IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Case No. 1:22-cv-00061-TSK **JURY TRIAL DEMANDED**

MOTION REQUESTING EXPEDITED STATUS CONFERENCE

This is a patent case concerning Eylea®, a market-leading drug for treating certain serious eye diseases that, if left untreated, can lead to permanent blindness. The plaintiff, Regeneron Pharmaceuticals, Inc. ("Regeneron"), invented and developed Eylea® and markets it in the United States, along with other life-transforming medicines for diseases including Ebola, COVID-19, cancer, and other cardiovascular and metabolic diseases. Compl. ¶ 1. The defendant, Mylan Pharmaceuticals Inc. ("Mylan"), is a generic drug company seeking to market a "biosimilar" copy of Eylea®.

To vindicate its patent rights, Regeneron seeks a statutory permanent injunction under 35 U.S.C. § 271(e)(4)(D). That statutory provision, which is unique to biosimilar patent litigation, contains a critical timing limitation: relief under § 271(e)(4)(D) requires resolving the parties' disputes through final judgment and appeal *before* the date on which FDA may approve the biosimilar product for marketing. Because FDA could approve Mylan's proposed Eylea® biosimilar in May 2024, Regeneron moves for an expedited status conference under Rule 40 and 28 U.S.C. § 1567 to position this case for trial no later than June 2023, so that Regeneron may avail itself of the relief provided by § 271(e)(4)(D).

Regeneron has conferred with Mylan regarding this request for an expedited status conference. Mylan has not stated its position.

I. BACKGROUND

Although Regeneron filed its Complaint just days ago on August 2, 2022, Dkt. No. 1, over the past several months the parties have exchanged their infringement and validity contentions regarding the twenty-four asserted patents as part of a statutorily-mandated process known informally as the "patent dance." Mandated by the Biologics Price Competition and Innovation Act ("BPCIA"), the patent dance requires a series of information exchanges between the parties, with the goal of identifying the issues for subsequent biosimilar patent litigation and thus facilitating adjudication of remaining disputes before commercialization of the proposed biosimilar product. *See* 42 U.S.C. § 262(*l*).

In October 2021, Mylan submitted a regulatory application seeking approval of a biosimilar version of Regeneron's Eylea® product. Pursuant to the BPCIA, 42 U.S.C. § 262(*l*)(2), Mylan was required to share information about its proposed biosimilar with Regeneron. That information revealed that any marketing of Mylan's biosimilar copy of Eylea® will infringe numerous Regeneron patents.

Mylan's regulatory filing also set in motion the parties' statutory patent dance exchanges, which have advanced the parties' understanding of what will be at issue in this case far beyond what would be achieved through the ordinary filing of a complaint. Pursuant to that statutory regime for exchanges of information, Mylan made available its regulatory application describing various aspects of its proposed biosimilar product. In response, Regeneron identified the patents that it believes Mylan's proposed biosimilar would infringe. The parties then exchanged detailed contentions containing their positions as to the infringement and validity of those patents.

The parties, thus, are not starting this case from scratch. On the contrary, prior to the filing of this lawsuit, the parties exchanged thousands of pages of information about their positions concerning the patents listed in Regeneron's Complaint. As such, the parties have already been working toward identifying and narrowing the issues for litigation pursuant to a statutory scheme intended to facilitate swift adjudication of patent disputes before commercialization of a proposed biosimilar product. 42 U.S.C. § 262(*l*); Compl. ¶¶ 17-22.

As part of the patent dance, Regeneron proposed litigating at this juncture only a subset of the patents it alleges Mylan infringes. Mylan, however, proposed litigating 25 patents in this case. Regeneron explained that attempting to litigate that many patents in a single proceeding would be inefficient for the parties and burdensome on the Court. But Mylan refused to narrow its list, and by the terms of the BPCIA, the biosimilar's list of patents dictates the scope of the Complaint. 42 U.S.C. §§ 262(*l*)(5), 262(*l*)(6). Accordingly, Regeneron was compelled by statute to bring suit on each of the patents on Mylan's list. Compl. ¶ 22. Regeneron did so.[1]

II. AN EXPEDITED STATUS CONFERENCE IS WARRANTED

Pursuant to Rule 40, Regeneron respectfully requests an expedited status conference to put in place a case schedule that will enable Regeneron to obtain the statutory relief it seeks under 35 U.S.C. § 271(e)(4)(D). Rule 40 requires courts to "give priority to actions entitled to priority by a federal statute." Fed. R. Civ. P. 40. One such priority statute, 28 U.S.C. § 1657, directs courts to expedite an action upon a showing of "good cause," which exists where a federal statutory right "would be maintained in a factual context that indicates that a request for expedited consideration has merit." *Id.* As the legislative history explains, "the 'good cause'

[1] During the patent dance, Regeneron did not contend infringement on one of the patents on its list and thus did not bring suit on that patent. The Complaint thus asserts 24 patents in total.

standard could properly come into play, for example, *in a case in which failure to expedite would result in mootness or deprive the relief requested of much of its value*." H.R. REP. 98-985, 1984 U.S.C.C.A.N. 5779, at 5784. Good cause exists here because without an expeditious case schedule, Regeneron could be deprived of the relief it seeks under § 271(e)(4)(D)—a form of injunctive relief created by statute specifically for biologic innovators in biosimilar patent actions like this one. *See* Compl. Prayer for Relief (b).

Section 271(e)(4)(D) provides that a court "shall order a permanent injunction" against a proposed biosimilar product upon issuance of "a final court decision" of patent infringement—provided that "the biological product has not yet been approved":

> (4) For an act of infringement described in paragraph (2)—
>
> . . .
>
> (D) the ***court shall order a permanent injunction*** prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), ***provided the patent is the subject of a final court decision***, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, ***and the biological product has not yet been approved because of section 351(k)(7) of such Act***.

A "final court decision" under § 271(e)(4)(D) is "a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken." 42 U.S.C. § 262(k)(6)(C)(ii). Here, that "final court decision" in all likelihood will require a decision from the United States Court of Appeals for the Federal Circuit, which has jurisdiction over appeals in patent cases. 28 U.S.C. § 1295(a)(1).

In addition, § 271(e)(4)(D) requires that at the time of the "final court decision," "the biological product has not yet been approved because of section 351(k)(7)." Section 351(k)(7) provides that approval of a biosimilar product "may not be made effective by the Secretary until

the date that is 12 years after the date on which the reference product was first licensed under subsection (a)," plus certain additional time conferred for regulatory exclusivities. Here, that date is at the latest May 18, 2024,[2] which includes an additional six months of exclusivity that Regeneron is seeking based on clinical trials to obtain approval for use of Eylea® in pediatric patients. 42 U.S.C. § 262(k)(7); Compl. ¶ 2.

Taken together, for Regeneron to avail itself of the statutory relief provided under § 271(e)(4)(D), a judgment must be issued by this Court in sufficient time for the Federal Circuit to issue a "final court decision" in advance of May 18, 2024. As a practical matter, Regeneron submits that doing so requires a trial no later than June 2023.

A prolonged trial schedule in this case, by contrast, would render Regeneron's claim for relief under § 271(e)(4)(D) a nullity, contrary to Rule 40 and the text and statutory design of the BPCIA. That the plain text of § 271(e)(4)(D) premises relief on a "final court decision" before biosimilar approval demonstrates that Congress contemplated such decision to precede approval, where possible. And the legislative history confirms that the BPCIA was designed to facilitate "litigat[ing] patent disputes quickly and efficiently." *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 110th Cong. 119 (2007) (statement of Bruce Downey, chairman of the Generic Pharmaceutical Association and CEO of Barr Pharmaceuticals, Inc.), *available at* https://www.govinfo.gov/app/details/CHRG-110hhrg40500/context; *see also Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1062 n.3 (Fed. Cir. 2016) (citing Downey statement as evidence of design of BPCIA). That is precisely what should happen here: in accordance with

[2] Regeneron expects to obtain pediatric exclusivity in the near future. Absent such exclusivity, Regeneron's regulatory exclusivity would expire six months earlier, which would make a fast trial even more critical.

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