UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY,	:	Civil Action No. 1:15-cv-10698-MLW
Plaintiffs,	:	Leave to File Granted on January 12, 2016 (Dkt. 90)
v.	:	
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC.,	:	
Defendants.	:	

DEFENDANTS' SUR-REPLY TO PLAINTIFFS' MOTION TO STAY
[LEAVE TO FILE GRANTED ON JANUARY 12, 2016]

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INTRODUCTION

Janssen's reply continues to talk in circles while failing to explain why it should be able to file a patent infringement lawsuit and then refuse to litigate the suit it has filed. Janssen's "file now but litigate later" strategy conflicts with the basic norms of judicial economy as well as the letter and spirit of the BPCIA statute pursuant to which this lawsuit was filed. The BPCIA gave Janssen a choice: assert patent infringement now and seek all available remedies, or assert patent infringement later and seek a reasonable royalty only.

Janssen elected to sue now on the '471 patent, gaining both the benefits (including the full panoply of potential remedies) and the risks (including invalidity challenges against the asserted claims) associated with that choice. The Court should hold Janssen to its choice and not permit it to have the best of all worlds by asserting a patent it knows to be invalid while shielding that patent from being promptly challenged in this litigation. Alternatively, if Janssen prefers, it can dismiss the lawsuit as to the '471 patent without prejudice, thus allowing it to reassert the patent later and seek a reasonable royalty if it were to emerge from reexamination. Reply, Dkt. 57-1, at 2. Either way, Janssen's motion to stay should be denied.

ARGUMENT

I. Janssen's efforts to circumvent the BPCIA fail.

Janssen's reply asserts a number of arguments that distort the clear language of the BPCIA and slant the facts of this case:

According to Janssen, Defendants rely on "a *sub silentio* requirement [in the BPCIA] to 'expedite competition.'" Pls.' Reply, Dkt. 57-1, at 1. Not so. Defendants point to an *express* statutory requirement that limits the "sole and exclusive remedy" to "a reasonable royalty" if Janssen's patent lawsuit is "dismissed without prejudice or . . . not prosecuted to judgment in

good faith." 35 U.S.C. §§ 271(e)(6)(A), (B). Janssen has no intent to "prosecute[the '471 patent] to judgment in good faith." *Id.* Its remedy, therefore, must be limited.

Attempting to avoid the statute's express remedy limitation, Janssen argues that "the BPCIA does not bar stays." Reply, Dkt. 57-1, at 2. This argument misses the point. To be sure, the Court has discretion to stay litigation as to the '471 patent. Defendants have never argued otherwise. But such a litigation stay prompted by Janssen would be the opposite of "prosecut[ing the infringement claim] to judgment in good faith"—an action that, by statute, requires the remedy to be limited. 35 U.S.C. §§ 271(e)(6)(A), (B). A litigation stay is not a statutory loophole that allows Janssen to delay patent litigation *and* reserve the right to seek lost profits.

Next, Janssen offers a *non-sequitur*: "the BPCIA does not assume that patent litigation must always be concluded before a biosimilar product enters the market." Reply, Dkt. 57-1, at 1. Again, Defendants never argued otherwise. Instead, our point is simple: as Congress made clear, if the plaintiff delays patent litigation—precisely what Janssen seeks to do here—its remedy is limited to "a reasonable royalty." 35 U.S.C. § 271(e)(6)(B). Defendants' argument does not turn on any assumption as to when patent litigation must be concluded—just that it must be "prosecuted to judgment in good faith." *Id.* § 271(e)(6)(A)(ii)(II).

Trying again, Janssen argues that "if the PTO upholds the patent (with its currently amended specification), the parties and the Court will be able to address the patent in the form that the PTO has determined correctly reflects its prosecution." Reply, Dkt. 57-1, at 2. But Janssen elected to sue based on the patent's current—and invalid—form. If Janssen wanted to wait to see if its patent emerges in a different "form," *id.*, it had every right under the statute to do so. The remedy for any infringement of such a newly formulated patent, however, is

statutorily limited to "a reasonable royalty." 35 U.S.C. § 271(e)(6)(B). As discussed, under the BPCIA, Janssen must either "prosecute[]" the '471 patent in its current form, or live with a limited remedy if it wishes to reserve the right to assert the patent later should it emerge from re-examination in a different form.

Undeterred, Janssen argues that it can avoid the remedy limitation because "Defendants are blatantly refusing to follow [the BPCIA] procedures." Reply, Dkt. 57-1, at 2. Janssen cannot avoid the remedy limitation on this basis, particularly because Defendants have complied with the BPCIA. Celltrion timely produced its aBLA. 42 U.S.C. § 262(*l*)(2). Defendants timely complied with the patent-exchange process by exchanging patent contentions. *Id.* § 262(*l*)(3)(B). And they timely consented to Janssen's patent list, thus reaching "agree[ment]" on which patents "shall be the subject of an action for patent infringement[.]" *Id.* § 262(*l*)(4); *see also* Defendants' Detailed Statement, Dkt. 53-3, at 2. This "agree[ment]," in turn, triggered the remedy limitation in the patent Act. 35 U.S.C. § 271(e)(6)(A), (B).

II. The requested stay would unduly prejudice Defendants and put them at a tactical disadvantage.

According to Janssen, Defendants are not prejudiced if Janssen were allowed to delay litigating the '471 patent for years and, if the patent were to emerge from reexamination, then try to seek tens if not hundreds of millions of dollars in lost profits after Defendants launch their product. That is precisely what Congress intended to avoid when it expressly limited the infringement remedy after delayed litigation.

Janssen argues that "Defendants provide no showing that any difference between lost-profits damages and reasonable-royalty damages in this case would be so substantial as to cause undue prejudice." Reply, Dkt. 57-1, at 6. This argument makes no sense. Absent the limited remedy prescribed by the BPCIA, Janssen could try to seek lost-profits damages that exceed

Defendants' own profits—after all, Defendants will be selling their product at a discount. In contrast, a reasonable royalty, by definition, is determined based upon what royalty rate the patentee and infringer would have agreed upon in a hypothetical negotiation. *See Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1554 (Fed. Cir. 1995). There is no question, therefore, that lost profits is a more onerous remedy than a reasonable royalty. *See Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1327 n.6 (Fed. Cir. 2014) ("[A] lost profits award is above and beyond the reasonable royalty floor required by the statute."), *overruled on other grounds by Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015). Congress thus penalized patentees like Janssen who choose to delay litigation by limiting their remedy to a reasonable royalty. 35 U.S.C. § 271(e)(6)(B).

Circumventing Congress' will and word here also could have an adverse effect on consumers. Defendants have not yet received FDA approval to market their product. If, as Janssen hopes, it can hold a potential lost-profits award over Defendants' head, their potential financial exposure certainly would be relevant to the timing of that launch.

III. Proceeding with the lawsuit Janssen itself brought would not be unjust.

Janssen seeks to divert the '471 patent from its present path toward providing patent certainty—a path voluntarily chosen by Janssen itself. In support, Janssen argues that forcing it to proceed with *its own case* "would be unfair." Reply, Dkt. 57-1, at 8. How so? The patent as it currently stands is invalid. If it were litigated, Defendants would be entitled to judgment on that patent as a matter of law. And that judgment, in turn, would bar Janssen from re-asserting the patent if it emerged from reexamination.[1] Such a result, however, would not be unfair.

[1] *See Senju Pharm. Co. v. Apotex Inc.*, 746 F.3d 1344, 1353 (Fed. Cir. 2014) (A patentee cannot "use reexamination to obtain a second bite at the apple, to assert its patent against the same party . . . and the same product . . . . [T]hat is exactly what claim preclusion was designed to

Janssen alone decided to bring suit on that invalid patent. It did not have to. Instead, Janssen consciously took the risk that the case could proceed, the Court could find the patent invalid, and that judgment would be given claim preclusion effect. Janssen apparently took that risk because it believed this Court would grant it a windfall—allowing Janssen to stay that litigation while preserving the right to seek lost profits damages in some future lawsuit on a patent they concede would be in a different "form."

It hardly would be "unjust" to make Janssen lie in the bed it made. Janssen had no obligation to sue on the '471 patent now. Having done so, it should either litigate that patent now, or dismiss the lawsuit—and accept the statutory limitation on Janssen's remedy.

IV. The requested stay would not simplify the litigation.

Defendants cited six decisions rejecting a litigation stay pending reexamination, including one authored by this Court. Opp., Dkt. 41, at 9. These cases illustrate that stays may not simplify the litigation. It certainly would not do so here.

Janssen proposes to proceed with this case in phases—complete fact discovery on the patents-in-suit, but stay expert discovery, claim construction, dispositive motions and trial as to the '471 patent. *Id.* This proposal sets an arbitrary cutoff at fact discovery for one patent, while this action continues on another patent. Thus, Janssen's proposal could lead to two phases of expert discovery—hardly simplifying the case.

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prevent."); *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1341 (Fed. Cir. 2012) ("[T]here is no force to [the patentee's] argument that the reexamination of the '545 patent created entirely new causes of action on which [the patentee] could freely sue, even though it had previously had an opportunity to sue on the corresponding original claims of the '545 patent. . . . [This] is forbidden by the principles of res judicata.").

CONCLUSION

Janssen's request for a litigation stay is extraordinary. It would circumvent the BPCIA, which limits the remedy when the patentee delays patent litigation and does not prosecute the patent suit to judgment in good faith. It would unduly prejudice Defendants. And it could adversely affect consumers by delaying competition. This District, including this Court, has historically denied requests to stay litigation pending a PTO reexamination. The same result is warranted here.

If Janssen wishes to preserve the right to assert the '471 patent in the future, it has a simple process at its disposal: dismiss the litigation as to that patent without prejudice. Alternatively, if the Court were to grant a stay, it should exercise its discretion to require, as a condition of that stay, a stipulation from Janssen that limits its remedy for any infringement to a reasonable royalty.

Dated: January 21, 2016

Respectfully submitted,

Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc.

By their attorneys,

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CERTIFICATE OF SERVICE

I, Andrea L. Martin, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on January 21, 2016.

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