and work product protection. In light of Supreme Court opinions since *Underwater Devices* and the practical concerns facing litigants under the current regime, we take this opportunity to revisit our willfulness doctrine and to address whether waiver resulting from advice of counsel and work product defenses extend to trial counsel. See *Knorr-Bremse*, 383 F.3d at 1343-44.

I. Willful Infringement

The term willful is not unique to patent law, and it has a well-established meaning in the civil context. For instance, our sister circuits have employed a recklessness standard for enhancing statutory damages for copyright infringement. Under the Copyright Act, a copyright owner can elect to receive statutory damages, and trial courts have discretion to enhance the damages, up to a statutory maximum, for willful infringement. 17 U.S.C. § 504(c). Although the statute does not define willful, it has consistently been defined as including reckless behavior. See, e.g., *Yurman Design, Inc. v. PAJ, Inc.*, 262 F.3d 101, 112 (2d Cir. 2001) ("Willfulness in [the context of statutory damages for copyright infringement] means that the defendant 'recklessly disregarded' the possibility that 'its conduct represented infringement.'") (quoting *Hamil Am., Inc. v. GFI, Inc.*, 193 F.3d 92, 97 (2d Cir. 1999) (additional citations omitted)); *Wildlife Express Corp. v. Carol Wright Sales*, 18 F.3d 502, 511-12 (7th Cir. 1994) (same); *RCA/Ariola Int'l, Inc. v. Thomas & Grayston Co.*, 845 F.2d 773, 779 (8th Cir. 1988) (same); see also *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 126 S. Ct. 1837, 1840, 164 L. Ed. 2d 641 (2006) (noting with approval that its resolution of the permanent injunction standard in the patent context created harmony with copyright law).

Just recently, the Supreme Court addressed the meaning of willfulness as a statutory condition of civil liability for punitive damages. *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. , 127 S. Ct. 2201, 167 L. Ed. 2d 1045 (June 4, 2007). *Safeco* involved the Fair Credit Reporting Act ("FCRA"), which imposes civil liability for failure to comply with its requirements. Whereas an affected consumer can recover actual damages for negligent violations of the FCRA, 15 U.S.C. § 1681o(a), he can also recover punitive damages for willful ones, 15 U.S.C. § 1681n(a). Addressing the willfulness requirement in this context, the Court concluded that the "standard civil usage" of "willful" includes reckless

behavior. *Id.*, 127 S. Ct. 2201, 2209; accord *McLaughlin v. Richland Shoe Co.*, 486 U.S. 128, 132-33, 108 S. Ct. 1677, 100 L. Ed. 2d 115 (1988) (concluding that willful violations of the Fair Labor Standards Act include reckless violations); *Trans World Airlines, Inc. v. Thurston*, 469 U.S. 111, 128, 105 S. Ct. 613, 83 L. Ed. 2d 523 (1985). Significantly, the Court said that this definition comports with the common law usage, "which treated actions in 'reckless disregard' of the law as 'willful' violations." *Id.*, 127 S. Ct. at 2208 (citing W. Keeton, D. Dobbs, R. Keeton, & D. Owen, *Prosser and Keeton on Law of Torts* § 34, p. 212 (5th ed. 1984)).

In contrast, the duty of care announced in *Underwater Devices* sets a lower threshold for willful infringement that is more akin to negligence. This standard fails to comport with the general understanding of willfulness in the civil context, *Richland Shoe Co.*, 486 U.S. at 133 ("The word 'willful' . . . is generally understood to refer to conduct that is not merely negligent."), and it allows for punitive damages in a manner inconsistent with Supreme Court precedent, see, e.g., *Safeco*, 127 S. Ct. 2201, slip op. at 6-7, 18-19, 21 n.20; *Smith v. Wade*, 461 U.S. 30, 39-49, 103 S. Ct. 1625, 75 L. Ed. 2d 632 (1983). Accordingly, we overrule the standard set out in *Underwater Devices* and hold that proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness. Because we abandon the affirmative duty of due care, we also reemphasize that there is no affirmative obligation to obtain opinion of counsel.

We fully recognize that "the term [reckless] is not self-defining." *Farmer v. Brennan*, 511 U.S. 825, 836, 114 S. Ct. 1970, 128 L. Ed. 2d 811 (1994). However, "[t]he civil law generally calls a person reckless who acts . . . in the face of an unjustifiably high risk of harm that is either known or so obvious that it should be known." *Id.* (citing Prosser and Keeton § 34, pp. 213-14; *Restatement (Second) of Torts* § 500 (1965)). Accordingly, to establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. See *Safeco*, 127 S. Ct. at 2215 ("It is [a] high risk of harm, objectively assessed, that is the essence of recklessness at common law."). The state of mind of the accused infringer is not relevant to this objective inquiry. If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer. We leave it to future cases to further develop the application of this standard.

Finally, we reject the argument that revisiting our willfulness doctrine is either improper or imprudent, as Convoke contends. The ultimate dispute in this case is the proper scope of discovery. While it is true that the issue of willful infringement, or even infringement for that matter, has not been decided by the trial court, it is indisputable that the proper legal standard for willful infringement informs the relevance of evidence relating to that issue and, more importantly here, the proper scope of discovery. See *United States Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 447, 113 S. Ct. 2173, 124 L. Ed. 2d 402 (1993) ("[A] court may consider an issue 'antecedent to . . . and ultimately dispositive of' the dispute before it, even an issue the parties fail to identify and brief." (quoting *Arcadia v. Ohio Power Co.*, 498 U.S. 73, 77, 111 S. Ct. 415, 112 L. Ed. 2d 374 (1990))); see also *Fed. R. Civ. Pro. R. 26(b)* (limiting discovery to

relevant, not necessarily admissible, information); accord *Singleton v. Wulff*, 428 U.S. 106, 121, 96 S. Ct. 2868, 49 L. Ed. 2d 826 (1976) ("The matter of what questions may be taken up and resolved for the first time on appeal is one left primarily to the discretion of the courts of appeals, to be exercised on the facts of individual cases."); *Forshey v. Principi*, 284 F.3d 1335, 1355-59 (Fed. Cir. 2002) (en banc). Accordingly, addressing willfulness is neither hypothetical nor advisory.

II. Attorney-Client Privilege

We turn now to the appropriate scope of waiver of the attorney-client privilege resulting from an advice of counsel defense asserted in response to a charge of willful infringement. Recognizing that it is "the oldest of the privileges for confidential communications known to the common law," we are guided by its purpose "to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice." *Upjohn Co. v. United States*, 449 U.S. 383, 389, 101 S. Ct. 677, 66 L. Ed. 2d 584 (1981). The privilege also "recognizes that sound legal advice or advocacy serves public ends and that such advice or advocacy depends upon the lawyer's being fully informed by the client." *Id.*

The attorney-client privilege belongs to the client, who alone may waive it. E.g., *Knorr-Bremse*, 383 F.3d at 1345; *Am. Standard, Inc. v. Pfizer, Inc.*, 828 F.2d 734, 745 (Fed. Cir. 1987). "The widely applied standard for determining the scope of a waiver . . . is that the waiver applies to all other communications relating to the same subject matter." *Fort James Corp. v. Solo Cup Corp.*, 412 F.3d 1340, 1349 (Fed. Cir. 2005). This broad scope is grounded in principles of fairness and serves to prevent a party from simultaneously using the privilege as both a sword and a shield; that is, it prevents the inequitable result of a party disclosing favorable communications while asserting the privilege as to less favorable ones. *Echostar*, 448 F.3d at 1301; *Fort James*, 412 F.3d at 1349. Ultimately, however, "[t]here is no bright line test for determining what constitutes the subject matter of a waiver, rather courts weigh the circumstances of the disclosure, the nature of the legal advice sought and the prejudice to the parties of permitting or prohibiting further disclosures." *Fort James*, 412 F.3d at 1349-50.

In considering the scope of waiver resulting from the advice of counsel defense, district courts have reached varying results with respect to trial counsel. Some decisions have extended waiver to trial counsel, e.g., *Informatica Corp. v. Bus. Objects Data Integration, Inc.*, 454 F. Supp. 2d 957 (N.D. Cal. 2006), whereas others have declined to do so, e.g., *Collaboration Props., Inc. v. Polycom, Inc.*, 224 F.R.D. 473, 476 (N.D. Cal. 2004); *Ampex Corp. v. Eastman Kodak Co.*, 2006 U.S. Dist. LEXIS 48702 (D. Del. July 17, 2006). Still others have taken a middle ground and extended waiver to trial counsel only for communications contradicting or casting doubt on the opinions asserted. E.g., *Intex Recreation Corp. v. Team Worldwide Corp.*, 439 F. Supp. 2d 46 (D.D.C. 2006); *Beneficial Franchise Co., Inc. v. Bank One, N.A.*, 205 F.R.D. 212 (N.D. Ill. 2001); *Micron Separations, Inc. v. Pall Corp.*, 159 F.R.D. 361 (D. Mass. 1995).

Recognizing the value of a common approach and in light of the new willfulness analysis set out above, we conclude that the significantly different functions of trial

counsel and opinion counsel advise against extending waiver to trial counsel. Whereas opinion counsel serves to provide an objective assessment for making informed business decisions, trial counsel focuses on litigation strategy and evaluates the most successful manner of presenting a case to a judicial decision maker. And trial counsel is engaged in an adversarial process. We previously recognized this distinction with respect to our prior willfulness standard in *Crystal Semiconductor Corp. v. TriTech Microelectronics International, Inc.*, 246 F.3d 1336, 1352 (Fed. Cir. 2001), which concluded that "defenses prepared [by litigation counsel] for a trial are not equivalent to the competent legal opinion of non-infringement or invalidity which qualify as 'due care' before undertaking any potentially infringing activity." Because of the fundamental difference between these types of legal advice, this situation does not present the classic "sword and shield" concerns typically mandating broad subject matter waiver. Therefore, fairness counsels against disclosing trial counsel's communications on an entire subject matter in response to an accused infringer's reliance on opinion counsel's opinion to refute a willfulness allegation.

Moreover, the interests weighing against extending waiver to trial counsel are compelling. The Supreme Court recognized the need to protect trial counsel's thoughts in *Hickman v. Taylor*, 329 U.S. 495, 510-11, 67 S. Ct. 385, 91 L. Ed. 451 (1947):

[I]t is essential that a lawyer work with a certain degree of privacy, free from unnecessary intrusion by opposing parties and their counsel. Proper preparation of a client's case demands that he assemble information, sift what he considers to be the relevant from the irrelevant facts, prepare his legal theories and plan his strategy without undue and needless interference. That is the historical and the necessary way in which lawyers act within the framework of our system of jurisprudence to promote justice and to protect their clients' interests.

The Court saw that allowing discovery of an attorney's thoughts would result in "[i]nefficiency, unfairness and sharp practices," that "[t]he effect on the legal profession would be demoralizing" and thus "the interests of the clients and the cause of justice would be poorly served." *Id.* at 511. Although *Hickman* concerned work product protection, the attorney-client privilege maintained with trial counsel raises the same concerns in patent litigation. In most cases, the demands of our adversarial system of justice will far outweigh any benefits of extending waiver to trial counsel. See *Jaffee v. Redmond*, 518 U.S. 1, 9, 116 S. Ct. 1923, 135 L. Ed. 2d 337 (1996) ("Exceptions from the general rule disfavoring testimonial privileges may be justified, however, by a 'public good transcending the normally predominant principle of utilizing all rational means for ascertaining the truth.'" (quoting *Trammel*, 445 U.S. 40, 50, 100 S. Ct. 906, 63 L. Ed. 2d 186 (1980) (quoting *Elkins v. United States*, 364 U.S. 206, 80 S. Ct. 1437, 4 L. Ed. 2d 1669 (1960) (Frankfurter, J., dissenting))) (additional internal quotation marks omitted).

Further outweighing any benefit of extending waiver to trial counsel is the realization that in ordinary circumstances, willfulness will depend on an infringer's prelitigation conduct. It is certainly true that patent infringement is an ongoing offense that can continue after litigation has commenced. However, when a complaint is filed, a patentee

must have a good faith basis for alleging willful infringement. *Fed. R. Civ. Pro.* 8, 11(b). So a willfulness claim asserted in the original complaint must necessarily be grounded exclusively in the accused infringer's pre-filing conduct. By contrast, when an accused infringer's post-filing conduct is reckless, a patentee can move for a preliminary injunction, which generally provides an adequate remedy for combating post-filing willful infringement. See 35 U.S.C. § 283; *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (*Fed. Cir.* 2001). A patentee who does not attempt to stop an accused infringer's activities in this manner should not be allowed to accrue enhanced damages based solely on the infringer's post-filing conduct. Similarly, if a patentee attempts to secure injunctive relief but fails, it is likely the infringement did not rise to the level of recklessness.

We fully recognize that an accused infringer may avoid a preliminary injunction by showing only a substantial question as to invalidity, as opposed to the higher clear and convincing standard required to prevail on the merits. *Amazon.com*, 239 F.3d at 1359 ("Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself."). However, this lessened showing simply accords with the requirement that recklessness must be shown to recover enhanced damages. A substantial question about invalidity or infringement is likely sufficient not only to avoid a preliminary injunction, but also a charge of willfulness based on post-filing conduct.

We also recognize that in some cases a patentee may be denied a preliminary injunction despite establishing a likelihood of success on the merits, such as when the remaining factors are considered and balanced. In that event, whether a willfulness claim based on conduct occurring solely after litigation began is sustainable will depend on the facts of each case.

Because willful infringement in the main must find its basis in prelitigation conduct, communications of trial counsel have little, if any, relevance warranting their disclosure, and this further supports generally shielding trial counsel from the waiver stemming from an advice of counsel defense to willfulness. Here, the opinions of Seagate's opinion counsel, received after suit was commenced, appear to be of similarly marginal value. Although the reasoning contained in those opinions ultimately may preclude Seagate's conduct from being considered reckless if infringement is found, reliance on the opinions after litigation was commenced will likely be of little significance.

In sum, we hold, as a general proposition, that asserting the advice of counsel defense and disclosing opinions of opinion counsel do not constitute waiver of the attorney-client privilege for communications with trial counsel. We do not purport to set out an absolute rule. Instead, trial courts remain free to exercise their discretion in unique circumstances to extend waiver to trial counsel, such as if a party or counsel engages in chicanery. We believe this view comports with Supreme Court precedent, which has made clear that rules concerning privileges are subject to review and revision, when necessary. See *Jaffee*, 518 U.S. at 9 (noting that federal courts are "to 'continue the evolutionary development of testimonial privileges.'" (quoting *Trammel*, 445 U.S. at 47)). ...

Conclusion

Accordingly, Seagate's petition for a writ of mandamus is granted, and the district court will reconsider its discovery orders in light of this opinion.

Add to page 1044, the following notes after existing note 2:

3. Marking After the Expiration Date. In *Pequignot v. Solo Cup*, 540 F. Supp. 2d 649, (E.D. Va. 2008) (denying Solo's motion to dismiss); 2009 U.S. Dist. LEXIS 26020 (E.D. Va. Mar. 27, 2009) (finding that plaintiff had standing to sue), the plaintiff in a qui tam action pursuant to the false marking statute claimed statutory damages for the defendant's continued marking of its lids and disposable cups even after the patents had expired. Solo did not dispute the underlying factual aspects of the case, admitting that they produced products that were marked as patented even though the patents had expired. Solo argued, however, that the false marking was done without any intention to deceive the public as required by the statute. Solo's intent argument was ultimately successful in obtaining a dismissal of the case, even though there was no dispute as to the falseness of the defendant's marking. See *False Marking Case Dismissed*, Patently-O, July 10, 2009, at <http://www.patentlyo.com/patent/2009/07/false-marking-case-dismissed.html> (reporting that the district judge dismissed the case based on reasoning announced from the bench).

On appeal, the Federal Circuit affirmed the district court's dismissal. See *Pequignot v. Solo Cup Co.*, 608 F.3d 1356 (Fed. Cir. 2010). The court first agreed with the district court that the statute, which creates liability for falsely marking an "unpatented" article, was applicable where a previously patented product is marked with an expired patent number. The court reasoned that, once the patent has expired, the product is in the public domain and the policies against false marking are fully applicable. See *id.* at 1361.

Nevertheless, Solo escaped liability because the court affirmed the district court's finding of no deceptive intent:

We agree with Solo that, under *Clontech* and under Supreme Court precedent, the combination of a false statement and knowledge that the statement was false creates a rebuttable presumption of intent to deceive the public, rather than irrebuttably proving such intent. Cf. *Sandstrom v. Montana*, 442 U.S. 510, 513-14, 99 S. Ct. 2450, 61 L. Ed. 2d 39 (1979) (holding conclusive presumption regarding intent in the criminal context unconstitutional). As we stated in *Clontech*, "the fact of misrepresentation coupled with proof that the party making it had knowledge of its falsity is enough to warrant drawing the *inference* that there was a fraudulent intent." 406 F.3d at 1352 (emphasis added) (quoting *Norton v. Curtiss*, 433 F.2d 779, 795-96, 57 C.C.P.A. 1384 (CCPA 1970)). Although the presumption cannot be rebutted by "the mere assertion by a party that it did not intend to deceive," *id.*, *Clontech* does not stand for the proposition that the presumption is irrebuttable. Indeed, as the district court stated, "to hold, as *Pequignot* suggests, that a party that knowingly made false patent markings is precluded from even offering evidence that it did not intend to deceive

would be inconsistent with the high bar that is set for proving deceptive intent." *SJ Op.*, 646 F. Supp. 2d at 796-97.

The bar for proving deceptive intent here is particularly high, given that the false marking statute is a criminal one, despite being punishable only with a civil fine. *See* S. Rep. No. 82-1979, 1952 U.S.C.C.A.N. 2394, 2424 (1952) ("This is a criminal provision."); *see also Clontech*, 406 F.3d at 1352 ("The statute supplies a civil fine."). Because the statute requires that the false marker act "for the purpose of deceiving the public," a purpose of deceit, rather than simply knowledge that a statement is false, is required. 35 U.S.C. § 292(a). As the Supreme Court has explained in distinguishing the mental states of "purpose" and "knowledge" in criminal statutes, "a person who causes a particular result is said to act purposefully if he consciously desires that result, whatever the likelihood of that result happening from his conduct, while he is said to act knowingly if he is aware that that result is practically certain to follow from his conduct, whatever his desire may be as to that result." *United States v. Bailey*, 444 U.S. 394, 404, 100 S. Ct. 624, 62 L. Ed. 2d 575 (1980) (quotation marks omitted). Thus, mere knowledge that a marking is false is insufficient to prove intent if Solo can prove that it did not consciously desire the result that the public be deceived.

Furthermore, we agree with Solo that it successfully rebutted the presumption. It provided credible evidence that its purpose was not to deceive the public with either the expired patent markings or the "may be covered" language, and Pequignot raised no genuine issue of material fact showing otherwise.

608 F.3d at 1362-63.

4. Presumed Intent for False Marking. Prior to *Pequignot*, one legal scholar posited that the intent to deceive should be presumed in a false marking case so that the patentee would have an incentive to take affirmative steps to ensure that products are no longer marked once the patents expire. *See generally* Elizabeth Winston, *The Flawed Nature of the False Marking Statute*, 77 Tenn. L. Rev. 111 (2009). Note that in *Pequignot*, the Federal Circuit allowed a presumption of intent, but also made it not too difficult to overcome the presumption. If the presumption could not be easily rebutted, would the fear of "false marking" liability lead to *overdeterrence*, with patentees devoting an excessive amount of resources to avoid small mistakes on marking? Or would such diligence by patentees be desirable?

CHAPTER 10: THE LEGAL PROCESS OF THE PATENT SYSTEM**A. THE ALLOCATION OF POWER**

Add to page 1073, the following two new subchapters:

5. ADMINISTRATIVE RULEMAKING.**NOTE ON THE PTO'S 2007 RULES AND TAFAS LITIGATION**

In 2007, the PTO promulgated a series of new rules intended to address the growing backlog of patent applications. Among the more contentious measures proposed by the PTO were (i) new rules limiting the number of continuation applications, and (ii) rules limiting the number of claims that an applicant could include in each application without filing an “examination support document.” See *Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications*, 72 Fed. Reg. 46,716 (Aug. 21, 2007).

A number of parties promptly filed suit for injunctive relief that would prevent the agency from implementing the rules. See *Tafas v. Dudas*, 541 F. Supp. 2d 805 (E.D. Va. 2008). The crux of the plaintiffs’ arguments was that the proposed Final Rules were substantive in nature and thus were in conflict with the Federal Circuit’s holding in *Merck v. Kessler* that the agency has no substantive rulemaking power. The district court agreed and enjoined implementation of the rules.

On appeal, a panel of the Federal Circuit disagreed and reversed in part. *Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009). In deciding the lawfulness of the proposed rules, the panel (per Prost, J.) first reviewed whether the PTO was entitled to the more deferential form of judicial review authorized under administrative law’s *Chevron* doctrine. See *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) To resolve that issue, the court had to decide whether the PTO’s statutory rulemaking authority authorized the agency to issue the general sort of rules at issue in the case.

The rulemaking authority in the Patent Act authorizes the PTO to “establish regulations, not inconsistent with law, which . . . shall govern *the conduct of proceedings* in the Office . . . [and] facilitate and expedite the processing of patent applications.” 35 U.S.C. § 2(b)(2) (emphasis added). The “conduct of proceedings” language in the statute is key; it means that the PTO has power to issue only *procedural regulations*, not *substantive regulations*. Thus, the Federal Circuit agreed with the premise of the district court’s analysis—the agency’s rules must be procedural—but the panel rejected the district court’s narrow view as to what counts as procedural:

We are most persuaded in this case by the D.C. Circuit's approach in *JEM [Broadcasting Co. v. FCC]*, 22 F.3d 320, 326 (D.C. Cir. 1994). At issue in that case were "hard look" rules adopted by the Federal Communications Commission ("FCC") in response to a significant number of "carelessly prepared and speculative applications" for broadcasting licenses. 22 F.3d at 327. Under those rules, applications that either failed to include necessary information or contained

incorrect or inconsistent information that could not be "resolved within the confines of the application and with a high degree of confidence" were dismissed with no opportunity to cure the defect. *Id.* at 322. The D.C. Circuit rejected JEM's contention that the rules were substantive because they "deprive[d] license applicants of the opportunity to correct errors or defects in their filings." *Id.* at 327. In doing so, the court noted that a "critical feature of the procedural exception [in section 553 of the APA] is that it covers agency actions that do not themselves alter the rights or interests of parties, although [they] may alter the manner in which the parties present themselves or their viewpoints to the agency." *Id.* at 326 (emphasis added) (quotation marks omitted). The "critical fact" that was "fatal to JEM's claim," the court held, was that the "hard look" rules "did not change the substantive standards by which the FCC evaluates license applications." *Id.* at 327. The court recognized that the rules could result in the loss of substantive rights, but found that they were nonetheless procedural because they did not "foreclose effective opportunity to make one's case on the merits." *Id.* at 327-28 (quoting *Lamoille Valley R.R. Co. v. Interstate Commerce Comm'n*, 229 U.S. App. D.C. 17, 711 F.2d 295, 328 (D.C. Cir. 1983)).

While we do not purport to set forth a definitive rule for distinguishing between substance and procedure in this case, we conclude that the Final Rules challenged in this case are procedural. In essence, they govern the timing of and materials that must be submitted with patent applications. The Final Rules may "alter the manner in which the parties present . . . their viewpoints" to the USPTO, but they do not, on their face, "foreclose effective opportunity" to present patent applications for examination. *JEM*, 22 F.3d at 326, 328.

Id. at 1356-57.

Because the challenged rules were procedural and the agency's rulemaking authority authorized such rules, the court applied the *Chevron* doctrine to determine whether the agency's rules were in conflict with any specific provisions of the Patent Act. (Under the *Chevron* doctrine, rules promulgated by an agency with rulemaking power must be sustained by the courts if (i) the rules do not conflict with the unambiguous meaning of a statute; and (ii) the rules are reasonable.)

For the agency rules that required applicants either to limit their claims to 25 or to submit an "examination support document" containing additional information, the court found no conflict between the rules and the statute:

Subject to the arguable requirement that an applicant cannot "obscure" his invention by "undue multiplicity," our precedent does not suggest that there is a limit on the number of claims. *In re Clark*, 97 F.2d 628, 631, 25 C.C.P.A. 1317, 1938 Dec. Comm'r Pat. 731 (CCPA 1938); see also *In re Wakefield*, 422 F.2d 897, 900, 57 C.C.P.A. 959 (CCPA 1970) (HN26Go to the description of this Headnote. "[A]n applicant should be allowed to determine the necessary number and scope of his claims . . ."); *In re Chandler*, 319 F.2d 211, 225, 50 C.C.P.A. 1422, 1963 Dec. Comm'r Pat. 642 (CCPA 1963) ("[A]pplicants should be allowed reasonable latitude in stating their claims in regard to number and phraseology

employed. The right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged."). However, we need not decide whether the USPTO may impose a limit on the number of claims an applicant can pursue because we do not find that the ESD requirement creates any such limit. Rather, it simply requires that an ESD be submitted if more than five independent or twenty-five total claims are included in certain sets of copending applications. Because we cannot, as discussed above, conclude that Final Rules 75 and 265, on their face, effectively foreclose applicants from successfully submitting ESDs, we similarly cannot conclude that these rules place an absolute limit on claim numbers in violation of § 112, P 2.

The district court also found that Final Rules 75 and 265 went too far by requiring applicants to "conduct a broad search of patents, patent applications, and literature, and provide, among other things, a 'detailed explanation' of 'how each of the independent claims is patentable over the cited references.'" *Tafas II*, 541 F. Supp. 2d at 816 (quoting 37 C.F.R. § 1.265(a)). The court relied on several of this court's inequitable conduct cases that noted that in general, there is "no duty to conduct a prior art search." *Frazier v. Roessel Cine Photo Tech., Inc.*, 417 F.3d 1230, 1238 (Fed. Cir. 2005) (quoting *FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 526 n.6 (Fed. Cir. 1987)). We agree with the USPTO that these cases do not speak to whether the USPTO may impose such a duty by regulation. Indeed, this court has already upheld the USPTO's authority to require from applicants "such information as may be reasonably necessary to properly examine or treat the matter." 37 C.F.R. § 1.105; see also *Star Fruits*, 393 F.3d at 1282-84. On this record, we see no persuasive reason to prohibit the USPTO from requesting the information required by Final Rule 265, even if the applicant must take action to acquire that information.

Finally, the district court found that Final Rules 75 and 265 improperly shift the burden away from the examiner and onto the applicant. *Tafas II*, 541 F. Supp. 2d at 817. The court relied on the language in § 102 that "[a] person shall be entitled to a patent unless," along with the requirement in § 131 that "[t]he director shall cause an examination to be made of the application." *Id.* Additionally, the district court noted that this court's precedent places the burden of putting forth a prima facie case of unpatentability on the USPTO. See *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). We agree with the district court that the USPTO bears the initial burden of proving unpatentability, but disagree that the ESD requirement shifts that burden. Final Rules 75 and 265 do not require an applicant to make a prima facie case of patentability. While the rules require an applicant to conduct a prior art search and report his view of why the invention is patentable based on the results, the content of this disclosure does not change the standards by which the application is examined. An examiner cannot reject an application because he believes that the applicant failed to find the most material references or if he is otherwise not persuaded by the applicant's view of the prior art. Even under the new rules, the examiner must examine the application in accordance with § 131 and the applicant will be "entitled to a patent

unless" the examiner can make a prima facie case of unpatentability. 35 U.S.C. § 102. Thus, while creating an additional procedural step for the submission of applications, the ESD requirement does not alter the ultimate burdens of the examiner or applicant during examination.

559 F.3d at 1363-64.

With respect to the rules limiting continuation applications, however, the court held those *did* conflict with the unambiguous meaning of section 120 of the Patent Act:

We agree with the district court that Final Rule 78 is inconsistent with § 120, although we rely on narrower grounds. Section 120 unambiguously states that an application that meets four requirements "shall have the same effect, as to such invention, as though filed on the date of the prior application." 35 U.S.C. § 120 (emphasis added). These requirements, which correspond to the bracketed enumeration above, include [1] the invention claimed in the application must have been properly disclosed in a prior-filed application; [2] the application must have been filed by inventor(s) named on the prior-filed application; [3] the application must have been "filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application"; and [4] the application must contain or be amended to contain a specific reference to the prior-filed application. The use of "shall" indicates that these are the exclusive requirements, and that all applications that meet these requirements must receive the benefit provided by § 120. See *Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556 (Fed. Cir. 1994) ("The plain and unambiguous meaning of section 120 is that any application fulfilling the requirements therein 'shall have the same effect' as if filed on the date of the application upon which it claims priority."). Thus, Rule 78 is invalid because it attempts to add an additional requirement--that the application not contain amendments, arguments, or evidence that could have been submitted earlier--that is foreclosed by the statute. Because the statute is clear and unambiguous with respect to this issue, the USPTO's reliance on *Chevron* ... unavailing.

559 F.3d at 1360-61.

The Federal Circuit panel only addressed issues related to whether the rules were inconsistent with the Patent Act. Many other issues were left for the district court on remand:

This opinion does not decide any of the following issues: whether any of the Final Rules, either on their face or as applied in any specific circumstances, are arbitrary and capricious; whether any of the Final Rules conflict with the Patent Act in ways not specifically addressed in this opinion; whether all USPTO rulemaking is subject to notice and comment rulemaking under 5 U.S.C. § 553; whether any of the Final Rules are impermissibly vague; and whether the Final Rules are impermissibly retroactive.

559 F.3d at 1365.

After the panel decision, the Federal Circuit granted a motion to vacate the court's earlier opinion in whole, and rehear the case en banc. *See Tafas v. Doll*, 2009 U.S. App. LEXIS 14611 (July 6, 2009). A few weeks later, the court granted a 60-day stay in the briefing schedule for the en banc case to allow time for the Senate to confirm the Obama Administration's nominee for PTO Director. *See Tafas v. Doll*, 2009 U.S. App. LEXIS 17667 (July 28, 2009). That nominee, David Kappos, was confirmed in early August and soon thereafter decided that the agency no longer supported the rules. The rules were formally rescinded in October of 2009, see 74 Fed. Reg. 52686 (Oct. 14, 2009), and both the PTO and the parties challenging the rules moved to dismiss the pending en banc appeal. The court dismissed the case in November. *See Tafas v. Kappos*, 586 F.3d 1369 (Fed. Cir. 2009). As a result of these developments, the scope of PTO's rulemaking authority remains unclear. The panel opinion in the *Tafas* case may give some indication as to the likely direction of the Federal Circuit, but since that opinion was vacated, it would not be binding on the court in the future.

The legal issues adjudicated in the *Tafas* case are highly likely to arise again as the agency attempts to reform its administrative processes and to eliminate its staggering backlog of applications. Indeed, the panel opinion in *Tafas* demonstrates the large range of options available to the agency. It could, for example, require applicants to search the prior art or demand that applicants provide more candid evaluations of their applications in light of the prior art. Could the agency require that applicants bear the burden of proving the patentability of their inventions? If not, which statute unambiguously imposes the burden of proof on the agency? Could the agency require that patent applicants obtain an independent expert opinion on patentability?

6. PRESUMPTION OF VALIDITY AND COURT REVIEW.

An important challenge to a basic aspect of the patent system originated in a run-of-the-mill infringement suit. The case of *z4 v. Microsoft*, 507 F.3d 1340 (Fed. Cir. 2007), involved a patent suit by patentee z4 against defendant Microsoft. At trial, Microsoft introduced a number of relevant prior art references in an attempt to invalidate the patents asserted against it. Some of these references had not been considered by the PTO during prosecution of z4's patents. Because of this, Microsoft – citing dictum in some earlier Federal Circuit cases – contended that the jury in the case ought to be instructed to apply a weakened or softened presumption of patent validity under the patent statute (35 U.S.C. § 282). The district court rejected Microsoft's suggested instruction, and Microsoft appealed this, together with other issues, to the Federal Circuit, which said this:

Although the district court properly instructed the jury that Microsoft had the burden of proving invalidity by clear and convincing evidence . . . Microsoft contends that the district court abused its discretion by refusing to further instruct the jury that Microsoft's "burden is more easily carried when the references on which the assertion is based were not directly considered by the examiner during

prosecution.” We disagree. See *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050 (Fed.Cir.1988) (“The burden of proof is not reduced when prior art is presented to the court which was not considered by the PTO.”). . . . Despite Microsoft's reliance on cases indicating that a party *may* more easily meet this clear and convincing evidence burden when the references at issue were not before the examiner, see, e.g., *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-60 (Fed.Cir.1984), it cites no authority compelling courts to provide such an instruction, and we agree with the district court that “it might lead the jury to believe that the burden of proof is less than clear and convincing when prior art was not considered by the PTO.” [District court] *JMOL Opinion* at 22. Accordingly, we hold that the district court did not abuse its discretion in refusing to provide the jury with Microsoft's requested instruction.

z4 v. Microsoft, 507 F.3d 1340, at 1354-1355.

Seeing perhaps a chance to both win this case and create some useful precedent for defendants in patent infringement suits, Microsoft has filed a petition for certiorari with the U.S. Supreme Court. As part of that petition, Microsoft relied heavily on statements in the Supreme Court's recent decision in *KSR v. Teleflex*:

In *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), however, this Court contemplated a far more pragmatic view of the statutory presumption of validity. There, the Court “th[ought] it appropriate to note that the rationale underlying the presumption—that the PTO, in its expertise, has approved the claim—seems much diminished” where a defense of invalidity rests on evidence that the PTO never had an opportunity to consider. *Id.* at 1745. That observation was in accord with the conclusion reached by all twelve regional circuits before the Federal Circuit assumed jurisdiction of most patent matters in 1982. . . .

Microsoft Corporation, Petition for Writ of Certiorari, *Microsoft v. z4*, avail. at <http://www.patentlyo.com/patent/2008/04/challenging-pat.html>, at 2. As noted on page 684 of the casebook, the *KSR* Court's statements on the presumption of validity reflected a pitched dispute between *KSR* and *Teleflex* over the general propriety of the clear and convincing standard. Microsoft took a cue from the dispute in that case and went on to argue (1) that under general principles of administrative law, an agency's decision receives less court deference when it is based on an incomplete factual record; and (2) the proliferation of weak patents, and the related growth in patent litigation, raise serious problems that can be ameliorated in part by effective court review of patents—a process that is stifled when courts are hindered by the application of a rigid “clear and convincing” evidence standard even when they are confronting evidence far outside the scope of what the PTO considered during original prosecution.

After filing the certiorari petition and before the time when amicus briefs in support of the petition were due to be filed, Microsoft settled the litigation with *z4* and withdrew the petition. Other litigants, however, are sure to raise this issue in the future, and various amici, including perhaps academic amici, are likely to support such a petition. (Amici opposed to such a change, of which there would also be many, would not file briefs unless the Court were to agree to hear the case.) Numerous questions arise

surround this issue, including: (1) Should a clear and convincing standard of proof be applied in any case, even where the PTO *has* reviewed the relevant materials? (The statute says only that issued patents are presumed valid; it does not specify a standard of proof.) (2) Are there reasons to apply a high presumption of validity even where the PTO has *not* reviewed the relevant evidence? (3) Is a standard of proof—“clear and convincing” or some other standard—the appropriate way to afford patents some presumptive validity? Patent validity is, after all, generally considered to be a question of law, not fact. A standard of proof might be used to describe the accused infringer’s burden of proving some historical facts (e.g., Was X in the prior art on such-and-such a date?), but does a standard of proof make sense for quintessential legal determinations (e.g., Is Z obvious in light of prior art X and Y)? (4) Microsoft framed its challenge to the presumption of validity in a request for a particular jury instruction, but doesn’t this strategy beg a larger question of whether the jury should have been ruling on patent validity?

CHAPTER 12: ANTITRUST AND PATENT MISUSE**A. CONTROL OVER GOODS BEYOND A PATENT'S SCOPE**

Add to page 1261, the following new subchapter and case:

2. EXHAUSTION OF PATENT RIGHTS AND THE "FIRST SALE" DOCTRINE**QUANTA COMPUTER, INC. V. LG ELECTRONICS, INC.**

128 S.Ct. 2109 (2008)

THOMAS, J., delivered the opinion for a unanimous Court.

For over 150 years this Court has applied the doctrine of patent exhaustion to limit the patent rights that survive the initial authorized sale of a patented item. In this case, we decide whether patent exhaustion applies to the sale of components of a patented system that must be combined with additional components in order to practice the patented methods. The Court of Appeals for the Federal Circuit held that the doctrine does not apply to method patents at all and, in the alternative, that it does not apply here because the sales were not authorized by the license agreement. We disagree on both scores. Because the exhaustion doctrine applies to method patents, and because the license authorizes the sale of components that substantially embody the patents in suit, the sale exhausted the patents.

I

Respondent LG Electronics, Inc. (LGE), purchased a portfolio of computer technology patents in 1999, including the three patents at issue here: U.S. Patent Nos. 4,939,641 ('641); 5,379,379 ('379); and 5,077,733 ('733) (collectively LGE Patents). The main functions of a computer system are carried out on a microprocessor, or central processing unit, which interprets program instructions, processes data, and controls other devices in the system. A set of wires, or bus, connects the microprocessor to a chipset, which transfers data between the microprocessor and other devices, including the keyboard, mouse, monitor, hard drive, memory, and disk drives.

The data processed by the computer are stored principally in random access memory, also called main memory. Webster's New World Dictionary of Computer Terms 334, 451 (8th ed.2000). Frequently accessed data are generally stored in cache memory, which permits faster access than main memory and is often located on the microprocessor itself. *Id.*, at 84. When copies of data are stored in both the cache and main memory, problems may arise when one copy is changed but the other still contains the original "stale" version of the data. J. Handy, *Cache Memory* Book 124 (2d ed.1993). The '641 patent addresses this problem. It discloses a system for ensuring that the most current data are retrieved from main memory by monitoring data requests and updating main memory from the cache when stale data are requested. *LG Electronics, Inc. v. Bizcom Electronics, Inc.*, 453 F.3d 1364, 1377 (C.A.Fed.2006).

The '379 patent relates to the coordination of requests to read from, and write to, main memory. *Id.*, at 1378. Processing these requests in chronological order can slow down a system because read requests are faster to execute than write requests. Processing

all read requests first ensures speedy access, but may result in the retrieval of outdated data if a read request for a certain piece of data is processed before an outstanding write request for the same data. The '379 patent discloses an efficient method of organizing read and write requests while maintaining accuracy by allowing the computer to execute only read requests until it needs data for which there is an outstanding write request. *LG Electronics, Inc. v. Asustek Computer, Inc.*, No. C 01-02187 CW et al., Order Construing Disputed Terms and Phrases, p. 42 (ND Cal., Aug. 20, 2002). Upon receiving such a read request, the computer executes pending write requests first and only then returns to the read requests so that the most up-to-date data are retrieved. *Ibid.*

The '733 patent addresses the problem of managing the data traffic on a bus connecting two computer components, so that no one device monopolizes the bus. It allows multiple devices to share the bus, giving heavy users greater access. This patent describes methods that establish a rotating priority system under which each device alternately has priority access to the bus for a preset number of cycles and heavier users can maintain priority for more cycles without “hogging” the device indefinitely. *Id.*, at 37-38.

LGE licensed a patent portfolio, including the LGE Patents, to Intel Corporation (Intel). The cross-licensing agreement (License Agreement) permits Intel to manufacture and sell microprocessors and chipsets that use the LGE Patents (the Intel Products). The License Agreement authorizes Intel to “ ‘make, use, sell (directly or indirectly), offer to sell, import or otherwise dispose of’ ” its own products practicing the LGE Patents. Brief for Petitioners 8 (quoting App. 154). Notwithstanding this broad language, the License Agreement contains some limitations. Relevant here, it stipulates that no license

“ ‘is granted by either party hereto ... to any third party for the combination by a third party of Licensed Products of either party with items, components, or the like acquired ... from sources other than a party hereto, or for the use, import, offer for sale or sale of such combination.’ ” Brief for Petitioners 8 (quoting App. 164).

The License Agreement purports not to alter the usual rules of patent exhaustion, however, providing that, “ ‘[n]otwithstanding anything to the contrary contained in this Agreement, the parties agree that nothing herein shall in any way limit or alter the effect of patent exhaustion that would otherwise apply when a party hereto sells any of its Licensed Products.’ ” Brief for Petitioners 8 (quoting App. 164).

In a separate agreement (Master Agreement), Intel agreed to give written notice to its own customers informing them that, while it had obtained a broad license “ ‘ensur[ing] that any Intel product that you purchase is licensed by LGE and thus does not infringe any patent held by LGE,’ ” the license “ ‘does not extend, expressly or by implication, to any product that you make by combining an Intel product with any non-Intel product.’ ” Brief for Respondent 9 (emphasis deleted) (quoting App. 198). The Master Agreement also provides that “ ‘a breach of this Agreement shall have no effect on and shall not be grounds for termination of the Patent License.’ ” Brief for Petitioners 9 (quoting App. 176).

Petitioners, including Quanta Computer (collectively Quanta), are a group of computer manufacturers. Quanta purchased microprocessors and chipsets from Intel and received the notice required by the Master Agreement. Nonetheless, Quanta manufactured computers using Intel parts in combination with non-Intel memory and buses in ways that practice the LGE Patents. Quanta does not modify the Intel components and follows Intel's specifications to incorporate the parts into its own systems.

LGE filed a complaint against Quanta, asserting that the combination of the Intel Products with non-Intel memory and buses infringed the LGE Patents. The District Court granted summary judgment to Quanta, holding that, for purposes of the patent exhaustion doctrine, the license LGE granted to Intel resulted in forfeiture of any potential infringement actions against legitimate purchasers of the Intel Products. *LG Electronics, Inc. v. Asustek Computer, Inc.*, 65 USPQ 2d 1589, 1593, 1600 (N.D.Cal.2002). The court found that, although the Intel Products do not fully practice any of the patents at issue, they have no reasonable noninfringing use and therefore their authorized sale exhausted patent rights in the completed computers under *United States v. Univis Lens Co.*, 316 U.S. 241, 62 S.Ct. 1088, 86 L.Ed. 1408 (1942). *Asustek, supra*, at 1598-1600. In a subsequent order limiting its summary judgment ruling, the court held that patent exhaustion applies only to apparatus or composition-of-matter claims that describe a physical object, and does not apply to process, or method, claims that describe operations to make or use a product. *LG Electronics, Inc. v. Asustek Computer, Inc.*, 248 F.Supp.2d 912, 918 (N.D.Cal.2003). Because each of the LGE Patents includes method claims, exhaustion did not apply.

The Court of Appeals for the Federal Circuit affirmed in part and reversed in part. It agreed that the doctrine of patent exhaustion does not apply to method claims. In the alternative, it concluded that exhaustion did not apply because LGE did not license Intel to sell the Intel Products to Quanta for use in combination with non-Intel products. 453 F.3d, at 1370.

We granted certiorari, 551 U.S. ----, 128 S.Ct. 28, 168 L.Ed.2d 805 (2007).

II

The longstanding doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item. This Court first applied the doctrine in 19th-century cases addressing patent extensions on the Woodworth planing machine. Purchasers of licenses to sell and use the machine for the duration of the original patent term sought to continue using the licenses through the extended term. The Court held that the extension of the patent term did not affect the rights already secured by purchasers who bought the item for use “in the ordinary pursuits of life.” *Bloomer v. McQuewan*, 14 How. 539, 549, 14 L.Ed. 532 (1853); see also *ibid.* (“[W]hen the machine passes to the hands of the purchaser, it is no longer within the limits of the monopoly”); *Bloomer v. Millinger*, 1 Wall. 340, 351, 17 L.Ed. 581 (1864). In *Adams v. Burke*, 17 Wall. 453, 21 L.Ed. 700 (1873), the Court affirmed the dismissal of a patent holder's suit alleging that a licensee had violated postsale restrictions on where patented coffin-lids could be used. “[W]here a person ha[s] purchased a patented machine of the

patentee or his assignee,” the Court held, “this purchase carri[e]s with it the right to the use of that machine so long as it [is] capable of use.” *Id.*, at 455.

Although the Court permitted postsale restrictions on the use of a patented article in *Henry v. A.B. Dick Co.*, 224 U.S. 1, 32 S.Ct. 364, 56 L.Ed. 645 (1912),¹¹ that decision was short lived. In 1913, the Court refused to apply *A.B. Dick* to uphold price-fixing provisions in a patent license. See *Bauer & Cie v. O'Donnell*, 229 U.S. 1, 14-17, 33 S.Ct. 616, 57 L.Ed. 1041 (1913). Shortly thereafter, in *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 518, 37 S.Ct. 416, 61 L.Ed. 871 (1917), the Court explicitly overruled *A.B. Dick*. In that case, a patent holder attempted to limit purchasers' use of its film projectors to show only film made under a patent held by the same company. The Court noted the “increasing frequency” with which patent holders were using *A.B. Dick*-style licenses to limit the use of their products and thereby using the patents to secure market control of related, unpatented items. 243 U.S., at 509, 516-517, 37 S.Ct. 416. Observing that “the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is ‘to promote the progress of science and useful arts,’ ” *id.*, at 511, 37 S.Ct. 416 (quoting U.S. Const., Art. I, § 8, cl. 8), the Court held that “the scope of the grant which may be made to an inventor in a patent, pursuant to the [patent] statute, must be limited to the invention described in the claims of his patent.” 243 U.S., at 511, 37 S.Ct. 416. Accordingly, it reiterated the rule that “the right to vend is exhausted by a single, unconditional sale, the article sold being thereby carried outside the monopoly of the patent law and rendered free of every restriction which the vendor may attempt to put upon it.” *Id.*, at 516, 37 S.Ct. 416.

This Court most recently discussed patent exhaustion in *Univis*, 316 U.S. 241, 62 S.Ct. 1088, 86 L.Ed. 1408, on which the District Court relied. Univis Lens Company, the holder of patents on eyeglass lenses, licensed a purchaser to manufacture lens blanks¹² by fusing together different lens segments to create bi- and tri-focal lenses and to sell them to other Univis licensees at agreed-upon rates. Wholesalers were licensed to grind the blanks into the patented finished lenses, which they would then sell to Univis-licensed prescription retailers for resale at a fixed rate. Finishing retailers, after grinding the blanks into patented lenses, would sell the finished lenses to consumers at the same fixed rate. The United States sued Univis under the Sherman Act, 15 U.S.C. §§ 1, 3, 15, alleging unlawful restraints on trade. Univis asserted its patent monopoly rights as a defense to the antitrust suit. The Court granted certiorari to determine whether Univis' patent monopoly survived the sale of the lens blanks by the licensed manufacturer and therefore shielded Univis' pricing scheme from the Sherman Act.

¹¹ The A.B. Dick Company sold mimeograph machines with an attached license stipulating that the machine could be used only with ink, paper, and other supplies made by the A.B. Dick Company. The Court rejected the notion that a patent holder “can only keep the article within the control of the patent by retaining the title,” *A.B. Dick*, 224 U.S., at 18, 32 S.Ct. 364, and held that “any ... reasonable stipulation, not inherently violative of some substantive law” was “valid and enforceable,” *id.*, at 31, 32 S.Ct. 364. The only requirement, the Court held, was that “the purchaser must have notice that he buys with only a qualified right of use,” so that a sale made without conditions resulted in “an unconditional title to the machine, with no limitations upon the use.” *Id.*, at 26, 32 S.Ct. 364.

¹² Lens blanks are “rough opaque pieces of glass of suitable size, design and composition for use, when ground and polished, as multifocal lenses in eyeglasses.” *Univis*, 316 U.S., at 244, 62 S.Ct. 1088.

The Court assumed that the Univis patents containing claims for finished lenses were practiced in part by the wholesalers and finishing retailers who ground the blanks into lenses, and held that the sale of the lens blanks exhausted the patents on the finished lenses. *Univis*, 316 U.S., at 248-249, 62 S.Ct. 1088. The Court explained that the lens blanks “embodi[ed] essential features of the patented device and [were] without utility until ... ground and polished as the finished lens of the patent.” *Id.*, at 249, 62 S.Ct. 1088. The Court noted that:

“where one has sold an uncompleted article which, because it embodies essential features of his patented invention, is within the protection of his patent, and has destined the article to be finished by the purchaser in conformity to the patent, he has sold his invention so far as it is or may be embodied in that particular article.”

Id., at 250-251, 62 S.Ct. 1088.

In sum, the Court concluded that the traditional bar on patent restrictions following the sale of an item applies when the item sufficiently embodies the patent—even if it does not completely practice the patent—such that its only and intended use is to be finished under the terms of the patent.

With this history of the patent exhaustion doctrine in mind, we turn to the parties' arguments.

III

A

LGE argues that the exhaustion doctrine is inapplicable here because it does not apply to method claims, which are contained in each of the LGE Patents. LGE reasons that, because method patents are linked not to a tangible article but to a process, they can never be exhausted through a sale. Rather, practicing the patent—which occurs upon each use of an article embodying a method patent—is permissible only to the extent rights are transferred in an assignment contract. Quanta, in turn, argues that there is no reason to preclude exhaustion of method claims, and points out that both this Court and the Federal Circuit have applied exhaustion to method claims. It argues that any other rule would allow patent holders to avoid exhaustion entirely by inserting method claims in their patent specifications.

Quanta has the better of this argument. Nothing in this Court's approach to patent exhaustion supports LGE's argument that method patents cannot be exhausted. It is true that a patented method may not be sold in the same way as an article or device, but methods nonetheless may be “embodied” in a product, the sale of which exhausts patent rights. Our precedents do not differentiate transactions involving embodiments of patented methods or processes from those involving patented apparatuses or materials. To the contrary, this Court has repeatedly held that method patents were exhausted by the sale of an item that embodied the method. In *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 446, 457, 60 S.Ct. 618, 84 L.Ed. 852 (1940), for example, the Court held that the sale of a motor fuel produced under one patent also exhausted the patent for a method

of using the fuel in combustion motors.¹³ Similarly, as previously described, *Univis* held that the sale of optical lens blanks that partially practiced a patent exhausted the method patents that were not completely practiced until the blanks were ground into lenses. 316 U.S., at 248-251, 62 S.Ct. 1088.

These cases rest on solid footing. Eliminating exhaustion for method patents would seriously undermine the exhaustion doctrine. Patentees seeking to avoid patent exhaustion could simply draft their patent claims to describe a method rather than an apparatus.¹⁴ Apparatus and method claims “may approach each other so nearly that it will be difficult to distinguish the process from the function of the apparatus.” *United States ex rel. Steinmetz v. Allen*, 192 U.S. 543, 559, 24 S.Ct. 416, 48 L.Ed. 555 (1904). By characterizing their claims as method instead of apparatus claims, or including a method claim for the machine's patented method of performing its task, a patent drafter could shield practically any patented item from exhaustion.

This case illustrates the danger of allowing such an end-run around exhaustion. On LGE's theory, although Intel is authorized to sell a completed computer system that practices the LGE Patents, any downstream purchasers of the system could nonetheless be liable for patent infringement. Such a result would violate the longstanding principle that, when a patented item is “once lawfully made and sold, there is no restriction on [its] use to be implied for the benefit of the patentee.” *Adams*, 17 Wall., at 457, 21 L.Ed. 700. We therefore reject LGE's argument that method claims, as a category, are never exhaustible.

B

We next consider the extent to which a product must embody a patent in order to trigger exhaustion. Quanta argues that, although sales of an incomplete article do not necessarily exhaust the patent in that article, the sale of the microprocessors and chipsets exhausted LGE's patents in the same way the sale of the lens blanks exhausted the patents in *Univis*. Just as the lens blanks in *Univis* did not fully practice the patents at issue because they had not been ground into finished lenses, Quanta observes, the Intel Products cannot practice the LGE Patents-or indeed, function at all-until they are combined with memory and buses in a computer system. If, as in *Univis*, patent rights are exhausted by the sale of the incomplete item, then LGE has no postsale right to require

¹³ The patentee held patents for (1) a fluid additive increasing gasoline efficiency, (2) motor fuel produced by mixing gasoline with the patented fluid, and (3) a method of using fuel containing the patented fluid in combustion motors. *Ethyl Gasoline Corp.*, 309 U.S., at 446, 60 S.Ct. 618. The patentee sold only the fluid, but attempted to control sales of the treated fuel. *Id.*, at 459, 60 S.Ct. 618. The Court held that the sale of the fluid to refiners relinquished the patentee's exclusive rights to sell the treated fuel. *Id.*, at 457, 60 S.Ct. 618.

¹⁴ One commentator recommends this strategy as a way to draft patent claims that “will survive numerous transactions regarding the patented good, allowing the force of the patent to intrude deeply into the stream of commerce.” Thomas, *Of Text, Technique, and the Tangible: Drafting Patent Claims Around Patent Rules*, 17 J. Marshall J. Computer & Info. L. 219, 252 (1998); see also *id.*, at 225-226 (advocating the conversion of apparatus claims into method claims and noting that “[e]ven the most novice claims drafter would encounter scant difficulty in converting a patent claim from artifact to technique and back again”).

that the patents be practiced using only Intel parts. Quanta also argues that exhaustion doctrine will be a dead letter unless it is triggered by the sale of components that essentially, even if not completely, embody an invention. Otherwise, patent holders could authorize the sale of computers that are complete with the exception of one minor step—say, inserting the microprocessor into a socket—and extend their rights through each downstream purchaser all the way to the end user.

LGE, for its part, argues that *Univis* is inapplicable here for three reasons. First, it maintains that *Univis* should be limited to products that contain all the physical aspects needed to practice the patent. On that theory, the Intel Products cannot embody the patents because additional physical components are required before the patents can be practiced. Second, LGE asserts that in *Univis* there was no “patentable distinction” between the lens blanks and the patented finished lenses since they were both subject to the same patent. Brief for Respondent 14 (citing *Univis, supra*, at 248-252, 62 S.Ct. 1088). In contrast, it describes the Intel Products as “independent and distinct products” from the systems using the LGE Patents and subject to “independent patents.” Brief for Respondent 13. Finally, LGE argues that *Univis* does not apply because the Intel Products are analogous to individual elements of a combination patent, and allowing sale of those components to exhaust the patent would impermissibly “ascrib[e] to one element of the patented combination the status of the patented invention in itself.” *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 344-345, 81 S.Ct. 599, 5 L.Ed.2d 592 (1961).

We agree with Quanta that *Univis* governs this case. As the Court there explained, exhaustion was triggered by the sale of the lens blanks because their only reasonable and intended use was to practice the patent and because they “embodie[d] essential features of [the] patented invention.” 316 U.S., at 249-251, 62 S.Ct. 1088. Each of those attributes is shared by the microprocessors and chipsets Intel sold to Quanta under the License Agreement.

First, *Univis* held that “the authorized sale of an article which is capable of use only in practicing the patent is a relinquishment of the patent monopoly with respect to the article sold.” *Id.*, at 249, 62 S.Ct. 1088. The lens blanks in *Univis* met this standard because they were “without utility until [they were] ground and polished as the finished lens of the patent.” *Ibid.* Accordingly, “the only object of the sale [was] to enable the [finishing retailer] to grind and polish it for use as a lens by the prospective wearer.” *Ibid.* Here, LGE has suggested no reasonable use for the Intel Products other than incorporating them into computer systems that practice the LGE Patents.¹⁵ Nor can we discern one: A microprocessor or chipset cannot function until it is connected to

¹⁵ LGE suggests that the Intel Products would not infringe its patents if they were sold overseas, used as replacement parts, or engineered so that use with non-Intel Products would disable their patented features. Brief for Respondent 21-22, n. 10. But *Univis* teaches that the question is whether the product is “capable of use only in practicing the patent,” not whether those uses are infringing. 316 U.S., at 249, 62 S.Ct. 1088 (emphasis added). Whether outside the country or functioning as replacement parts, the Intel Products would still be practicing the patent, even if not infringing it. And since the features partially practicing the patent are what must have an alternative use, suggesting that they be disabled is no solution. The disabled features would have no real *use*.

buses and memory. And here, as in *Univis*, the only apparent object of Intel's sales to Quanta was to permit Quanta to incorporate the Intel Products into computers that would practice the patents.

Second, the lens blanks in *Univis* “embodie[d] essential features of [the] patented invention.” *Id.*, at 250-251, 62 S.Ct. 1088. The essential, or inventive, feature of the *Univis* lens patents was the fusing together of different lens segments to create bi- and tri-focal lenses. The finishing process performed by the finishing and prescription retailers after the fusing was not unique. As the United States explained:

“The finishing licensees finish *Univis* lens blanks in precisely the same manner as they finish all other bifocal lens blanks. Indeed, appellees have never contended that their licensing system is supported by patents covering methods or processes relating to the finishing of lens blanks. Consequently, it appears that appellees perform all of the operations which contribute any claimed element of novelty to *Univis* lenses.” Brief for United States in *United States v. Univis Lens Co.*, O.T.1941, No. 855 et al., p. 10 (footnote and citations omitted).

While the Court assumed that the finishing process was covered by the patents, *Univis*, *supra*, at 248-249, 62 S.Ct. 1088, and the District Court found that it was necessary to make a working lens, *United States v. Univis Lens Co.*, 41 F.Supp. 258, 262-263 (S.D.N.Y.1941), the grinding process was not central to the patents. That standard process was not included in detail in any of the patents and was not referred to at all in two of the patents. Those that did mention the finishing process treated it as incidental to the invention, noting, for example, that “[t]he blank is then ground in the usual manner,” U.S. Patent No. 1,876,497, p. 2, or simply that the blank is “then ground and polished,” U.S. Patent No. 1,632,208, p. 1, Tr. of Record in *United States v. Univis Lens Co.*, O.T.1941, No. 855 et al., pp. 516, 498.

Like the *Univis* lens blanks, the Intel Products constitute a material part of the patented invention and all but completely practice the patent. Here, as in *Univis*, the incomplete article substantially embodies the patent because the only step necessary to practice the patent is the application of common processes or the addition of standard parts. Everything inventive about each patent is embodied in the Intel Products. They control access to main and cache memory, practicing the '641 and '379 patents by checking cache memory against main memory and comparing read and write requests. They also control priority of bus access by various other computer components under the '733 patent. Naturally, the Intel Products cannot carry out these functions unless they are attached to memory and buses, but those additions are standard components in the system, providing the material that enables the microprocessors and chipsets to function. The Intel Products were specifically designed to function only when memory or buses are attached; Quanta was not required to make any creative or inventive decision when it added those parts. Indeed, Quanta had no alternative but to follow Intel's specifications in incorporating the Intel Products into its computers because it did not know their internal structure, which Intel guards as a trade secret. Brief for Petitioners 3. Intel all but practiced the patent itself by designing its products to practice the patents, lacking only the addition of standard parts.

We are unpersuaded by LGE's attempts to distinguish *Univis*. First, there is no reason to distinguish the two cases on the ground that the articles in *Univis* required the *removal* of material to practice the patent while the Intel Products require the *addition* of components to practice the patent. LGE characterizes the lens blanks and lenses as sharing a “basic nature” by virtue of their physical similarity, while the Intel Products embody only some of the “patentably distinct elements and steps” involved in the LGE Patents. Brief for Respondent 26-27. But we think that the nature of the final step, rather than whether it consists of adding or deleting material, is the relevant characteristic. In each case, the final step to practice the patent is common and noninventive: grinding a lens to the customer's prescription, or connecting a microprocessor or chipset to buses or memory. The Intel Products embody the essential features of the LGE Patents because they carry out all the inventive processes when combined, according to their design, with standard components.

With regard to LGE's argument that exhaustion does not apply across patents, we agree on the general principle: The sale of a device that practices patent A does not, by virtue of practicing patent A, exhaust patent B. But if the device practices patent A *while substantially embodying* patent B, its relationship to patent A does not prevent exhaustion of patent B. For example, if the *Univis* lens blanks had been composed of shatter-resistant glass under patent A, the blanks would nonetheless have substantially embodied, and therefore exhausted, patent B for the finished lenses. This case is no different. While each Intel microprocessor and chipset practices thousands of individual patents, including some LGE patents not at issue in this case, the exhaustion analysis is not altered by the fact that more than one patent is practiced by the same product. The relevant consideration is whether the Intel Products that partially practice a patent – by, for example, embodying its essential features – exhaust *that* patent.

Finally, LGE's reliance on *Aro* is misplaced because that case dealt only with the question whether replacement of one part of a patented combination infringes the patent. First, the replacement question is not at issue here. Second, and more importantly, *Aro* is not squarely applicable to the exhaustion of patents like the LGE Patents that do not disclose a new combination of existing parts. *Aro* described combination patents as “cover [ing] only the totality of the elements in the claim [so] that no element, separately viewed, is within the grant.” 365 U.S., at 344, 81 S.Ct. 599; see also *Mercoind Corp. v. Mid-Continent Investment Co.*, 320 U.S. 661, 667-668, 64 S.Ct. 268, 88 L.Ed. 376 (1944) (noting that, in a combination patent, “the combination is the invention and it is distinct from any” of its elements). *Aro*'s warning that no element can be viewed as central to or equivalent to the invention is specific to the context in which the combination itself is the only inventive aspect of the patent. In this case, the inventive part of the patent is not the fact that memory and buses are combined with a microprocessor or chipset; rather, it is included in the design of the Intel Products themselves and the way these products access the memory or bus.

C

Having concluded that the Intel Products embodied the patents, we next consider whether their sale to Quanta exhausted LGE's patent rights. Exhaustion is triggered only by a sale authorized by the patent holder. *Univis*, 316 U.S., at 249, 62 S.Ct. 1088.

LGE argues that there was no authorized sale here because the License Agreement does not permit Intel to sell its products for use in combination with non-Intel products to practice the LGE Patents. It cites *General Talking Pictures Corp. v. Western Elec. Co.*, 304 U.S. 175, 58 S.Ct. 849, 82 L.Ed. 1273 (1938), and *General Talking Pictures Corp. v. Western Elec. Co.*, 305 U.S. 124, 59 S.Ct. 116, 83 L.Ed. 81 (1938), in which the manufacturer sold patented amplifiers for commercial use, thereby breaching a license that limited the buyer to selling the amplifiers for private and home use. The Court held that exhaustion did not apply because the manufacturer had no authority to sell the amplifiers for commercial use, and the manufacturer “could not convey to petitioner what both knew it was not authorized to sell.” *General Talking Pictures*, *supra*, at 181, 58 S.Ct. 849. LGE argues that the same principle applies here: Intel could not convey to Quanta what both knew it was not authorized to sell, *i.e.*, the right to practice the patents with non-Intel parts.

LGE overlooks important aspects of the structure of the Intel-LGE transaction. Nothing in the License Agreement restricts Intel's right to sell its microprocessors and chipsets to purchasers who intend to combine them with non-Intel parts. It broadly permits Intel to “ ‘make, use, [or] sell’ ” products free of LGE's patent claims. Brief for Petitioners 8 (quoting App. 154). To be sure, LGE did require Intel to give notice to its customers, including Quanta, that LGE had not licensed those customers to practice its patents. But neither party contends that Intel breached the agreement in that respect. Brief for Petitioners 9; Brief for Respondent 9. In any event, the provision requiring notice to Quanta appeared only in the Master Agreement, and LGE does not suggest that a breach of that agreement would constitute a breach of the License Agreement. Hence, Intel's authority to sell its products embodying the LGE Patents was not conditioned on the notice or on Quanta's decision to abide by LGE's directions in that notice.

LGE points out that the License Agreement specifically disclaimed any license to third parties to practice the patents by combining licensed products with other components. Brief for Petitioners 8. But the question whether third parties received implied licenses is irrelevant because Quanta asserts its right to practice the patents based not on implied license but on exhaustion. And exhaustion turns only on Intel's own license to sell products practicing the LGE Patents.

Alternatively, LGE invokes the principle that patent exhaustion does not apply to postsale restrictions on “making” an article. Brief for Respondent 43. But this is simply a rephrasing of its argument that combining the Intel Products with other components adds more than standard finishing to complete a patented article. As explained above, making a product that substantially embodies a patent is, for exhaustion purposes, no different from making the patented article itself. In other words, no further “making” results from the addition of standard parts—here, the buses and memory—to a product that already substantially embodies the patent.

The License Agreement authorized Intel to sell products that practiced the LGE Patents. No conditions limited Intel's authority to sell products substantially embodying the patents. Because Intel was authorized to sell its products to Quanta, the doctrine of patent exhaustion prevents LGE from further asserting its patent rights with respect to the patents substantially embodied by those products.¹⁶

IV

The authorized sale of an article that substantially embodies a patent exhausts the patent holder's rights and prevents the patent holder from invoking patent law to control postsale use of the article. Here, LGE licensed Intel to practice any of its patents and to sell products practicing those patents. Intel's microprocessors and chipsets substantially embodied the LGE Patents because they had no reasonable noninfringing use and included all the inventive aspects of the patented methods. Nothing in the License Agreement limited Intel's ability to sell its products practicing the LGE Patents. Intel's authorized sale to Quanta thus took its products outside the scope of the patent monopoly, and as a result, LGE can no longer assert its patent rights against Quanta. Accordingly, the judgment of the Court of Appeals is reversed.

It is so ordered.

NOTES AND QUESTIONS ON *QUANTA COMPUTER*

1. Complex Licensing. This case is a bit complex factually, and it is important to understand the structure of the licensing arrangement between LGE, Intel, and Intel's customers (such as defendant/petitioner, Quanta). Two features are important, especially for understanding Part III C of the Court's opinion: (1) the two-part nature of the LGE-Intel contractual relationship, consisting of (a) a Master Agreement governing the overall relationship, and (b) the specific licensing agreement at issue in this case, actually a cross-license, which the Court calls "the Licensing Agreement."

2. Supreme Court Patent Sophistication. This case is one in a long line of patent cases the Supreme Court has considered over the past ten or so years. Can you detect signs of sophistication regarding the patent system in the Court's opinion? Consider the point the Court makes with respect to LGE's argument that exhaustion doctrine should apply differentially to process and product claims: that patent claim drafters can easily draft around such a rule. It might be interesting to compare this opinion with one of the earlier patent cases from the Court's recent history. In *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), for example, the Court's opinion begins with a reference to "so-called patent claims" (517 U.S. at 372) – a sign of distance

¹⁶ We note that the authorized nature of the sale to Quanta does not necessarily limit LGE's other contract rights. LGE's complaint does not include a breach-of-contract claim, and we express no opinion on whether contract damages might be available even though exhaustion operates to eliminate patent damages. See *Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 666, 15 S.Ct. 738, 39 L.Ed. 848 (1895) ("Whether a patentee may protect himself and his assignees by special contracts brought home to the purchasers is not a question before us, and upon which we express no opinion. It is, however, obvious that such a question would arise as a question of contract, and not as one under the inherent meaning and effect of the patent laws").

from (and, just maybe, a hint of disdain for) the field. The deft handling of the claim drafting dimension of the *Quanta* case is a far cry from this.

3. “Substantially Embodies.” In Part III B of the opinion, the Court deals with the extent to which a purchased product must embody a claimed invention for a patent or patents on that invention to be exhausted by an authorized sale. Here is where the Court announces the “substantially embodies” test. Does this test make sense to you in this case? What are the ramifications of rejecting it (or some alternative that leads to a finding of exhaustion/noninfringement)? How much of the analysis here seems to be premised on the reasonable expectations of the end-purchasers of the patented product – here, Quanta’s customers? How might more explicit notice from Intel concerning LGE’s patent rights – that is, a statement from Intel when it sold each shipment of chips to customers, to the effect that LGE had patent rights that were not being implicitly licensed with the sale – change your understanding of these expectations? Is it fundamentally unfair for LGE to collect royalties from Intel *and* Intel’s customers for the same patented invention?

4. More Licensing Complexities. Part III C contains a number of interesting points. First, how would it have changed the Court’s analysis if the License Agreement had been made explicitly *conditional* on Intel providing notice to its customers regarding LGE’s patents and the potential for infringement liability that would follow from the customer’s use of those patented inventions? What remedies could LGE have provided in this hypothetical conditional agreement with Intel? Why didn’t LGE in fact insist on such a provision? (Hint: Intel is very large, and has lots of bargaining power.) Assuming that Intel did not have good information about its customers’ uses of, and profits from, LGE’s patented inventions, why might it be more efficient and effective for LGE to get a separate royalty stream from Intel and from its customers? Based on this, can you tell a Chicago-school style law and economics story about why an expansive exhaustion doctrine has the potential to undermine efficiency in this area?

5. International Exhaustion. The Supreme Court’s holding in *Quanta* raises the issue whether a patent owner’s activities abroad may cause exhaustion of their patent rights in the United States.

In today’s globalized economy the traditional channels of development, manufacturing and commercialization of a product are often not the result of activities by a single entity in a single country. As the *Quanta* case illustrates, a product may be conceived, developed and patented in a foreign country (LG Electronics); its rights may be licensed and sold to a manufacturer in a second country (Intel, Corp.); and the products encompassing the patented technology may be sold by parties all over the world (Quanta Computer, Inc. et. al). Thus, a key issue is what types of activities occurring internationally may qualify as an “authorized sale or other disposition” within the U.S. in order to implicate the patent exhaustion doctrine.

Currently, the predominant view is that foreign activity cannot trigger U.S. exhaustion because the patent exhaustion doctrine “requires a showing of an (1) authorized sale or other disposition (2) of a patented article (3) within the United States.” *Cornell Univ. v. Hewlett-Packard Co.*, 2008 U.S. Dist. LEXIS 60209 (N.D.N.Y Aug. 1,

2008) (Rader, J., sitting by designation) (citing *Quanta*). But older precedent is not necessarily consistent with the modern view. Thus, in *Holiday v. Mattheson*, 24 F. 185 (S.D.N.Y. 1885), the district court held that the patentee's sale of their patent rights abroad exhausted their right to seek relief for infringement in the United States. Because the purchasers in that case had acquired the right to sell the product in England without restrictions or conditions, the patentees could not prevent them from using or selling the same products in the U.S.

Even in the nineteenth century, however, international exhaustion had at least one very significant limitation: The sale or authorization to use must come from the U.S. patentee. Thus, in *Dickerson v. Matheson*, 57 F. 524 (2d Cir. 1893), the court held that “a purchaser in a foreign country of an article patented in that country and also in the United States, from a licensee under the foreign patent only, does not give the purchaser a right to import the article into, and to sell it in, the United States, without the license or consent of the owner of the United States patent.” *Id.* at 527; see also *Dickerson v. Tinling*, 84 F. 192 (8th Cir. 1897).

To what extent should international transactions affect U.S. patent rights? Note that patent rights (and other intellectual property rights) are highly territorial, so that U.S. patent rights are generally limited quite strictly to the territory of the United States. This “territoriality” is the reason why inventors have to seek and obtain rights in multiple countries if they want to have their rights enforced in those countries. Does the territorial nature of patent rights provide a good limitation on exhaustion principles? Are such territorial restrictions fair to purchasers of patented products? Consider also this hypothetical: While on vacation in Germany, I buy a MP3 player covered by U.S. and EPO patents. Am I an infringer when I return to the U.S. with the MP3 player after my vacation? Should the answer turn on my contractual relationship the MP3 manufacturer?

At least some of these questions may be answered by the Supreme Court in the 2010-2011 term, now that the Court has granted certiorari to review a Ninth Circuit decision on the international exhaustion / first sale doctrine as it applies to copyright.. See *Omega v. Costco Wholesale Corp.*, 541 F. 3d 982 (9th Cir. 2008) (exhaustion in copyright case), cert. granted No. 08-1423. April 19, 2010, 130 S.Ct. 2089 (Mem), 176 L.Ed.2d 720 (2010). The question presented in the case is:

Under the Copyright Act's first-sale doctrine, 17 U.S.C. § 109(a), the owner of a copy “lawfully made under this title” may resell that copy without the authority of the copyright holder. In *Quality King Distribs., Inc. v. L'anza Research Int'l, Inc.*, 523 U.S. 135, 138 (1998), this Court held that “the ‘first sale’ doctrine endorsed in § 109(a) is applicable to imported copies.” In the decision below, the Ninth Circuit held that *Quality King* is limited to its facts, which involved goods manufactured in the United States, sold abroad, and then re-imported. The question presented here is:

Whether the Ninth Circuit correctly held that the first-sale doctrine does not apply to imported goods manufactured abroad.