UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. ET AL, Plaintiffs, v. CELLTRION HEALTHCARE CO. INC., ET AL., Defendants.	)	C.A. No. 15-10698-MLW 16-11117-MLW

MEMORANDUM AND ORDER

WOLF, D.J. March 2, 2017

At the January 18 and February 14, 2016 scheduling conferences, the parties requested the court's guidance on the appropriate measure of damages to which plaintiff Janssen Biotech, Inc. ("Janssen") would be entitled if defendants Celltrion Healthcare, Co. and Celltrion, Inc. (together, "Celltrion") and Hospira, Inc. ("Hospira") are found to have infringed U.S. Patent No. 7,598,083 (the "'083 Patent"). The parties represented that such guidance would facilitate informed settlement discussions. A hearing on issues concerning the standards for determining damages was held on February 23 and 24, 2017. For the reasons explained in detail at those hearings, the court provided the following guidance to the parties.

1. A plaintiff is entitled to compensation for reasonably foreseeable lost profits that it would not have suffered "but for" the defendant's infringement. See Rite-Hite Corp. v. Kelley Co., Inc., 56 F. 3d 1538, 1545 (Fed. Cir. 1995). "A fair and accurate

reconstruction of the 'but for' market...must take into account, where relevant, alternative actions the infringer foreseeably would have undertaken had he not infringed" and, therefore, "takes into account any [adequate] alternatives available to the infringer." Grain Processing Corp. v. American Maize, 185 F. 3d 1341, 1350-51 (Fed. Cir. 1999). Accordingly, if Celltrion could, as a practical matter, have made the Remicade biosimilar, Inflectra, that it began marketing in the United States on about January 1, 2017--at a competitive price and on a comparable schedule--without infringing the '083 Patent, Janssen would not be entitled to recover any profits on Remicade that it lost to Inflectra. It would, instead, be limited to a reasonable royalty.

2. The fact that Celltrion produces Inflectra abroad would not prevent Janssen from recovering lost profits relating to sales of Inflectra in the United States if those sales could not have been made without the production and sale of the infringing media powders in the United States.

In Power Integrations v. Fairchild Semiconductor, the Federal Circuit held that the presumption against the extraterritorial application of the United States Patent laws prevented a patentee from recovering damages measured by its foreign sales. 711 F. 3d 1348, 1371-72 (Fed. Cir. 2013). It held that "where the direct measure of damages was foreign activity, i.e., making, using, selling outside the United States, it was not enough, given the

required strength of the presumption against extraterritoriality, that the damages measuring foreign activity have been factually caused, in the ordinary sense, by domestic activity constituting infringement under [35 U.S.C.] Section 271(a)." Carnegie Mellon Univ. v. Marvell Tech. Group, 807 F. 3d 1283, 1307 (Fed. Cir. 2015).

In the instant case, it is alleged that Celltrion's agent, HyClone Laboratories, Inc. ("HyClone"), infringed the '083 Patent by making and selling its powder in the United States. In contrast to Power Integrations, however, the resulting sale of the damages-measuring product, Inflectra, also occurred in the United States. In these circumstances, the presumption against extraterritoriality would not overcome the principle of full compensation, and the usual "but-for" causation test would apply.

The fact that Remicade is not now itself patented because this court has found the patent on which it is based invalid, see August 19, 2016 Memorandum and Order (Docket No. 226), does not affect plaintiff's entitlement to damages, including lost profits, for any proven infringement of the '083 Patent. A patentee may recover damages in the form of lost profits to compensate for sales of an unpatented product (i.e., Remicade) lost to an infringer's non-infringing product (i.e., Inflectra), if the infringer could only have captured the patentee's sales by infringing the patent by, in this case, using an infringing powder. See Micro-Chem. Inc.

v. Lextron, Inc., 318 F. 3d 1119, 1125-26 (Fed. Cir. 2003). More specifically, a patentee is entitled to lost profits, even on unpatented products, if a competitor makes the sales-capturing end-product using an infringing method or product, where the competitor could have only captured the sales by infringing the patent. See Minco Inc. v. Combustion Eng'g, 95 F. 3d 1109, 1119 (Fed. Cir. 1996).

3. To decide whether it was feasible for Celltrion to have used a non-infringing media powder to produce Inflectra, it must be determined whether, starting on the date of first infringement, Celltrion could have switched to using a non-infringing alternative. The fact-finder must consider how the market would have developed "absent the infringing product," if the infringement had not occurred. Grain Processing, 185 F. 3d at 1350-51. "A proper reconstruction of the 'but for' world that would have existed absent infringement must consider actions the infringer would have taken to avoid infringement--including designing around the patented intellectual property--starting on the date of first infringement and not on some later date, such as the date of first notice" or the date the infringement began generating lost profits. Apple Inc. v. Samsung Electronics Co. Ltd., 2013 WL 5958172, *2-3 (N.D. Cal. 2013). Before the date of sales that cause the patentee to lose profits, any infringement would justify damages in the amount of a reasonable royalty.

4. If the pending cases are dismissed without prejudice for lack of standing because all owners if the '083 Patent are not joined as plaintiffs and a new case is brought, 35 U.S.C. §271(e)(6) will not limit Janssen's damages to a reasonable royalty for any proven infringement of the '083 Patent. Celltrion initiated the process prescribed by the Biologics Price Competition and Innovation Act (the "BPCIA"), 42 U.S.C. §262(l), but did not properly complete it as required to obtain the limitation of damages to a reasonable royalty provided by §271(e)(6).

"The Biologics Act lays out a step-by-step process for exchanging information and channeling litigation about patents relevant to the application." Amgen Inc. v. Apotex Inc., 827 F.3d 1052, 1054 (Fed. Cir. 2016). Section 271(e)(6) limits a patentee's damages to a reasonable royalty if it proves infringement of a patent identified under 42 U.S.C. §§262(l)(4) and (5)(B) in a suit filed more than 30 days after the end of the process prescribed by the BPCIA. As one step in that process, §262(l)(4) requires that each party negotiate in good faith in an attempt to agree on a list of patents that will be subject to an immediate infringement action. Section 262(l)(5) provides a particular dispute resolution procedure for identifying such patents if good faith negotiations fail. It is only the patents that emerge from this negotiation and, if necessary, dispute resolution procedure that are subject to a reasonable royalty damages limitation if the patentee does

not sue within 30 days of the end of this process. See 35 U.S.C. §271(e)(6).

More specifically, §§262(l)(4) and (5) state that the parties "shall" engage in "good-faith negotiations" and "shall" engage in the specified dispute resolution procedure if those negotiations fail. 42 U.S.C. §§262(l)(4) & (5). "The word 'shall' generally indicates that [a] directive is mandatory." Apotex, 827 F.3d at 1061; see also Amgen Inc. v. Sandoz Inc., 794 F.3d 1347, 1359 (Fed. Cir. 2015) ("[T]he word 'shall' . . . presumptively signals a statutory requirement."). The court construes the term "shall" in §§262(l)(4) and (5) to mean that the alleged infringer must comply with each step of the BPCIA process in order to limit the patentee to a reasonable royalty if it does not sue within 30 days of the end of that process. Requiring the good faith completion of the prescribed process gives the term "shall" its usual meaning. It also serves the BPCIA's purpose of "avert[ing] and [] expedit[ing] litigation." See Sandoz, 794 F.3d at 1365 (Newman, J., concurring in part and dissenting in part).

On the present record, a reasonable fact-finder could not conclude that Celltrion engaged in the good-faith negotiations required by the BPCIA or in the dispute resolution procedure that is required if no agreement was reached through those negotiations. It is only the list of patents that emerge from the properly completed BPCIA procedure that are potentially subject to the

reasonable royalty damages limitation. On the present record, it could not be found that the six patents originally subject to litigation in this case emerged from a properly completed statutory process.

As stated at the scheduling conference on February 24, 2017, it is hereby ORDERED that:

1. The parties shall, by March 17, 2017, confer to discuss the possible settlement of these cases. Such discussions shall include, among other things, the implications of the court's guidance regarding the appropriate measure of damages and the possibility of a settlement involving forms of relief other than the payment of money damages.

2. The parties shall, by March 17, 2017, report, jointly if possible but separately if necessary, concerning:

a. The status of their discussions regarding settlement.

b. Whether they wish to engage in mediation with a private mediator, a magistrate judge, or this court.

c. If necessary, their positions regarding how this case should proceed, including whether the issues of liability and damages should continue to be bifurcated for trial.

d. Dates on which the parties, including representatives with full settlement authority, are available for a hearing on defendants' Motion to Dismiss for lack of standing.

UNITED STATES DISTRICT JUDGE