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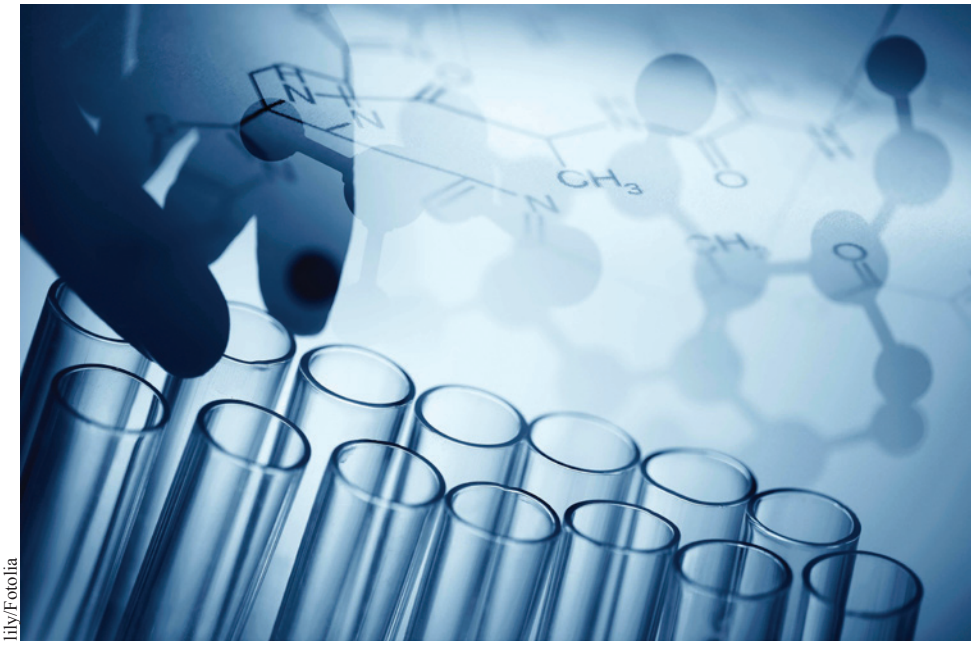
PATENT LAW

Patent Disputes Over Biologics: Will Anyone Come To The Dance?

By Tracey Davies, Michael Valek, Andrew Lin and Theo Kwong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Interest in biological medical products continues to increase. A biologic, as its name implies, is manufactured using biological processes which often entail growing the biologic inside living cells followed by an extraction or purification step. Biologics are more complex to manufacture than small molecule drug products. Not surprisingly, developing a generic copy of a biologic, a biosimilar, is also more challenging than developing a generic small molecule drug product.

The Biologics Price Competition and Innovation Act of 2009 sets forth the regulatory and legal framework governing biosimilars, just as the Drug Price Competition and Patent Restoration Act of 1984 did for generic small molecule drug products. Under both, generics may file abbreviated applications (an Abbreviated New Drug Application for small molecules, and an Abbreviated Biologic License Application or for biologics) and may rely on clinical studies conducted by the innovator. Approval of an ABLA requires a "biosimilar" to demonstrate a certain degree of similarity to the reference innovator product. ABLA applicants may also seek to have their product be deemed "interchangeable," which is a higher level of "generic" drug approval than "biosimilar." This designation allows pharmacies to swap the reference biologic for the "interchangeable" biosimilar, provided the biosimilar is shown to "produce the same clinical result as the reference product in any given patient" such that no safety risk arises from switching between the two.

While abbreviated approval processes are provided for in both Acts, branded and generic company interests are not similarly balanced. The Hatch-Waxman Act awarded innovator companies enhanced patent protection through patent term extensions and a mandatory 30-month stay of generic approval in the event of patent litigation. For their part, the first generic challenger is awarded a 180-day exclusivity period against subsequent generic entrants. This exclusivity

period, combined with the requirement that innovator companies publicly list the patents protecting their drug products (the "Orange Book" listings), effectively places a "bounty" on weak patents, incentivizing patent litigation.

In contrast, under the BPCIA the incentives to challenge patents to achieve market entry, including the "patent bounty" incentive present in the Hatch-Waxman Act, are diminished, if not entirely absent.

First, unlike the Hatch-Waxman Act's Orange Book listings, the BPCIA does not mandate a public listing of patents covering innovator biologics. The lack of a public listing restricts information from which biosimilar developers may identify "weak" patents directed to a product, limiting the weight potential ABLA filers can attribute to patent protection (or lack thereof) when identifying biologics for generic development.

More fundamentally, the patent litigation framework implemented by the BPCIA has, so far, served to discourage early patent challenges. At the outset, the framework itself is highly complex, having been described by the appellate court charged with construing its provisions as "a riddle wrapped in a mystery inside an enigma." The statute purports to establish a two-phase process for biosimilars: no ABLA can be 1. filed until four years after the approval of the reference biologic it relies upon; or 2. approved until 12 years after the approval of the reference biologic.

The first phase begins after filing of the ABLA. During this phase, the ABLA filer and reference biologic product sponsor are supposed to undertake a carefully orchestrated process referred to as the "patent dance," during which certain high-priority patents are selected by negotiation and immediately litigated. It is the ABLA filer that ultimately dictates the number of patents that may be litigated in the patent dance, though, giving them the power to control the extent to which innovator patents are challenged at the outset.

The second phase begins much later, after approval of the ABLA, when the ABLA filer gives the required 180 day notice before commercial marketing of its biosimilar. Here, the RPS may file suit on any patents that were identified, but not litigated during the patent dance.

The recent Amgen decision increases the strategic options available to the ABLA filer as it allows them to opt out of the patent dance entirely. In Amgen, the ABLA filer withheld access to its ABLA until after its product had already been approved, effectively avoiding the patent dance. The RPS contested that the patent dance was mandatory. But Amgen holds that participation is optional, and that the sole recourse against an ABLA filer that declines to participate is to file suit once the RPS learns of the ABLA filer's actions, which is unlikely to occur until marketing notice is given and the launch is imminent.

Nor does the BPCIA provide the same scope of exclusivity rewards to incentivize companies to challenge patents and open the market to biosimilar competition. A period of exclusivity is available only to the first biosimilar that obtains an interchangeability designation (no exclusivities are awarded for mere "biosimilar" products). This exclusivity begins upon receipt of the interchangeability designation, and ends when any of the conditions in § 262(k)(6) are met. Critical to the conclusion that the BPCIA dissuades patent challenges is that multiple § 262(k)(6) conditions spring from participation in the patent dance. Stated differently, if the ABLA filer simply declines to participate in the patent dance, certain conditions that could lead to a premature loss of interchangeable exclusivity can be avoided altogether.

This creates another incentive for ABLA filers to opt out of the patent dance, and, accordingly, dissuades ABLA filers from challenging patents early. It remains uncertain whether this consequence was accidental, and if so, whether Congress will step in to address this flaw in the BPCIA.

Tracey Davies is partner and co-chair of the Life Science Practice in Gibson, Dunn & Crutcher in Dallas. **Michael Valek** is of counsel with the firm, and **Andrew Lin** and **Theo Kwong** are associates at the firm in Dallas.