wiley

ALERT

Federal Circuit Patent Bulletin: *Sandoz Inc. v. Amgen Inc.*

June 12, 2017

"[The BPCIA] requirement that an applicant provide its application and manufacturing information to the manufacturer of the biologic is [not] enforceable by injunction [but may be] available under state law. [The biosimilar] applicant [need not] give notice to the manufacturer after, rather than before, obtaining a license from the FDA for its biosimilar."

On June 12, 2017, in *Sandoz Inc. v. Amgen Inc.*, the U.S. Supreme Court (Thomas*) vacated-in-part and reversed-in-part the Federal Circuit's judgment, which affirmed-in-part, vacated-in-part, and remanded the district court's judgment, inter alia, that the Biologics Price Competition and Innovation Act of 2009 (BPCIA) provided no remedy for Sandoz's refusal, as the applicant for Zarxio—a filgrastim biosimilar to Neupogen, to provide the reference product sponsor Amgen with Sandoz's biosimilar application and manufacturing information, and that Sandoz could market Zarxio as of March 6, 2015. The Court stated:

These cases involve 42 U. S. C. §262(l), which was enacted as part of the Biologics Price Competition and Innovation Act of 2009 (BPCIA). The BPCIA governs a type of drug called a biosimilar, which is a biologic product that is highly similar to a biologic product that has already been approved by the Food and Drug Administration (FDA). Under §262(l), an applicant that seeks FDA approval of a biosimilar must provide its application materials and manufacturing information to the manufacturer of the corresponding biologic within 20 days of the date the FDA notifies the applicant that it has accepted the application for review. The applicant then must give notice to the manufacturer at least 180 days before marketing the biosimilar commercially. . . .

Authors

Neal Seth
Partner
202.719.4179
nseth@wiley.law

Practice Areas

Intellectual Property
Patent

A biologic is a type of drug derived from natural, biological sources such as animals or microorganisms. Biologics thus differ from traditional drugs, which are typically synthesized from chemicals. A manufacturer of a biologic may market the drug only if the FDA has licensed it pursuant to either of two review processes set forth in §262.The default pathway for approval, used for new biologics, is set forth in §262(a). Under that subsection, the FDA may license a new biologic if, among other things, the manufacturer demonstrates that it is "safe, pure, and potent." In addition to this default route, the statute also prescribes an alternative, abbreviated route for FDA approval of biosimilars, which is set forth in §262(k).

To obtain approval through the BPCIA's abbreviated process, the manufacturer of a biosimilar (applicant) does not need to show that the product is "safe, pure, and potent." Instead, the applicant may piggyback on the showing made by the manufacturer (sponsor) of a previously licensed biologic (reference product). An applicant must show that its product is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the two in terms of "safety, purity, and potency." An applicant may not submit an application until 4 years after the reference product is first licensed, and the FDA may not license a biosimilar until 12 years after the reference product is first licensed. As a result, the manufacturer of a new biologic enjoys a 12-year period when its biologic may be marketed without competition from biosimilars.

A sponsor may hold multiple patents covering the biologic, its therapeutic uses, and the processes used to manufacture it. Those patents may constrain an applicant's ability to market its biosimilar even after the expiration of the 12-year exclusivity period contained in §262(k)(7)(A). The BPCIA facilitates litigation during the period preceding FDA approval so that the parties do not have to wait until commercial marketing to resolve their patent disputes. It enables the parties to bring infringement actions at certain points in the application process, even if the applicant has not yet committed an act that would traditionally constitute patent infringement. Specifically, it provides that the mere submission of a biosimilar application constitutes an act of infringement. We will refer to this kind of preapproval infringement as "artificial" infringement. Section 271(e)(4) provides remedies for artificial infringement, including injunctive relief and damages.

The BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement. When the FDA accepts an application for review, it notifies the applicant, who within 20 days "shall provide" to the sponsor a copy of the application and information about how the biosimilar is manufactured. The applicant also "may provide" the sponsor with any additional information that it requests. These disclosures enable the sponsor to evaluate the biosimilar for possible infringement of patents it holds on the reference product (i.e., the corresponding biologic). The information the applicant provides is subject to strict confidentiality rules, enforceable by injunction. The first question presented by these cases is whether §262(l)(2)(A)'s requirement—that the applicant provide its application and manufacturing information to the sponsor—is itself enforceable by injunction. After the applicant makes the requisite disclosures, the parties exchange information to identify relevant patents and to flesh out the legal arguments that they might raise in future litigation. Within 60 days of receiving the application and manufacturing information, the sponsor "shall provide" to the applicant "a list of patents" for which it believes it could assert an infringement claim if a person without a license made, used, offered to sell, sold, or imported "the biological product that is the

subject of the [biosimilar] application." The sponsor must also identify any patents on the list that it would be willing to license.

Next, within 60 days of receiving the sponsor's list, the applicant may provide to the sponsor a list of patents that the applicant believes are relevant but that the sponsor omitted from its own list, and "shall provide" to the sponsor reasons why it could not be held liable for infringing the relevant patents. The applicant may argue that the relevant patents are invalid, unenforceable, or not infringed, or the applicant may agree not to market the biosimilar until a particular patent has expired. The applicant must also respond to the sponsor's offers to license particular patents. Then, within 60 days of receiving the applicant's responses, the sponsor "shall provide" to the applicant its own arguments concerning infringement, enforceability, and validity as to each relevant patent.

Following this exchange, the BPCIA channels the parties into two phases of patent litigation. In the first phase, the parties collaborate to identify patents that they would like to litigate immediately. The second phase is triggered by the applicant's notice of commercial marketing and involves any patents that were included on the parties' §262(l)(3) lists but not litigated in the first phase.

At the outset of the first phase, the applicant and the sponsor must negotiate to determine which patents included on the §262(l)(3) lists will be litigated immediately. If they cannot agree, then they must engage in another list exchange. The applicant "shall notify" the sponsor of the number of patents it intends to list for litigation, and, within five days, the parties "shall simultaneously exchange" lists of the patents they would like to litigate immediately. This process gives the applicant substantial control over the scope of the first phase of litigation: The number of patents on the sponsor's list is limited to the number contained in the applicant's list, though the sponsor always has the right to list at least one patent.

The parties then proceed to litigate infringement with respect to the patents they agreed to litigate or, if they failed to agree, the patents contained on the lists they simultaneously exchanged under §262(l)(5). Section 271 (e)(2)(C)(i) facilitates this first phase of litigation by making it an act of artificial infringement, with respect to any patent included on the parties' §262(l)(3) lists, to submit an application for a license from the FDA. The sponsor "shall bring an action" in court within 30 days of the date of agreement or the simultaneous list exchange. If the sponsor brings a timely action and prevails, it may obtain a remedy provided by §271(e)(4).

The second phase of litigation involves patents that were included on the original §262(l)(3) lists but not litigated in the first phase (and any patents that the sponsor acquired after the §262(l)(3) exchange occurred and added to the lists. The second phase is commenced by the applicant's notice of commercial marketing, which the applicant "shall provide" to the sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." The BPCIA bars any declaratory judgment action prior to this notice. Because the applicant (subject to certain constraints) chooses when to begin commercial marketing and when to give notice, it wields substantial control over the timing of the second phase of litigation. The second question presented is whether notice is effective if an applicant provides it prior to the FDA's decision to license the biosimilar.

In this second phase of litigation, either party may sue for declaratory relief. In addition, prior to the date of first commercial marketing, the sponsor may "seek a preliminary injunction prohibiting the [biosimilar] applicant from engaging in the commercial manufacture or sale of [the biosimilar] until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that" was included on the §262(l)(3) lists but not litigated in the first phase.

If the parties comply with each step outlined in the BPCIA, they will have the opportunity to litigate the relevant patents before the biosimilar is marketed. To encourage parties to comply with its procedural requirements, the BPCIA includes various consequences for failing to do so. Two of the BPCIA's remedial provisions are at issue here. Under §262(l)(9)(C), if an applicant fails to provide its application and manufacturing information to the sponsor—thus effectively pretermitting the entire two-phase litigation process—then the sponsor, but not the applicant, may immediately bring an action "for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product." Section 271(e)(2)(C)(ii) facilitates this action by making it an artificial act of infringement, with respect to any patent that could have been included on the §262(l)(3) lists, to submit a biosimilar application. Similarly, when an applicant provides the application and manufacturing information but fails to complete a subsequent step, §262(l)(9)(B) provides that the sponsor, but not the applicant, may bring a declaratory-judgment action with respect to any patent included on the sponsor's §262(l)(3)(A) list of patents (as well as those it acquired later and added to the list). As noted, it is an act of artificial infringement, with respect to any patent on the §262(l)(3) lists, to submit an application to the FDA. . . .

We agree with the Federal Circuit that an injunction under federal law is not available to enforce §262(l)(2)(A), though for slightly different reasons than those provided by the court below. [The Federal Circuit appeared to conclude] that an applicant's noncompliance with §262(l)(2)(A) is an element of the act of artificial infringement (along with the submission of the application). We disagree. [T]he two clauses of §271(e)(2)(C) work in tandem. They both treat submission of the application as the act of artificial infringement for which §271(e)(4) provides the remedies. And they both identify the patents subject to suit, although by different means depending on whether the applicant disclosed its application and manufacturing information under §262(l)(2)(A). If the applicant made the disclosures, clause (i) applies; if it did not, clause (ii) applies. In neither instance is the applicant's failure to provide its application and manufacturing information an element of the act of artificial infringement, and in neither instance does §271(e)(4) provide a remedy for that failure.

A separate provision of §262, however, does provide a remedy for an applicant's failure to turn over its application and manufacturing information. When an applicant fails to comply with §262(l)(2)(A), §262(l)(9)(C) authorizes the sponsor, but not the applicant, to bring an immediate declaratory-judgment action for artificial infringement as defined in §271(e)(2)(C)(ii). Section 262(l)(9)(C) thus vests in the sponsor the control that the applicant would otherwise have exercised over the scope and timing of the patent litigation. It also deprives the applicant of the certainty that it could have obtained by bringing a declaratory-judgment action prior to marketing its product.

The remedy provided by §262(l)(9)(C) excludes all other federal remedies, including injunctive relief. Where, as here, "a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." The BPCIA's "carefully crafted and detailed enforcement scheme provides strong evidence that Congress did not intend to authorize other remedies that it simply forgot to incorporate expressly." The presence of §262(l)(9)(C), coupled with the absence of any other textually specified remedies, indicates that Congress did not intend sponsors to have access to injunctive relief, at least as a matter of federal law, to enforce the disclosure requirement. . . .

On remand, the Federal Circuit should determine whether California law would treat noncompliance with §262 (l)(2)(A) as "unlawful." If the answer is yes, then the court should proceed to determine whether the BPCIA preempts any additional remedy available under state law for an applicant's failure to comply with §262(l)(2) (A) (and whether Sandoz has forfeited any preemption defense). The court is also of course free to address the preemption question first by assuming that a remedy under state law exists.

The second question at issue in these cases is whether an applicant must provide notice after the FDA licenses its biosimilar, or if it may also provide effective notice before licensure. Section 262(l)(8)(A) states that the applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." The Federal Circuit held that an applicant's biosimilar must already be "licensed" at the time the applicant gives notice. We disagree. The applicant must give "notice" at least 180 days "before the date of the first commercial marketing." "[C]ommercial marketing," in turn, must be "of the biological product licensed under subsection (k)." Because this latter phrase modifies "commercial marketing" rather than "notice," "commercial marketing" is the point in time by which the biosimilar must be "licensed." The statute's use of the word "licensed" merely reflects the fact that, on the "date of the first commercial marketing," the product must be "licensed." Accordingly, the applicant may provide notice either before or after receiving FDA approval.

[B]ecause Sandoz fully complied with §262(l)(8)(A) when it first gave notice (before licensure) in July 2014, the Federal Circuit erred in issuing a federal injunction prohibiting Sandoz from marketing Zarxio until 180 days after licensure. Furthermore, because Amgen's request for state-law relief is predicated on its argument that the BPCIA forbids prelicensure notice, its claim under California's unfair competition law also fails. We accordingly reverse the Federal Circuit's judgment as to the notice provision.