FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

KAISER FOUNDATION HEALTH PLAN INC., *Plaintiff-Appellant,* v. ABBOTT LABORATORIES, INC.; GENEVA PHARMACEUTICALS TECHNOLOGY CORPORATION, *Defendants-Appellees.*	No. 06-55687 D.C. No. CV-02-02443-JFW
KAISER FOUNDATION HEALTH PLAN INC., *Plaintiff-Appellee,* v. ABBOTT LABORATORIES, INC.; GENEVA PHARMACEUTICALS TECHNOLOGY CORPORATION, *Defendants-Appellants.*	No. 06-55748 D.C. No. CV-02-02443-JFW OPINION

Appeal from the United States District Court
for the Central District of California
John F. Walter, District Judge, Presiding

Argued and Submitted
February 4, 2008—Pasadena, California

Filed January 13, 2009

Before: Alex Kozinski, Chief Judge,
Diarmuid F. O'Scannlain, and William A. Fletcher,
Circuit Judges.

Opinion by Judge William A. Fletcher

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OPINION

W. FLETCHER, Circuit Judge:

Plaintiff-Appellant Kaiser Foundation Health Plan, Inc. ("Kaiser") sued Defendants-Appellees Abbott Laboratories ("Abbott") and Geneva Pharmaceuticals ("Geneva") for violations of the Sherman Antitrust Act and analogous provisions of California law. Kaiser brought a claim under Section One of the Sherman Act against both Abbott and Geneva, and a claim under Section Two against only Abbott. A multidistrict litigation federal district court in Florida allowed Kaiser's Section One claim to go to trial. The suit was transferred to a federal district court in California for trial on that claim. The jury returned a verdict against Kaiser. The district court in

Florida granted summary judgment against Kaiser on its Section Two claim.

We affirm the judgment entered on the jury's verdict on Kaiser's Section One claim. We reverse summary judgment on Kaiser's Section Two claim and remand for further proceedings.

I. Regulatory Background

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, governs the sale and manufacture of prescription drugs in the United States. Any entity seeking to distribute a new prescription drug must file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA"). The application must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1)(A). Upon approval by the FDA, a drug may be manufactured and sold in the United States. Drugs approved by the FDA under the NDA process are commonly referred to as "brand-name" drugs.

Brand-name drugs are typically protected by patents at the time of their approval by the FDA, and for a number of years thereafter. A patent holder has the exclusive right to make, use and sell the patented invention during the life of the patent. 35 U.S.C. § 154(a). A manufacturer of a brand-name drug protected by a patent is able to sell the drug at monopoly prices.

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the "Hatch-Waxman Act" or "Hatch-Waxman," was passed to facilitate the approval of generic versions of brand-name drugs. 21 U.S.C. § 355. Under Hatch-Waxman, a manufacturer seeking FDA approval of a new brand-name drug must file with its NDA the patent number and expiration date of

> any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

Id. § 355(b)(1). The brand-name drug and its associate patent or patents are then published in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book."

Under Hatch-Waxman, a drug manufacturer seeking FDA approval for a generic version of a brand-name drug may file an Abbreviated New Drug Application ("ANDA") showing that its proposed generic drug is the "bioequivalent" of an already approved brand-name drug. *Id.* § 355(j). The ANDA shall contain, with respect to patents for the already approved brand-name drug listed in the Orange Book,

> a certification . . .
>
> (I) that such patent information has not been filed,
>
> (II) that such patent has expired,
>
> (III) of the date on which such patent will expire, or
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted[.]

Id. § 355(j)(2)(A)(vii). Such a certification is referred to as a "Paragraph I," "Paragraph II," "Paragraph III," or "Paragraph IV" certification. The first ANDA applicant for approval of a generic version of a particular brand-name drug who makes a Paragraph IV certification is guaranteed a 180-day period of

exclusive distribution of the generic drug if that drug is approved by the FDA. The 180-day period begins either on the date the applicant notifies the FDA of its first "commercial marketing" of the generic drug, or on the date of the judicial decision holding the patent invalid or not infringed, whichever is earlier. *Id.* § 355(j)(5)(B)(iv).

An ANDA applicant who makes a Paragraph IV certification must notify the patent holder of that certification. *Id.* § 355(j)(2)(B). If an ANDA contains a Paragraph IV certification, FDA approval of the proposed generic drug must be "made effective immediately unless . . . an action is brought for infringement of the patent that is the subject of the certification" within forty-five days of the patent holder receiving notice of the certification. *Id.* § 355(j)(5)(B)(iii). If a patent holder brings suit within forty-five days, FDA approval will not become effective until thirty months after the receipt of the notice, subject to certain exceptions. *Id.* This thirty-month delay is commonly referred to as the "automatic stay." An exception to the thirty-month automatic stay is a final court decision in the patent holder's infringement suit that the patent is invalid or not infringed. In the event of such a court decision, FDA approval "shall be made effective on the date on which the court enters judgment reflecting the decision" if the court decision is less than thirty months after receipt of the notice.[1] *Id.* § 355(j)(5)(B)(iii)(I).

If a patent holder fails to bring an infringement suit within forty-five days of receipt of a Paragraph IV notification, it loses the right to the thirty-month automatic stay of FDA approval of the proposed generic drug. However, the patent holder does not lose the right to bring an infringement suit against the generic drug manufacturer; the patent holder simply loses the right to bring the infringement suit under Hatch-

[1]At the time relevant to our case, FDA regulations provided that a final court decision meant the decision of an appellate court or an unappealed decision of a district court. 21 C.F.R. § 314.107(e) (1989).

Waxman. A patent holder who misses the forty-five day deadline for bringing a Hatch-Waxman infringement suit suffers two significant disadvantages. First, the patent holder cannot bring an infringement suit immediately upon the filing of the ANDA; it must wait until the generic drug is sold commercially. *See* 35 U.S.C. § 271(e)(1). *See generally Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005). Second, there is no automatic stay barring the FDA from approving the generic drug. Once approved, its manufacturer may sell the generic drug during the pendency of any infringement suit brought by the patent holder.

II. Factual Background and Procedural History

Plaintiff-appellant Kaiser is a health care provider that buys large quantities of prescription drugs. Defendant-appellee Abbott is a large developer and manufacturer of brand-name drugs. Defendant-appellee Geneva is a large developer and manufacturer of generic drugs.

Abbott sought and obtained FDA approval through the NDA process to sell terazosin hydrochloride as a brand-name drug to treat hypertension and enlarged prostate. Abbott began selling terazosin hydrochloride, in tablet and capsule form, under the brand name Hytrin in 1987. The sale of Hytrin was extremely lucrative. In 1998, Hytrin generated $540 million in sales, accounting for more than twenty percent of Abbott's domestic sales of pharmaceutical products.

Abbott submitted three patents, described below, for inclusion in the Orange Book in connection with its NDA for terazosin hydrochloride.

Patent 4,026,894 ("the '894 patent") was filed on October 14, 1975, and issued on May 31, 1977. It protected terazosin hydrochloride. The '894 patent expired on May 31, 1994. No generic drug manufacturer ever challenged the validity of the

'894 patent or sought to market a generic terazosin hydrochloride product before its expiration.

Patent 4,112,097 ("the '097 patent"), a divisional application of the '894 patent, was filed on January 21, 1977, and issued on September 5, 1978. It protected a pharmaceutical composition of terazosin hydrochloride for treating hypertension and a method for treating hypertension with the drug. The '097 patent was scheduled to expire on September 5, 1995. In separate litigation, Abbott argued that the Uruguay Round Agreements Act extended the '097 patent's term until January 21, 1997. The Federal Circuit rejected Abbott's argument and held that the patent had expired on October 14, 1995. *See Abbott Labs. v. Novopharm Ltd.*, 104 F.3d 1305, 1308-09 (Fed. Cir. 1997). No generic drug manufacturer ever challenged the validity of the '097 patent or sought to market a generic terazosin hydrochloride product before October 14, 1995. However, Geneva and two other generic drug manufacturers filed ANDAs before January 21, 1997, certifying under Paragraph III that the '097 patent had expired on October 14, 1995.

Patent 4,251,532 ("the '532 patent") was filed on September 24, 1979, and issued on February 17, 1981. It protected dihydrate terazosin hydrochloride, its pharmaceutical composition, and a method for treating hypertension with dihydrate terazosin hydrochloride. The '532 patent expired on February 17, 2000. No generic drug manufacturer ever challenged the validity of the '532 patent.

Just as the '894 and '097 patents were about to expire, or had expired, Abbott filed three more patents for terazosin hydrochloride. They were as follows.

Patent 5,294,615 ("the '615 patent") was filed on July 13, 1993, and issued on March 15, 1994. It protected a crystalline polymorph of terazosin hydrochloride with a certain x-ray diffraction pattern ("Form II"). The '615 patent was listed in the

March 1995 supplement to the Orange Book, and was scheduled to expire on April 29, 2013.

Patent 5,412,095 ("the '095 patent") was filed on May 20, 1994, and issued on May 2, 1995. It protected a crystalline polymorph of terazosin hydrochloride with a different x-ray diffraction pattern ("Form III"). The '095 patent was listed in the Orange Book on May 8, 1995, and was scheduled to expire on April 29, 2013.

Patent 5,504,207 ("the '207 patent") was filed on October 18, 1994, and issued on April 2, 1996. It protected a crystalline polymorph of terazosin hydrochloride with a different x-ray diffraction pattern ("Form IV") and a process for preparing terazosin hydrochloride dihydrate using Form IV. The '207 patent was submitted to the FDA for listing in the Orange Book on April 2, 1996, and was scheduled to expire on April 29, 2013.

Geneva began work on a generic version of Hytrin in 1990 and subsequently filed two ANDAs related to terazosin hydrochloride. Geneva filed its first ANDA in January 1993, for a tablet form of generic terazosin hydrochloride ("tablet ANDA"). In December 1995, Geneva filed its second ANDA for a capsule form of generic terazosin hydrochloride ("capsule ANDA"). Between 1993 and 1996, Geneva made six Paragraph IV certifications related to these ANDAs and provided notice to Abbott for each certification. We describe the certifications in turn.

First, on January 12, 1993, Geneva provided Abbott notice of a Paragraph IV certification for its tablet ANDA with respect to the '532 patent. It asserted that its proposed generic terazosin hydrochloride would not infringe the '532 patent because its product was anhydrous ("without water") rather than dihydrate ("including water") terazosin hyrdochloride.

Second, on October 5, 1995, Geneva provided Abbott notice of a Paragraph IV certification for its tablet ANDA

with respect to the '097 patent. It asserted that the '097 patent expired on October 14, 1995. Geneva proposed to sell generic terazosin hydrochloride after October 14, 1995, but before January 21, 1997, the date Abbott claimed its '097 patent expired.

Third, also on October 5, 1995, Geneva provided Abbott notice of a Paragraph IV certification for its tablet ANDA with respect to the '095 patent. It asserted that its proposed generic terazosin hydrochloride would not infringe the '095 patent because its product used an anhydrous form of terzosin hyrdochloride different from the "Form III" claimed in the '095 patent.

Fourth, on February 16, 1996, Geneva provided Abbott notice of a Paragraph IV certification for its capsule ANDA with respect to the '615 patent. It asserted that its proposed generic terazosin hydrochloride would not infringe the '615 patent because its product contained "Form IV" terazosin hydrochloride rather than the "Form II" claimed in the '615 patent. (Abbott's '207 patent claiming Form IV terazosin hydrochloride was not issued until April 2, 1996, a month and a half after Geneva's Paragraph IV certification.)

Finally, on April 29, 1996, Geneva provided Abbott notice of two Paragraph IV certifications with respect to the '207 patent. One certification supplemented Geneva's tablet ANDA and the other supplemented Geneva's capsule ANDA. Geneva conceded that these two proposed products infringed the part of the '207 patent that protected Form IV terazosin hydrochloride, but it asserted this part of the '207 patent was invalid under 35 U.S.C. § 102(b). Section 102(b) bars patents on inventions that already have been patented, described in a printed publication, or sold in the United States more than one year before the patent application. The bar on patents for inventions previously sold in the United States is commonly referred to as the "on-sale bar."

Abbott filed timely suits under Hatch-Waxman in response to five of Geneva's six Paragraph IV certifications. In those five suits, Abbott received the thirty-month automatic stay of FDA approval. However, Abbott neglected to file a timely suit under Hatch-Waxman in response to Geneva's Paragraph IV certification with respect to the '207 patent for the capsule form of generic terazosin hydrochloride. The FDA proceeded to evaluate Geneva's capsule ANDA. Geneva received final FDA approval to market its capsule form of terazosin hydrochloride on March 30, 1998. At the time of the FDA approval, there had been no judicial determination of the validity of the '207 patent.

Between 1993 and 1998, seven generic drug manufacturers filed ANDAs seeking FDA approval of generic terazosin hydrochloride accompanied by Paragraph IV certifications. In chronological order of their ANDAs, those manufacturers were (in addition to Geneva) Novopharm, Zenith-Goldline ("Zenith"), Invamed, Lemmon Pharmacal, Warner-Chilcott, and Mylan Pharmaceuticals. Abbott filed infringement suits in response to all of the ANDAs, with the exception of Geneva's capsule ANDA that infringed the '207 patent. All told, Abbott filed seventeen patent infringement suits during this period in an attempt to preserve its Hytrin market monopoly.

On April 1, 1998, two days after the FDA approved Geneva's capsule ANDA, Abbott and Geneva entered into a contract. In brief, Geneva agreed to keep its generic capsule form of terazosin hydrochloride off the market until the earliest of (1) the sale of generic terazosin hydrochloride by another generic manufacturer, (2) the expiration date of the '532 patent (February 17, 2000), or (3) a final unappealable judgment holding the '207 patent invalid. In return, Abbott agreed to pay Geneva $4.5 million dollars per month during this period. If a final but appealable judgment holding the '207 patent invalid was rendered during the period, Abbott would pay the $4.5 million per month into escrow until the earliest of the three above-specified events occurred.

Abbott and Zenith had entered into a comparable contract the day before, on March 31, 1998. Like Geneva, Zenith had filed an ANDA in June 1994 seeking approval of a generic terazosin hydrochloride drug. Zenith successfully opposed two patent infringement suits brought by Abbott under its '615 patent. *See Abbott Labs. v. Zenith Labs.*, 934 F. Supp. 925, 928, 933-36 (N.D. Ill. 1995) ("*Zenith*"). Abbott then submitted its '095 and '207 patents for inclusion in the Orange Book. In March 1996, the FDA informed Zenith that it would have to amend its ANDA to provide a Paragraph IV certification with respect to these patents. Zenith declined to do so. Instead, it filed suit against Abbott alleging that the '095 and '207 patents had been improperly listed in the Orange Book and seeking an injunction requiring that they be delisted. Abbott counterclaimed for infringement.

In brief, Zenith agreed in its contract with Abbott to dismiss its delisting suit and not to sell any form of terazosin hydrochloride until another generic manufacturer began to sell generic terazosin hydrochloride or until the '532 patent expired (February 17, 2000), whichever occurred first. In return, Abbott agreed to dismiss its counterclaim and to pay Zenith $3 million immediately, $3 million after three months, and $6 million every three months thereafter until March 1, 2000, unless excused earlier by the terms of the contract. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1300 (11th Cir. 2003).

Among the seventeen suits brought by Abbott was an infringement suit under Hatch-Waxman against Geneva, Novopharm and Invamed alleging infringement of the '207 patent, which protected Form IV terazosin hydrochloride. (The suit against Geneva was based on its tablet ANDA rather than its capsule ANDA.) All three defendants contended that the '207 patent was invalid under the on-sale bar of 35 U.S.C. § 102(b). It was undisputed that there had been at least three sales of Form IV terazosin hydrochloride more than a year prior to the date Abbott filed its '207 patent. *Abbott Labs. v.*

Geneva Pharms., Inc., 182 F.3d 1315, 1317 (Fed. Cir. 1999) ("*Geneva II*"). At the time of the prior sales, neither the buyers nor the sellers knew that the terazosin hydrochloride sold was Form IV. However, the district court held that whether the parties to the prior sales were aware that the product contained Form IV terazosin hydrochloride was immaterial for purposes of the on-sale bar of § 102(b). *Abbott Labs. v. Geneva Pharms., Inc.*, 1998 WL 566884 (N.D. Ill. Sept. 1, 1998). The Federal Circuit affirmed, agreeing with the district court that the parties' knowledge was irrelevant under § 102(b), and holding the '207 patent invalid. *Geneva II*, 182 F.3d at 1318-19.

After the Federal Circuit held that Abbott's '207 patent was invalid, Abbott terminated its contracts with Geneva and Zenith. Geneva then entered the market with its generic capsule form of terazosin hydrochloride. Before Geneva entered the market, Kaiser had been buying brand-name Hytrin from Abbott for between 67 and 70 cents per tablet. After Geneva entered the market, Abbott offered to sell Hytrin to Kaiser at 10 cents per tablet. Kaiser declined Abbott's offer. Instead, it began purchasing generic terazosin hyrdochloride from Geneva.

On March 22, 2002, Kaiser filed suit against Abbott and Geneva in the Central District of California. Kaiser brought two claims under the Sherman Act, 15 U.S.C. §§ 1-2, and claims under the analogous provisions of California's Cartwright Act, California Business & Professional Code §§ 16720 *et seq.* (For simplicity's sake, we will refer only to Kaiser's claims under the Sherman Act.) Kaiser brought a restraint-of-trade claim against Abbott and Geneva under Section One of the Sherman Act, and a monopolization claim against only Abbott under Section Two. In 2003, Kaiser's suit was transferred to the District Court for the Southern District of Florida ("the MDL court") under 28 U.S.C. § 1407. Kaiser had not sued Zenith as part of its Section One claim, but

plaintiffs in other Section One suits transferred to the MDL court had done so.

The MDL court granted partial summary judgment to Kaiser on its restraint-of-trade claim, holding that Abbott and Geneva's agreement constituted a per se violation of Section One. *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1354 (S.D. Fla. 2000) ("*In re Antitrust Litig. I*"). It later granted summary judgment to Abbott on Kaiser's Section Two monopolization claim, holding that the *Noerr-Pennington* doctrine immunized Abbott's patent and litigation activity. *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1370 (S.D. Fla. 2004) ("*In re Antitrust Litig. II*"). The Eleventh Circuit reversed the district court's finding of a per se violation under Section One. *Valley Drug*, 344 F.3d at 1304-06. It remanded to the district court, indicating that the district court might be able to find a per se violation if it reframed its analysis. *Id.* at 1311-13. On remand, the district court again found a per se violation of Section One. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319-20 (S.D. Fla. 2005) ("*In re Antitrust Litig. III*"). At that point, all plaintiffs except Kaiser settled their Section One claims.

The MDL court then transferred Kaiser's entire suit back to the Central District of California. Kaiser's Section One claim went to trial on the issue of causation and damages. The jury was asked to decide whether Abbott and Geneva's contract had delayed Geneva's commercial sale of generic terazosin hydrochloride, and, if so, whether Kaiser had suffered damages as a result of the delay. After an eleven-day trial, the jury found that the contract had not caused any delay and that Kaiser had therefore suffered no injury.

Kaiser appeals. First, Kaiser appeals the entry of judgment on the jury's verdict on its Section One claim, contending that the district court made several erroneous evidentiary rulings. Second, Kaiser appeals the MDL court's grant of summary

judgment to Abbott on its Section Two claim. For the reasons that follow, we affirm the California district court's judgment on the jury's verdict on Kaiser's Section One claim. We reverse the MDL court's grant of summary judgment on Kaiser's Section Two claim.

III. Standard of Review

We review a grant of summary judgment de novo. *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883, 912 (9th Cir. 2008). We review the trial court's evidentiary rulings for abuse of discretion. *Hoffman v. Constr. Prot. Servs., Inc.*, 541 F.3d 1175, 1178 (9th Cir. 2008).

IV. Discussion

A. Section One Restraint-of-Trade Claim

Section One of the Sherman Act makes unlawful "[e]very contract, combination . . . , or conspiracy, in restraint of trade or commerce among the several States." 15 U.S.C. § 1. The MDL court held that Abbott and Geneva's agreement was a per se violation of Section One before transferring the case back to the California district court for trial. We do not revisit that holding.

1. Trial Court's Evidentiary Rulings

Kaiser challenges several evidentiary rulings made by the district court during the trial of Kaiser's Section One restraint-of-trade claim against Abbott and Geneva. We reverse an evidentiary ruling only if we find "that the district court abused its discretion and that the error was prejudicial." *Columbia Pictures Television, Inc. v. Krypton Broad. of Birmingham, Inc.*, 259 F.3d 1186, 1195 (9th Cir. 2001). We hold that all of Kaiser's evidentiary challenges fail and affirm the district court's entry of judgment against Kaiser.

a. Advice-of-Counsel Defense

Kaiser first challenges a ruling that prevented it from discovering privileged opinions of Geneva's counsel. Kaiser sought these opinions in order to counter what Kaiser portrayed as Geneva's advice-of-counsel defense. Abbott and Geneva presented evidence at trial that their agreement did not delay Geneva's marketing of its generic terazosin hydrochloride drug because Geneva did not want to risk bringing its product to market without the protection of an appellate decision holding the '207 patent invalid. If Abbott had prevailed in the '207 litigation and Geneva had already sold its generic version of the drug, Geneva would have faced potentially disastrous damages.

[1] "The privilege which protects attorney-client communications may not be used both as a sword and a shield. Where a party raises a claim which in fairness requires disclosure of the protected communication, the privilege may be implicitly waived." *Chevron Corp. v. Pennzoil Co.*, 974 F.2d 1156, 1162 (9th Cir. 1992) (citing *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991)). *See also United States v. Amlani*, 169 F.3d 1189, 1195-96 (9th Cir. 1999). Kaiser contends that Geneva was advised by its counsel to avoid taking its product to market without the protection of an appellate decision on Abbott's '207 patent, and that this alleged advice of counsel was used as a sword in the Section One litigation. Therefore, according to Kaiser, Geneva could not use the attorney-client privilege as a shield to conceal the actual advice given by counsel.

[2] If, as Kaiser argues, Geneva's defense was based on the advice of its attorneys, Kaiser should have had access to those otherwise privileged attorney-client communications. However, we agree with the district court that Geneva did not actually rely on an advice-of-counsel defense at trial. Geneva presented evidence that regardless of the assurances from Geneva's counsel and from Geneva's parent company's coun-

sel that Geneva would likely prevail in the '207 litigation, Geneva's Board of Directors did not want to undertake the business risk of marketing its generic terazosin hydrochloride drug so long as the validity of the '207 patent had not been authoritatively determined. Thus, Geneva's defense at trial was not that it acted based on advice of counsel. Instead, its defense was that it acted without regard to, or even contrary to, what counsel advised. Therefore, it was not an abuse of discretion for the district court to deny Kaiser access to Geneva's privileged communications. *See Home Indem. Co. v. Lane Powell Moss & Miller*, 43 F.3d 1322, 1326-27 (9th Cir. 1995).

b. Abbott's '207 Patent Litigation

Kaiser next challenges the district court's decision excluding evidence of Abbott's conduct in seeking the '207 patent. Kaiser hoped to use the evidence to demonstrate that Abbott had not acted in good faith when applying for the '207 patent, that Geneva knew about the nature of Abbott's conduct, and that Geneva therefore had no reason to believe that Abbott would prevail in the '207 patent litigation. The court excluded this evidence because of the MDL court's ruling that there was no evidence of misconduct in Abbott's patent prosecution and litigation activity, because the evidence was irrelevant to Geneva's liability, and because the prejudicial effect of the evidence "substantially outweighed" its probative value.

[3] Abbott's '207 patent application and its litigation defending the patent's validity were only marginally relevant to Kaiser's Section One causation and damages trial. *But see MCI Commc'ns Corp. v. AT&T*, 708 F.2d 1081, 1159-60 (7th Cir. 1983) (allowing evidence of behavior protected under *Noerr-Pennington* to be introduced for other relevant purposes). Even though Abbott might have acted improperly in seeking the '207 patent, as we discuss in a moment, the district court did not abuse its discretion in excluding the evidence.

c. Cumulative Effect of Other Evidentiary Decisions

[4] Finally, Kaiser challenges a series of exclusions that it argues compound the prejudice it suffered from the other two evidentiary rulings it challenges. Even viewed cumulatively, the exclusions do not constitute abuse of the district court's broad discretion on evidentiary matters, and we find no prejudice. *See Harper v. City of Los Angeles*, 533 F.3d 1010, 1030 (9th Cir. 2008).

2. Abbott and Geneva's Cross-Appeal

Because we affirm the district court's entry of judgment for Abbott and Geneva on Kaiser's Section One claim, we need not address Abbott and Geneva's cross-appeal of the MDL court's holding that the contract was a per se violation.

B. Section Two Monopolization Claim

Section Two of the Sherman Act makes it unlawful to "monopolize, or attempt to monopolize . . . trade or commerce among the several States." 15 U.S.C. § 2. Kaiser pursues both monopolization and attempted monopolization claims against Abbott. For a successful Section Two monopolization claim, a plaintiff must establish: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). For a successful attempted monopolization claim, a plaintiff must establish: "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993).

The holder of a patent enjoys a lawful monopoly to prevent others from "making, using, offering for sale, or selling" the

patented invention during the term of the patent. 35 U.S.C. § 154(a)(1)-(2). Abbott's initial patent-based monopoly in the terazosin hydrochloride market is not at issue. Rather, Kaiser contends that Abbott improperly tried to extend its patent monopoly by filing sham lawsuits in order to delay the entry of generic competition, and by fraudulently obtaining an invalid patent for the same purpose.

Even though Kaiser must ultimately prove the existence of a "sham" by clear and convincing evidence, it need only show that there is a genuine issue of material fact to avoid summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). This determination is made "through the prism" of the clear and convincing evidentiary standard. *Id.* at 254-55. There is no antitrust exception to the standard set forth in Federal Rule of Civil Procedure 56.

1. *Noerr-Pennington* Framework

[5] The *Noerr-Pennington* doctrine allows private citizens to exercise their First Amendment rights to petition the government without fear of antitrust liability. *See Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) ("*Noerr*"); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965) ("*Pennington*"). The Supreme Court has explained, "In light of the government's 'power to act in [its] representative capacity' and 'to take actions . . . that operate to restrain trade,' we reasoned that the Sherman Act does not punish 'political activity' through which 'the people . . . freely inform the government of their wishes.' " *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 56 (1993) (all alterations in original) (quoting *Noerr*, 365 U.S. at 137). *Noerr-Pennington* originally immunized only petitions to legislative officials, but the Supreme Court extended *Noerr-Pennington* immunity to petitions to administrative agencies and courts. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972).

[6] An entity loses *Noerr-Pennington* immunity from antitrust liability if its conduct falls within the "sham" exception to the doctrine. That is, "[t]here may be situations in which a publicity campaign, ostensibly directed toward influencing governmental action, is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor and the application of the Sherman Act would be justified." *Noerr*, 365 U.S. at 144. The Court has elaborated:

> The "sham" exception to *Noerr* encompasses situations in which persons use the governmental *process* —as opposed to the *outcome* of that process—as an anticompetitive weapon. A classic example is the filing of frivolous objections to the license application of a competitor, with no expectation of achieving denial of the license but simply in order to impose expense and delay. A "sham" situation involves a defendant whose activities are not genuinely aimed at procuring favorable government action at all, not one who genuinely seeks to achieve his governmental result, but does so *through improper means*.

City of Columbia v. Omni Outdoor Adver., Inc., 499 U.S. 365, 380 (1991) (citations and internal quotation marks omitted). We recently described three situations where the sham exception applies:

> [F]irst, where the lawsuit is objectively baseless and the defendant's motive in bringing it was unlawful; second, where the conduct involves a series of lawsuits brought pursuant to a policy of starting legal proceedings without regard to the merits and for an unlawful purpose; and third, if the allegedly unlawful conduct consists of making intentional misrepresentations to the court, litigation can be deemed a sham if a party's knowing fraud upon, or its inten-

> tional misrepresentations to, the court deprive the litigation of its legitimacy.

Sosa v. DIRECTV, Inc., 437 F.3d 923, 938 (9th Cir. 2006) (citations and internal quotation marks omitted).

[7] The third situation described in *Sosa* — "knowing fraud upon" or "intentional misrepresentations to" a court — has a particular meaning in patent infringement suits. In such suits, the fraud or misrepresentation may have been directed to the federal Patent and Trademark Office ("PTO"), not merely to a court. In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965), the Court held that an entity that obtains a patent fraudulently and then uses that patent to exclude a competitor from the market through infringement suits is not protected by *Noerr-Pennington*. This fraud-based exception to *Noerr-Pennington* is commonly called *Walker Process* fraud. *See also Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998) ("A patentee who brings an infringement suit may be subject to antitrust liability for the anti-competitive effects of that suit if the alleged infringer (the antitrust plaintiff) proves . . . that the asserted patent was obtained through knowing and willful fraud within the meaning of *Walker Process Equipment*[.]").

2. Application of the "Sham" Exception

Kaiser contends that two versions of the "sham" exception to *Noerr-Pennington* immunity apply in this case. First, Kaiser contends that Abbott's seventeen patent infringement suits against would-be generic manufacturers of terazosin hydrochloride between 1993 and 1998 constituted sham litigation. Second, Kaiser contends that Abbott obtained its '207 patent by *Walker Process* fraud and that its infringement suits based on the '207 patent therefore were a sham. The MDL district court granted summary judgment to Abbott, holding that there were no genuine issues of material fact with respect to either

contention, thereby upholding Abbott's defense of *Noerr-Pennington* immunity.

For the reasons that follow, we reverse the MDL court's grant of summary judgment. We agree with the MDL court's conclusion that Kaiser has not produced evidence that would allow it to avoid summary judgment on its claim of sham litigation. However, we disagree with the MDL court's conclusion that Kaiser has not produced sufficient evidence to avoid summary judgment on its claim of *Walker Process* fraud.

a. Sham Litigation

Kaiser contends that Abbott's seventeen infringement suits against the seven would-be manufacturers of generic terazosin hydrochloride constitute sham litigation. Kaiser argues that Abbott's litigation was an attempt to use the judicial process, rather than favorable judicial outcomes, to extend improperly its terazosin hydrochloride monopoly. *See Omni Outdoor Adver., Inc.*, 499 U.S. at 380.

[8] We discussed the sham litigation exception to *Noerr-Pennington* at length in *USS-POSCO Industries v. Contra Costa County Building & Construction Trades Council*, 31 F.3d 800 (9th Cir. 1994). We took pains in *USS-POSCO* to reconcile the Supreme Court's opinions in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries*, 508 U.S. 49 (1993), and *California Motor Transport v. Trucking Unlimited*, 404 U.S. 508 (1972), both of which dealt with the sham litigation exception to *Noerr-Pennington*. We wrote:

> We reconcile these cases by reading them as applying to different situations. *Professional Real Estate Investors* provides a strict two-step analysis to assess whether a single action constitutes sham petitioning. This inquiry is essentially retrospective: If the suit turns out to have objective merit, the plaintiff

> can't proceed to inquire into subjective purposes, and the action is perforce not a sham.
>
> *California Motor Transport* deals with the case where the defendant is accused of bringing a whole series of legal proceedings. Litigation is invariably costly, distracting and time-consuming; having to defend a whole series of such proceedings can inflict a crushing burden on a business. *California Motor Transport* thus recognized that the filing of a whole series of lawsuits and other legal actions without regard to the merits has far more serious implications than filing a single action, and can serve as a very effective restraint on trade. When dealing with a series of lawsuits, the question is not whether any one of them has merit—some may turn out to, just as a matter of chance—but whether they are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival. The inquiry in such cases is prospective: Were the legal filings made, not out of a genuine interest in redressing grievances, but as part of a pattern or practice of successive filings undertaken essentially for purposes of harassment?

USS-POSCO, 31 F.3d at 810-11 (internal citation omitted).

Kaiser asks us to apply the *California Motor Transport* test for sham litigation, as we described that test in *USS-POSCO*, because Abbott brought a "series of legal proceedings." Abbott objects to our application of *USS-POSCO* (and *California Motor Transport*) on the ground that Kaiser asked the MDL court to apply only the *Professional Real Estate Investors* test. We need not decide whether Kaiser has waived its argument that the *California Motor Transport* test applies, for even under that test Kaiser loses its sham litigation claim.

The MDL court carefully analyzed each of the seventeen suits brought by Abbott against the would-be generic manu-

facturers. *In re Antitrust Litig. II*, 335 F. Supp. 2d at 1356-65. Abbott won seven of the seventeen suits. It lost the other ten, but in each of the ten cases it had a plausible argument on which it could have prevailed.

Two of the ten suits depended on whether a Hatch-Waxman infringement suit could be brought based on a patent that was not listed in the Orange Book. This was a question of first impression. The district court held against Abbott, but only after detailed and careful analysis. *Zenith*, 934 F. Supp. at 933-36. Two more of the suits depended on whether the Uruguay Round Agreements Act of 1994 extended the life of Abbott's '097 patent for three years. The MDL court wrote, "The [Uruguay Round] treaty was new, the provision had not been the subject of prior interpretation, and [Abbott's] argument, while hypertechnical, passed the 'straight face' test." *In re Antitrust Litig. II*, 335 F. Supp. 2d at 1359.

The last six suits were all infringement suits brought by Abbott to enforce its '207 patent. The MDL court viewed these suits as presenting the closest question. *Id.* at 1360. The same issue was litigated in all six of these suits — whether the on-sale bar of 35 U.S.C. § 102(b) invalidated Abbott's '207 patent on Form IV terazosin hydrochloride. Abbott admitted that Form IV terazosin hydrochloride had been sold more than a year before Abbott sought its '207 patent, but it argued that the on-sale bar did not apply because neither the seller nor the buyer knew that Form IV terazosin hydrochloride had been sold. The Federal Circuit ultimately resolved all six suits by holding that the sellers' and buyers' knowledge was irrelevant to the on-sale bar. *Geneva II*, 182 F.3d at 1318-19. The court's decision was influenced by the Supreme Court's decision in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), which was rendered after Abbott filed its suits.

[9] There is insufficient evidence in this record to allow a jury to conclude that Abbott's seventeen suits constituted "sham" litigation within the meaning of the exception to

Noerr-Pennington. It is true that Abbott was litigious, but to some degree its litigiousness was a product of Hatch-Waxman. Abbott filed suit quickly in order to preserve its rights under Hatch-Waxman, but it did not persist in litigating when it became obvious that the suits were baseless. Further, the volume of Abbott's suits was dependent on the number of generic companies attempting to enter the terazosin hydrochloride marketplace, a matter over which Abbott had no control.

b. *Walker Process* Fraud

Kaiser contends that Abbott obtained its '207 patent through *Walker Process* fraud. The district court concluded that Kaiser had not presented "any evidence" to support its *Walker Process* fraud contention. *In re Antitrust Litig. II*, 335 F. Supp. 2d at 1370. We disagree.

[10] "[T]he enforcement of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act . . . ." *Walker Process*, 382 U.S. at 174. " '[T]o strip [a patentee] of its exemption from the antitrust laws' because of its attempting to enforce its patent monopoly, an antitrust plaintiff is first required to prove that the patentee 'obtained the patent by knowingly and willfully misrepresenting facts to the [PTO].' " *Nobelpharma AB*, 141 F.3d at 1068 (quoting *Walker Process*, 382 U.S. at 177) (alterations in original). "The plaintiff in the patent infringement suit must also have been aware of the fraud when bringing suit." *Id.* at 1069. An antitrust plaintiff must produce "independent and clear evidence of deceptive intent [on the part of the patentee] together with a clear showing . . . that the patent would not have issued but for the misrepresentation or omission." *Id.* at 1071. "Direct evidence of intent to deceive or mislead the PTO is rarely available but may be inferred from clear and convincing evidence of the surrounding circumstances." *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1133-34 (Fed. Cir. 2006) (internal quotation marks omitted).

The patentee's good faith before the PTO "would furnish a complete defense." *Walker Process*, 382 U.S. at 177. "This includes an honest mistake as to the effect of prior [art] upon patentability—so-called 'technical fraud.' " *Id.* Inequitable conduct may render a patent invalid, but it is not enough to bring a patentee's conduct within the *Walker Process* exception to *Noerr-Pennington* immunity. *See Nobelpharma AB*, 141 F.3d at 1070 ("Inequitable conduct is thus an equitable defense in a patent infringement action and serves as a shield, while a more serious finding of fraud potentially exposes a patentee to antitrust liability and thus serves as a sword."); 37 C.F.R. § 1.56 ("[N]o patent will be granted on an application in connection with which fraud on the [PTO] was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct.").

[11] Rule 56 of the PTO specifies that a patent applicant has "a duty to disclose to the [PTO] all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a). Materiality is broadly defined under the rule: "[I]nformation is material to patentability when it . . . establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or it refutes, or is inconsistent with, a position the applicant takes in . . . [a]sserting an argument of patentability." *Id.* § 1.56(b)(1), (b)(2)(ii). A patent may not issue if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b).

Kaiser claims that Abbott committed *Walker Process* fraud in seeking its '207 patent. Kaiser points to two pieces of information that it contends were material to the § 102(b) bar but that Abbott failed to provide to the PTO in connection with its application for the '207 patent.

[12] First, Kaiser points to Abbott's failure to provide with its '207 patent application an English translation of an earlier

Japanese patent application for Form IV terazosin hydrochloride. Abbott applied for its '207 patent on October 18, 1994. More than a year earlier, in March 1993, the Sumika Fine Chemical Company published a Japanese Patent Application ("the Sumika reference") disclosing seven crystal forms of terazosin hydrochloride. It is undisputed that one of the crystal forms in the Sumika reference was the Form IV terazosin hydrochloride described in Abbott's application for the '207 patent. Thus, if the patent examiner had fully understood the Sumika reference, he would have concluded that Abbott's patent application should have been denied because it was "described in a printed publication in . . . a foreign country . . . more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b).

Abbott submitted a PTO Form 1449 in connection with its patent application for Form IV terazosin hydrochloride. The Form indicated that an English translation of the Sumika reference was included in the application. However, the patent examiner testified in his deposition that the English translation was not, in fact, included in the application. The examiner had written "(Abstract only)" in the file, thereby indicating that only an English-language abstract, rather than an English translation of the entire reference, had been provided.

The Abbott in-house attorney who prepared and submitted the application for the '207 patent testified in a 1997 deposition that he had intended to submit the English translation of the Sumika reference with the application, but that he could not remember actually having done so:

> Q: What was your general practice at the time in having your secretary fill out Form 1449s? How did you generally do that in the '94-'95 time frame?
>
> A: Generally by giving her a stack of copies of the references.

Q: And that is what you did in this instance?

A: I don't recall.

. . .

Q: Do you recall whether or not you included [the English translation of the Sumika reference] in the documents that you gave to your secretary to fill out Form 1449?

A: I just answered no, I don't recall whether that document was in that collection.

. . .

Q: Did you submit an English-language translation of Japanese Patent Application 5-78,352 to the United States Patent Office during the prosecution of the application upon which the '207 patent was issued?

A: That was certainly my intent and —

Q: Well, did you do that?

A: Do I recall specifically doing that? No.

The patent examiner could not read Japanese. However, he could read Chinese, and could understand kanji characters in Japanese because they are the same as Chinese characters.[2] He testified that he was able to read words such as "invention" and "name," and he remembered that he had been able to read two tables, including one referring to "crystalline forms and their characteristics." But he testified that he was unable to

[2]The patent examiner spelled out "K-A-N-G-I" in his deposition. The more common spelling is "kanji."

read the entire Sumika reference. The examiner also testified that he had seen the English translation of the Sumika reference because it had been submitted in connection with Abbott's earlier application for the '095 patent, which was still pending when he was considering Abbott's application for the '207 patent.

Second, Kaiser points to Abbott's failure to mention a decision of the Federal Circuit, *J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577 (Fed. Cir. 1986), in its application for the '207 patent. In December 1995, more than a year after its initial application for the '207 patent for Form IV terazosin hydrochloride, Abbott submitted an Information Disclosure Statement ("IDS") and a Supplemental IDS to the PTO. These documents were prepared by the same in-house Abbott attorney who had prepared the initial application. These supplemental documents revealed that there had been two prior public sales of Form IV terazosin hydrochloride, more than one year before the patent application was filed. *In re Antitrust Litig. II*, 335 F. Supp. 2d at 1354. These prior sales had come to light in the litigation challenging patent '207's validity, to which Abbott was a party. Independently of the Sumika reference, these sales likely prevented Abbott from obtaining a patent on Form IV terazosin hydrochloride because they appeared to come within the on-sale bar of § 102(b). Abbott's only hope was to argue that the parties to these prior sales had not known that the product contained Form IV terazosin hydrochloride, and that the sales had therefore not come within the scope of the on-sale bar.

Abbott first made this knowledge-of-the-parties-to-the-sale argument in a brief in the litigation in which these sales had come to light. Abbott's in-house attorney later made the same argument to the PTO in Abbott's IDS and Supplemental IDS. The in-house attorney used substantially the same language as in the litigation brief, but with one exception. Abbott's litigation brief had included a citation to the *LaPorte* case, and an attempt to distinguish it. Abbott's in-house attorney failed to

include any reference to *LaPorte* in the documents submitted to the PTO.

In *LaPorte*, the inventor of an extension to a dredging drill had allowed others to sell his invention. More than a year later, the inventor and two assignees sought to patent the extension. They argued that the on-sale bar did not apply to sales by anyone other than the inventor unless the invention was publicly disclosed at the time of the sale. In this case, there had been no such disclosure. The Federal Circuit rejected the inventor's argument. It wrote, *inter alia*, "[O]ur precedent holds that the question is not whether the sale, even a third party sale, 'discloses' the invention at the time of the sale, but whether the sale relates to a device that *embodies* the invention." 787 F.2d at 1583 (emphasis in original).

The Federal Circuit ultimately resolved the on-sale bar issue adversely to Abbott, holding in *Geneva II*, that the buyers' and sellers' lack of knowledge of the presence of Form IV terazosin hydrochloride was irrelevant to the on-sale bar. The court principally relied on *Pfaff*, a recent Supreme Court case, but it also relied on *LaPorte*, quoting the sentence that we have quoted in the previous paragraph. 182 F.3d at 1318-19.

When the MDL court granted summary judgment to Abbott on the *Walker Process* fraud issue, it wrote, "Plaintiffs . . . have not presented any evidence that Abbott acted knowingly and willfully with a clear intent to deceive the PTO, or that the omission of either the complete English-language translation of the Sumika reference or the *LaPorte* decision would have prevented the PTO from issuing the '207 patent." *In re Antitrust Litig. II*, 335 F. Supp. 2d at 1370. We disagree with the district court that Kaiser did not present "any evidence" that there was an intent to deceive or that, in the absence of the deceit, the patent would nonetheless have issued. We divide our discussion of the evidence into two parts — evi-

dence of intent to deceive the PTO, and evidence of the effect of the deceit.

First, we believe that Kaiser provided sufficient evidence to get to the jury on whether Abbott intended to deceive the PTO. As the Federal Circuit wrote in *Purdue Pharma L.P.*, direct evidence of intent to deceive the PTO in a patent application is "rarely available." 438 F.3d at 1133-34. For example, it would be naive to expect that someone who had sought to deceive the PTO would state in a deposition that this had been his intent. We are therefore generally obliged to rely on circumstantial evidence in *Walker Process* fraud cases.

Abbott needed the '207 patent to maintain its monopoly on Hytrin. In its original NDA for terazosin hydrochloride, Abbott had relied on three patents — the '894, '097 and '532 patents. The '894 patent expired on May 31, 1994. The '097 patent was scheduled to expire on September 5, 1995. And the '532 patent did not protect certain forms of terazosin hydrochloride. Therefore, beginning on July 13, 1993, Abbott applied for three additional patents, to protect Forms II, III, and IV terazosin hydrochloride. The '207 patent, protecting Form IV terazosin hydrochloride, was the last of these three additional patents to be filed.

[13] It is of course possible that a competent in-house attorney could indicate on PTO Form 1449 that a particular document was included in a patent application, but then inadvertently fail to include that document in the application. But several things suggest that the failure to include the English translation of the Sumika reference was not inadvertent. We begin with the unavoidable fact that the English translation of the Sumika reference was the only document in the initial application that, if fully understood by the patent examiner, would have resulted in a denial of the application. There was thus a substantial incentive not to include the translation.

[14] Later conduct by Abbott's in-house attorney in connection with the application for the '207 patent suggests that the omission of the English translation was not inadvertent. When the attorney submitted supplemental information to the PTO about prior sales of Form IV terazosin hydrochloride, he failed to mention the *LaPorte* case when arguing that lack of knowledge of the parties to an earlier sale of the invention meant that the sale did not trigger the on-sale bar of 35 U.S.C. § 102(b). The attorney's failure to mention *LaPorte* was unlikely to have been inadvertent, given that the attorney took his argument from a litigation brief filed by Abbott that had specifically mentioned and distinguished *LaPorte*.

Prior conduct by the same in-house attorney, in connection with Abbott's application for the '095 patent, also suggests that the omission was not inadvertent. Five months before its application for the '207 patent for Form IV terazosin hydrochloride, Abbott submitted its application for the '095 patent for Form III terazosin hydrochloride. In connection with this '095 application, the in-house attorney submitted the English translation, as well as a different English abstract, of the Sumika reference. Why, if he had submitted the translation with the application for the '095 patent, would he have failed to include it with the application for the '207 patent? A possible answer is that the Sumika reference was fatal to the patentability of Form IV terazosin hydrochloride (the '207 patent), but did not pose a substantial threat to the patentability of Form III (the '095 patent).

The English language abstracts submitted by Abbott's in-house attorney in connection with the two applications suggest that the in-house attorney knew he had more to fear from an accurate description of the Sumika reference in the '207 application than in the '095 application. The English abstract of the Sumika reference submitted with the '095 application specifically stated that the Sumika reference contained seven crystal forms:

> Japanese KoKai Patent . . . , published March 30, 1993 to Sumika Fine Chemicals, Ltd., which discloses seven crystalline modifications of terazosin hydrochloride and their preparation.

By contrast, the English abstract of the Sumika reference submitted with the '207 application, five months later, was less specific:

> Published Japanese Patent Application . . . to Sumika Fine Chemical Co., Ltd., which discloses and claims crystalline modifications of anhydrous terazosin hydrochloride.

An affidavit from Kaiser's scientific expert shows why Abbott had less to fear from the Sumika reference in its application for the '095 patent than in its application for the '207 patent. The expert compared the crystalline forms contained in the Sumika reference to Form III and Form IV. In assessing the match between the relevant Sumika crystal and Form III (the '095 patent), the expert could not say conclusively that they were the same, even though it was in Kaiser's interest that he do so. He could write only that the "two powder patterns are actually a reasonably good match" and that the Sumika crystal "appears" to be the same as Form III. By contrast, in assessing the match between the relevant Sumika crystal and Form IV (the '207 patent), the expert was confident that they were the same. He wrote that "the two patterns [ ] match up very well. . . . I conclude that the Sumika Type A-2 crystal form . . . is the same crystal form as the Abbott Form IV . . . reported in the '207 patent."

[15] We do not, of course, ourselves conclude that Abbott's in-house attorney deliberately failed to include the English translation of the Sumika reference. But we hold that there is enough circumstantial evidence in the record to support a jury's conclusion to that effect.

Second, we believe that Kaiser presented sufficient evidence to get to the jury on whether the failure to include the English translation of the Sumika reference enabled Abbott to obtain a patent that it would not have otherwise obtained. We start with the undisputed proposition that if the patent examiner had fully understood the Sumika reference, he would have denied Abbott's application for a patent of Form IV terazosin hydrochloride. The question then becomes whether the patent examiner would have understood the significance of an English translation of the Sumika reference if it had been part of the application for the '207 patent, and whether he would have concluded that the application therefore had to be denied.

Abbott contends that it would have made no difference if the examiner had had the English translation in connection with the '207 patent application. Abbott points out that during the period the examiner was evaluating the '207 patent application, he had the English translation of the Sumika reference before him as part of Abbott's earlier application for the '095 patent. Therefore, Abbott argues, the failure to submit the English translation with the '207 application made no difference to the outcome of that application.

However, the examiner did not testify that he even read the English translation from the '095 application when he was evaluating the '207 application. The examiner testified that he saw the English translation of the Sumika reference, but that he did not recall reading it:

> Q: Do you recall at any time during the pendency of the application upon which the '207 patent issued seeing a full English language translation of [the Sumika reference]?
>
> A: Yes, I do.
>
> Q: Under what circumstances did you see that translation?

A: It was in the file of a related case filed by the same applicant on this related subject matter, terazosin.

Q: What were the full facts and circumstances under which you saw that full English translation of the Japanese application?

A: I can only remember that when I was looking at files of related cases I recall seeing such a translation.

Q: Did you read it if you recall?

A: I cannot recall that I read it now.

Abbott argues further that because the English translation of the Sumika reference was included in the application for the '095 patent, and because that patent was granted, we should conclude that the '207 patent would also have been granted. Abbott writes in its brief to us, "[T]he PTO issued the '095 patent even though Abbott indisputably submitted the translation with that application . . . . There is no reason to believe that the outcome for the '207 patent would have been any different." In making this argument, Abbott fails to take into account the significantly weaker match between the Sumika reference crystals with Form III (the '095 patent) than with Form IV (the '207 patent) terazosin hydrochloride. Contrary to Abbott's contention, the significantly weaker match with Form III is a "reason to believe that the outcome for the '207 patent would have been different."

We do not, of course, decide that if the English translation had been included with Abbott's '207 patent application the application would have been denied. But we hold that there is enough evidence in the record to support a jury's conclusion to that effect.

3. Statute of Limitations

Because the MDL court ruled against Kaiser based on *Noerr-Pennington*, it did not reach Abbott's statute of limitations defense. We decline to decide that question in the first instance. That question may be presented to the district court on remand.

V. Conclusion

[16] For the foregoing reasons, we affirm the California district court's entry of judgment against Kaiser on its Sherman Act Section One claim. We reverse the MDL court's summary judgment against Kaiser on its Section Two claim. We remand for further proceedings consistent with this opinion.

AFFIRMED in part, REVERSED in part and REMANDED for further proceedings. Each side is to bear its own costs on appeal.