PROFESSIONAL INSIGHT

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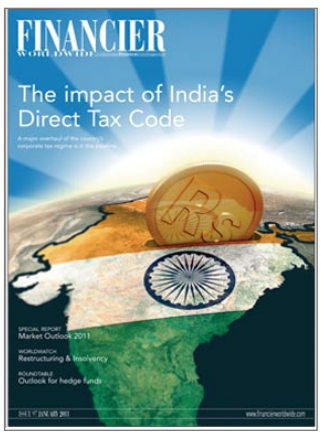

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INTELLECTUAL PROPERTY

Preparing for uncertainties in biosimilars litigation

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Congress passed the Biologics Price Competition and Innovation Act (BPCIA) to facilitate marketing of 'follow-on', or 'biosimilar', versions of biologic drugs. The BPCIA includes a complex framework for patent litigation between innovators ('reference product sponsors') and biosimilar applicants. These intricate statutory provisions may contain hidden advantages and potential pitfalls for future litigants. Many of these provisions could potentially be interpreted in ways that could significantly impact the rights of both innovators and biosimilar applicants. This article highlights a few examples of the many issues that may arise as litigation unfolds under the BPCIA.

When can a reference product sponsor sue?

The BPCIA added Section 271(e)(2)(C) to the Patent Act, which makes it an act of patent infringement to submit an application for a biosimilar covered by a patent identified on a reference product sponsor's (RPSs) 'initial patent list.' 35 U.S.C. § 271(e)(2)(C). The BPCIA also amended the Public Health Service Act (PHSA) to include Section 262(k), which creates an abbreviated application for a biosimilar (a '262(k) application'), and Section 262(l), which contains various patent litigation provisions. 42 U.S.C. §§ 262(k), (l).

Because of an apparent conflict between the Patent Act's infringement provisions and the PHSA's litigation provisions, the point at which an RPS can sue for infringement is unclear. Section 262(l) of the PHSA requires the parties to engage in a complex, pre-suit 'Patent Information Exchange' framework. As explained in more detail below, this framework forces the RPS and the 262(k) applicant ('Applicant') to exchange patent lists and information in a series of steps, including where the RPS provides an initial list of patents it could assert against the Applicant (the 'initial patent list.') At the conclusion of the Patent Information Exchange, the PHSA only allows the RPS to assert a limited subset of these patents. However, since Section 271(e)(2)(C) states that an act of infringement exists upon filing an application for a biosimilar covered by a patent on the initial patent list, it would appear that the RPS can sue the Applicant any time after the RPS provides its initial patent list.

Thus, it is uncertain whether an RPS will be able to sue for infringement under Section 271(e)(2)(C) upon providing its initial patent list, thereby avoiding the rest of the Patent Information Exchange. Moreover, the ability to sue for infringement upon exchanging the initial patent list might avoid other PHSA provisions that limit the RPS's ability to bring a declaratory judgment ('DJ') action on patents in the initial patent list.

Uncertainties in the Patent Information Exchange

The Patent Information Exchange begins when the Applicant provides the RPS with a copy of its 262(k) application. The RPS then provides the Applicant with its initial patent list. Thereafter, the Applicant responds to each listed patent either by stating that it will not market its biosimilar before the patent expires, or by challenging the patent and providing detailed invalidity, unenforceability, and/or noninfringement contentions. The Applicant can also add patents to the initial patent list. Next, the RPS must respond with detailed validity, enforceability and/or infringement contentions for each challenged patent.

The next part of the Patent Information Exchange limits the patents the RPS can assert in an 'immediate patent infringement action'. First, the RPS and the Applicant must negotiate regarding which patents the RPS should assert against the Applicant. If the parties do not reach an agreement within 15 days, they must engage in a 'final list exchange' process. In this final list exchange process, the RPS and Applicant simultaneously exchange lists of patents that the RPS should assert in the immediate patent infringement action ('final patent lists'). The RPS's final patent list usually cannot include more patents than the Applicant's final patent list. The RPS must assert in the immediate patent infringement action all patents either negotiated for or included in the final patent lists.

One uncertainty in the Patent Information Exchange concerns the information an Applicant is required to provide at the outset of the process. In addition to its 262(k) application, an Applicant must provide an RPS with "such other information that describes the process or processes used to manufacture the [biosimilar]". 42 U.S.C. § 262(l)(2)(A). This 'other information' requirement is ambiguous, and there are significant consequences for failing to comply. If this 'other information' is not provided, ▸▸

the RPS can potentially sue the Applicant on any patent claiming the biosimilar at any time. Thus, future Applicants must carefully determine what 'other information' to provide with their 262(k) applications.

If an Applicant fails to provide its 262(k) application, it is unclear how an RPS will know that it was filed, or the identity of the Applicant. Although the BPCIA includes multiple provisions allowing an RPS to sue on 'any patent' in this situation, it does not include an alternative mechanism for notifying the RPS that an application was filed. In the small molecule pharmaceutical context, the FDA only publishes the filing date of the first generic drug application that challenges a listed patent. However, the FDA does not publish the identity of applicants or the number of applications filed. It is unclear whether, and to what extent, the FDA will publish information about 262(k) applications. Thus, an Applicant might choose not to provide its application, hoping that the RPS will never find out. This could render the BPCIA provisions allowing the RPS to sue on 'any patent' less useful.

The BPCIA also has no provision governing how and when an Applicant can change its response to the RPS's initial patent list. After initially responding, an applicant might subsequently choose to challenge a patent or state that a previously challenged patent is valid and would be infringed. If an Applicant later chooses to challenge a patent, it is unclear whether it must notify the RPS. As a consequence, it is also unclear whether the RPS will have an opportunity to sue under the BPCIA's patent litigation framework.

Uncertainties in declaratory judgment actions

Section 262(l) includes limits on DJ jurisdiction for both the RPS and the Applicant. For example, Section 262(l)(9)(A) prohibits the RPS and the Applicant from seeking a DJ on any patents that were included in the initial patent list, but that were not part of the immediate patent infringement action. (This provision also prohibits DJ actions on patents issued or licensed after the Patent Information Exchange.) However, these restrictions are likely lifted once the Applicant gives the RPS a mandatory notification at least 180-days in advance of marketing its biosimilar.

The DJ provisions could possibly be interpreted to allow an RPS or Applicant to force litigation over certain patents. For example, an Applicant might try to use Section 262(l)(9)(A) to assert more control over the timing, forum, or patents included in the litigation. The BPCIA provision mandating the 180-day notification contains no additional timing requirements other than that notice be given "not later than 180 days before the date of first commercial marketing". 42 U.S.C. § 262(l)(8)(A). Since this notification likely lifts the DJ restrictions in Section 262(l)(9)(A), an Applicant might try to force litigation by sending this notification at an early, strategic time and then immediately seeking a DJ action on certain patents in a favourable forum.

Conclusion

The ambiguities in the BPCIA's provisions may cause unintended consequences to parties in biosimilars litigation. The above is just a sample of the various uncertainties created by the BPCIA. Consequently, before litigation begins under the BPCIA, members of the biologics industry must be aware of the intricacies in the BPCIA, the uncertainty surrounding its interpretation, and its application to their specific circumstances. ■

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