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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

'Patent Dance' Ruling Means Sponsors Must Plan Ahead

By **Justin Weiner and Sara Margolis**
December 20, 2017, 1:04 PM EST

Justin Weiner

Sara Margolis

On Dec. 14, 2017, the Federal Circuit ruled that the Biologics Price Competition and Innovation Act of 2009 preempts any potential state law remedies for failure to comply with certain provisions of the BPCIA. While this holding leaves open many questions about what kinds of disclosures comply with the BPCIA's requirements, it clarifies the penalties (or lack thereof) if a biosimilar applicant fails to comply with those requirements: The applicant loses control over which of a sponsor's patents get litigated preapproval, but it faces no other legal consequence for a lack of disclosure.

The ruling stems from ongoing litigation between Amgen Inc. and Sandoz Inc. over Sandoz's Zarxio, the first biosimilar approved by the U.S. Food and Drug Administration under the BPCIA. The BPCIA set out an abbreviated pathway to FDA approval, and therefore to market, for generic biologics, called biosimilars. The BPCIA also established a dispute resolution mechanism — often referred to as the "patent dance" — in an attempt to facilitate and streamline patent litigation between the biosimilar applicant and the sponsor of the reference product.

In the first step of the patent dance, the applicant provides the sponsor a copy of its application and certain information about how the biosimilar is manufactured.[1] The sponsor then provides a list of patents for which it believes it could assert an infringement claim if the biosimilar was marketed.[2] The parties next exchange information about why each believes it would succeed in patent litigation against the other.[3] Following this exchange, the parties negotiate to determine which patents will be litigated immediately.[4] If they cannot agree, the applicant largely gets to decide which patents are litigated first: The applicant sends the sponsor a list of patents it thinks should be litigated immediately, and the sponsor can initiate litigation with respect to any of those — but only those — patents.[5]

If the applicant misses a step, however, the sponsor may immediately bring a declaratory judgment action for infringement.[6] Thus, if the applicant chooses not to participate in the dance, control over any potential litigation shifts to the sponsor. The sponsor — rather than the applicant — now controls which patents are included in the suit. The sponsor also controls the timing of the litigation: The sponsor could choose to initiate litigation right away, or it might wait until the biosimilar is closer to approval in an attempt to delay marketing based on pending litigation. Finally, the sponsor can select which court it

would like to litigate in.

In June, the U.S. Supreme Court held that a sponsor cannot obtain an injunction under the BPCIA to force a biosimilar applicant to turn over its application and manufacturing information under the first step of the patent dance.[7] However, the Supreme Court left open the possibility that state law might provide such a remedy. Accordingly, the court left it to the Federal Circuit to determine whether the BPCIA preempts any potential remedies available under state law.[8]

On remand at the Federal Circuit, the U.S. Department of Justice weighed in on the side of preemption. It argued that "[a]llowing fifty states to provide additional remedies ... would undermine the uniformity of the federal scheme, subjecting applicants and sponsors to different, and potentially inconsistent, state-law remedies."[9] The Federal Circuit ultimately agreed, holding that both field and conflict preemption applied to preempt state law remedies for failure to comply with the steps of the patent dance.[10]

The combined effect of the Supreme Court and Federal Circuit's decisions is that an applicant that fails to comply with the patent dance loses some control over when and how patents get litigated, but nothing else.[11] Consequently, whether applicants participate in the patent dance will depend entirely on the benefit they see from early resolution of certain patent claims.

Those benefits will vary case by case and may depend on the scope of the sponsor's patent portfolio. Applicants facing down a broad swath of patents may wish to retain control over the sequence of litigation, as early victories may build momentum or set up favorable settlements. Those applicants may be more likely to tango. But applicants going up against just a few patents may see little to gain by controlling early litigation and hence may be less likely to disclose information about their proposed biosimilars.

Even apart from these considerations, applicants' desire for control over the sequence of litigation may depend upon a host of factors that have nothing to do with legal strategy: the firm's investment in the biosimilar, the investment's expected return, and the firm's general tolerance for risk.

A few uncertainties remain. First, just what kind of disclosure complies with the patent dance remains an open question.[12] Second, sponsors will soon need to decide when to sue in the absence of information. Amgen has already argued that when applicants opt out of the patent dance, the resulting absence of information about the biosimilar could make it difficult for the sponsor to assess whether it will infringe.[13] While one Federal Circuit opinion tried to ameliorate those concerns (urging that "if a sponsor forms a belief based on an inquiry limited by an applicant's withholding of information, the sponsor has still satisfied Rule 11"),[14] no one has yet tested the bounds of that opinion.

Notwithstanding those remaining issues, the one-two punch of decisions in the Amgen v. Sandoz matter settles a lot. Sponsors now know that applicants need not dance, and the decision of whether the patent dance happens or not will be a major inflection point in every biosimilars dispute. Smart sponsors (and their attorneys) will plan for that point and will craft two litigation strategies well in advance — one for the litigation controlled by the applicant that dances and the other for the sponsor-controlled litigation when the applicant is unwilling to dance.

Justin B. Weiner is a partner in the Chicago office of MoloLamken LLP. Sara E. Margolis is an associate in

the firm's New York office and former staff member at the Biotechnology Industry Organization.

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[1] 42 U.S.C. §262(l)(2)(A).

[2] Id. §262(l)(3)(A).

[3] Id. §262(l)(3)(B)-(C).

[4] Id. §262(l)(4)(A), (l)(6)(A).

[5] Id. §262(l)(4)(B), (5), (6)(B). If the applicant does not list any patents, the sponsor may list one. Id. §262(l)(5)(B)(ii)(II).

[6] Id. §262(l)(9)(B)-(C).

[7] Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1675 (2017).

[8] Id. at 1676. Note that the Supreme Court left open the possibility that the Federal Circuit would not resolve the issue in this particular case. There were arguments that Sandoz had waived the preemption argument that the Supreme Court did not address.

[9] Amgen Inc. v. Sandoz Inc., No. 15-1499 (Fed. Cir.), Dkt. #207 at 5.

[10] Amgen Inc. v. Sandoz Inc., — F.3d —, 2017 WL 6375146, at *7-8 (Fed. Cir. Dec. 14, 2017).

[11] 42 U.S.C. §262(l)(9)(B)-(C).

[12] Amgen Inc., v. Hospira, Inc., 866 F.3d 1355, 1357-58 (Fed. Cir. 2017).

[13] Id. at 1361-62.

[14] Id. at 1362.