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Cleantech Innovators Should Be Aware of Certain Global Intellectual Property Issues 1

While most agree that global warming is real and clean technologies are needed to counter global warming, not everyone agrees how clean technologies should be diffused. To counter those that have proposed and will undoubtedly continue to propose weakening or eliminating intellectual property rights, clean technology innovators should not be passive and wait for forced technology diffusion measures to be implemented. In this article, **Todd R. Miller** and **Dawn M. Amos** of Jones Day explore the intellectual property issues that innovators should be aware of and suggest a number of proactive courses of action that intellectual property rights holders may consider in an effort to control their own destiny for their own benefit as well as society as a whole.

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A recent case may change the calculus that generic drug manufacturers use when determining whether to file Paragraph IV challenges. In *Takeda Chemical Industries, Ltd. v. Mylan Pharmaceuticals, Inc.*, the US Court of Appeals for the Federal Circuit affirmed a district court decision that required two generic companies to pay a patentee $16.8 million in attorney fees, expert fees, and expenses. *Takeda* demonstrates that generic companies challenging pharmaceutical patents put themselves at risk of having to pay attorney fee awards when they shift their invalidity defenses from those initially asserted in their Paragraph IV certifications. **Matthew Avery** of Baker Botts L.L.P. discusses this case, Paragraph IV certifications, and shifting obviousness defenses.

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Behind every legal principle is a somewhat muddled and torturous history, and the right of publicity is no exception. In this article, **James J.S. Holmes** and **Afigo I. Okpewho** of Sedgwick, Detert, Moran & Arnold LLP explore the fascinating progression of the *right of publicity*: a person's exclusive right to control and derive revenue from the commercial uses of one's name, likeness, or other aspects of one's persona. Although we can think of the legal right to the commercial value in one's likeness as a mechanism by which society rewards people who work hard to create value in their identity, this quasi-privilege is not quite so clear cut and simple. The law does not exactly afford the celebrity figure absolute enjoyment of this intellectual "property" right.

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Developers of all stripes, including those working on proprietary and other "closed-source" solutions, have discovered the wealth of free and open-source software (FOSS) circulating on the Internet. Depending on the FOSS and the developer's plans for it, complying with the applicable license may be relatively easy and painless. But, if a developer wants to avoid potentially serious consequences, it needs to take a systematic approach to managing the FOSS opportunity. **David A. Wormser** of Pepper Hamilton LLP advises vendors wanting to take control of their FOSS exposure, particularly those that have been in business for a while, to initiate two separate but related initiatives. One of these initiatives should be focused on establishing policies and procedures for managing FOSS issues going forward. The other effort focuses on identifying and resolving FOSS issues that have snuck into their products in the past.

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Baseless Paragraph IV Certifications and Shifting Obviousness Defenses

By Matthew Avery

A recent case may change the calculus that generic drug manufacturers use when determining whether to file Paragraph IV challenges.[1] In *Takeda Chemical Industries, Ltd. v. Mylan Pharmaceuticals, Inc.*, the US Court of Appeals for the Federal Circuit affirmed a district court decision that required two generic companies to pay a patentee $16.8 million in attorney fees, expert fees, and expenses.[2] In the case, Mylan and Alphapharm filed abbreviated new drug applications to make generic versions of Takeda's diabetes treatment Actos. As required by the Hatch-Waxman Act, the applications included Paragraph IV certifications asserting that Takeda's patent on the drug was invalid. During the subsequent patent litigation, the generic challengers shifted their obviousness defenses from the theories originally presented in their Paragraph IV certifications. When Takeda ultimately prevailed, the district court granted Takeda's motion for attorney fees, finding that Mylan's and Alphapharm's shifting obviousness defenses showed that they had filed "baseless" Paragraph IV certifications in violation of their "duty of care" under the Hatch-Waxman Act.[3] *Takeda* demonstrates that generic companies challenging pharmaceutical patents put themselves at risk of having to pay attorney fee awards when they shift their invalidity defenses from those initially asserted in their Paragraph IV certifications.

The Hatch-Waxman Act and Paragraph IV Certifications

The marketing of generic drugs is regulated by the Hatch-Waxman Act.[4] Under Hatch-Waxman, before a generic drug manufacturer can enter the market, it must seek regulatory approval from the Food and Drug Administration by filing an abbreviated new drug application (ANDA).[5]

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As part of the ANDA, the generic applicant is required to make one of the following certifications regarding *each* patent that claims the drug that it seeks to copy:

I. That the drug is not patented or that patent information has not been filed;

II. That the patent has expired;

III. That the generic drug will not enter the market until the patent expires; or

IV. That the patent is invalid or will not be infringed by the manufacture, use or sale of the generic drug for which the application is submitted.[6]

These are called Paragraph I, II, III, and IV certifications, respectively.

By making a Paragraph IV certification, a generic manufacturer can seek FDA approval to market a generic equivalent of a pioneer's patented drug before the patent term has expired.[7] The Hatch-Waxman Act requires all Paragraph IV ANDA applicants to provide notice of the application to the challenged patent holder, including "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."[8] Furthermore, § 271(e) of the Patent Act provides that making a Paragraph IV certification alone is an act of patent infringement.[9] Therefore, the mere filing of an ANDA with a Paragraph IV certification is sufficient to enable the pioneer to sue the generic challenger.

Attorney Fee Awards in Patent Litigation Under § 285

According to the so called American Rule, each party pays for its own attorney fees.[10] However, in patent litigation, § 285 of the Patent Act authorizes the court to "award reasonable attorney fees to the prevailing party" in "exceptional cases."[11] The judge

must engage in a two-step process to determine whether to award attorney fees. First, the court must make a specific factual finding that the case is exceptional.[12] The moving party has the burden of showing that the case is exceptional by clear and convincing evidence.[13] The Federal Circuit has stated that "only a limited universe of circumstances warrant a finding of exceptionality in a patent case: 'inequitable conduct before the [Patent and Trademark Office]; litigation misconduct; vexatious, unjustified and otherwise bad faith litigation; a frivolous suit or willful infringement.'"[14]

The Federal Circuit held that more than just the mere filing of an ANDA is necessary to support a finding of willful infringement.

If the court determines that the case is exceptional, it must then decide whether it is appropriate to award attorney fees.[15] The decision to award attorney fees under § 285 is within the discretion of the judge.[16] The court can consider many factors in making this decision, including the "fair allocation" of costs between the parties and whether it would be unjust to make the prevailing party pay its own attorney fees.[17]

In the context of ANDA litigation, the Federal Circuit has found cases to be exceptional when a generic applicant violates its "duty of care" under the Hatch-Waxman Act by making a "baseless" Paragraph IV certification. For example, in *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc.*, the Federal Circuit affirmed an award of attorney fees based on the finding that the generic challenger made a baseless Paragraph IV certification and engaged in litigation misconduct.[18] The *Yamanouchi* court emphasized that a generic applicant must use due care when following the strict standards of the Hatch-Waxman Act and must certify that, to the best of its knowledge, each challenged patent is invalid or not infringed.[19] However, the generic challenger's obviousness argument failed to show any motivation to combine prior art compounds and presented unfounded arguments. Consequently, the court held that the certification was baseless, in part because the ANDA filer had failed to present a *prima facie* case of invalidity in its certification. In contrast, in *Glaxo Group, Ltd. v. Apotex, Inc.*, the Federal Circuit reversed an award of attorney fees because there was no specific finding that the generic applicant had made a baseless certification in its ANDA.[20] In *Glaxo*, the district court found that, by filing an ANDA, the generic challenger willfully had infringed the pioneer's patent, thereby making the case exceptional for purposes of awarding attorney fees. The Federal Circuit reversed the attorney fees award and held that more than just the mere filing of an ANDA is necessary to support a finding of willful infringement. The court clarified that only limited types of conduct related to ANDA filings are considered exceptional. Citing *Yamanouchi*, the court noted that a baseless Paragraph IV certification coupled with litigation misconduct was sufficient to make an exceptional case finding. However, these cases leave open the question of exactly when a Paragraph IV certification is "baseless."

The Federal Circuit's Decision in *Takeda v. Mylan*

In July 2003, Mylan Laboratories and Alphapharm each filed Paragraph IV ANDAs to make generic versions of Actos (pioglitazone), a diabetes treatment marketed by Takeda Pharmaceuticals.[21] In their Paragraph IV certifications, the generic challengers asserted that Takeda's patent covering Actos, U.S. Patent No. 4,687,777, was invalid and not infringed. In response, Takeda sued Mylan and Alphapharm for patent infringement under 35 U.S.C. § 271(e)(2)(A).

In February 2006, the district court issued a 124-page opinion in which it found that the '777 Patent was not invalid, not obvious, and not unenforceable due to inequitable conduct.[22] The court commented that "[t]he length of this Opinion is occasioned by the need to address the many iterations of the defendants' arguments, as they searched for a viable theory to attack the '777 Patent."[23]

After prevailing on the patent infringement issue, Takeda filed a motion seeking an award of attorney fees, contending that the generic challengers lacked a good faith basis for their Paragraph IV certifications.[24] The court again sided with Takeda, granted its motion, and awarded Takeda $16.8 million ($5.4 million from Alphapharm; $11.4 million from Mylan) in attorney fees, expenses, and expert fees.[25] In its opinion granting the motion, the court

found this to be an exceptional case under § 285. Relying on *Yamanouchi*, the court explained that both Alphapharm and Mylan had filed baseless Paragraph IV certifications in violation of their "duty of due care" under the Hatch-Waxman Act.

Regarding Alphapharm, the court found numerous shortcomings in its Paragraph IV certification. The primary deficiency was Alphapharm's complete failure to establish a *prima facie* case of invalidity in the Paragraph IV certification. In its Paragraph IV certification, Alphapharm argued that the '777 Patent was invalid as obvious over two prior art compounds described in a 1982 scientific article.[26] However, at trial, Alphapharm shifted its position and argued that Takeda's patent was actually obvious over a third compound described in the same 1982 article.[27]

The court faulted Alphapharm for its inconsistent obviousness argument, its failure to identify the third compound as its lead compound in the Paragraph IV certification, and its failure to explain why one skilled in the art would even select the third compound as a lead compound. The court also found numerous scientific errors in Alphapharm's certification, one of which it characterized as "insidious," and these errors showed that it had failed to use due care or act in good faith. Considering the totality of the circumstances, the court concluded that Alphapharm's Paragraph IV certification was "so devoid of merit . . . that it must be described as baseless."[28]

As for Mylan, the court found that the generic company had filed its Paragraph IV certification "in bad faith and with no reasonable basis to claim that the '777 Patent was invalid."[29] In its Paragraph IV certification, Mylan asserted that the '777 Patent was invalid as obvious over a fourth compound from the same 1982 scientific article.[30] At the close of discovery, Mylan abandoned this theory of obviousness and presented a new theory of obviousness based on a fifth compound from the same article.[31]

However, the court noted, "Mylan did not give any detailed explanation of why [the fifth compound] would have been identified by one skilled in the art as a lead compound, or how its optimization would have led to the discovery of pioglitazone."[32] The court also found that this new theory of obviousness was "presented in bad faith" because one of Mylan's expert witnesses had previously "indicated that an analysis of the toxicity and efficacy profile of [the fifth compound] would have ruled it out as a lead compound."[33] Consequently, the court concluded that Mylan's Paragraph IV certification was "utterly frivolous."[34]

In addition to the baseless Paragraph IV filings, the court found that both Mylan and Alphapharm had engaged in other acts of litigation misconduct. For example, Alphapharm "constantly shift[ed] its theory of obviousness" in bad faith, presented "entirely frivolous" arguments of inequitable conduct at trial, ignored a court order, and offered an untimely advice of counsel defense. Similarly, Mylan acted "without a reasonable basis and in bad faith in pursuit of its inequitable conduct claim."[35] Reviewing the totality of the circumstances, the court found that "[t]his case was not close" and that it was clearly an exceptional case justifying an award of attorney's fees.[36]

Applicants fail to meet their duty of care "when they file 'baseless' certifications" and that such certifications "would amount to litigation misconduct supporting an exceptional case finding."

Both Mylan and Alphapharm appealed the attorney fee awards.[37] The generic manufacturers were aided in their appeal by the Generic Pharmaceutical Association (GPhA) as *amicus curiae*.[38] GPhA argued that "the district court's decision placed too much weight on Mylan's and Alphapharm's decision to take the case to trial on grounds other than the particular theories of invalidity that they had stated in their respective pre-suit notice letters."[39] GPhA then asserted that Mylan and Alphapharm had merely modified their infringement defenses in response to discovery provided by Takeda. The *amicus* argued that "there are myriad legitimate reasons why infringement defendants change defenses during litigation, and making such a change does not suggest that a defendant lacks faith in its earlier arguments or that those earlier arguments were frivolous or asserted in bad faith."[40] "[W]hen [discovery] reveals new defenses, ANDA applicants must be permitted to assert them and to do so without a negative inference being drawn should the applicant ultimately lose."[41]

On December 8, 2008, the Federal Circuit affirmed the district court's decision, finding no

clear error in the lower court's opinion.[42] The appellate court approved of the district court's analysis in finding that Mylan and Alphapharm had filed baseless Paragraph IV challenges and engaged in other litigation misconduct.

The Federal Circuit emphasized its prior decision in *Yamanouchi*, which held that that Paragraph IV challengers must "display care and regard for the strict standards of the Hatch-Waxman Act when challenging patent validity. . . . The Hatch-Waxman Act thus imposes a duty of care on an ANDA certifier."[43] The opinion explained that applicants fail to meet their duty of care "when they file 'baseless' certifications" and that such certifications "would amount to litigation misconduct supporting an exceptional case finding."[44] But the court noted that "ANDA applicants who are merely negligent" will not necessarily trigger § 285.[45]

The court also rejected GPhA's argument that the defendants were being punished for merely expanding their defenses beyond those mentioned in their Paragraph IV certifications.[46] "Rather, the district court found the case exceptional based on the specific circumstances involved in this case, *viz.*, baseless certification letters compounded with litigation misconduct."[47] However, at least with respect to the shifting obviousness defense, the court was skeptical of the defendants good faith since "it seems reasonable to expect assertions of invalidity based on prior art to remain relatively consistent as the prior art should be known when the certification of invalidity is made."[48]

Conclusion

Takeda shows that generic challengers put themselves in potential risk under § 285 if they deviate from the defenses asserted in their Paragraph IV certifications. Under *Yamanouchi* and *Takeda*, a pharmaceutical patent holder that prevails in ANDA litigation should succeed in a motion for attorney fees if it can show that the generic challenger filed a Paragraph IV certification with a baseless invalidity argument and also engaged in some type of litigation misconduct. *Takeda* also confirmed that an obviousness invalidity argument is baseless if the certification fails to establish a *prima facie* case of invalidity and that a shifting obviousness defense is evidence that the original defense asserted in the Paragraph IV certification was baseless. More generally, *Takeda* suggests that a Paragraph IV certification could be found baseless whenever a generic challenger shifts or abandons *any* of the invalidity or non-infringement defenses asserted in the certification or raises new defenses not found in the certification. Therefore, pharmaceutical patent holders that prevail against generic challengers should emphasize these shifting defenses as evidence that the challenge was baseless when moving for attorney fee awards. Similarly, counsel for generic drug manufactures must take care to present strong invalidity and non-infringement arguments in their Paragraph IV ANDAs and to be cautious about abandoning such defenses during litigation.

Notes

1. It has been argued that generic drug manufacturers have an enormous incentive to challenge the patents of pioneering pharmaceutical companies and that these challengers arguably have little to lose beyond litigation costs. *See* Matthew Avery, Note, "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments," 60 *Hastings L.J.* 171, 195 (2008).
2. *See* Takeda Chem. Indus. v. Mylan Labs., Inc., 549 F.3d 1381, 1383 (Fed. Cir. 2008), *cert. denied*, 130 S. Ct. 106 (2009).
3. *Id.* at 1385, 1388.
4. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) [hereinafter Hatch-Waxman Act] (codified as amended at 21 U.S.C. § 355(j) (2006), 35 U.S.C. §§ 156, 271(e) (2006)).
5. *See* H.R. Rep. No. 98-857, pt. 1, at 16 (1984).
6. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).
7. Consequently, patent challenges pursuant to Paragraph IV are a frequently deployed mechanism for the early introduction of generic competition. *See* Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study 10 (2002) (reporting challenges involving 130 drugs between 1984 and 2000); Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act": Hearing Before the S. Comm. on the Judiciary, 108th Cong. 113, 117 (2003) (statement of Timothy Muris, Chairman, Federal Trade Commission) (noting challenges involving more than 80 drugs between January 2001 and June 2003).
8. 21 U.S.C. § 355(j)(2)(B).
9. 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . .").
10. Mathis v. Spears, 857 F.2d 749, 757 (Fed. Cir. 1988).

11. 35 U.S.C. § 285.
12. Hughes v. Novi Am., Inc., 724 F.2d 122 (Fed. Cir. 1984); Super. Fireplace Co. v. Majestic Prods. Co., 270 F.3d 1358, 1376 (Fed. Cir. 2001).
13. Wedgetail Ltd. v. Huddleston Deluxe, Inc., 576 F.3d 1302, 1304 (Fed. Cir. 2009).
14. *Id.* (quoting Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1034 (Fed. Cir. 2002)).
15. *Super. Fireplace Co.*, 270 F.3d at 1376.
16. Delta-X Corp. v. Baker Hughes Prod. Tools, Inc., 984 F.2d 410, 414 (Fed. Cir. 1993).
17. S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc., 781 F.2d 198, 201 (Fed. Cir. 1986) (The court may consider "factors that may contribute to a fair allocation of the burden of litigation as between winner and loser."); J.P. Stevens Co. v. Lex Tex Ltd., Inc., 822 F.2d 1047, 1052 (Fed. Cir.1987) (The court may consider whether "it would be grossly unjust that the winner be felt to bear the burden of his own counsel.").
18. Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1347 (Fed. Cir. 2000).
19. *Id.* at 1347 (citing 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).
20. Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1350 (Fed. Cir. 2004).
21. Takeda Chem. Indus. v. Mylan Labs., No. 03 Civ. 8253, 2006 U.S. Dist. LEXIS 8384, at *4 (S.D.N.Y. Mar. 6, 2006).
22. Takeda Chem. Indus. v. Mylan Labs., 417 F. Supp. 2d 341 (S.D.N.Y. 2006) [hereinafter *Takeda I*].
23. *Id.* at 344.
24. Takeda Chem. Indus. v. Mylan Labs., 459 F. Supp. 2d 227, 230 (S.D.N.Y. 2006) [hereinafter *Takeda II*].
25. *Id.* at 231; Takeda Chem. Indus. v. Mylan Labs., Nos. 03 CIV. 8253(DLC) & 04 CIV.1966(DLC), 2007 WL 840368, at *14 (S.D.N.Y Mar. 21, 2007) [hereinafter *Takeda III*]. Note that the expert fees were awarded pursuant to the judge's inherent authority as a sanction against the defendants.
26. *Id.* at 235-236.The two compounds were from T. Sohda, *et al.*, "Studies on Antidiabetic Agents. II. Synthesis of 5-[4-(1Methylcyclohexylmethoxy)-benzyl])thiazolidine-2, 4-dione (ADD-3878) and its Derivatives," 30 *Chem. Pharm. Bull.* 3580 (1982) [hereinafter Sohda II].
27. The third compound was "compound 58" (also known as "compound b") from Sodha II.
28. *Takeda II,* 459 F. Supp 2d at 235.
29. *Id.* at 245.
30. *Id.* Mylan relied on "compound 14" described in Sohda II.
31. *Id.* at 246. Mylan switch from "compound 14" to "compound 57" in Sohda II. At the same time, Mylan raised a new defense of inequitable conduct. *Id.* at 249.
32. *Id.* at 246.
33. *Id.*
34. *Id.* at 247.
35. *Id.* at 250.
36. *Id.* at 244.
37. Takeda Chem. Indus. v. Mylan Labs., 549 F.3d 1381, 1385 (Fed. Cir. 2008). The appeals were consolidated before the Federal Circuit.
38. Brief for the Generic Pharm. Ass'n as Amici Curiae Supporting Appellants at 7, Takeda Chem. Indus. v. Mylan Labs., Inc., 549 F.3d 1381 (Fed. Cir. 2008) (Nos. 2007-1269, 2007-1270) [hereinafter Brief for GPhA].
39. *Id.* at 5-6.
40. *Id.* at 7-8.
41. *Id.* at 9. The brief also argued that "[r]eversal is vital because [the attorney fee award] will undermine the efficacy of the Hatch-Waxman scheme by deterring future ANDA filings by many companies, keeping generic drugs off the market and increasing the cost of drugs to the consumers who depend on them." *Id.* at 7. It also warned that "the district court's decision will have a chilling effect on future ANDA patent challenges as many generic companies become reluctant to assert new defenses and abandon old ones: the companies will fear being hit with millions of dollars in fees and costs if unsuccessful." *Id.* at 15-16. In the wake of *Takeda v. Mylan*, there is little evidence that GPhA's predictions are coming true. Courts are not relying on the case to justify attorney fee awards against generic challengers.To date, only one Paragraph IV case has cited the Federal Circuit's decision in *Takeda*, but in that case the district court distinguished *Takeda* and denied the prevailing party's motion for attorney fees. *See* Abraxis BioScience, Inc. v. Navinta, LLC, No. 07-1251, 2009 WL 5174454 (D.N.J. Dec. 18, 2009). However, the decision may still be having a chilling effect on generic challenges. The number of Paragraph IV certifications filed annually has declined since the decision. In 2008, 97 certifications were filed, while in 2009, only 80 certifications were filed. *See* Food and Drug Admin., Paragraph IV Patent Certifications as of January 25, 2010 (2010). Though this one-year trend is inconclusive, it suggests that the *Takeda* decision may be deterring at least some generic companies from filing Paragraph IV challenges.
42. *Takeda*, 549 F.3d at 1384.
43. *Id.* at 1387-1388 (quoting *Yamanouchi*, 231 F.3d at 1347).
44. *Id.* at 1388.
45. *Id.*
46. *Id.* at 1390.
47. *Id.*
48. *Id.* at 1387.