Legal Backgrounder

Washington Legal Foundation
Advocate for freedom and justice®
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Vol. 17 No. 51 December 6, 2002

BITING THE HAND THAT FEEDS?: GENERIC DRUGS AND ABUSE OF THE HATCH-WAXMAN LAW

by

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On October 21, 2002, President Bush announced newly-proposed rules designed to halt "delays and abuses in the process of bringing generic drugs to the market." Allegations of these so-called abuses by developers of patented drugs lie at the heart of the generics' efforts to remold a bargain struck eighteen years ago by the Hatch-Waxman Act. But the generics' allegations of abuses have conveniently omitted abuses by the generics themselves when they attempt to bring drugs to the market.

The Hatch-Waxman Act created today's generic drug industry. Before 1984, generic drug manufacturers faced two significant hurdles to bringing a generic version of an innovator's branded drug to market. First, the generics could not rely on the innovator's extensive and costly clinical trials to demonstrate the generic drug's safety and effectiveness. Instead, they had to perform their own clinical trials or rely on published reports to obtain FDA approval. Second, the generic manufacturers could not perform the limited testing needed to obtain FDA approval without infringing the innovator's patent. Their arguments that this testing came within the "experimental-use exception" of the patent law carried no weight with the U.S. Court of Appeals for the Federal Circuit, which held in *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984), that conducting tests needed to obtain FDA approval of generic versions of drugs was patent infringement. Ominously, the court also suggested that infringement by performing these tests might warrant payment of substantial damages to the innovator.

Then came Hatch-Waxman. The Hatch-Waxman Act eliminated both hurdles. A generic could now rely on the innovator's clinical studies to demonstrate safety and effectiveness by filing an "Abbreviated New Drug Application" (ANDA). The Act also overruled both aspects of the *Bolar* decision and created a new approval process for generic drug manufacturers. First, the Act excluded testing needed to obtain FDA approval to market generic drug products from the definition of patent infringement. Second, the Act provided for no damages arising from the making and testing of a generic version of a patented drug or the filing of an ANDA challenging that patent.

The Act also provided an incentive for generic drug manufacturers to be the first to challenge a patent on an innovator's drug: the lucrative possibility of 180 days of marketing free from all competition from other generic drug manufacturers, regardless of whether it is the first to obtain FDA approval.

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ABUSES BY THE GENERIC DRUG INDUSTRY

The absence of any risk of damages, coupled with the potential exclusivity, has prompted the abuse of the provisions of Hatch-Waxman by a number of generic manufacturers. Specifically, generics have adopted several strategies to exploit provisions of the Act to the detriment of the judicial process and the public. Each of those strategies flows directly from the lucrative incentive the Act dangles before them: the 180-day marketing exclusivity period. Because generic manufacturers obtain the highest profits during that period, they have acted improperly to obtain that exclusivity period and have even devised ways of extending it.

In any other industry, testing activities would constitute patent infringement. When that activity is excepted *and* the first to challenge the patent by filing an ANDA is eligible for 180 days of market exclusivity, we have a built-in incentive for abuse. This LEGAL BACKGROUNDER explores two of the more common types of abuses.

First, and not surprisingly, the Hatch-Waxman Act has spawned a significant increase in the number of challenges to unexpired patents. Some of those challenges had been made without any legitimate basis and would never have been initiated had the challenger been subject to the normal risks of patent litigation, such as having to pay the innovator's lost profits or a reasonable royalty on the patent, and possibly incurring liability for triple damages.

Second, the Act has caused the hurried filing of non-final ANDAs with patent challenges merely to preserve "first-filer" status and the resulting eligibility for the 180-day exclusivity period.

Each of those abuses merits a closer look.

Filing Meritless Patent Challenges. A patent challenger found to have engaged in egregious conduct can be found to be a "willful" infringer. Normally, a holding of willful infringement exposes the infringer to the risk of triple damages and paying the patent owner's attorneys' fees. In ANDA cases, however, damages virtually never arise because the generics generally do not enter the market before resolution of the suit. Consequently, ANDA applicants that willfully infringe a patent by filing a patent challenge had no potential liability. Recently, courts have held generics submitting baseless patent challenges as willful infringers. Those holdings, however, expose generics to at most the patentee's attorney's fees. Thus, the Act has granted the generics an essentially risk-free chance to challenge patents and an incentive to ignore the duty of care in doing so. Predictably, some generic manufacturers have filed baseless challenges supported only by incompetent opinions, a practice that wastes the courts' time and resources, and provides no benefit to the public. Two recent cases dramatically illustrate this point.

In *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir. 2000), the Federal Circuit blasted Danbury's baseless challenge of the patent on Pepcid®, holding that Danbury had engaged in "misconduct in filing a wholly unjustified ANDA certification." *Yamanouchi*, 231 F.3d at 1347. It concluded that Danbury had made a "baseless certification," stating:

> Danbury's case for obviousness presented at trial contained *glaring weaknesses*. . . . When Danbury proceeded in the face of these weaknesses, its certification amounted to *baseless and unjustified misconduct*. In certifying invalidity, Danbury *disregarded its duty to exercise due care.*

Id. (emphasis added).

Danbury tried to justify its challenge by relying on a defective opinion from its patent attorney. That opinion contained "an acknowledged error in chemistry, which was critical to its conclusion of [invalidity]."

  ISBN 1056 3059

Id. Danbury's own expert conceded at trial that the patent attorney's interpretation of a prior-art reference was "patently incorrect." *Id.* That opinion was only one of several commissioned by Danbury as part of a shotgun approach to challenging patents:

> [Danbury] contracted . . . with outside counsel Engelberg . . . to identify up to six potential challenges to existing drug patents and to provide written invalidity opinions to [Danbury]. . . . Once Engelberg chose the various challenges, [Danbury] would then go forward with development of the pertinent drugs, providing that a commercial market for the drug existed and the raw materials necessary for its production were available. Engelberg was not to be directly compensated for writing the challenge opinions, but instead would receive fifty percent of the "Marginal Gross Profit" of any of the drugs' sales if its corresponding patent challenge was successful.

Id. at 375.

The lure of 180 days of exclusivity also prompted Zenith Goldline to file a meritless patent challenge in *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 2001 WL 1397304 (S.D. Ind. 2001). In that case, the district court held that "Zenith did not have a reasonable basis for believing [that the challenged] patent [on Lilly's drug Axid®] was invalid." Like Danbury, Zenith ignored a series of "serious factual errors" in its patent attorney's opinion:

> On first reading by someone not familiar with the issues, the opinion appears to reflect some key indicia of reliability. It discusses prior art, the file history, and one case as a source of applicable law, and it is from reputable outside patent attorneys. *But upon closer reading-upon the kind of reading that Zenith's own patent attorneys should have given it-several glaring errors of fact and omissions of law come to light.* These errors and omissions weigh heavily against Zenith's claim that it reasonably relied on advice of counsel.

Eli Lilly, 2001 WL 1397304, at *20 (emphasis added).

Zenith's decision to ignore those errors apparently rested on its desire to reap a financial windfall from the 180-day exclusivity period:

> *Zenith rushed to file its Paragraph IV Certification as quickly possible* on the basis of a hurried oral opinion that no participants can describe so as to give anyone confidence that sufficient care had been taken. *The financial incentives to file immediately were great, as Zenith noted at the time.* Those involved in the October 5 conference call knew that the opinion was highly likely to result in expensive litigation, but also that *the potential rewards of success would be measured in many millions of dollars.*

Id. at *25 (emphasis added). In fact, the court found that Zenith's basis for challenging the Axid® patent was a sham:

> The evidence shows clearly and convincingly that Zenith and its lawyers were going through the motions of preparing an advice of counsel defense. The evidence shows that the advice of counsel was more of a protective device than a genuine effort to determine before infringing whether the patent was invalid.

Id. at *26.

Yamanouchi and *Lilly* show how the financial incentives created by Hatch-Waxman result in meritless challenges to patents by generics. Because the potential 180-day reward outweighs the potential damages of being branded a willful infringer in ANDA cases, the generic drug applicants apparently did not hesitate in filing meritless patent challenges based on inadequate opinions.

Filing Non-final ANDAs to Ensure "First-Filer" Status. A second strategy of the generics involves filing a non-final ANDA merely to obtain first-filer status, and then amending that ANDA throughout the approval process. That strategy may be dubbed "file first, fix later." As with the filing of baseless certifications, the strategy flows directly from the 180-day exclusivity reward for the first challenger. At a minimum, that strategy results in wasting years of scarce judicial resources by forcing the innovator to litigate over a constantly morphing ANDA. That strategy also constitutes an attempt to game the system by allowing the generic to obtain a noninfringement decision based on its original ANDA but to market a different, potentially infringing product. The Tiazac® case may be an example of the file-first, fix-later strategy.

In *Tiazac*®, Andrx challenged the patent in 1998. Biovail, the patent owner, brought suit, and litigation over that original ANDA ensued. Unbeknownst to Biovail, Andrx filed approximately twelve amendments to its original ANDA without notifying either Biovail or the court. Andrx finally notified Biovail only weeks before the appeals court heard the case, long after Biovail could have addressed those amendments. That tactic prompted the appeals court to hold that Andrx had violated its obligation to Biovail and the district court. *See Biovail Corp. Int'l v. Andrx Pharms., Inc.*, 239 F.3d 1297, 1304 (Fed. Cir. 2001). Thus, the parties litigated for three years over Andrx's original ANDA even though Andrx modified the application during the course of the litigation.

The file-first, fix-later strategy is not uncommon. An article published in *Baron's Technology Week* entitled "Dirty Tricks in the Land of Generic Drugs" exposed the prevalence of the file-first, fix-later approach. That article identified four generics as "extreme amenders," those that have amended an application more than twelve times: Andrx, Mylan Laboratories, Teva Pharmaceuticals, and Watson Pharmaceuticals. Indeed, according to *Baron's*, Andrx had engaged in "extreme" amending of its applications for three different drugs. And Mylan and Teva had implemented that strategy on two different drugs each. Thus, the generics cannot be heard to claim that *Tiazac* constitutes an isolated occurrence of the file-first, fix-later strategy.

CONCLUSION

As these cases show, the 180-day exclusivity period, coupled with a risk-free opportunity to challenge patents regardless of their apparent validity, has spawned a series of abuses of the Hatch-Waxman Act by generic drug manufacturers. But these examples are only the tip of the iceberg, illustrating just a few public examples of abuse by generic drug manufacturers. Many others lie just beneath the surface, obstructed from public view by court-ordered confidentiality agreements in litigation and by the FDA approval process.

ISBN 1056 3059