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FEATURE: Pharmaceutical Patents

STRIKING THE BALANCE: PHARMACEUTICAL PATENT VALUES AND CONSUMER AVAILABILITY

By Valerie Sarigumba

Pharmaceutical companies, ("Brands") have long benefited from laws allowing extensive patent protection on their products. The Brands assert that pharmaceutical patent laws protect their products' value, resulting in profits that allow the Brands to continue developing new drugs. Furthermore, Brands argue, it is necessary to protect these profits due to the high cost of bringing new drugs to the market.

However, companies producing generic versions of the Brands' pharmaceuticals ("generics") hold that the current patent laws prevent cheaper, but identical, versions of pharmaceuticals from reaching the consumers in a timely manner. All three branches of the federal government have been wrestling with this issue to find the balance between protecting and promoting pharmaceutical innovation while upholding consumer interests.

In 1984, Congress passed the Drug Price Competition & Patent Term Restoration Act, commonly known as "Hatch-Waxman." Drug Price Competition & Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). According to Christopher T. Griffith, an intellectual property attorney with Leydig Voit & Mayer, Ltd. in Chicago, "The underlying purpose behind Hatch-Waxman was an effort to strike a balance between the interests of the generic companies and the Brands." Hatch-Waxman shortened approval for generic versions of Brand drugs by creating the Abbreviated New Drug Application ("ANDA"). The act also allowed generics to develop their own version of a Brand drug while it was still under patent. While for any other industry this practice would constitute patent infringement, it allowed generics to be released into the market as soon as the Brand's patent expired.

ANDA rules provide several routes for marketing generic drugs, but one particular route, Paragraph IV certification, is used when the patent has not expired but the generic claims that the patent is invalid or that its own product does not infringe upon the patent. However, Paragraph IV also leads to an elaborate litigation chess game between the generics and the Brands to protect the intellectual property and marketing rights for the drug at issue.

"The FDA proposal asserts that innovation will not be infringed upon because Brands will still be free to litigate patent infringements... However, [b]rands must dedicate significant time, energy, and money to court battles, all of which could otherwise be spent developing new pharmaceuticals."

THE MARKETING EXCLUSIVITY PERIOD

The first generic to file the ANDA — with respect to a particular Brand's drug — using Paragraph IV becomes eligible for an exclusive 180-day marketing period. During this

time, the Food and Drug Administration ("FDA") may not approve any other ANDAs on that drug. This exclusivity period promises huge profits for the first-filing generic.

To be able to take advantage of Paragraph IV's exclusivity period, the generics aim to develop drugs with the same function as the Brand's drug but with enough differences to distinguish the generic version from the patent-protected Brand version. In the vast majority of cases though, the Brand responds to the Paragraph IV ANDA filing by suing the generic for patent infringement.

The 30-Month Stay

The Brand's patent infringement suit automatically triggers a 30-month stay. During the 30-month stay, the FDA may not act on the Paragraph IV ANDA filed by the generic. Additionally, under the current law, the Brand may eventually get more than one 30-month stay.

To further explore what this entails, it is important to know how the Brand's patents are initiated. The Brand's patents are listed in the FDA's Orange Book. The Orange Book is the common name for the FDA publication entitled, "Approved Drug Products With Therapeutic Equivalents Evaluations," which lists the patents claiming a drug or method of using a drug. As the Brand makes improvements or changes to the drug, the Brand can patent these changes and list them in the Orange Book. Because the FDA has no authority to review patents to determine their validity, it has to list them. This allows the Brand to patent new changes when the old patents expire. Then, the Brand can get multiple 30-month stays—a new stay for each new patent—in response to a generic's Paragraph IV ANDA.

Agreements Not to Market

Faced with a patent challenge, the Brand may take an additional step outside the normal Hatch-Waxman litigation process. According to a study issued in July, 2002 by the Federal Trade Commission ("FTC"), Brands have pursued settlement agreements with generics. Generic Drug Entry Prior to Patent Expiration: An FTC Study, at *http:www.ftc.gov/os/2002/07/genericdrugstudy.pdf* (July, 2002). For example, a generic that gets the 180-day exclusivity period may agree to a settlement with the Brand, in which the generic refrains from marketing its version of the drug in exchange for a significant payment. The FTC study recommended that Brands should file such settlement agreements with the FTC. This point was included in a recent legislative move by the Senate to alter Hatch-Waxman.

Legislative Action

In July 2001 the Senate approved the Greater Access to Affordable Pharmaceuticals Act ("GAAP"), brought by Senators John McCain (R-AZ) and Charles Schumer (D-NY). S. 812, 107th Cong. (2001). Besides requiring Brands to file settlements with the FTC, the GAAP also allows for only one 30-month stay. Thus, the 30-month stay would no longer apply to every new Brand patent for a particular drug. Instead, the Brand would only be granted a 30-month injunction against the generic when the generic gets a Paragraph IV certification for a patent listed within 30 days after the Brand's New Drug Application ("NDA") is approved. Furthermore, the Brand would not receive a 30-month stay for Paragraph IV certifications against later Brand patents. Rather, to protect new patents, the Brand would have to seek a preliminary injunction from the court against the generic, and then it would wait until the court determines whether or not the Brand's new patent is valid.

Another change in the GAAP from Hatch-Waxman is that the Brand would have to bring an infringement action within 45 days of the generic providing notice to the Brand that it filed a Paragraph IV ANDA. If the Brand fails

to do so, the Brand is then barred from bringing the action.

The future of the GAAP is uncertain, as it remains in the House after being referred to the House Subcommittee on Health in June, 2001, but the make-up of Congress has since changed. H.R. 1862, 107th Cong. (2001). President George W. Bush, however, has joined the movement to alter the provisions of Hatch-Waxman.

"The underlying purpose behind Hatch-Waxman was an effort to strike a balance between the interests of the generic companies and the Brands."

– Intellectual Property Attorney Christopher T. Griffith, Leydig Voit & Mayer, Ltd.

Statements by the President in Support of Change

In an October 2002 statement, President Bush recognized the need to balance intellectual property rights while ensuring that consumers were not overpaying for needed pharmaceuticals. *President George W. Bush, Remarks on Prescription Drugs at The Rose Garden* (Oct. 21, 2002) (transcript available at *http://www.whitehouse.gov/news/releases/2002/10/20021021-2.html*). The President referred to the FTC study that asserted that Brands were manipulating Hatch-Waxman in order to protect patents at the expense of consumers. Additionally, President Bush backed a proposal about to be issued by the FDA containing similar features as the GAAP. Applications for FDA Approval to Market a New Drug, 67 Fed. Reg. 65447 (proposed Oct. 24, 2002). The FDA proposal would present a list of patents that should not be issued, such as those for product packaging and the addition of intermediates. (Intermediates are materials produced during the processing of the Brand's active pharmaceutical ingredient but are not present in the final drug product.) The proposal would also limit the number of 30-month stays to one.

Statements from the Courts

While the FDA's proposal would allow the FDA to determine what does and does not establish a valid patent, the courts have disagreed with this position. Specifically, the Fourth Circuit has declared that "the FDA has no expertise in making patent law judgments." *aaiPharma v. Thompson*, 296 F.3d 227 (4th Cir. 2002). Furthermore, courts have not been hesitant to protect Brand patents. (See *Astra Aktiebolag v. Andrx Pharmaceuticals, Inc.*, 222 F.Supp.2d 423.)

The Argument for Protecting Innovation

Brands argue that patents promote innovation in the pharmaceutical industry. In his statement, President Bush even acknowledged that it can cost as much as $800 million to bring a new drug to the market. Additionally, the patent on a new Brand is filed when it is first developed. The Brand may undergo years of testing before getting FDA approval to market the drug, which often comes close to the patent's expiration date. As a result, the Brand's opportunity to realize a return on its efforts is significantly diminished, unless some kind of patent extension is achieved.

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