Generic Litigation In The ITC: A New Trend?

Pharmaceutical companies are not strangers to the US International Trade Commission (ITC or Commission), although they generally have appeared as respondents, such as in a recent investigation initiated by a Florida patent-holding company against Merck over the Nuvaring birth control device.[1] Recently, however, Eli Lilly created a small stir in the pharmaceutical and ITC legal communities when it filed a complaint at the ITC as a petitioner, affirmatively requesting the institution of an ITC § 337 investigation. The complaint lists Hospira as a proposed respondent over claims of patent infringement in the method of manufacture of a generic version of Eli Lilly's chemotherapy drug, Gemzar.

Eli Lilly's suit has raised questions as to whether this is the start of a new trend in intellectual property enforcement in generic litigation. Although only time will tell, an analysis of the differences between ITC litigation and district court litigation, as well as some of the public facts surrounding the Gemzar litigation particularly, suggests that while the ITC forum can be effective in certain circumstances involving pharmaceuticals, it will not, and probably cannot, replace the familiar branded/generic litigation schema set up by the Hatch-Waxman Act.

Briefly, ITC litigation commences when one party requests that the Commission institute an investigation into, among other things, allegations of violations of intellectual property rights. After a review period, if the Commission determines to institute the investigation, the requesting party (the petitioner) and the various alleged infringing parties (the respondents) commence a quasi-litigation before an administrative law judge. The parties are also joined by a representative of the Office of Unfair Import Investigations who represents the public interest during the course of the investigation.

The petitioner must establish that it has a "domestic industry" implicated by the at-issue intellectual property (e.g., the petitioner practices the at-issue patents domestically), as well as establish that the respondents both infringe the at-issue intellectual property and import infringing products into the United States. One of the significant, substantive differences between an ITC investigation and a district court proceeding is that, while damages are unavailable at the ITC, the remedy that *is* available is an exclusion order

1 *See, In Re Certain Vaginal Ring Birth Control Devices,* Inv. No. 337-TA-768.

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that can stop infringing product at the border. An exclusion order can be a powerful injunctive remedy, although it is only useful in situations where product is being imported into the United States; ITC remedies have little or no effect on purely domestic infringement.

A review of some of the history of Eli Lilly's litigation over generic Gemzar provides some insight into how Eli Lilly came to be a petitioner at the ITC. Eli Lilly had listed two patents in the Orange Book for Gemzar, one of which was set to expire in May 2010, and the other of which had a claimed expiration date of November 2012. Eli Lilly sued Hospira and others over the listed patents in district courts in Indiana and Michigan. However, the later-expiring patent was held invalid for obviousness-type double patenting, a holding that was affirmed by the Federal Circuit in July 2010.[2]

In the ITC investigation, Eli Lilly placed a different patent at issue, namely US Patent No. 5,606,048 (the '048 patent), which allegedly covers a manufacturing process for the active ingredient in Gemzar. The complaint names Hospira and several alleged suppliers for Hospira's generic equivalent to Gemzar. The complaint also claims a domestic industry in the technology covered by the '048 patent.

Based on this history and the patents involved, it is understandable how the ITC litigation came about. First, Eli Lilly has already gone through the litigation process outlined under Hatch-Waxman. Once the Federal Circuit ruled on the Orange Book patents, generics were then not subject to the 30-month stay of FDA approval.

At that point, Eli Lilly was in the same position as any other patent litigant facing infringement, and the ITC was worth consideration. Where at least one of the generic manufacturers is actively taking sales by offering imported infringing material, an exclusion order is an effective injunctive remedy as against that party, especially considering that the ITC is known for offering speedy resolution of infringement cases. And, Eli Lilly's decision to use the '048 patent in the ITC, as opposed to during the Hatch Waxman litigation, is understandable since the '048 patent purportedly covers a method of manufacture, and may not fall within the scope of a "patent which claims the drug…or which claims a method of using such drug" in the Hatch-Waxman regulatory scheme.[3]

Based on these facts, the ITC makes sense for Eli Lilly, where there is a generic manufacturer that is importing product and may be infringing a patent that would not have otherwise been listed in the Orange Book. But, the facts suggest that the ITC will not be a substitute for Hatch Waxman litigation any time soon. First, the language of Hatch Waxman suggests that a district court proceeding may be specifically required in order to trigger the benefit of a 30-month stay of approval for an abbreviated new drug application (ANDA).[4] Also, while an ITC proceeding can be instituted at the same time as a district court litigation (and can subject the district court proceeding to a mandatory stay), it is not clear what benefit an ITC proceeding would provide in the time frame before generic entry, or whether an ANDA filing can trigger subject matter jurisdiction in the ITC in the same way that it can in district court.

In conclusion, as apparently evidenced by Eli Lilly's actions, the ITC is worth considering, but as a court of second resort where litigation under the normal course provided by the Hatch Waxman Act has not prevented generic entry.

We hope you have found this Advisory useful. If you have any questions about any of the topics discussed above, please contact your Arnold & Porter attorney or:

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2 *Sun Pharm. Indus., Ltd.* v. *Eli Lilly and Co.,* 611 F.3d 1381 (Fed. Cir. 2010).

3 21 U.S.C. § 355(b)(1)(G).

4 *See,* 21 U.S.C. § 355(j)(5)(B)(iii) (discussing actions "brought for infringement" and referring to the "district court" as a forum).