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Section 337's Potential for Defending Biologics Market Share Against Biosimilars

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Enforcement of biologic patents at the United States International Trade Commission under Section 337 provides certainty and tactical advantages to patent holders that are unavailable in district court under the BPCIA. For example, broad domestic and international discovery obligations commence immediately upon institution, a greater selection of patents may be enforced, equitable remedies prohibiting importation and sales are mandatory, and the accelerated schedule will not be derailed by IPRs, counterclaims, or process patent defenses under Section 271(g). Based upon these benefits (and others discussed below), Section 337 is a valuable biologic enforcement mechanism for therapeutic companies who have historically underutilized the tactical advantages offered by this forum.

Background regarding the BPCIA

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") was enacted on March 23, 2010, as part of the Patient Protection and Affordable Care Act. It provides that the submission of a biosimilar application can be an act of infringement of patents that are or could be identified through the BPCIA's patent dispute process (the "Patent Dance").

In theory, the BPCIA allows biosimilar applicants and the reference product sponsor ("RPS") to begin resolving patent disputes before the U.S. Food and Drug Administration ("FDA") approves the biosimilar application. After the FDA accepts the biosimilar application for review, the applicant has 20 days to initiate the Patent Dance by providing the application and relevant manufacturing info to the RPS. Then both parties, after a series of exchanges over about 8 months, agree to a list of patents that can be asserted. In practice, however, the courts and the FDA to date have not required an applicant to share its application with the RPS.[1]

Unless and until such a requirement is imposed, the option to initiate the Patent Dance provides strategic advantages to the applicant. The applicant may be able to launch the biosimilar by using the Patent Dance to delay a lawsuit and preliminary injunction motion long enough for the biosimilar to be approved. Or by opting out of the Patent Dance entirely, the applicant can prepare for launch while concealing the biosimilar's precise composition and, more importantly, its manufacturing processes and opposing any infringement complaint for lack of evidentiary support under Rule 11. Further, foreign affiliates of the applicant can oppose discovery on jurisdictional grounds. How can the RPS faced with this dilemma obtain the information needed to support its infringement allegations in time to prevent launch of the biosimilar through a preliminary injunction?

The savvy RPS can use Section 337 to supplement enforcement under the BPCIA

To overcome these problems and gain additional tactical advantages unavailable under the BPCIA, the RPS can file a complaint alleging patent infringement at the U.S. International Trade Commission ("ITC"), an agency that investigates acts of unfair competition in the import trade under Section 337 of the Tariff Act. These advantages are discussed below.

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1 See FDA Denial of Citizen's Petition of Jeffrey Kushan, Docket No. 2014-P-1771 (March 25, 2015) (denying request to require biosimilar applications to include a certification that the applicant will provide the RPS with a copy of the biosimilar application); *Amgen v. Sandoz*, Case No. 14-cv-04741-RS (N.D. Cal. Mar. 19, 2015) (denying motion for preliminary injunction against biosimilar applicant Sandoz because Sandoz's "decision not to [disclose its application to Amgen] was within its rights"), *appeal docketed*, No. 15-1499 (Fed. Cir. Mar. 26, 2015).

First, as noted above, to date courts have not required the applicant to disclose the biosimilar application and manufacturing information, so the RPS may have to file a declaratory judgment action for infringement and seek the application through discovery. This process will take several months and may yield only incomplete information because district courts lack jurisdiction to compel a foreign manufacturer to disclose its manufacturing process or permit site inspections. But at the ITC, discovery begins immediately upon institution of the investigation and the Commission has power to compel discovery from any respondent anywhere in the world.

Second, the BPCIA can limit the ability of the RPS to assert method-of-manufacture claims. These claims are important for biologics whose complex structures often require that they be described in terms of the process by which they are made. But at the ITC, the RPS can assert method-of-manufacture claims in addition to product and method-of-use claims.[2]

Third, to obtain an injunction under the BPCIA the RPS must satisfy the *eBay* standard including irreparable harm—a high bar if the biosimilar has already launched. But at the ITC, by prevailing on the merits an RPS is virtually guaranteed to receive an injunction against biosimilar imports and may also receive a cease-and-desist order preventing sales and marketing in the U.S.

Fourth, biosimilar applicants may petition for *inter partes* review (IPR) at the USPTO in order to invalidate patents identified during the Patent Dance or asserted in district court.[3] District court actions are frequently stayed pending IPRs, but ITC investigations are far less vulnerable to such stays.

Finally, the BPCIA provides safe harbors to the biosimilar applicant who chooses the Patent Dance. The RPS may file a complaint on a listed patent only after the Patent Dance concludes, and the RPS will forfeit the right to seek an injunction if it waits more than 30 days. Moreover, the RPS may not seek a preliminary injunction until the applicant provides the 180-day marketing notice, regardless of whether the applicant chooses the Patent Dance. But the ITC is not subject to any of these restrictions. The RPS may file an action on any patent at any time provided the jurisdictional and standing requirements are met. In addition, the ITC has a much faster docket where temporary exclusion orders can be obtained in 4 to 6 months *including time for discovery,* and investigations typically reach a final decision in 16 to 18 months.

Past investigations show the Commission is willing to investigate the importation of biologics awaiting FDA approval

Although there have only been three biologics-based investigations at the Commission since its inception, they show that the Commission's doors have been open to life science therapeutic companies attempting to enforce their patent rights.

In the first investigation the Federal Circuit held that if there is a factual dispute as to jurisdiction, the Commission should assume it exists and hear the case on the merits, refusing to provide an early end to an otherwise instituted investigation.[4] Nearly two decades later, the Federal Circuit reviewed whether the importation of an unapproved biologic (erythropoietin) was exempted from infringement by the FDA safe harbor provision of 35 U.S.C. § 271(e)(1).[5] The Federal Circuit agreed that this defense was available for both product and process patents but remanded to determine whether all of the respondent's specific activities fell within the safe harbor. *Id.* In December 2009 before resolving the dispute, Amgen and Roche agreed to a settlement that would allow Roche to begin importing and selling the biologic in mid-2014.

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2 See Christopher M. Gallo, Looking Forward: Section 337 Investigations as Big Pharma's New Enforcer, Vol. XXXIV 337 Rep., ITC Trial Law. Ass'n, The Paul J. Luckern Summer Associate Edition 2 (2011).

3 Timothy J. Shea & Paul A. Calvo, Federal Circuit's Sandoz Decision Increases Importance of Post-Grant Proceedings to Biosimilar Developers (Dec. 10, 2014).

4 *Amgen v. ITC*, 902 F.2d 1532, 1536 (Fed. Cir. 1990).

5 *Amgen v. ITC*, 565 F.3d 846, 855 (Fed. Cir. 2009).

In the most recent biologics investigation, BTG International, Inc. sought to exclude a snake antivenom product manufactured by Laboratorios Silanes, S.A. de C.V., and Instituto Bioclon, S.A. de C.V. ("Silanes").[6] Silanes opposed institution of the investigation and later moved for summary determination, arguing that its unapproved antivenom was imported to seek FDA approval and therefore exempt under § 271(e)(1). The Commission, however, instituted over this objection without comment, and the administrative law judge denied summary determination by finding that issues of fact remained to be resolved through the hearing.[7]

The holdings in these investigations send a message to the biologics community that the Commission is open to using Section 337 to investigate biologics that have been brought into the United States before approval by the FDA. At a minimum this will allow an RPS discovery to assess the applicant's § 271(e)(1) exemption claim and, more importantly, discovery of critical information that is unobtainable under the BPCIA such as the biosimilar application, the manufacturing process, and inspection of foreign manufacturing sites. At a maximum, if a violation is shown, the RPS will secure exclusion and cease and desist orders preventing the launch of a competing product.

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6 *Certain Antivenom Products and Components Thereof*, Inv. No. 337-TA-903.

7 Despite these setbacks, Sterne Kessler attorneys succeeded in negotiating a favorable settlement for Silanes that included a payment of $6 million approved by the Commission.

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