Protecting IP and Litigating into Uncertainty:

Challenges from Sections 101 and 112 in the Life Sciences

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Natalie M. Derzko

Key biographical details

- 1 patent & regulatory life sciences practitioner
- 2 practice includes focus on IP policy and patent reform efforts
- 3 testified before Congressional Committee on § 101 matters

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Colleen Tracy James

WHITE & CASE

- Partner at White & Case
- First chair patent litigator who represents life science clients in litigations involving billion-dollar-a-year products and bet-the-company cases
- Extensive experience litigating both biological and chemical cases, including Hatch-Waxman litigations
- Provides strategic counseling through an array of IP services, such as freedom-to-operate opinions and licensing and due diligence advice

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Eugene Novikov

Durie Tangri

Gene is a partner at Durie Tangri LLP where he has litigated and advised on a wide range of high-stakes patent matters for technology, biotechnology, and pharmaceutical companies of all sizes.

Most recently, Gene was part of a Durie Tangri team that secured a $178 million patent infringement verdict for Plexxikon, Inc. on its kinase inhibitor patents in the Northern District of California.

Learn more @ LinkedIn

Richard Torczon

- Senior Counsel, post-grant trials group
- former Administrative Patent Judge, PTAB
- former Associate Solicitor, USPTO
- Masters, Biotechnology, Hopkins
- Practice focus: PTAB trials and Federal Circuit review

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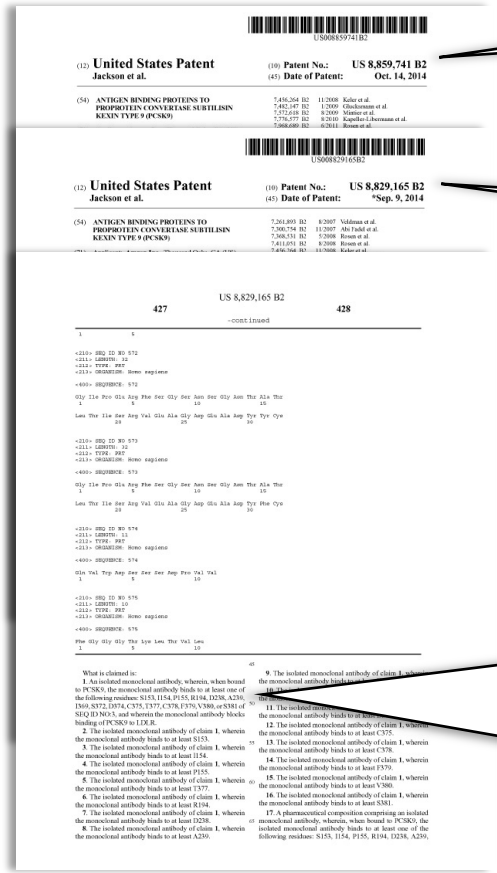
1. The §§101 and 112 environment is currently challenging for life sciences
2. Patent policy efforts addressing §§101/112 are ongoing and showing modest success
3. §101, §112, and prior art issues are intertwined

How we will get there

1. Colleen will present two biotech cases exemplifying the Federal Circuit's recent focus on the 112 written description requirement
2. Gene will tell you about challenges facing genus claims and the interaction of §101 utility and §112 enablement
3. Natalie will present a life sciences view of § 101 legislative and policy activity
4. Rick will tell you how these challenges play out at the patent board

Amgen v. Sanofi (Fed. Cir. 2017)



US 8,859,741 B2

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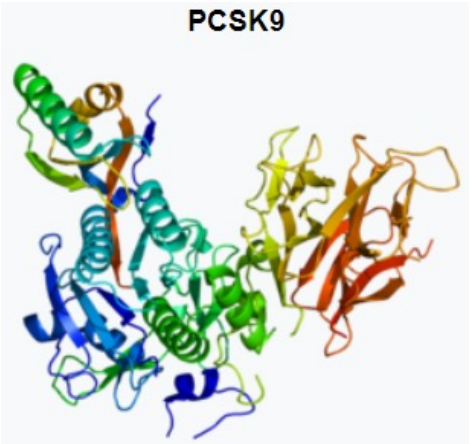


1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.

Can Post-Priority Date Evidence Be Used to Show Lack of Written Description for Genus Claims? – Yes

"Appellees are correct that written description is judged based on the state of the art as of the priority date. Accordingly, **evidence illuminating the state of the art subsequent to the priority date is not relevant to written description**. Appellants, however, are also correct that a patent claiming a genus must disclose "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." **Evidence showing that a claimed genus does not disclose a representative number of species may include evidence of species that fall within the claimed genus but are not disclosed by the patent, and evidence of such species is likely to postdate the priority date**. If such evidence predated the priority date, it might well anticipate the claimed genus."

Amgen Inc. v. Sanofi, 872 F.3d 1367, 1373–74 (Fed. Cir. 2017) (citations omitted)

"**Here . . . Appellants were not offering post-priority-date evidence to show that Appellees' claimed genus is not enabled because of a change in the state of the art. Instead, Appellants offered Praluent and other post-priority-date antibodies to argue that the claimed genus fails to disclose a representative number of species**. . . . It was thus legal error for the district court to categorically preclude all of Appellants' post-priority-date evidence of Praluent and other antibodies."

Id.

Was the Jury Instruction on the "Newly Characterized Antigen" Test Proper?

"The district court correctly instructed the jury that in order to satisfy the written description requirement, a patentee may disclose either a representative number of species falling within the scope of the genus or disclose 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. Additionally, however, **the district court further instructed the jury that:** '**In the case of a claim to antibodies, the correlation between structure and function may also be satisfied by the disclosure of a newly characterized antigen by its structure, formula, chemical name, or physical properties if you find that the level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against such an antigen was conventional or routine**.'"

Amgen Inc. v. Sanofi, 872 F.3d 1367, 1375–76 (Fed. Cir. 2017)

The Jury Instruction Was Improper

"**The essential problem** with the jury instruction given in this case **is that it effectively permitted the jury to dispense with the required finding of a 'written description of the invention.**' . . . A jury would naturally understand the instruction to permit it to deem any antibody within the claim adequately described merely because the antibody could easily be 'produc[ed]' (and, implicitly, used as an antibody).

Amgen Inc. v. Sanofi, 872 F.3d 1367, 1377 (Fed. Cir. 2017)

"**An adequate written description** must contain enough information about the actual makeup of the claimed products—'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,' which **may be present in 'functional' terminology 'when the art has established a correlation between structure and function.' But both in this case and in our previous cases, it has been, at the least, hotly disputed that knowledge of the chemical structure of an antigen gives the required kind of structure-identifying information about the corresponding antibodies**."

Id. at 1378 (citations omitted)

"Further, **the 'newly characterized antigen' test flouts basic legal principles of the written description requirement. Section 112 requires a 'written description of the invention.' But this test allows patentees to claim antibodies by describing something that is not the invention, i.e., the antigen**. The test thus contradicts the statutory 'quid pro quo' of the patent system where 'one describes an invention, and, if the law's other requirements are met, one obtains a patent.'"

Id. at 1378–79 (citations omitted)

Subsequent Case History

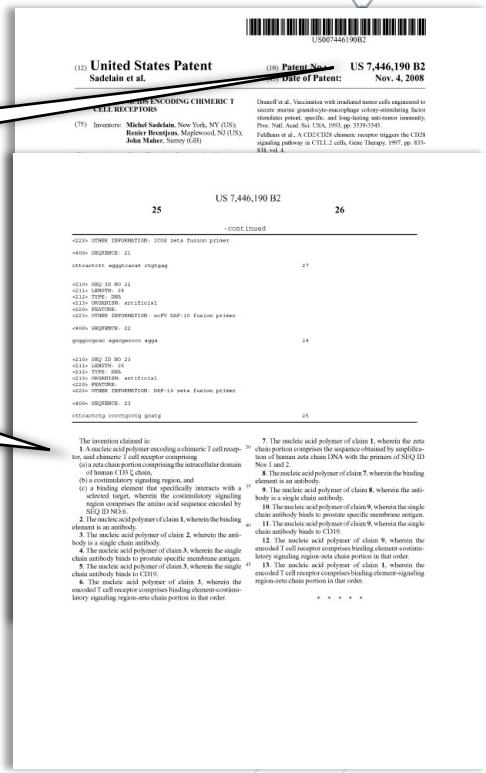
- On remand, the jury found that Sanofi failed to prove that the asserted claims were invalid for lack of written description and enablement
- The district court granted Sanofi's motion for JMOL for lack of enablement, denied its motion for lack of written description, and conditionally denied its motion for a new trial
- Sanofi appealed, but the Federal Circuit did not reach the written description issue—it disposed of the case by ruling on the enablement issue

Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021)

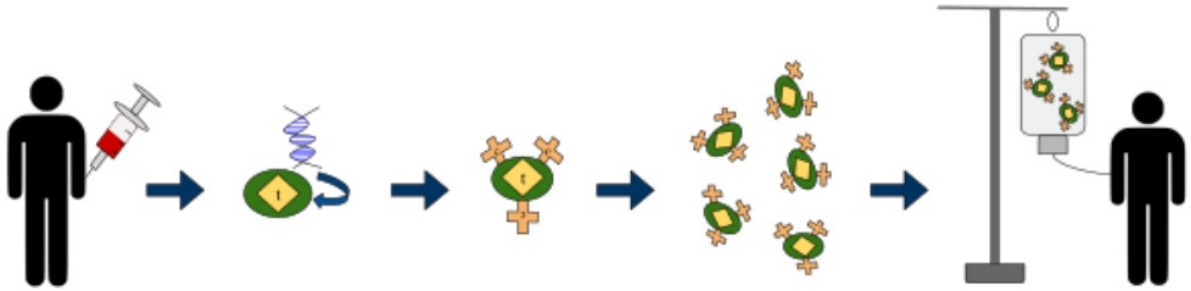
Juno v. Kite (Fed. Cir. 2021)

1. A nucleic acid polymer encoding a chimeric T cell receptor, said chimeric T cell receptor comprising
(a) a zeta chain portion comprising the intracellular domain of human CD3 ζ chain,
(b) a costimulatory signaling region, and
(c) a binding element that specifically interacts with a selected target, wherein the costimulatory signaling region comprises the amino acid sequence encoded by SEQ ID NO:6.

US 7,446,190 B2



Chimeric antigen receptor (CAR) T-cell therapy



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Are Two Examples of One Type of Binding Element Enough?

- Kite argued:
  - No disclosure of representative species or common structural features of the genus to identify which single-chain antibody variable fragment (scFv) would function as claimed.
  - Enormous genus, only a fraction of which satisfy the functional binding limitation for any given target
  - Unpredictable art because scFv binding ability depends on many factors
- Juno argued:
  - Two working embodiments in patent representative of all scFVs
  - scFVs and methods of making them well known
  - scFVs have common structural features and are interchangeable

Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1336 (Fed. Cir. 2021)

Not in This Instance

The ’190 patent’s written description contains scant details about which scFvs can bind which target antigens. The '190 patent discloses two example scFvs for binding two different targets: one derived from J591, which targets a PSMA antigen on prostate cancer cells, and another derived from SJ25C1, which targets CD19. The ’190 patent contains no details about these scFv species beyond the alphanumeric designations J591 and SJ25C1 for a skilled artisan to determine how or whether they are representative of the entire claimed genus. . . . **The disclosure of one scFv that binds to CD19 and one scFv that binds to a PSMA antigen on prostate cancer cells in the manner provided in this patent does not provide information sufficient to establish that a skilled artisan would understand how to identify the species of scFvs capable of binding to the limitless number of targets as the claims require.**”

Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1336–37 (Fed. Cir. 2021) (citations omitted)

It is undisputed that scFvs generally have a common structure, as described by Dr. Brocker. But, as Dr. Brocker acknowledged, an scFv with the same general common structure but with a different amino acid sequence would recognize a different antigen. Dr. Brocker also testified that all scFvs have a common structure, regardless of whether they bind. **The ‘190 patent not only fails to disclose structural features common to scFvs capable of binding specific targets, it also fails to disclose a way to distinguish those scFvs capable of binding from scFvs incapable of binding those targets. The ’190 patent provides no amino acid sequences or other distinguishing characteristics of the scFvs that bind. Simply put, the ’190 patent claims a ‘problem to be solved while claiming all solutions to it ... cover[ing] any compound later actually invented and determined to fall within the claim's functional boundaries,’ which fails to satisfy the written description requirement**.”

Id. at 1339 (citations omitted)

“Death of the Genus Claim”?

1. A **method for the treatment of a hepatitis C virus infection**, comprising administering **an effective amount** of a purine or pyrimidine β-D-2'-methyl-ribofuranosyl nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof.

Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1155 (Fed. Cir. 2019)

“Death of the Genus Claim”?

As described above, a reasonable jury could only have found that at least **many, many thousands of 2'-methyl-up nucleosides meet the structural limitations of claim 1**, not all of which are effective to treat HCV. Due to the unpredictability of the art . . . **each of these compounds would need to be screened** in order to know whether or not they are effective against HCV. Moreover, a significant number of candidate 2'-methyl-up nucleosides would need to be synthesized before they could be screened, which increases at least the quantity of experimentation required, even if the synthesis was routine. Although the level of skill in the art is high, the ’597 patent **does not provide enough meaningful guidance or working examples, across the full scope of the claim, to allow a POSA to determine which 2'-methyl-up nucleosides would or would not be effective** against HCV without extensive screening. The immense breadth of screening required to determine which 2'-methyl-up nucleosides are effective against HCV can only be described as undue experimentation.

Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1162 (Fed. Cir. 2019)

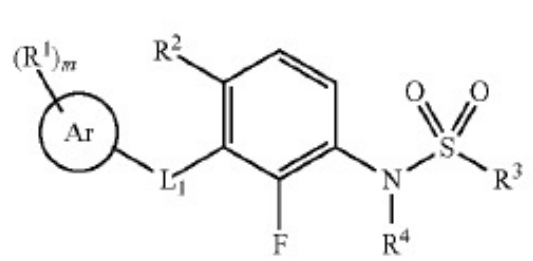
“Death of the Genus Claim”?

Entitlement to broad genus claims thus requires disclosure and enablement of species supportive of the genus that a patentee claims to have invented. That requirement is based on the concept that in order to have invented a genus, one needs to have invented species that constitute the genus. Drawing a broad fence around subject matter, without filling in the holes, is not inventing the genus. It in fact discourages invention by others. **If one has disclosed or enabled only a small number of invented species, then one has not invented a broad genus.** Invention of a genus means to conceive and reduce to practice a reasonable number and distribution of species constituting the genus. **Mere statement of a genus does not demonstrate that one has invented a generic concept, without the enablement of constituent species.**

Amgen Inc. v. Sanofi, Aventisub LLC, 850 F. App'x 794, 796 (Fed. Cir. 2021)

What About Purely Structural Claims?

1. A compound of formula (Ia):



(Ia)

or a pharmaceutically acceptable salt thereof,
wherein:
L_1 is a bond or —N(H)C(O)—;
each R^1 is optionally substituted lower alkyl or optionally substituted heteroaryl;
R^2 is hydrogen or halogen;
R^4 is hydrogen;
R^3 is optionally substituted lower alkyl or optionally substituted aryl;
m is 0, 1, 2, 3, 4, or 5; and
Ar is a monocyclic heteroaryl containing 5 to 6 atoms wherein at least one atom is nitrogen.

U.S. Patent No. 9,469,640

Does § 101 Inform the Enablement Inquiry?

- Things the Federal Circuit has said:
  - "The how to use prong of section 112 **incorporates as a matter of law the requirement of 35 U.S.C. § 101** that the specification disclose as a matter of fact a practical utility for the invention." *In re Cortright*, 165 F.3d 1353, 1356 (Fed.Cir.1999).
  - "Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. . . . Of course, **if the number of inoperative combinations becomes significant**, and in effect **forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention**, the claims might indeed be invalid." *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576–77 (Fed. Cir. 1984).
  - A patent fails to satisfy the utility requirement under 35 U.S.C. § 101 only if the invention is 'totally incapable of achieving a useful result.' For pharmaceutical patents, **practical utility may be shown by evidence of 'any pharmacological activity.'**" *Grunenthal GMBH v. Alkem Lab'ys Ltd.*, 919 F.3d 1333, 1345 (Fed. Cir. 2019).

A Life Sciences View of § 101 Legislative and Policy Activity

Natalie M. Derzko

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Past Policy & Legislative Activity

- Earlier activities of USPTO post *Mayo* and *Myriad* to provide guidance to examiners, including flowcharts, examples
- Extensive USPTO comments, roundtables for public comment
- Reform proposals presented by various organizations (2018)
  - IPO/AIPLA
  - ABA
- H.R. 6264 (introduced by Rep. Massie, 06/28/2018)
- Tillis/Coons Senate Proposal & "The State of Patent Eligibility in America" Hearings (June 2019)
- USPTO Patent Eligibility Jurisprudence Study, 86 Fed. Reg. 36257 (2021)

Tillis/Coons Draft Legislative Language (June 2019)

Section 100:

(k) The term “useful” means any invention or discovery that provides specific and practical utility in any field of technology through human intervention.

Section 101:

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

(b) Eligibility under this section shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation.

Section 112

(f) Functional Claim Elements—

An element in a claim expressed as a specified function without the recital of structure, material, or acts in support thereof shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Tillis/Coons Draft Legislative Language (June 2019)

Additional Legislative Provisions:

The provisions of section 101 shall be construed in favor of eligibility.

No implicit or other judicially created exceptions to subject matter eligibility, including “abstract ideas,” “laws of nature,” or “natural phenomena,” shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated.

The eligibility of a claimed invention under section 101 shall be determined without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112 of this title.

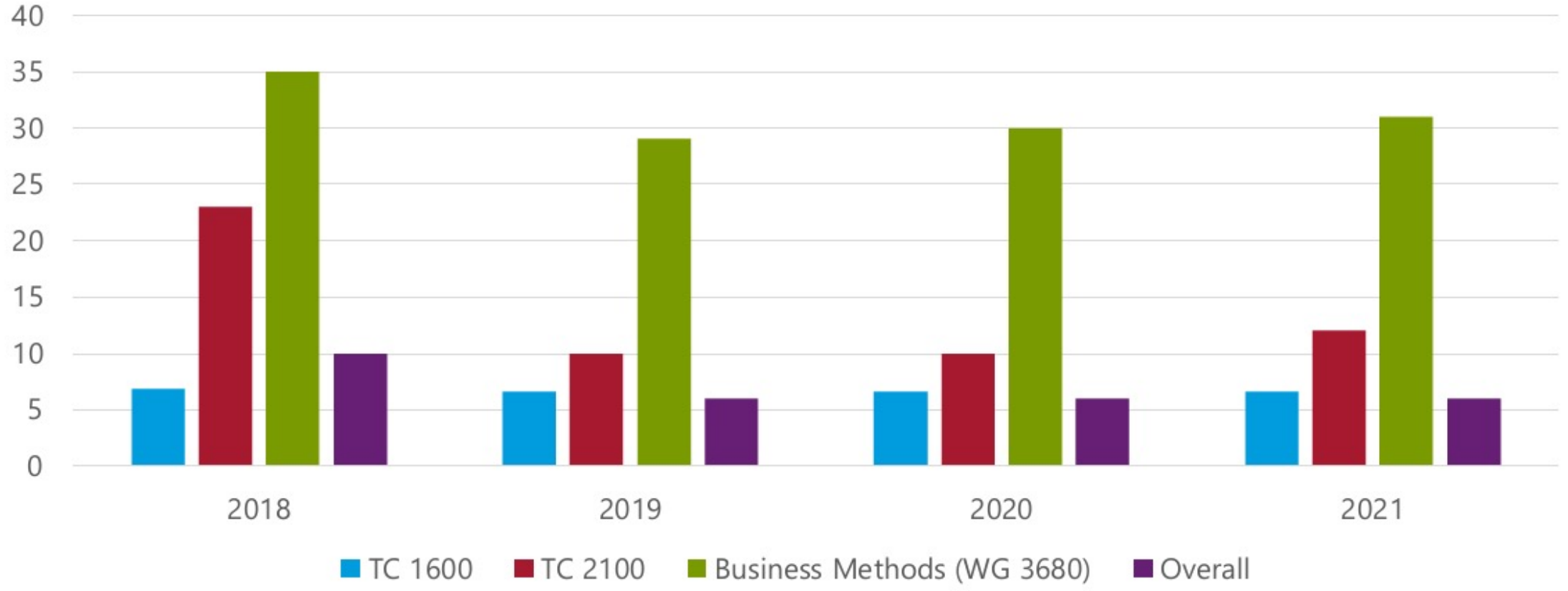
Considerations for Reformed § 101

- Restore gatekeeping function of § 101
- Retain the current statutory categories of eligible subject matter
  - processes, machines, manufactures, or compositions of matter, or useful improvements thereof
- Require consideration of claim as a whole
- Separate §§ 102, 103, 112 considerations from § 101
- Abrogate problematic § 101 case law

Next Steps

- USPTO Director Iancu calls for § 101 subject matter eligibility (SME) reform at farewell speech (January 2021)
- Deferred Subject Matter Eligibility Response (DSMER) Pilot Program (Feb 1 to July 30 2022) (87 Fed. Reg. 776 (1/6/22)
  - Initiated to respond to letter from Senators Tillis/Coons
  - temporary program deviating from traditional compact prosecution; available by invitation
  - participating applicants can defer SME rejections
  - Evaluate effect of deferral on exam efficiency, patent quality
- USPTO Welcomes New Director Kathi Vidal (April 2022)

101 Rejections as a Percentage of all Rejections



Matthew Sked OPLA/USPTO Presentation, "35 USC §101 Subject Matter Eligibility USPTO Guidance and Policy" (2/15/2022)

Divergence Between USPTO and Courts

- USPTO Director has a policy role
  - Issues guidelines on substantive patentability issues
  - Post-*Arthrex*, Patent Board will follow Director guidelines
  - Has no authority to make binding patentability rules
- Courts get to say what the law is
  - Courts can—and sometimes do—disagree with the guidelines
- Generous guidelines lead to marginal patents
  - §101 guidelines permit issuance of some patents that courts will not uphold

Patentability Issues Are Interrelated

- §101 utility interacts with §112
  - §112 enablement to use = §101 utility
    - Although they have different standards of review(!)
  - §112 description can depend on a plausible §101 utility
    - Limited/high-level description may suggest judicial exception
    - Laundry-list description may suggest simply routine & conventional
- §101 eligibility interacts with prior art
  - §101 judicial exceptions might not provide point of novelty
- Yet USPTO may defer examining §101 eligibility

Patentability “Squeezes”

- §102 anticipation is in tension with §112
  - §112 definiteness require a broad construction
    - Sufficient to be anticipated
    - Otherwise, the basis for a narrower construction might be missing
  - §112 description might require inherent disclosure
    - Which might support inherent anticipation
- §103 obviousness is in tension with §112 enablement
  - Lack of enabling disclosure might support obviousness
    - Or nonobviousness might support a lack of enablement

Post Grant Review (PGR) Implications

- PGRs can address §§101/112 issues
  - Can leverage the interplay with prior-art issues
- PGRs only cover AIA patents
  - Soon all patents will be AIA patents
- PGRs create broader estoppels for challengers but
  - They also prevent filing inter partes reviews for 9 months
  - Institution discretion might prevent waiting
- Amended claims in PGRs/IPRs can be challenged on any ground of unpatentability, including §§101/112

Some Further Reading

- V. Carrington & J. Contreras, *Assessing Responses to the PTO's 2021 Patent Eligibility Study*, PatentlyO (Feb. 1, 2022)
  - https://patentlyo.com/patent/2022/02/assessing-responses-eligibility.html
- C. Jacobsen et al., *Recent Trends For § 112 Challenges In PGRs*, Kluwer Patent Blog (Dec. 6, 2021)
  - http://patentblog.kluweriplaw.com/2021/12/06/recent-trends-for-%c2%a7-112-challenges-in-pgrs/

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