U.S. ITC: A Powerful Forum for Biologics Patent Owners

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For manufacturers of biologics and biosimilars facing potential patent litigation in the U.S., the Biologics Price Competition and Innovation Act (BPCIA) imposes a complex statutory scheme that restricts the timing and control of disputes in federal district court. Biosimilar applicants who find themselves on the receiving end of a potential patent infringement complaint in district court have the advantage of (and have utilised) patent challenges at the U.S. Patent Trial and Appeal Board (PTAB).
However, another option also exists for biologics patent owners—one that proceeds at a fast pace using specialised rules and judges and that eschews stays pending PTAB challenges: the International Trade Commission (ITC).

The ITC provides a potentially robust supplement to BPCIA litigation in federal court—with distinct strategic considerations and powerful potential remedies for patent owners. Most significantly, the ITC may permit earlier resolution of 'second phase' BPCIA patent disputes and avoid the need for a preliminary injunction to prevent an at-risk biosimilar launch.

Patent owners who resort to ITC litigation can avoid certain BPCIA obstacles. The statutory 'patent dance'—identification and negotiation of disputed patents—is not a prerequisite to an ITC complaint, and the reference product sponsor (RPS) can assert any number of patents without negotiating its selection with the abbreviated biologic licence application (aBLA) holder. Thus, a patent owner can assert patents at the ITC even without identifying them in the initial BPCIA patent exchange, which could be advantageous when new information about the biosimilar product arises only after the exchange.

Once an investigation is instituted, the ITC's specialised administrative law judges (ALJs) preside over these so-called 'section 337' proceedings, and often have substantially more experience with patent litigation issues than a typical U.S. district court judge.

The ITC also moves much more quickly than the district courts, providing final determinations within 16 to 18 months. Additionally, because it is required to complete section 337 proceedings 'at the earliest practicable time' after the investigation begins, the ITC does not stay investigations pending parallel patent challenges such as *inter partes* review or reexamination.

While the ITC cannot award monetary damages, the remedies it does issue are extremely powerful: the ITC is empowered to issue exclusion orders, which are effectively injunctions enforced by U.S. customs to stop infringing products at the border, as well as cease-and-desist orders to prohibit the sale of infringing products that are already present in the country.

Obtaining an exclusion order or cease-and-desist order at the ITC is simpler than seeking a permanent injunction in district court, as the ITC is not bound by the equitable test of *eBay v MercExchange* (U.S. Supreme Court, 2006).

For the unsuccessful complainant, moreover, ITC rulings on invalidity or infringement issues lack preclusive effect in district courts, allowing patent owners in certain instances a second opportunity to enforce their patent rights.

ITC barriers

For these reasons, the ITC allows the RPS greater control over the timing and scope of biosimilar litigation, but the unique barriers to ITC access by an RPS warrant closer examination.

First, the relative amount and scope of domestic and foreign activities of the RPS may affect ITC jurisdiction in a given case. ITC complainants must show a 'domestic industry'—a significant or substantial investment in the U.S. relating to products or processes that practise the asserted patents. Merely manufacturing the reference product abroad and importing it for sale in the U.S. generally will not suffice. However, the RPS usually engages in domestic, post-marketing regulatory and sales activity that could satisfy this requirement.

Second, ITC complainants must also establish the aBLA applicant's importation, sale for importation, or sale after importation of products that either infringe an asserted patent or were made by a process that infringes an asserted patent. Showing such importation or sale is 'imminent' may suffice, but the Federal Circuit appeals court has not resolved how imminent the importation or sale must be in order to establish ITC jurisdiction or whether the filing of an aBLA is enough to make launch imminent, even if the RPS has years of exclusivity remaining.

While importation solely for testing and regulatory approval cannot constitute infringement under § 271(e)(1), the scope of this safe harbour itself remains disputed (*e.g.*, *Amgen v Hospira*, No. 15-cv-839-RGA, slip op. D. Del. Aug. 27, 2018).

If the importation for testing and regulatory approval—or the filing of an aBLA combined with the technical act of infringement under 35 U.S.C. § 271—creates standing to file an ITC complaint before the aBLA applicant provides its statutory notice of commercial marketing, the ITC offers the possibility of litigating 'second phase' patents and obtaining an exclusion order before the U.S. Food and Drug Administration approves the aBLA. Critically, this would avoid the need to obtain a preliminary injunction within the statutorily-mandated 180-day period between the applicant's notice of intent to market and the potential first commercial marketing of the biosimilar—a significant obstacle created by the BPCIA.

Third, the ITC's detailed pleading requirements may also affect the ability to assert biologic patents in that forum. Compared to the district courts, the ITC requires a higher level of fact pleading, including detailed claim charts for all asserted patents. Importantly, however, there is a pre-suit avenue for complainants at the ITC to receive feedback on the sufficiency of their complaints. The Office of Unfair Import Investigations Staff will, if requested, review draft complaints on a confidential basis and provide feedback to complainants so that any deficiencies may be remedied before filing.

Provided the RPS has sufficient information and standing to invoke the ITC's jurisdiction, the timing and scope of discovery in ITC section 337 proceedings represents another advantage over the district courts. In the biologics context, if the aBLA holder refuses to comply with the statutory requirement to produce its application to the RPS, the patent owner may lack information about the applicant's manufacturing process necessary for complete infringement contentions in the district court.

Courts have also held that the RPS cannot obtain an injunction to enforce the application disclosure requirement (*Sandoz v Amgen*, 137 S. Ct. 1664, 2017; *Amgen v Sandoz*, 877 F.3d 1315, Fed. Cir. 2017). By contrast, the ITC has *in rem* jurisdiction over the articles accused of infringement in the complaint, and takes a wide-ranging view of what discovery is appropriate—even from foreign entities. If the aBLA holder refuses to comply with its ITC discovery obligations, ALJs can and will enter adverse inferences.

In conclusion, biologics patent owners should consider the ITC as a supplement (or alternative) to district court litigation that could mitigate the BPCIA's limitations on timing of 'second phase' litigation, choice of patents, and disclosure of the biosimilar applicant's information. Those advantages must be balanced against the speed and costs associated with the fast pace and wide-ranging discovery obligations in an ITC investigation.

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