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. 22: DENYING REGENERON'S MOTION TO TERMINATE THE INVESTIGATION BASED ON LACK OF STANDING

(January 7, 2020)

On November 6, 2020, respondent Regeneron Pharmaceuticals, Inc. ("Regeneron") filed a motion and supporting memorandum ("Memo") seeking to terminate this investigation on grounds that complainants Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, "Novartis") do not possess a statutory cause of action to assert U.S. Patent No. 9,220,631 ("the '631 patent") without adding non-party Vetter Pharma International GmbH ("Vetter") as a complainant. Motion Docket No. 1207-010. Novartis filed a brief in opposition ("Opp'n") on November 18, 2020, and the Commission Investigative Staff ("Staff") filed a response opposing the requested relief ("Staff Resp.") on November 20, 2020.

Factual Background

The relationship between Novartis and Vetter dates back to 2009 and was memorialized in an agreement dated January 27, 2009. *See* Mot. Ex. 17 ("2009 Agreement"). At that time, "Novartis was engaged in the development, manufacture, and sale of pharmaceutical products," while Vetter "possesse[d] the requisite expertise, personnel, know-how, and facilities" needed to

provide Novartis with a supply of "pre-filled pharmaceutical products." *Id.* at 2. Accordingly, Novartis "entrust[ed] Vetter to perform certain services" for it, including "[redacted] . . . ." *Id*. The 2009 Agreement provided that certain intellectual property developed "which solely relates to [redacted]" would belong to Novartis and that all other intellectual property developed under the 2009 Agreement would belong to Vetter. *See id*. at 17.

A dispute between the parties over intellectual property ensued. On February 14, 2013, Vetter informed Novartis by letter that, pursuant to the terms of the 2009 Agreement, Vetter owned certain intellectual property claimed in Novartis patent applications. *See* Mot. Ex. 18 (letter from Vetter to Novartis dated Feb. 27, 2013); Mot. Ex. 19 (letter from Novartis to Vetter dated Mar. 5, 2013). Vetter's letter specifically asserted ownership in a German patent application filed by Novartis (DE 20 2012 011 016 U), which is one of the foreign priority applications identified on the face of the '631 patent asserted in this investigation. *See* Mot. Ex. 18 at VETTER_00000223.

The 2013 dispute led to Vetter and Novartis executing a fourth amendment to the 2009 Agreement. *See* Mot. Ex. 4 ("2013 Amendment"). In the 2013 Amendment, Vetter and Novartis acknowledged a dispute "as to the ownership of, and the rights of and use related to, the [redacted] IP." *Id.* at NOVITC(CH)00170689. As defined in the relevant documents "[redacted] IP" includes, *inter alia*, the '631 patent. *See id.* at 14 (listing U.S. Patent App. No. 13/750,352, which issued as the '631 patent).

On December 19, 2019, Novartis and Vetter executed a seventh amendment ("2019 Amendment") to the 2009 Agreement, a copy of which is attached as Exhibit 1 to the pending motion. The current dispute between the parties centers on the scope of patent rights granted to

Vetter in the 2019 Amendment. Regeneron argues that the 2019 Amendment grants Vetter such substantial rights in the '631 patent that Vetter must be joined as a co-complainant in this investigation. *See* Memo at 14–19.

Legal Principles

Commission Rule 210.12 requires that intellectual property-based complaints "include a showing that at least one complainant is the owner or exclusive licensee of the subject intellectual property." 19 C.F.R. § 210.12(a)(7). In applying this rule, the Commission has adopted the standing requirement established by the federal courts in patent infringement cases. *See SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1326 n.4 (Fed. Cir. 2010) (noting the Commission strictly reads the federal standing precedent into its rules of procedure); *Certain Optical Drives, Components Thereof, and Products Containing the Same*, Inv. No. 337-TA-897, Comm'n Op. at 4, EDIS Doc. No. 548902 (Dec. 4, 2014) (public version Jan. 7, 2015) ("*Optical Drives*"). Complainants bringing an action under 19 U.S.C. § 1337(a)(1)(B) based on patent infringement must therefore show that they have constitutional standing to assert patent rights. *Optical Drives*, Comm'n Op. at 4.

Constitutional standing arises from the "case or controversy" clause in Article III, Section 2 of the U.S. Constitution. *Arizonans for Official English v. Arizona*, 520 U.S. 43, 64 and 67 (1997) (citations omitted); *Lone Star Silicon Innovations LLC v. Nanya Tech. Corp.*, 925 F.3d 1225, 1234 (Fed. Cir. 2019). Under that provision, the federal courts only have jurisdiction to hear disputes brought by a party who has suffered or is imminently threatened with "a concrete and particularized 'injury in fact' that is fairly traceable to the challenged action of the defendant and likely to be redressed by a favorable judicial decision." *Lexmark Int'l, Inc. v. Static Control Components, Inc*., 572 U.S. 118, 125 (2014); *see also Morrow v. Microsoft Corp*., 499 F.3d 1332,

1338–39 (Fed. Cir. 2007). In causes of action involving patent infringement, the "injury in fact" is derived from the legal right to exclude others from practicing the patented invention created by the Patent Act. *See, e.g.*, *Optical Drives*, Comm'n Op. at 5. Thus, "when a party performs at least one prohibited action with respect to the patented invention that violates these exclusionary rights," the party holding those rights is injured and has constitutional standing. *Morrow*, 499 F.3d at 1339.

In addition to the constitutional standing requirement, the federal courts also require a complainant to demonstrate a statutory cause of action at the time of filing suit. *Optical Drives*, Comm'n Op. at 4; *Lone Star Silicon Innovations*, 925 F.3d at 1234 (Fed. Cir. 2019).[1] The Supreme Court has explained that "a statutory cause of action extends only to plaintiffs whose interests 'fall within the zone of interests protected by the law invoked.'" *Lexmark*, 572 U.S. at 126 (citations omitted). In the scheme the Commission has adopted from the federal courts, the relevant statute for this analysis is the Patent Act, which grants exclusive rights to a patentee. *See* 35 U.S.C. §§ 154(a)(1), 281; *Optical Drives*, Comm'n Op. at 4–5. The Patent Act requires that a complaint of patent infringement "be brought by a party holding legal title to the patent." *Abbott Labs. v. Diamedix Corp.*, 47 F.3d 1128, 1130 (Fed. Cir. 1995); *see also Ball v. Coker*, 168 F. 304, 307 (C.C.D.S.C. 1909) ("[N]o person may bring suit for profits or damages for infringement who is not the patentee, or such assignee or grantee as the statute points out.").

[1] The Federal Circuit has clarified that whether a party has a statutory cause of action under the Patent Act is not a question of constitutional standing. *Lone Star Silicon Innovations*, 925 F.3d at 1235–36 ("We therefore firmly bring ourselves into accord with *Lexmark* and our sister circuits by concluding that whether a party possesses all substantial rights in a patent does not implicate standing or subject-matter jurisdiction."). A party that does not possess all substantial rights in a patent may yet satisfy the standing requirement of Article III of the Constitution, *id*. at 1236, but such a party may not have a statutory cause of action under the Patent Act, *id*. at 1234.

In certain circumstances, however, the federal courts have allowed parties that do not hold legal title to a patent to join the patentee as a co-plaintiff. To be joined as a co-plaintiff with the patentee, a party "must have the right to exclude others from making, using, or selling the invention in the United States." *Morrow*, 499 F.3d at 1340. Anyone "who lacks exclusionary rights has no authority to assert a patent (even along with the patentee)." *Lone Star Silicon Innovations*, 925 F.3d at 1228; *see also Ortho Pharm. Corp. v. Genetics Inst., Inc*., 52 F.3d 1026, 1032 (Fed. Cir. 1995) (it is the "right to prevent others from making, using or selling the patented technology that provides the foundation for co-plaintiff standing").

Analysis

Here, Regeneron asserts that Vetter should — and must — be a co-complainant with Novartis. The first step in the standing inquiry is determining who holds legal title to the '631 patent. *See Abbott Labs. v. Diamedix Corp*., 47 F.3d at 1130. The record in this investigation demonstrates that Novartis is the owner of the '631 patent. The certified assignment history of the '631 patent is included as Exhibit 2 to the Complaint and demonstrates that the inventors assigned their rights in the '631 patent to Novartis.[2] Compl. Ex. 2. Regeneron does not dispute that Novartis owns the '631 patent. *See* Memo. at 20–22 (conceding that Novartis possesses constitutional standing).

Having established that Novartis holds title to the '631 patent, the next question is whether Vetter has been granted rights in the '631 patent such that it has standing to assert the patent. An analysis of the 2019 Amendment shows that Vetter has not been granted exclusionary rights

[2] Following a series of assignments, complainant Novartis Technology LLC is the current assignee of the '631 patent. *See* Compl. Ex. 2 at 29–33.

sufficient to confer standing to sue, let alone mandating that Vetter be a necessary party to this investigation.

Vetter's [redacted]. Under Section 2.2(d)(i) of the 2019 Amendment, Vetter is obligated to [redacted] of the '631 patent. 2019 Amendment § 2.2(d)(i). If that happens, "Novartis shall [redacted]. *Id.* § 2.2(d)(ii). If Novartis [redacted], and the [redacted]." *Id.* If Novartis [redacted]. *Id.* Vetter [redacted] claimed by the '631 patent [redacted].

Moreover, Section 2.4(b) of the 2019 Amendment reserves to Novartis the right to [redacted]." 2019 Amendment § 2.4(b). The [redacted]. *Id.* And even Vetter's contingent right to [redacted] discussed above, may be nullified by Novartis [redacted]

[redacted].[3] Thus, Vetter's rights to exclude others from using the claimed invention are wholly contingent on Novartis's actions and are, ultimately, illusory. *See Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1251 (Fed. Cir. 2000) ("In addition, Bryne and Zoumaras's right to sue an infringer if Speedplay does not is illusory, because Speedplay can render that right nugatory by granting the alleged infringer a royalty-free sublicense.").

Regeneron relies on language from the 2019 Amendment granting Vetter a "co-exclusive" license to the '631 patent to argue that Vetter is a necessary party here, but that argument ultimately fails. *See* Memo at 1, 2, 10, 14, 16, 19, 28. Section 2.3(a)(i) of the 2019 Amendment characterizes the license granted to Vetter as a "co-exclusive" license "[redacted]," but the use of the term "co-exclusive" is not talismanic. *See* 2019 Amendment § 2.3(a)(i); *Ortho Pharm. Corp.*, 52 F.3d at 1032 ("[I[t is the licensee's beneficial ownership of a right to prevent others from making, using or selling the patented technology that provides the foundation for co-plaintiff standing, not simply that the word 'exclusive' may or may not appear in the license."). The 2019 Amendment narrowly defines Vetter's license as "[redacted]." 2019 Amendment § 2.3(a)(i). Vetter's "co-exclusive" license to the '631 patent is thus limited to a

[3] Section 2.4(c) of the 2019 Amendment requires that [redacted]

[redacted]. This is not enough to confer standing on Vetter.

Vetter's limited right to sublicense the '631 patent also demonstrates that Vetter lacks standing to assert the '631 patent. *See Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1380 (Fed. Cir. 2000) ("A licensee's right to sub-license is an important consideration in evaluating whether a license agreement transfers all substantial rights."). Specifically, under Sections 2.3(c)(i)–(ii) of the 2019 Amendment, Vetter has the right to grant sublicenses to the '631 patent [redacted], but [redacted]" 2019 Amendment §§ 2.2(c)(i)–(ii). Vetter also cannot license a party [redacted]. *Id.* § 2.3(c)(iii). Thus, Vetter has no right to [redacted] the '631 patent but instead only has the right to [redacted] by Vetter. By contrast, Novartis retains discretion to [redacted]. *Id.* § 2.4(c).

Regeneron argues that the potential for serial litigation weighs in favor of making Vetter a party to this investigation. *See* Memo at 22–26. Although the "necessary party" analysis in district courts and at the Commission allows consideration of that concern, the provisions of the 2019 Amendment outlined above demonstrate that Vetter has no right to re-litigate this investigation as a complainant after this investigation is terminated. *Aspex Eyewear, Inc. v. Miracle Optics*, Inc., 434 F.3d 1336, 1344 (Fed. Cir. 2006); *Certain GPS Devices & Products Containing Same*, Inv. No. 337-TA-602, Comm'n Op., 2009 WL 10721154, *4 (Jan. 27, 2009) ("co-owners" of a patent

must be named as complainants in an investigation in order to "prevent the possibility of two suits on the same patent against a single infringer").

Regeneron argues that, when litigation between Novartis and Regeneron concludes, "there is nothing in the [2019] amendment to the Agreement to prevent Vetter from providing a notice of infringement and, after six months, filing a lawsuit against Regeneron in its own name and under its own direction and control." Memo at 22. Regeneron's argument seems predicated on the assumption that Vetter would notify Novartis of the same allegedly infringing acts at issue in this investigation, *i.e.*, the importation into the United States of the EYLEA pre-filled syringe. But that "[redacted] infringement" (as defined in the 2019 Amendment) is in fact being litigated by Novartis in this investigation. The 2019 Amendment does not permit Vetter to bring suit regarding that act of alleged infringement once Novartis has done so.

In sum, I determine Novartis has standing to assert a claim of infringement without joining Vetter as a co-complainant. Accordingly, Motion No. 1207-010 to terminate this investigation for lack of standing is denied.

Within two days of the date of this document, the parties shall jointly submit a single proposed public version with any proposed redactions indicated in red. If the parties submit excessive redactions, they may be required to provide declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in 19 C.F.R. § 201.6(a). To the extent possible, the proposed redactions should be made electronically, in a single PDF file using the "Redact Tool" within Adobe Acrobat. The proposed

redactions should be submitted as "marked" but not yet "applied." The proposed redactions should be submitted via email to Cheney337@usitc.gov and not filed on EDIS.

SO ORDERED.

Clark S. Cheney
Administrative Law Judge

CERTAIN PRE-FILLED SYRINGES FOR INTRAVITREAL INJECTION AND COMPONENTS THEREOF **Inv. No. 337-TA-1207**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** has been served via EDIS upon the Commission Investigative Attorney, **W. Peter Guarnieri, Esq.**, and the following parties as indicated, on **March 12, 2021.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC:

Elizabeth J. Holland, Esq.
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
Email: EHolland@goodwinlaw.com

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

On Behalf of Respondent Regeneron Pharmaceuticals, Inc.:

Anish R. Desai, Esq.
WEIL, GOTSHAL & MANGES LLP
767 5th Avenue
New York, NY 10153
Email: anish.desai@weil.com

☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download