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September 21, 2020

The Honorable Colm F. Connolly
United States District Court
844 N. King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *ChromaDex, Inc., et al. v. Elysium Health, Inc.,*
C.A. No. 18-1434-CFC

Dear Judge Connolly:

Defendant Elysium Health, Inc. (“Elysium”) writes in response to the letter-brief submitted by Plaintiffs on Friday evening (D.I. 91). Plaintiffs’ unauthorized submission was improper and should either be disregarded or stricken. If the Court is inclined to consider Plaintiffs’ submission, then Elysium respectfully requests that the Court also consider the following in response:

The Supreme Court held over a century ago that the right to bring a patent suit requires holding an “exclusive right” under the patent. *Waterman v. Mackenzie*, 138 U.S. 252, 255 (1890). This right either must be held by the patentee or must have been received from the patentee, because the right must derive from the patent. The *en banc* Federal Circuit in *Rite-Hite v. Kelley Co.* followed *Waterman*, holding that for an exclusive licensee to have standing, it must have received the patentee’s “**promise** that others shall be excluded from practicing the invention within [licensee’s] territory.” 56 F.3d 1538, 1552 (Fed. Cir. 1995) (emphasis added). Only then has the licensee suffered “a legally cognizable injury when an unauthorized party encroaches” on its right to exclude. *WiAV Sols. LLC v. Motorola, Inc.*, 631 F.3d 1257, 1264-65 (Fed. Cir. 2010). In *Textile Products v. Mead Corp.*, the Federal Circuit explained that whether a party received a promise of exclusivity is “a question of ascertaining the intent of the parties to the license as manifested by the terms of their agreement and examining the substance of the grant.” 134 F.3d 1481, 1484 (Fed. Cir. 1998).

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WiAV did not depart from these bedrock principles. It recognized that “the touchstone of constitutional standing in a patent infringement suit is whether a party can establish that it has an exclusionary **right** in a patent that, if violated by another, would cause the party holding the **exclusionary right** to suffer legal injury.” 631 F.3d at 1265(emphases added). *WiAV* simply clarified that under the terms of the license agreement, a licensee might have standing to sue some parties but not others. *WiAV*’s holding was that an exclusive licensee does not lack standing merely because the license is subject to rights existing at the time of the license and “also to future licenses that may be granted **only to parties other than the accused.**” *Id.* at 1267 (emphasis added). Where the license permits future sublicenses and does not convey the right to exclude the accused infringer, the licensee suffers no legally cognizable patent injury and it lacks standing to sue.

Here, ChromaDex lacks standing because the patentee conveyed no right to exclude Elysium; on the contrary, it gave a second licensee, Healthspan, the right to sublicense anyone. ChromaDex’s alleged right to exclude Elysium is not based on a promise ChromaDex received from the patentee and thus it is not derived from the patents. Rather, it is based on ChromaDex’s belief that its sister corporation would never in practice exercise its right to sublicense Elysium. This belief, whether true or not, is irrelevant to standing.

Plaintiffs cite to four district court cases purporting to follow *WiAV* but focus on two as “particularly instructive”: *Smith v. Garlock Equip. Co.*, 2014 WL 12606667 (W.D. Mo. Nov. 4, 2014) and *AstraZeneca AB v. Apotex Corp.*, 985 F. Supp. 2d 452, 492 (S.D.N.Y. 2013). Neither changes the analysis.

In *Smith*, the district court found standing where a verbal exclusive license agreement was not limited by a non-exclusive license granted as part of the settlement of an “unrelated” litigation. 2014 WL 12606667. *Smith* stands for the unremarkable proposition that existing non-exclusive settlements do not destroy the standing of an exclusive licensee.

Plaintiffs’ second case, *AstraZeneca*, likewise does not support their arguments. There, the district court focused on the ability of each alleged exclusive licensee to “prevent others from practicing the invention.” 985 F. Supp. 2d at 493. One licensee, AstraZeneca AB, had a sole exclusive license for a limited period, and thus was an exclusive licensee during that period. *See id.* at 495. It then conveyed its patents rights to two affiliated companies, KBI-E and KBI. KBI-E received an exclusive license, while KBI retained only a non-

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exclusive right to manufacture. The district court held that “KBI-E... has standing, while KBI does not.” *Id.*

The court in *AstraZeneca* properly focused on each affiliate’s contractual right to exclude, without considering extrinsic evidence related to its motivations or corporate relationships. In the one post-*WiAV* district court decision that does discuss relationships among affiliates, *Hill-Rom Co. v. GE*, 2014 US Dist. LEXIS 108428 at *4-6 (E.D. Va. Aug. 6, 2014) (discussed in Elysium’s Reply), the court denied standing to two sister corporations despite in-house counsel’s declaration that the license agreement was in reality exclusive because the affiliates would always act in concert and were unwilling to license the accused infringer.¹

Plaintiffs also cite Delaware and California corporate law decisions, apparently to suggest that state law overrides the constitutional standing requirement that ChromaDex and Healthspan each independently have received exclusionary rights under the patents. However, as the Federal Circuit explained in *Spine Solutions*, basing standing on corporate relationships would be wrong because it “would mean that any company related to a patent owner could be treated as an exclusive licensee.” *Spine Sols., Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F3d 1305, 1318 (Fed. Cir. 2010).²

¹ The other cases cited (but not discussed) by Plaintiffs are inapposite. In *Ivera Med. Corp. v. Excelsior Med. Corp.*, 2013 WL 12170511 (S.D. Cal. Oct 18, 2013), the plaintiff’s license was “exclusive to the field in which [Defendant’s] alleged infringement operates, and [defendant] has not attempted to show otherwise.” *Id.* Plaintiffs’ cryptic “see also” citation to *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc.*, 748 F.3d 1354 (Fed. Cir. 2014) is perplexing, as the case **does not even mention *WiAV***, the ostensible excuse for their letter. In any event, *Sanofi* turned on patent licenses *implied* by the exclusive assignment of a New Drug Application and exclusive distribution agreements. The opinion does not describe specific license terms, and the court held only that the district judge’s findings that any necessary licenses existed, expressly or impliedly, were not clearly erroneous. *Id.* at 1364. The case before this Court involves an express, written license with clear, unambiguous terms.

² Further, Plaintiffs’ cases involve fiduciary obligations a subsidiary and its corporate parent owe one another. ChromaDex, Inc. and Healthspan are sister corporations: neither one owns the other. Their corporate parent, ChromaDex Corp., is not a plaintiff in this case and holds no rights or interest in the patents.

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Respectfully,

/s/ Steven J. Balick

Steven J. Balick (#2114)

SJB/nlm

cc: All counsel of record (via electronic mail)