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EXECUTIVE SUMMARY

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PRACTICE GROUPS

Patent Litigation as a Business Tool: The Case Study of Bayer HealthCare LLC v. Abbott Laboratories

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Patents and patent litigation are critical business tools for technology-driven companies. The current dispute between Bayer HealthCare LLC (Bayer) and Abbott Laboratories over rights to patented human monoclonal antibodies offers an excellent case study of the use of patent litigation as a business tool. It involves numerous procedural issues relating not only to the filing and defense of such lawsuits, but also to the process by which patent rights that have real value as market exclusion tools may be obtained.

The Lawsuits

Bayer sued Abbott Laboratories and two related defendants (collectively, Abbott) in the United States District Court for the Eastern District of Texas on December 24, 2008.[1] The complaint alleges that Abbott Laboratories' HUMIRA® antibody product infringes Bayer's U.S. Patent No. 5,654,407 (the '407 patent).[2] The complaint also alleges that the defendants had been aware of the '407 patent and thus are willfully infringing the patent.

[1] No. 6:08-cv-00507 (E.D. Tex.).
[2] The '407 patent issued on August 5, 1997 on Application No. 08/435,246 (the '246 application), filed on May 5, 1995. The '246 application, however, was preceded by and claimed priority to two earlier applications. This priority claim allowed the '246 application to benefit from the filing dates of the earlier applications. *See* 35 U.S.C. § 120 (2006). Neither of the earlier applications resulted in an issued patent, and there are no other related patent applications pending.

Abbott responded twelve days later by filing a separate lawsuit against Bayer in the United States District Court for the District of Massachusetts, requesting a declaratory judgment that the '407 patent was not infringed, was invalid, and was unenforceable.[3]

On February 11, 2009, Abbott filed an unopposed motion to transfer the Texas case to the district court in Massachusetts.[4] The Eastern District of Texas granted the motion on February 13, 2009, and transferred the case to the Massachusetts court on March 6, 2009.

On February 26, 2009, Bayer filed its answer to Abbott's complaint in the Massachusetts case. In its answer, Bayer denies Abbott's allegations that the '407 patent is not infringed, is invalid, and is unenforceable, and adds its own allegation of infringement as a counterclaim. On March 2, 2009, Abbott filed its answer to Bayer's complaint; this answer is somewhat more informative than Bayer's answer. Abbott denies Bayer's infringement allegation, and raises the affirmative defenses of failure to state a claim, noninfringement, invalidity, waiver and equitable estoppel, laches, implied license, prosecution history estoppel, and limitation of damages under 35 U.S.C. § 287. Additional information pertaining to some of these defenses is discussed below.

The Patent Claims at Issue

Critical to success of patent litigation as a business tool is selection of the proper patent claims to assert. The claims of a patent define the scope of the property rights granted to or held by the patent holder.[5] In the cases under consideration, the '407 patent contains twelve claims, the broadest of which reads:

> 1. A composition comprising human monoclonal antibodies that bind specifically to human tumor necrosis factor alpha.[6]

[3] No. 4:09-cv-40002 (D. Mass.).
[4] Technically, this was a motion to "change venue"; *see infra* at 4-5 for a discussion of the concept of venue.
[5] *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) ("It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" (citing *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004))).
[6] '407 patent, claim 1.

The Product at Issue

Also critical to the success of patent litigation is selection of an appropriate product target. The Abbott product accused of infringement is known variously as HUMIRA® or adalimumab. It is a human-derived recombinant IgG1 monoclonal antibody that binds to TNF-α. The Food and Drug Administration (FDA) first approved the drug on December 31, 2002, for the treatment of rheumatoid arthritis; the FDA has since approved the drug for two other forms of arthritis, as well as for ankylosing spondylitis, Crohn's disease, and plaque psoriasis.[7] HUMIRA® has generated significant revenues for Abbott, with 2008 sales reaching $4.5 billion.[8]

Law Relating to the Suits

Jurisdiction: Where Patent Suits Can Be Brought

All suits for patent infringement must be brought in federal district courts, which have exclusive "subject matter jurisdiction" over such lawsuits.[9] Theoretically, a patent suit could be brought in any federal district court that has "personal jurisdiction" over the defendant. The determination of whether a court has personal jurisdiction is based largely on whether the defendant actively conducts business in the judicial district in which the court sits.[10] Because Abbott presumably sells its product in all fifty states, Bayer probably could have established personal jurisdiction over Abbott in any district court in the United States. Bayer likely selected the Eastern District of Texas because of a widely held perception that that court offers a shorter time to trial and plaintiff-friendly

[7] The FDA approved use for psoriatic arthritis on October 4, 2005, for ankylosing spondylitis on July 31, 2006, for Crohn's disease on February 27, 2007, for moderate to severe chronic plaque psoriasis on January 18, 2008, and for moderately to severely active polyarticular juvenile idiopathic arthritis on February 22, 2008.

[8] *HUMIRA sales lift Abbott 4Q profit 28%*, ASSOCIATED PRESS, Jan. 21, 2009.

[9] 28 U.S.C. 1338(a) (2006) ("The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents . . . .").

[10] For out-of-state defendants, the district court must follow a two-step test, first determining whether the state "long-arm" statute permits service of process on the defendant, and if so, then determining whether the court's exercise of personal jurisdiction would satisfy due process requirements. *Breckenridge Pharm., Inc. v. Metabolite Lab., Inc.*, 444 F.3d 1356, 1360-61 (Fed. Cir. 2006). In the latter step, the court considers whether the defendant "purposefully directed" its activities at the forum state and, if so, whether the litigation resulted from alleged injuries that arise out of or relate to those activities. *Id.* at 1361-62. Even if the court answers both of these questions in the affirmative, the defendant can still defeat jurisdiction if it can present a compelling case that the presence of other considerations would render jurisdiction unreasonable. *Id.*

juries. Not surprisingly, when Abbott filed its own suit, it chose to file closer to home in the District of Massachusetts; Abbott Bioresearch Center Inc., one of the related defendants in the Texas lawsuit, is headquartered in Massachusetts.

As a declaratory judgment plaintiff, Abbott also had to establish that there was a substantial controversy between the parties. This is often shown by the patent holder's conduct, such as an overt threat to enforce its patent. In this case, Abbott used Bayer's Texas lawsuit to establish that there was a substantial controversy and that the Massachusetts court thus had jurisdiction.

Venue: Where a Particular Suit Should Be Heard

Where parallel lawsuits relating to the same controversy are pending in different district courts—as they were here before the grant of Abbott's motion to transfer—one early procedural matter for the two courts to resolve is to determine which court will hear the dispute. This involves an assessment as to whether "venue" is proper in the particular court under 28 U.S.C. § 1404.[11] While personal jurisdiction involves the question of whether the court has the power to hear the suit at all, venue involves the question of whether the court is the best forum for the suit. The factors a district court will consider in deciding whether to transfer a case under Section 1404 include, among others, the ease of access to sources of proof; the availability of witnesses and the cost for them to attend the proceedings; issues of court congestion; and the public interest in having localized interests decided at home.[12]

Recently, the Court of Appeals for the Federal Circuit, which is the appellate court that hears appeals of patent cases, considered a venue dispute that arose in the Eastern District of Texas, where Bayer's suit was filed.[13] In that case, an Ohio-based defendant had petitioned to transfer a patent suit from the court in Texas to an Ohio court, but the Texas judge denied the defendant's motion. On appeal, the Federal Circuit reversed the Texas judge's ruling and ordered the case to be transferred. The Federal Circuit's

[11] "[F]or the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to another district court or division where it might have been brought." 28 U.S.C. § 1404(a) (2006).
[12] *See Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 241 n.6 (1981); *In re Volkswagen of Am., Inc.*, 545 F.3d 304, 315 (5th Cir. 2008) (en banc).
[13] *In re TS Tech USA Corp.*, 551 F.3d 1315 (Fed. Cir. 2008).

decision will likely make it easier to transfer cases out of district courts within the Fifth Circuit, which includes Texas.[14] The decision already has been cited by at least two judges in the Eastern District of Texas in ruling to transfer cases out of the Eastern District of Texas.[15] In view of these developments, Bayer may have believed that it had little chance of successfully opposing a motion to transfer its lawsuit to Massachusetts and thus chose not to oppose Abbott's motion.

Patent Infringement Basics

A patent can be infringed by making, using, importing, selling, or offering to sell anything that contains elements corresponding to all the limitations of at least one claim of the patent.[16] Patent claims that use the term "comprising," like Claim 1 of the '407 patent, will be infringed if all of the elements set forth in the claim are found in the accused product, even if the product also contains other features.[17] In simplified terms, "comprising" means "including but not limited to," such that a "comprising"-type patent claim with limitations A, B, and C would still be infringed by a product having elements A, B, C, and D, but would not be infringed by a product having elements A, B, and D, because of the missing element C. Thus, for Bayer to establish that HUMIRA® infringes Claim 1 of the '407 patent, it will only be necessary to show that HUMIRA® meets all of the limitations of that claim, including that it contains "human" monoclonal antibodies that bind "specifically" to human tumor necrosis factor alpha.

Although at times raised as part of an accused infringer's defenses, it is not a separate defense to a charge of patent infringement that the defendant owns a patent that

[14] The Federal Circuit noted that the plaintiff's choice of court is not a separate factor in the venue analysis and emphasized that the cost of witness attendance and the ease of access to sources of proof, as well as the public interest in having localized interests decided at home, must be given weight in the venue analysis. *Id.* at 1320-21.

[15] *See Odom v. Microsoft*, No. 6:08cv331 (E.D. Tex. Jan. 30, 2009); *Novartis Vaccines & Diagnostics v. Hoffman-La Roche*, No. 2:07cv507 (E.D. Tex. Feb. 3, 2009).

[16] 35 U.S.C. § 271(a) (2006)*; Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350, 1357-58 (Fed. Cir. 2006).

[17] *Free Motion Fitness, Inc. v. Cybex Int'l, Inc.*, 423 F.3d 1343, 1353 (Fed. Cir. 2005) ("[A] party may not avoid infringement of a patent claim using an open transitional phrase, such as comprising, by adding additional elements."). In contrast, the transitional phrase "consisting essentially of" will not be infringed by a product that has additional elements that change the novel and basic properties of the product, while claims employing the closed transitional phrase "consisting of" will not be infringed if the accused product adds any elements not in the claim.

allegedly covers the product that is accused of infringement.[18] Thus, the fact that Abbott owns rights in another patent that may cover the HUMIRA® product, U.S. Patent No. 6,090,382, will be of limited use to it in defending against Bayer's suit.

Patent Remedies

Remedies available to a plaintiff after a verdict of patent infringement include both injunctions and money damages. An injunction essentially is an order by the court that the infringer must stop its infringing activities. A court may issue a permanent injunction once infringement, validity, and enforceability have been adjudicated, typically after a trial on the merits of the case. Courts can also issue preliminary injunctions at the outset of a lawsuit, when it appears that the plaintiff is likely to win at trial and would be irreparably harmed if the defendant were allowed to continue its infringing activities while the lawsuit progressed.[19] In this case, Bayer makes no competing product and has stated that it is not seeking an injunction. It is seeking monetary damages only.

In awarding monetary damages for patent infringement, the court seeks to compensate the patent holder for the defendant's infringing conduct. Monetary damages are governed by 35 U.S.C. § 284, which states that "[u]pon 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."[20]

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[18] *See National Presto Indus. v. West Bend Co.*, 76 F.3d 1185, 1192 (Fed. Cir. 1996) ("The grant of a separate patent on the accused device does not automatically avoid infringement, either literal or by equivalency. Improvements or modifications may indeed be separately patentable if the requirements of patentability are met, yet the device may or may not avoid infringement of the prior patent.").

[19] *See Abbott Lab. v. Sandoz, Inc.*, 544 F.3d 1341, 1344 (Fed. Cir. 2008) (listing the four factors to be considered as "(1) likelihood of success on the merits of the underlying litigation, (2) whether irreparable harm is likely if the injunction is not granted, (3) the balance of hardships as between the litigants, and (4) factors of the public interest.").

[20] In addition, damages can be limited by 35 U.S.C. § 287, which allows patentees to mark patented articles with the patent number in order to provide notice to the public of the patent. The statute also provides that '[i]n the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice." Abbott has raised this defense in its answer, and may seek to exclude from any calculation of damages those sales of HUMIRA® that occurred before Bayer contacted Abbott in 2003 about licensing the '407 patent.

Because no damages can be collected for acts of infringement occurring more than six years before the filing of the infringement lawsuit, patent holders have a limited period of time in which to seek such monetary damages.[21] This time limit in part explains the timing of Bayer's lawsuit. Bayer filed its complaint one week before the sixth anniversary of the FDA's initial approval letter for HUMIRA®, presumably so that any monetary damages awarded to Bayer would be based on *all* of the commercial sales of HUMIRA®.

Monetary damages in patent cases are generally calculated using one of two analytic frameworks: assessment of lost profits or assessment of a royalty. In some cases, a combination of these two frameworks is applied.

A lost-profits analysis is based on an assessment of the profits that the patent holder would have made for sales of its own product but for the infringement by the defendant.[22] Since Bayer does not currently make a product that competes with HUMIRA®, a lost-profits analysis would not be appropriate.[23] Instead, if the court finds that Abbott infringes the '407 patent, the court will probably employ a royalty analysis that's purpose is to reconstruct a hypothetical licensing negotiation between Bayer and Abbott before the introduction of HUMIRA®, and award Bayer monetary damages based on royalties Bayer would have received as a result of a hypothetical license agreement.[24]

In addition to the compensatory damages described above, the court also has discretion to award up to treble damages in cases of proved willful infringement.[25] To establish that an infringer's conduct was willful, "a patentee must show by clear and convincing

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[21] 35 U.S.C. § 286 (2006) ("Except as otherwise provided by law, no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action.").

[22] To prove that it is entitled to lost profits, the plaintiff is generally required to establish (1) demand for the patented product, (2) an absence of acceptable noninfringing substitutes, (3) manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit it would have made. *See Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995).

[23] Even if Bayer had such a product under development, a lost-profits analysis would not be applicable until Bayer actually marketed the product.

[24] *See Minks v. Polaris Indus., Inc.*, 546 F.3d 1364, 1372 (Fed. Cir. 2008).

[25] *See* 35 U.S.C. § 284 (2006).

evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent."[26]

Abbott's Defenses and Counterclaims

Noninfringement

The claims of a patent define the scope of the property right. However, claims must be interpreted in light of the patent specification, i.e., the full description of the invention submitted to the U.S. Patent and Trademark Office (PTO) and the prosecution history before the PTO.[27] In patent parlance, "prosecution" means the process conducted before a patent examiner to obtain a patent on a specific application. Because the interpretation of the patent claims is outcome determinative in patent cases, before considering specific infringement allegations, the court interprets the asserted claims or specific claim terms during a special proceeding called a "Markman hearing." The resulting Markman ruling sets forth the judge's interpretation of the patent claims or claim terms at issue, and thereafter is used by the judge or jury during the subsequent trial to determine whether the accused infringer infringed. It is not unusual for the Markman ruling to cause one of the parties to stipulate that it cannot prevail under the claim construction reached in the Markman ruling and then seek an immediate appeal of the ruling to the Federal Circuit.

In the Bayer-Abbott case, the claims of the '407 patent are quite broad, claiming any human monoclonal antibodies that bind specifically to human TNF-α. It is difficult to predict what Abbott's basis will be for its contention that it does not infringe the claims. It may be that Abbott will argue for a narrow interpretation of "human monoclonal antibodies" that excludes those in HUMIRA®. Perhaps more likely, Abbott may argue that the broad claims of the '407 patent are invalid or unenforceable, and rely on noninfringement arguments for the narrower patent claims only.[28]

[26] *In re Seagate Tech. LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc).
[27] *See Phillips*, 415 F.3d at 1315-17.
[28] In its complaint filed in the Massachusetts court, Abbott seeks a determination that it "does not infringe any *valid and enforceable* claim of the '407 patent." Complaint for Declaratory Judgment at 3, *Abbott Lab. v. Bayer Healthcare LLC*, Case No. 4:09-cv-40002-TSH (D. Mass. 2009) (emphasis added).

In addition to its contention that it does not infringe the ’407 patent, Abbott has raised a number of other legal defenses that are common in patent suits.

Limiting or Barring a Particular Patent Suit: Laches, Equitable Estoppel, Waiver, Implied License

The equitable doctrine of laches bars any recovery of damages from pre-lawsuit infringing activity, where the plaintiff delayed bringing suit for an unreasonable and inexcusable length of time from the time the plaintiff knew or should have known of its claims against the defendant, and the delay caused prejudice or injury to the defendant.[29] The doctrine does not bar the lawsuit itself, but rather limits the damages to those that accrued after the filing of the lawsuit. Furthermore, when laches is found to apply, the patent holder will not be able to stop the use of products that were sold during the laches period. There is a rebuttable presumption that laches applies when an infringement suit is brought more than six years after the patent holder knew or should have known of the infringement; this may be another reason why Bayer chose to file its suit before the six-year anniversary of the FDA’s approval letter for HUMIRA® (and associated Abbott press releases), which would very likely have established that Bayer had notice of its possible claim against Abbott.

In contrast to the laches doctrine, which only affects the scope of the infringing acts that a court can consider, the doctrines of equitable estoppel, waiver, and implied license can make a patent completely unenforceable against a defendant. In order to establish a defense of equitable estoppel, a defendant needs to show that the patent holder engaged in misleading conduct and thereby led the defendant to conclude that the patent holder did not intend to enforce its patent; the defendant also needs to show that it relied on the patent holder’s conduct and would be materially prejudiced if the patent holder were allowed to proceed with its claim.[30] If the defendant establishes these facts, the patent holder’s lawsuit will be barred. The lawsuit may also be barred if the defendant can establish facts that would support a finding of waiver. To do this, the

[29] *See A. C. Aukerman Co. v. R.L. Chaides Constr. Co*., 960 F.2d 1020, 1028-29 (Fed. Cir. 1992) (defining laches as “the neglect or delay in bringing suit . . . which . . . causes prejudice to the adverse party.”).
[30] *Id.* at 1042-43.

defendant needs to show that the patent holder's conduct was so inconsistent with an intent to enforce its patent rights as to induce a reasonable belief that those rights had been extinguished.[31] Similar facts are sometimes used as a basis for an implied license defense. A defendant can rely on an implied license in such cases if it can establish that there was an "affirmative grant of consent or permission to make, use, or sell" the patented invention.[32]

In its answer, Abbott has made allegations relevant to these defenses. Specifically, it has alleged that: (1) Dr. Dietrich Brocks, a Bayer vice president, contacted Suzanne A. Lebold, an Abbott divisional vice president, before September 22, 2003, regarding HUMIRA®; (2) Lebold responded that "she had been advised that HUMIRA was not subject to Bayer's patents," and Brocks responded that "the next step was proceedings"; (3) a teleconference between the parties' patent attorneys occurred on September 22, 2003; (4) Bayer proposed licensing terms to Abbott on October 7, 2003 that Abbott rejected, although it continued discussions; and (5) the last contact between the parties on the subject of Bayer's patents was on August 9, 2004, when Lebold sent an email to her counterpart at Bayer seeking information about Bayer's patent prosecution, to which Bayer did not respond.

If these allegations are true, there was no contact between the parties on the subject of the '407 patent for approximately three and a half years—after Bayer had already approached Abbott, at least indirectly suggested that Bayer might choose to sue, and initiated licensing negotiations. Without more, however, Bayer's period of silence may be insufficient to bar Bayer's suit entirely. In general, a patent holder's silence alone will not create an estoppel unless the patent holder had a clear duty to speak, or somehow its continued silence reinforced the accused infringer's inference from the patent holder's known acquiescence that the patent holder would refrain from enforcing its patent.[33] Abbott will likely need to show additional facts relating to the communication between the parties in order to support its view that Bayer had acquiesced in Abbott's sale of HUMIRA®. A laches defense, which does not require Abbott to show that

[31] *See Qualcomm Inc. v. Broadcom Corp.*, 548 F.3d 1004, 1019-20 (Fed. Cir. 2008).
[32] *Wang Labs. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1581 (Fed. Cir. 1995).
[33] *A. C. Aukerman Co.,* 960 F.2d at 1044.

Bayer's course of conduct was misleading, might be easier to establish. However, Abbott will still have to show that Bayer's delay in bringing suit caused it prejudice or injury other than those additional damages that accrued during the period of delay.[34] Abbott might, for example, attempt to establish that it would have acted differently (perhaps not seeking additional indications for HUMIRA®) if Bayer had promptly filed suit.

Attacking the Validity or Enforceability of the Patent Generally: Invalidity, Unenforceability

In contrast to the defenses above, which at most operate to limit or bar a lawsuit against a particular defendant, there are several ways that a defendant can establish that a patent is either simply invalid or is unenforceable against any defendant.

Invalidity of a patent can be established under a number of statutory provisions that govern standards patent applications must meet to result in a valid, issued patent. Patent claims can for example be found to be anticipated by or obvious in light of prior art—patents and other publications that existed before the priority date of the patent.[35] A patent claim is "anticipated" when all of the limitations are found in a single prior art reference.[36] A claim is "obvious" when a person with skill in the technology covered by the patent would have been able to make or use the claimed invention based on his or her knowledge and the prior art reference or references cited, even though there is no single reference that contains all of the limitations of the claim.[37] Because the PTO is presumed to have done a thorough job examining an application before a patent is granted, each patent is presumed to be valid; a defendant must either prove noninfringement or overcome this presumption of validity to prevail.[38] This presumption

[34] *Id.* at 1033 ("[D]amages which likely would have been prevented by earlier suit . . . . are not merely those attributable to a finding of liability for infringement . . . . The courts must look for a *change* in the economic position of the alleged infringer during the period of delay.")
[35] The priority date is the date of the earliest patent application that led to the grant of the patent.
[36] *See* 35 U.S.C. § 102(a), (b) (2006).
[37] *See* 35 U.S.C. § 103(a) (2006). This has become easier to show in the wake of the recent decision by the U.S. Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).
[38] *See Impax Lab., Inc. v. Aventis Pharm., Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008).

is even stronger when the PTO already has considered the prior art references that the defendant attempts to rely upon to establish invalidity of the patent.[39]

A defendant can also invalidate a patent based on earlier public disclosures of the invention by the patentee himself. If the invention was made public more than one year before the patent application was filed, then any resulting patent is invalid.[40] Finally, a patent can be invalidated by the patentee's failure during prosecution of the patent application to comply with other requirements. Invalidity can be based, for example, on a failure to disclose the "best mode contemplated by the inventor of carrying out his invention,"[41] or by a failure with deceptive intent to name the correct inventors in the application.[42]

Finally, the court also may judge a patent to be unenforceable if the defendant can establish that the patentee committed "inequitable conduct" during the prosecution of the patent application.[43] The most frequent context for such a ruling is an intentional failure by the patentee to fulfill its duty of candor to the PTO. This often involves the failure to submit known relevant prior art references[44] to the patent examiner during prosecution, although other intentional misrepresentations can also trigger a finding of unenforceability.

Conclusion

Patents and patent litigation can be effective business tools. Their value, however, rests on the patent holder's ability to use them to exclude competitors based on the scope of the patent claims. If the patent holder wants to exclude competition in a given market, the patent holder can seek an injunction. If the patent holder instead wishes to license

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[39] *Id.* The references considered during prosecution are normally listed on the front page of the granted patent. For example, the '407 patent is listed on Abbott's '382 patent, and the '382 patent is thus presumptively valid over the '407 patent.
[40] *See* 35 U.S.C. § 102(b) (2006).
[41] *Id.* § 112.
[42] *Id.* § 256.
[43] "Inequitable conduct" must be shown by "clear and convincing evidence of (1) affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information and (2) an intent to deceive." *Impax Lab, Inc.. v. Aventis Pharm*., *Inc.* 468 F.3d 1366, 1374 (Fed. Cir. 2006).
[44] Generally, prior art references are those that were published before the priority date of the patent (i.e., the filing date of the earliest application that led to the patent grant).

the patent to a competitor or, does not operate in the market at issue (as in this case), it can seek a royalty or monetary damages.[45]

Regardless of the strategy, the prosecution and scope of patent claims require considerable strategic attention and care. Without such strategy and care, the issued patent claims may fail to protect a market position or strategy, and the patent will have little value to exploit.

Accordingly, it is critical that patent applicants work closely with patent counsel and review the patent specification and claims carefully before filing any patent application. Patent applicants should participate in the process to ensure that the application contains a full disclosure of the invention and all of the subject matter that the applicant might later seek to claim in furtherance of market-focused business strategies. Later developments in the patented technology can be captured in follow-on patent filings. Attention paid to a single, full, and complete original patent application, together with prompt updating of the application portfolio as the technology is improved can thus potentially result in the issuance of a number of patents with valuable granted claims. As patent attorneys frequently say to their clients, “file early and file often.”

Indeed, the strategy that led to the issuance of the ’407 patent involved such an approach. The applicants filed an original application and followed six months later with a continuation-in-part application[46] that likely added new material to the original application. Both were prosecuted in parallel for the next four years before the same examiner. When the later application received a notice of allowance with broad claims, the applicant abandoned the earlier application. Possibly Bayer had decided not to further develop the technology, and those claims were all that it considered necessary to preserve the possibility of licensing revenue if a commercial monoclonal antibody were later marketed by a competitor. Had the technology been of greater importance to the company, however, it could have pursued other claims in follow-on applications.

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[45] As is now evident from the papers filed in this case, Bayer and Abbott were in licensing negotiations prior to the filing of Bayer’s complaint. Abbott was likely well aware of the ’407 patent even before Bayer approached it, as demonstrated by citation of the ’407 patent during the prosecution of Abbott’s own ’382 patent.

[46] A “continuation in part” application is filed during the life of its parent application and repeats some substantial portion or all of the parent application, while adding matter not disclosed in the parent application. Manual of Patent Examining Procedure § 201.08.

Two further issues are not directly raised by the Bayer/Abbott cases at this point but are important maxims for patent applicants. First, a patent applicant should never withhold from the PTO any relevant information in his or her possession. This violates the duty of candor to the PTO and is an excellent basis for an infringer to argue that the patent is unenforceable. Note that this does not mean that an applicant must conduct a separate search for relevant prior art references, although that can be a useful tool at the outset for determining if a patent application should be filed at all; it simply needs to provide any relevant prior art of which it is aware. Second, patent applicants should carefully control public disclosures (written or oral) relating to inventions, particularly before patent applications are filed, so as to avoid creating prior art that might serve as a basis for a later invalidity challenge. This can be a particular problem when working with academic inventors whose instinct is to collaborate with colleagues and to publish interesting results as soon as possible.

Closing Words on Patent Litigation

For plaintiffs: You are in control of the timing and in most respects the location of your lawsuit. To ensure that you maintain this control, you should police your pre-litigation communications with possible defendants carefully before filing your lawsuit. An incautious communication can serve to provide an infringer with enough evidence of a controversy to establish declaratory-judgment jurisdiction, allowing the infringer to file suit first and deprive you of the choice of when and where to file the first lawsuit. An overt threat to sue followed by a lengthy period of inaction may also allow an infringer to make out a defense of laches, equitable estoppel, or waiver. Also, keep in mind the six-year clock that governs both the damages you can seek and the presumption that laches applies.

For defendants: If you are sued in a distant or inconvenient forum, such as the Eastern District of Texas, you can try to use recent case law to transfer the case to your home forum. And to more affirmatively protect your rights, if you have communicated with a patent holder, consider whether the statements made by the patent holder would provide a basis for your own lawsuit or would allow you to make a case that the patent

owner had given up its right to sue, thus limiting or barring any lawsuit the patent holder might file against you.