PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN PRE-FILLED SYRINGES FOR INTRAVITREAL INJECTION AND COMPONENTS THEREOF**	**INV. NO. 337-TA-1207**

ORDER NO. 31: INITIAL DETERMINATION GRANTING COMPLAINANTS' MOTION FOR SUMMARY DETERMINATION AS TO DIRECT INFRINGEMENT AND THE ECONOMIC AND TECHNICAL PRONGS OF THE DOMESTIC INDUSTRY REQUIREMENT

(April 2, 2021)

On February 18, 2021, complainants Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, "Novartis") filed a motion ("Mot."), supporting memorandum ("Memo"), and a chart of undisputed material facts ("UMF") seeking findings on summary determination that (1) respondent Regeneron Pharmaceuticals, Inc.'s ("Regeneron") EYLEA® prefilled syringe and/or its administration to patients directly infringes claims 1, 3–6, 11–13, 16, 17, and 20–25 of U.S. Patent No. 9,220,631 ("the '631 patent");[1] (2) Novartis's BEOVU® prefilled syringe practices claims 1, 3–7, 16–17, 22, and 23 of the '631 patent; and (3) Novartis has satisfied the economic prong of the domestic industry requirement under 19 U.S.C. § 1337(a)(3)(B). Motion Docket No. 1207-021. Regeneron filed a brief in partial opposition ("Opp'n") and a response to Novartis's chart of undisputed material facts ("RUMF")

[1] A copy of the '631 patent is attached as Exhibit 1 to the pending motion.

on March 1, 2021. The Commission Investigative Staff ("Staff") filed a response supporting the pending motion ("Staff Resp.") on March 1, 2021.[2]

I. Legal Standards

Summary determination is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to a determination as a matter of law. *See* 19 C.F.R. § 210.18. In determining whether there is a genuine issue of material fact, "the evidence must be viewed in the light most favorable to the party opposing the motion with doubts resolved in favor of the non-movant." *Crown Operations Int'l, Ltd v. Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002) (citations omitted).

In a section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *See Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1349 (Fed. Cir. 2010). This standard "requires proving that infringement was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008). "Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s). If any claim limitation is absent, there is

[2] After briefing for the pending motion was complete, Novartis filed an unopposed motion seeking partial termination of this investigation based on withdrawal of the complaint with respect to asserted claims 18, 19, and 20 of the '631 patent. I granted this motion in an initial determination that was not reviewed by the Commission. Order No. 29 (Mar. 17, 2021), *unreviewed*, Comm'n Notice (Apr. 1, 2021). As claim 20 has been terminated from this investigation, this order will consider Novartis's arguments that I should find infringement of claims 1, 3–6, 11–13, 16, 17, and 21–25 of the '631 patent on summary determination.

no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp*., 212 F.3d 1241, 1247 (Fed. Cir. 2000).

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*) (internal citations omitted), *aff'd*, 517 U.S. 370 (1996). Claim construction resolves legal disputes between the parties regarding claim scope. *See Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1319 (Fed. Cir. 2016).

For a patent-based complaint, a violation of section 337 can be found "only if an industry in the United States, relating to the articles protected by the patent . . . concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). The complainant bears the burden of establishing that the domestic industry requirement is satisfied. *John Mezzalingua Assocs., Inc. v. Int'l Trade Comm'n*, 660 F.3d 1322, 1331 (Fed. Cir. 2011). The domestic industry requirement of section 337 is often described as having an economic prong and a technical prong. *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 707 F.3d 1295, 1298 (Fed. Cir. 2013); *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 12–14, USITC Pub. No. 4120 (Dec. 2009). "The technical prong concerns whether complainant practices at least one claim of the asserted patents. The economic prong concerns domestic activities with respect to the patent or patented article." *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 25, USITC Pub. No. 4289 (Nov. 2011) ("*Certain Printing and Imaging Devices*").

Section 337(a)(3) sets forth the following economic criteria for determining whether the economic prong of the domestic industry requirement is satisfied in such investigations:

> [A]n industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –
>
> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or
>
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3). Given that these criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the economic prong of the domestic industry requirement. *See Certain Printing and Imaging Devices*, Comm'n Op. at 26.

The technical prong of the domestic industry requirement is satisfied when the complainant in a patent-based section 337 investigation establishes that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. § 1337(a)(2) and (3). "The test for satisfying the 'technical prong' of the industry requirement is essentially [the] same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). To prevail, the patentee must establish by a preponderance of the evidence that the domestic product practices one or more valid claims of the patent. *See id.*; *Spansion*, 629 F.3d at 1349. It is sufficient to show that the products practice any claim of that patent, not necessarily an asserted claim of that patent. *See Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 38 (Aug. 1, 2007).

II. Claim Construction

There are no claim construction disputes between the parties requiring resolution before a finding of infringement can be made. Accordingly, I decline to construe any claim terms at this summary determination stage.

III. Economic Prong of the Domestic Industry Requirement

A. Novartis's Domestic Expenditures

Novartis's economic activities in the United States are related to its VEGF-antagonist drug brolucizumab, which is marketed under the name "BEOVU." UMF Nos. 31, 71. BEOVU comes in two presentations for delivering the drug to a patient: a vial and a prefilled syringe. UMF Nos. 31–32. The vial presentation has already been approved by the FDA and the prefilled syringe presentation is pending approval from the FDA. UMF Nos. 32–33. Novartis is seeking FDA approval for the prefilled syringe presentation through a supplemental biologics license application that relies on the underlying data contained in the original biologics license application filed on the vial presentation. UMF No. 37. To prove satisfaction of the economic prong of the domestic industry requirement, Novartis relies on investments in labor and capital related to research and development efforts for BEOVU, including clinical trials and the related FDA approval process. Memo at 14–20.

Novartis has a Medical Affairs Team in the United States consisting of [redacted] to [redacted] employees with various medical and science backgrounds who "coordinat[e] clinical trials and assess[] the impact of data collected." UMF Nos. 42–43; *see* Mot. Ex. 11 (Expert Report of Christopher Bakewell) ¶¶ 71–76 ("Bakewell Rpt."). Novartis also employs approximately [redacted] full-time equivalent clinical development employees who perform work related to ongoing clinical studies for BEOVU in the United States. UMF No. 46; *see* Bakewell Rpt. ¶¶ 84, 92. These employees support Novartis's seven ongoing clinical trials for BEOVU, which are spread across at least 200 clinical sites in the United States. UMF No. 49; *see* Bakewell Rpt. ¶¶ 90–92. Novartis also incurs external project-related study costs and logistics expenses such as scientific meeting costs, lab

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