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BIOTECH UPDATE
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THE BIOSIMILARS ARE COMING – BUT IS IT BY LAND OR BY SEA?

*Nimalka R. Wickramasekera**

Biosimilars are coming. They are already in Europe, and there is significant momentum to develop a regulatory framework for their approval in the US. But the big questions – what must be shown to establish "biosimilarity" and what is the proper regulatory and patent framework – still remain to be resolved by Congress. It seems nearly everyone has an opinion, and the branded biotech and generic companies are both making their cases to Congress and in the court of public opinion. With the prospect of legislation being enacted sooner rather than later, this article provides an update on the competing legislative proposals and how they might play out in the form of patent litigation in the years to come.

Hatch-Waxman Mechanism For Generic "Small Molecule" Drugs

Congress is not writing on a blank slate as it looks to establish a statutory scheme for the approval of biosimilars. We now have a 25-year history with the Hatch-Waxman Act, which governs the approval of generic "small molecule" drugs. The Hatch-Waxman Act sought to strike a balance between competing public policies: encouraging research and development investment in the discovery of new pharmaceuticals by brand-name drug companies and reducing the cost and perceived delay of generic drug approval.[1] The Act made sweeping changes in creating a statutory and regulatory framework for the approval of generic small molecule drugs. These included substantial revisions of the Federal Food Drug and Cosmetic Act and the Patent Act to allow submission and approval of Abbreviated New Drug Applications (ANDAs), and to create an entire scheme for addressing patent infringement issues.[2]

But the Hatch-Waxman Act does not apply to biosimilars, nor should it. Small molecule generic drugs, for which ANDA approval is sought under Hatch-Waxman based on a showing of bioequivalence, contain the same active ingredient as the reference drug. Biological products, however, are different: they are generally large, complex molecules produced by living organisms. As a result, slightly different production processes used by a follow-on manufacturer will at best yield a biological product similar, but not identical, to the reference product. These differences may have significant impacts on the efficacy and safety of the drug. It is this lack of identity between a reference biological product and a follow-on product that renders the Hatch-Waxman framework largely unworkable in the context of biosimilars.

Rival Biosimilars Bills In Congress

Competing bills have recently been introduced in Congress to establish an abbreviated pathway for approval of follow-on biological products. One bill comes from Rep. Henry Waxman, introduced on March 11, 2009 with the politically-attractive title of "Promoting Innovation and Access to Life-Saving Medicine Act." (H.R. 1427) Sen. Charles Schumer introduced an identically-worded companion bill (S. 726) in the Senate on March 26, 2009. One week after Waxman's proposal, Rep. Anna Eshoo introduced a bill with the decidedly less

compelling title of "Pathway for Biosimilars Act." (H.R. 1548). Several key distinctions between the rival bills have led the branded biotech and generic industries to support, respectively, the Eshoo and Waxman bills.

Data Exclusivity and Biosimilarity/ Interchangeability

First and foremost, the bills differ significantly in the period of data exclusivity during which the FDA cannot approve a follow-on biologic that chooses to rely on clinical data submitted by the branded biotech company. The Waxman bill affords only five years of data exclusivity, which has evoked an outcry that such limited protection would seriously undercut the incentive for innovation of new biological products. The Eshoo bill, on the other hand, affords twelve years of exclusivity, with two additional years available where a new indication has been sought and approved for the product.

The bills also provide different data requirements for demonstrating the "biosimilarity" and "interchangeability" of a follow-on and reference product. While both bills leave many issues to the discretion of the FDA, the Eshoo bill requires the applicant to conduct analytical, animal, and clinical (including immunogenicity and pharmacokinetic) studies on the follow-on product. The FDA is permitted to waive these requirements, but in the case of immunogenicity studies only if the FDA has published a final guidance (regarding the science and data that supports immunogenicity similarity) after receipt and consideration of public comments on a draft guidance. The Waxman bill does not include a similar provision requiring immunogenicity data. The Waxman bill even contemplates giving biosimilars the same drug name if they are found interchangeable, whereas the Eshoo preserves a unique name for the reference product.

Patent Provisions

Although some in industry have questioned the need for a biosimilar-specific patent scheme, the competing bills both acknowledge that a special framework for patent notice and litigation should be adopted. There is further agreement among the bills that a formal patent listing system, such as the Orange Book approach provided for in the Hatch-Waxman Act, should not be adopted. But this is where the agreement between the proposed patent provisions ends.

The Waxman bill would permit the biosimilar applicant at any time (including before filing a biosimilar application) to request patent information from the branded biotech company, which must then respond within 60 days with a list of all patents it believes "in good faith relate to the reference product." After it has filed its application, the applicant may, but is not required to, send notice to the branded biotech company of the application, and such notice must include a statement of the factual and legal basis for its belief that the patents listed with respect to the referenced product are invalid, unenforceable, and/or not infringed. After receiving this statement, the patent holder may sue for infringement within 45 days, but only with respect to the patents included in the biosimilar applicant's notice. The key, and one sticking point for branded companies, is that the Waxman voluntary provisions afford biosimilar applicants with the option to provoke early patent litigation upon filing of an application, or to alternatively fly below the radar and possibly avoid suit until after approval of the biosimilar.

The Waxman bill contains other provisions that tilt the patent playing field in favor of the follow-on applicant. The bill provides a mechanism by which the applicant can move to transfer lawsuits to courts they perceive as being more favorable, with special preference articulated for courts that can expeditiously resolve the lawsuits. In certain cases, the Waxman bill also limits the remedy available to the patent holder to a reasonable royalty, eliminating all other measures of damages and injunctive relief. This provision applies where the action was brought either after the expiration of the 45-day period following notice of filing a biosimilar application or before expiration of the 45-day period where

the action was dismissed without prejudice or was not prosecuted to judgment in good faith.

The Eshoo bill differs in significant respects by providing for the mandatory exchange of patent information after the filing of a biosimilar application. Under the Eshoo bill, the applicant is required to provide the branded biotech company a copy of the biosimilar application, and a detailed description of the product, the methods of manufacture, and the materials used in manufacture. Within 60 days, the branded company must provide a list of patents relating to the biosimilar product, along with an explanation for why it believes each patent would be infringed. The biosimilar applicant then has 45 days either to notify the branded company that it will not commence marketing of the product before the listed patents expire, or to explain why the product would not infringe and/or why the patent is invalid or unenforceable. The branded company then has 60 days to file suit for infringement of any patent on the list. If no affirmative suit is filed, the Eshoo bill allows a biosimilar applicant to bring a declaratory judgment action, but not until 120 days after the applicant provided its detailed explanation.

Concluding Thoughts

The political will to adopt biosimilars legislation seems to be growing, with odds now in favor of legislation being adopted in the next year. If provisions more like those proposed in the Waxman bill are adopted, allowing generic companies to seek patent information "at any time" and with a much shorter period of data exclusivity, biosimliars patent litigation is likely right around the

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1 Critics of the Hatch-Waxman Act take aim at it from both sides. Some say it went too far, removing the incentive for pharmaceutical research and development, contributing to a decrease in the discovery of new drugs, and allowing approval upon a mere showing of bioequivalence. Others argue it didn't go far enough, providing too much protection for the branded products, unnecessarily delaying approval and entry of generic competition, and failing to control spiraling health care costs.

2 Under the Act, the brand-name drug company is required to list in its New Drug Application all patents claiming the drug or methods of using the drug "with respect to which a claim of patent infringement could reasonably be asserted." The FDA publishes this information in its Orange Book. Generic companies submitting an ANDA must file one of four different patent certifications with respect to the patents listed in the Orange Book for the brand-name drug to which they claim equivalence. If seeking to market its generic drug prior to expiration of one or more of the listed patents, the required certification — a "Paragraph IV" certification — must include a statement that the listed patent is invalid, unenforceable, and/or not infringed. The patent holder may then bring suit within 45 days of receiving notice, with such a suit triggering a 30-month stay of any approval of the generic application by the FDA.

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IT'S A LIVING THING: THE CHANGING NATURE OF PATENT EXHAUSTION LAW

*David MacDonald**

Beware – that shaking beneath your feet is the ground shifting with respect to the law governing patent licenses and agreements. Recent decisions by the United States Supreme Court and the Federal Circuit Court of Appeals relating to the patent exhaustion doctrine have sent tremors though the patent licensing landscape. Prudent lawyers are now looking back at their old agreements, and trying to determine how to draft new agreements, to avoid the impact of the decisions in *Quanta Computer, Inc. v. LG Electronics, Inc.* and *TransCore, LP v. Electronic Transaction Consultants Corp*. And these cases and the shifting law are especially important in the context of biotech patent licenses and related agreements, where the nature of the technology sometimes leads to attempts to allocate different rights for different entities that may be involved. To help your company navigate this new landscape, this article summarizes the recent *Quanta* and *TransCore* decisions and their potential impacts on patent agreements.

Patent Exhaustion And The First Sale Doctrine

Companies selling their patented inventions as products, or licensing others under their patents to sell such products, must take account of the *first sale doctrine* under U.S. patent law. In general, the first sale doctrine provides that the first authorized sale of a patented item terminates all patent rights embodied in that item. The first sale doctrine is also often referred to as the doctrine of *patent exhaustion* because the first authorized sale is said to *exhaust the patents* embodied in the sold item, preventing patent infringement claims against downstream users or sellers of the patented item.

Patent exhaustion can be a particularly acute issue for biotechnology companies that seek to impose post-sale restrictions such as "for research use only," "for single use only," and "not for resale." Such restrictions are sometimes critical to preserving the value of products subject to easy and unlimited replication, *e.g.* recombinantly-generated seeds, DNA, or bio-fuel-producing microbes. Patent exhaustion can thus potentially frustrate patent owners seeking to license their patents across multiple levels of a development or distribution chain. Patent owners may seek to enforce restrictions under contract or other applicable law, but patent owners aren't always a party to the purchase agreement and, even if they are, contract remedies can often fall short (*e.g.,* injunctions are not as easy to obtain).

Companies facing patent exhaustion issues have historically found some relief under the Federal Circuit's *conditional sale rule*, which provides that a "validly conditioned" sale (*i.e.,* where the condition or restriction is within the scope of the patent grant) does not exhaust patents. In *Mallinckrodt v. Medipart,* the Federal Circuit held that the sale of medical devices to hospitals with a "single use only" restriction, both as inscription on the product and as a package insert, was a validly

conditioned sale that did not exhaust the asserted patents and therefore could be remedied by claims for patent infringement.[1] But that all became subject to new questions last year.

Quanta Changes The Landscape

On June 9, 2008, the Supreme Court issued its unanimous opinion in *Quanta Computer v. LG Electronics*,[2] overturning an application of the conditional sale rule by the Federal Circuit. In *Quanta*, LG licensed patents to Intel to make and sell Intel chipsets with the express stipulation that no license was granted to any Intel customers to use or sell the chipsets in combination with third party products. LG further required Intel to give its customers written notice that the LG license rights did not cover any customer products made by combining an Intel product with any non-Intel product. Quanta purchased Intel chipsets under the required notice and used the chipsets to make computers in combination with non-Intel parts. LG then sued Quanta for infringement of the LG patents.

The Federal Circuit had concluded that because the LG-Intel license expressly disclaimed any license for the combination of Intel's licensed parts with non-Intel components, and because Intel was required to and did notify Quanta of the limited scope of the license, the sales of chipsets by Intel to Quanta were validly conditioned, and therefore LG's patent rights were not exhausted.[3] The Supreme Court unanimously reversed, finding that Intel was in fact authorized to "make, use and sell" under LG's patents without restriction[4] and that the notice to purchasers purporting to limit patent rights was merely a disclaimer of implied license rights and "irrelevant" to the application of the patent exhaustion doctrine.[5]

Surprisingly, the *Quanta* decision does not mention any Federal Circuit cases, but at least one district court has concluded that the Supreme Court in *Quanta* has "overruled *Mallinckrodt sub silentio*."[6] Whether that interpretation is correct, or whether *Quanta* is just a case about contracts that could have been written more effectively, will undoubtedly be the subject of further litigation.

And Then Came *TransCore*

In *TransCore v. ETC*,[7] the Federal Circuit took the next step and addressed the question of whether a covenant not to sue is the equivalent of a patent license for purposes of patent exhaustion. Following *Quanta's* lead, the Federal Circuit held in *TransCore* that "an unconditional covenant not to sue" *does* authorize sales "by the covenantee for purposes of patent exhaustion."

TransCore involved a situation wherein TransCore had entered into a settlement agreement with its competitor Mark IV, granting Mark IV an unconditional covenant not to sue under the litigated patents, while attempting to make clear that it was not granting any rights to Mark IV's customers. In the subsequent suit against one of Mark IV's customers, TransCore pointed to its express reservation and argued that the covenant to Mark IV did not authorize the sale of the patented products because it only provided a promise not to sue Mark IV, not an affirmative grant of any license rights or other permission to sell. The Federal Circuit rejected the distinction, however, explaining that a license passes no affirmative rights under the patent but is merely a waiver of the right to sue by the patent owner: "a patentee, by license or otherwise, cannot convey an affirmative right to practice a patented invention by way of making, using, selling, etc.; the patentee can only convey a freedom from suit."[8] The Federal Circuit concluded that a covenant not to sue "for future infringement," without further restriction, "thus authorizes all acts that would otherwise be infringements: making, using, offering for sale, selling, or importing."[9] Therefore, the unconditional covenant not to sue in the settlement agreement unambiguously authorized Mark IV's sales without restriction and exhausted TransCore's patents.

Under *TransCore's* holding, the key question for purposes of patent exhaustion is not

whether an agreement includes a "covenant not to sue" or a "license," but whether the agreement ultimately authorizes sales of the patented products. Covenants not to sue are often used by parties who seek to avoid not only patent exhaustion, but other implications of licenses as well (*e.g.,* creating a basis for royalties under most favored nation obligations to existing licensees or for purposes of future litigation damage awards). Covenants not to sue are also often more broadly drafted than licenses (*e.g.,* covenants not to sue are not limited to fields of use or specific territories as often as licenses) perhaps because of the belief that covenants are somehow more limiting than licenses.

Where Are We At Post-*Quanta* And Post-*TransCore*?

After *Quanta*, the application of the conditional sale rule appears to have been limited at least in certain respects (*i.e.,* it appears sales cannot be validly conditioned by mere notice or disclaimers) if not impliedly overturned. After *TransCore*, the differences between patent licenses and covenants not to sue for patent infringement appear to have been narrowed, and it remains to be seen how much daylight future cases will find between them for patent exhaustion purposes. As a result, patent owners should diligently review their sales and licensing transactions and their settlement agreements

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1 *Mallinckrodt, Inc. v. Medipart, Inc.,* 976 F.2d 700 (1992).

2 *Quanta Computer, Inc. v. LG Electronics, Inc.,* 128 S.Ct. 2109, 170 L.Ed.2d 996, 76 USLW 4375, 86 U.S.P.Q.2d 1673 (2008).

3 *LG Electronics, Inc. v. Bizcom Electronics, Inc.,* 453 F.3d 1364 (2006).

4 *Quanta*, 128 S. Ct. at 2121.

5 *Id.* at 2122.

6 Memorandum Opinion and Order, *Static Control Components, Inc. v. Lexmark Intern., Inc.,* Civil Action Nos. 5:02-571 and 5:04-84 (E.D. Ky. Mar. 31, 2009).

7 *TransCore, LP v. Electronic Transaction Consultants Corp.,* No. 2008-1430 (Fed. Cir. Apr. 8, 2009).

8 *Id.* at 5.

9 *Id.*

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