Bloomberg BNA

Pharmaceutical Law & Industry Report®

Reproduced with permission from Pharmaceutical Law & Industry Report, 14 PLIR 10 , 03/04/2016. Copyright © 2016 by The Bureau of National Affairs, Inc. (800-372-1033) http://www.bna.com

The ITC and Biosimilars: Strategies for Brand-Biologics Companies Against Biosimilar Applicants



BY DANIEL E. YONAN, DALLIN G. GLENN AND AISHA M. HALEY

Biologics companies should consider using the United States International Trade Commission's ("ITC") Section 337 investigations as a forum for enforcement of intellectual property rights against unwanted competition from biosimilars that are manufactured abroad and subsequently imported and distributed domestically.[1] Specifically, Section 337 provides four advantages to a biologics company seeking to protect its market share against increasing competition that are not available to litigants in district courts: (1) an ITC investigation does not depend on emerging BPCIA jurisprudence; (2) the brand-biologics company can more easily obtain faster injunctive relief at the ITC; (3) the breadth and pace of discovery at the ITC allows the brand-biologics company to understand key substantive issues earlier; and (4) an Administrative Law Judge is unlikely to stay a Section 337 investigation pending *inter partes* review.

[1] *See* Daniel E. Yonan & Dallin G. Glenn, Section 337's Potential for Defending Biologics Market Share Against Biosimilars, Sterne, Kessler, Goldstein & Fox P.L.L.C. (2015), http://skgf.com/uploads/1380/doc/Section_337_Potential_for_Defending_Biologics_Market_Share_Against_Biosimilars.pdf.

Daniel E. Yonan is a Director in Sterne, Kessler, Goldstein & Fox's Litigation Practice Group. Dallin G. Glenn and Aisha M. Haley are associates in the firm's Litigation Group.

Background

Congress passed the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") to outline a procedure for companies to seek approval of generic biologics therapies. There are several steps to filing for generic approval under the BPCIA: A brand-biologics company (the "reference product sponsor" or "RPS") seeks approval for a biologic therapy by filing a biologics licensing application. Four years after the FDA approves the RPS's BLA, a biosimilar applicant can file a biosimilar application on a bioequivalent product under 42 U.S.C. § 262(k). The FDA cannot approve a biosimilar application until 12 years after the FDA's approval of the RPS's product.

The statute contains a framework for information disclosure between the biosimilar and the RPS, colloquially known as the "patent dance." The patent dance allows the RPS and the biosimilar applicant to engage in a series of information exchanges before engaging in litigation.[2] To initiate the patent dance, the biosimilar applicant provides the RPS with access to the biosimilar application and manufacturing information. In *Amgen v. Sandoz*, the Federal Circuit found that the patent dance is not mandatory, and the biosimilar applicant may choose whether to initiate the patent dance by dis-

[2] For a description of how the filing process and the patent dance operate, *see Amgen v. Sandoz*, 794 F.3d 1347, 1352-1353 (Fed. Cir. 2014).

COPYRIGHT © 2016 BY THE BUREAU OF NATIONAL AFFAIRS, INC. ISSN 1542-9547

closing its biosimilar application and manufacturing information. [3]

The statute further requires that the biosimilar applicant give notice of commercial marketing to the RPS at least 180 days before launching its product. During the 180 days, the RPS can file a declaratory-judgment action to seek a preliminary injunction based on patents that were either newly issued to or exclusively licensed by the RPS or patents that were initially identified but not ultimately selected during the patent dance. The Federal Circuit in *Amgen v. Sandoz* held that a biosimilar who opted out of the patent dance was required to provide the notice of commercial marketing *after* the FDA approved the biosimilar application. But the case did not resolve whether the 180-day marketing notice is mandatory when biosimilar applicants *do* engage in the patent dance. Only one judge has addressed this issue, and that judge found that the 180-day notice is mandatory—regardless of whether or not the biosimilar decided to initiate the patent dance.[4] The case is pending appeal at the Federal Circuit.[5]

(1) An ITC Action Does Not Depend on Emerging BPCIA Jurisprudence

Because the BPCIA is in its infancy, biologics companies should consider using ITC actions to avoid the uncertainty presented by this new law. The statute is complex and difficult to parse: In the first Federal Circuit case interpreting the statute, Judge Lourie described it as ''a riddle wrapped in a mystery inside an enigma.''[6]

The contours of the BPCIA are still being resolved by the courts, and this creates uncertainty for biologics companies seeking to protect their patents. Only a few biosimilar cases have been filed in district court, so there is virtually no data on how courts approach BPCIA and biosimilar issues. And the statute is so different from its counterpart for small molecules, the Hatch-Waxman Act, that lessons from the Hatch-Waxman context may not be transferrable.

If an RPS can meet the jurisdictional requirements for an ITC action,[7] filing at the ITC avoids the uncertainty created by the dearth of case law on the BPCIA patent dance and notice provisions. Whether or not the ITC issues an exclusion order is completely independent of the BPCIA framework and emerging BPCIA jurisprudence.

(2) The RPS Can Secure More Extensive Injunctive Relief Faster and More Easily at the ITC

Patent enforcement is an essential part of protecting a biologics-patent portfolio. Speedy resolution of patent disputes is especially important for biologics: A biosimilar competing with the RPS for even a short time can cause irreversible price erosion. Additionally, one competing biosimilar may attract other generic companies to challenge the RPS's patents or develop their own bioequivalent products. Enforcing patents against infringers early and effectively minimizes their effects on the market and protects the RPS's market exclusivity.

An RPS can obtain both preliminary and permanent injunctive relief much quicker at the ITC than it could in comparable district court litigation. The BPCIA contemplates a 180-day window to secure a preliminary injunction in district court, but the ITC could grant a temporary exclusion order within 90 to 150 days of filing the complaint. Moreover, securing a permanent injunction in a district court case could take well over two years, but the ITC can issue a permanent exclusion order within 14-18 months of filing the complaint. In terms of time-to-resolution, the ITC wins for both preliminary and permanent relief.

Additionally, injunctive relief at the ITC is easier to secure than comparable district-court relief. To obtain an injunction—preliminary or permanent—in district court, a patentee has to establish the *eBay* factors, including, most notably, irreparable harm.[8] But at the ITC, a biologics company that prevails on the merits is virtually guaranteed to receive an injunction against biosimilar imports and may also receive a cease-and-desist order preventing sales and marketing of the biosimilar in the U.S.

The ITC also provides the ability to enforce all relevant patents at once—another distinct advantage over district court BPCIA litigation. At the ITC, the RPS can allege infringement of any method or apparatus patent that covers its biological product. This would include method-of-manufacture claims which are particularly relevant for biologics, as large biologics molecules may be easiest to describe in terms of the process by which they are manufactured.[9]

Furthermore, at the ITC the RPS can enforce its patents regardless of whether the biosimilar applicant initiated the patent dance. In district court, when the biosimilar opts into the patent dance, the RPS is limited to

---

[3] The Federal Circuit found that opting out of the patent dance was ''a path expressly contemplated by the BPCIA.'' *Id.* at 1357.

[4] *Amgen v. Apotex*, No. 0:15-cv-61631 (S.D. Fla. Dec. 9, 2015).

[5] *Amgen, Inc. v. Apotex, Inc.*, No. 16-1308 (Fed. Cir. filed Dec. 11, 2015).

[6] *Amgen v. Sandoz,* 794 F.3d at n1.

[7] In addition to winning on substantive positions, an RPS will need to prove three fundamental requirements at the ITC: (1) the conflict must implicate actual or imminent import or sale of the accused infringing biosimilar into the U.S.; (2) the RPS must demonstrate that its biologic product is covered by its asserted patents and that it has sufficient domestic manufacturing, research operations, or other qualifying domestic economic activity as to satisfy the Commission's domestic industry requirement; and (3) the investigation must be in furtherance of the public interest.

[8] *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

[9] In *Amgen v. Sandoz*, the Federal Circuit suggested in a footnote that method-of-manufacture claims could be included in district court litigation: ''While it is true that 42 U.S.C. § 262(l)(9)(C) premises the declaration judgment action on ''*any patent that claims the biological product or a use of the biological product*'' (emphasis added), which does not appear to include process patents, 35 U.S.C. § 271(e)(2)(C)(ii) does contemplate an infringement action based on ''a patent that *could be identified pursuant to [paragraph] (l)(3)(A)(i)* '' (emphasis added), which does not exclude process patents. Section 271(e)(2)(C)(ii) allows the RPS to assert process patents, ''if the [subsection (k)] applicant . . . fails to provide the application and information'' and ''the purpose of [the subsection (k)] submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a . . . biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.'' 35 U.S.C. § 271(e)(2).'' *Amgen v. Sandoz*, 794 F.3d. at n.3.

 COPYRIGHT © 2016 BY THE BUREAU OF NATIONAL AFFAIRS, INC. PLIR ISSN 1542-9547

asserting agreed-upon patents in the first round of litigation. The RPS can later bring a declaratory-judgment action to enforce non-listed patents after the biosimilar provides its 180-day notice of commercial marketing, but the Federal Circuit has not yet resolved whether this notice is mandatory when the biosimilar chooses to initiate the patent dance.[10] If the courts find that notice is not mandatory in this scenario, the RPS may have to wait until the biosimilar product launches to seek injunctive relief for its non-listed patents in district court. Time spent waiting can cost an RPS revenues, market share, and preferential pricing.

(3) The Breadth and Pace of Discovery at the ITC Allows the RPS to Understand Key Issues of the Case Earlier

Discovery at the ITC is fast-tracked and allows the RPS to secure important information about the case earlier than would be possible in district court. ITC actions also operate outside of the BPCIA framework: In cases where the biosimilar opts out of the patent dance, the RPS would have to file a declaratory judgment in district court and seek the biosimilar application and manufacturing information via discovery.[11] This process would take several months and may only yield incomplete information.

Conversely, at the ITC, discovery begins immediately after the investigation is instituted, and the Commission has power to compel discovery from any respondent anywhere in the world. This provides unrivaled access to foreign manufacturing information. The RPS can quickly gain access to information regarding the biosimilar's manufacturing and launch plans—even if it sources all or part of its biosimilar product from foreign countries. And Section 337 even allows for domestic and foreign site inspections.

Earlier and more comprehensive discovery means that the RPS will be able to more quickly develop case strategy for both the ITC and potentially co-pending district court actions. The information will allow the RPS to appraise its likelihood of success on its allegations of patent infringement and plan accordingly.

(4) An Administrative Law Judge is Unlikely to Stay a Section 337 Investigation Pending *Inter Partes Review*

Inter partes review (''IPR'') proceedings are increasingly used to challenge biologic patents:[12] For instance, an IPR challenging a patent covering Amgen's Enbrel® therapy is currently pending.[13] Although a district court may likely stay its proceedings pending the outcome of an IPR,[14] an Administrative Law Judge at the ITC is much less likely to do so. This means that the ITC investigation will progress towards a final resolution despite the filing of an IPR—further reinforcing the notion that the ITC is an appealing forum for biosimilar disputes. And an ITC investigation can be crafted so as to not interfere with a co-pending district court proceeding based upon careful consideration of the asserted patents in the district court complaint,[15] offering a complementary, parallel proceeding to ensure another layer of added protection against biosimilar competition.

Conclusion

In summary, biologics companies should consider use of ITC investigations to protect their biologics from unwanted biosimilar competition. Initiating an ITC investigation provides a number of advantages to an RPS seeking to prevent the launch of a biosimilar. For example, an ITC action provides relief without relying on emerging BPCIA jurisprudence. Additionally, an ITC action can provide injunctive relief from patent infringement on a larger number of patents than a district court action. This relief is available earlier than would be possible in district court, and the RPS would not have to prove the *eBay* factors to secure injunctive relief. The breadth and pace of discovery at the ITC minimizes uncertainty, allowing the RPS to understand key issues of the case earlier. And finally, especially in a climate where IPRs are becoming more popular, an ITC action is especially valuable because it will likely not be stayed pending IPR.

---

[10] Sandoz petitioned for certiorari on February 16, 2016, asking the Supreme Court to resolve whether the notice provision was ''a standalone requirement'' that applies to all biosimilar applicants. Petition for Writ of Certiorari at ii, *Sandoz, Inc. v. Amgen, Inc*., No. 15A672 (Feb. 16, 2016).

[11] But filing this type of declaratory-judgment action presents its own challenges. A complaint for a declaratory judgment without access to the biosimilar application or manufacturing information may lack the evidentiary support required by Rule 11 or 35 U.S.C. § 285 after *Octane Fitness v. Icon Health*, 134 S.Ct. 1749 (2014). Filing an action that does not meet the requirements of Rule 11 or § 285 could expose the RPS to both a dismissal of the declaratory-judgment action and liability for attorney's fees.

[12] *See* Paul Calvo and Eldora Ellison, The 1st IPR Institution Decisions for Biosimilars, *Law360* (2015), http://www.skgf.com/news/the-1st-ipr-institution-decisions-for-biosimilars.

[13] *Coalition for Affordable Drugs V, LLC v. Hoffman-LaRoche Inc.*, IPR2015-01792 (filed Aug. 22, 2015).

[14] As of October 2014, approximately 67% of motions to stay pending IPR and Covered Business Method Review have been granted in district court. Jon E. Wright & Deborah A. Sterling, Two Years Later: Observations from the second year of contested proceedings at the USPTO, Sterne, Kessler, Goldstein & Fox P.L.L.C. (2014), http://www.skgf.com/uploads/1232/doc/2_Years_Later_IPR_report.pdf.

[15] A defendant in district court can stay its proceedings pending the resolution of an ITC action on the same patents under 28 U.S.C. § 1659, but this risk is minimized when the patents at issue in each forum are different, i.e., the RPS can assert different patents in the district court action to avoid a stay. *See Humanscale Corp. v. Compx International, Inc*., No. 3:09-cv-86 (E.D. Va. Mar. 21, 2009).