IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action No. 1:15-cv-10698**
	)	
	)	**Leave to file granted**
	)	**January 12, 2016**
	)	
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC.	)	
Defendants.	)	
	)	

REPLY MEMORANDUM IN SUPPORT OF
PLAINTIFFS' MOTION TO STAY

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

I. SUMMARY OF REPLY

The factors traditionally considered in deciding whether to stay a case call for staying this litigation so that the reexamination instituted by Defendants more than two years ago can be completed. In their opposition, Defendants say little about these factors. Instead, they accuse Plaintiffs of "gamesmanship" for filing a lawsuit on the 471 patent and then seeking to stay it pending reexamination. To the contrary, this suit was filed to protect Plaintiffs' legal interests, to defeat Defendants' baseless attempt to limit Plaintiffs to reasonable royalty damages. Promptly seeking a stay pending the completion of the ongoing reexamination, before the parties or the Court have expended resources addressing the lawsuit, is not "gamesmanship," but rather a common sense approach for conserving judicial resources. In these circumstances, an early stay motion is favored, not disfavored.

Defendants premise their opposition to a stay on the erroneous supposition that the Biologics Price Competition and Innovation Act ("BPCIA") contains a *sub silentio* requirement to "expedite litigation." There is no such requirement. The BPCIA promotes *early* litigation, not expedited litigation. Rather, it provides for up to *eight years* for the litigation to take place, allowing ample time for a stay pending reexamination during the course of this litigation.

Furthermore, the BPCIA does not assume that patent litigation must always be concluded before a biosimilar product enters the market. As Defendants acknowledge by their focus on damages, the BPCIA expressly contemplates a damages remedy, which is meaningful only if the biosimilar is on the market. The only relevant procedures that must be expedited by statute are the reexamination proceedings, which Defendants do not deny they instituted. Those proceedings – not this lawsuit – must be conducted with "special dispatch." 35 U.S.C. § 305.

The reasons for staying this case in the interests of justice are compelling. If the PTO invalidates the patent, this aspect of the present case will be moot and the parties and the Court

will be spared the unnecessary burden and expense of litigation. But 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. The reexamination is two years old and is now reaching the appeals stage; its resolution will not unfairly delay this lawsuit. Awaiting the outcome is the fair result, not a "tactical advantage" to either side. Indeed, a stay of this litigation is the predictable outcome of Defendants' decision to file for a reexamination when they did.

Meanwhile, Defendants' claim of unfair prejudice is based on the argument that by asserting the 471 patent now, Plaintiffs will be able to seek lost-profits damages instead of reasonable-royalty damages. But Plaintiffs have properly asserted their claims and are entitled to seek lost-profits damages. In any event, the BPCIA requires that, before damages can be limited to a reasonable royalty, the biosimilar applicant must have followed the early litigation procedures of the statute. Yet here, the Defendants are blatantly refusing to follow these procedures. Finally, it is wholly premature to argue today about the measure of damages that Plaintiffs may seek one day. Whether the measure is lost profits or a reasonable royalty, it will be a large amount due to the facts in this case. Defendants do not assert, and could not credibly assert, that they *will* launch at risk if Defendants are limited to reasonable royalty damages, but *will not* launch at risk if Defendants may recover lost profits.

In short, the traditional stay factors govern this motion and warrant a stay.

II. THE COURT SHOULD STAY LITIGATION ON THE 471 PATENT

A. The BPCIA Does Not Bar Stays

The BPCIA does not require patent holders to litigate patents that should be stayed in order to avoid forfeiting patent rights. Although the BPCIA encourages *early* litigation, it does not require *expedited* litigation, as Defendants contend (Opp. Br. at 2, 10 (D.I. 41)). On the

contrary, the BPCIA provides ample time for early litigation to be conducted at an ordinary pace. The BPCIA provides makers of innovative biological products with 12 years of exclusivity before a biosimilar version of the product can be marketed. 42 U.S.C. § 262(k)(7)(A). At the same time, the statute allows the biosimilar application to be filed as early as four years into the 12-year exclusivity period, 42 U.S.C. § 262(k)(7)(B), and creates an elaborate process whereby patent disputes must be identified and litigation initiated within months of when the application is accepted for review. 42 U.S.C. § 262(l). Thus, the BPCIA provides *eight years* for patent disputes to be resolved. This period allows ample time for a stay of litigation, if one is warranted, including a stay to await the completion of a previously pending reexamination.

Nothing in the BPCIA suggests that litigation must be accelerated where, as here, a biosimilar applicant waits until four years after the passage of the BPCIA to file an aBLA that could have been filed years earlier and where there is no 12-year statutory period of exclusivity in which to litigate. In contrast, when Congress wants to expedite a specific type of litigation, it says so in the statute. *See, e.g.*, 47 U.S.C. § 332(c)(7)(B)(v) (certain court challenges to be heard "on an expedited basis"); 12 U.S.C. § 5229(a)(2)(C), (D) (certain injunction requests to be "expedited"). Indeed, the only statute relevant to this motion that calls for expedited proceedings is the reexamination statute, which specifically requires the PTO to conduct reexamination proceedings with "special dispatch." 35 U.S.C. § 305.

Defendants are also incorrect in suggesting that the BPCIA requires pre-launch resolution of patent disputes (Opp. Br. at 2-3). Rather, the BPCIA specifically contemplates that a biosimilar maker may launch its product "at risk" by dictating different types of damages that may be available. 35 U.S.C. § 271(e)(6)(B). Interpreting the BPCIA to guarantee "patent certainty" before launch would render these damages provisions superfluous. Indeed, based on

Defendants' representation that "FDA will approve Celltrion's aBLA this year" (Opp. Br. at 6), it is not possible for Defendants to obtain "patent certainty" – a decision from this Court affirmed by the Federal Circuit – before approval, no matter how the Court rules on this stay motion.

B. A Stay Would Not Put Defendants at a Tactical Disadvantage

Defendants erroneously contend that a stay would prejudice them and somehow place them at a tactical disadvantage simply because it would allow Plaintiffs to await resolution of the reexamination proceeding while preserving their rights to seek lost-profits damages (*id.* at 9-15). But the fact is that, as Defendants acknowledge (*id.* at 10), the BPCIA specifies the exact circumstances in which a patent holder will be limited to reasonable-royalty damages: if it fails to file a timely suit, or if the suit is "dismissed without prejudice" or "not prosecuted to judgment in good faith." 35 U.S.C. § 271(e)(6)(B). Obtaining a stay that is warranted under the traditional stay factors and approved by the Court does not lead to forfeiture of lost-profits damages and so would not unduly prejudice or disadvantage Defendants.

Nor are Plaintiffs attempting to "circumvent" any requirements of the BPCIA (Opp. Br. at 11). Rather, Plaintiffs have followed the BPCIA to the letter of the law even in the face of Defendants' attempts to undermine the statute. Pursuant to the BPCIA, Plaintiffs listed the 471 patent as one that could reasonably be asserted against Defendants' product. 42 U.S.C. § 262(l)(3)(A). Thereupon *Defendants*, without bothering to engage in the statutorily mandated good-faith negotiations, "consented" to litigating the 471 patent and demanded that Plaintiffs assert the patent now or forfeit their right to lost-profits damages, even though the reexamination proceeding was pending. Compl. ¶¶ 111-113 (D.I. 1); Carey Decl. ¶ 25 (D.I. 37). Plaintiffs would never have asserted the 471 patent at this time had Defendants not insisted that they do so and it was only to avoid a needless dispute about their right to lost profits that Plaintiffs filed this

claim when they did – a rationale that Plaintiffs spelled out clearly in the complaint. Compl. ¶¶ 114-117.

In any event, even if Defendants believe they would face some tactical disadvantage from a stay pending reexamination (Opp. Br. at 13-15), any disadvantage is one of Defendants' own making and does not militate against a stay. Defendants have not denied in their Answer – and therefore have admitted – that *they* filed the request for reexamination. Answer ¶ 47 (D.I. 39); *see* Fed. R. Civ. P. 8(b)(6). They did that a year and a half before they filed their aBLA, which was filed before the reexamination was completed. Defendants knew that filing the aBLA would prompt litigation and it is *Defendants* who insisted that Plaintiffs file suit on the 471 patent immediately or risk losing their right to seek lost-profits damages. Compl. ¶ 113. The timing of this suit and the timing of the reexamination are both consequences of Defendants' own actions and do not weigh against a stay.

C. A Stay Would Not Unduly Prejudice Defendants

Defendants' argument that Plaintiffs' preservation of their rights to lost-profits damages would unduly prejudice Defendants is also contrary to the statute (Opp. Br. at 9-12). Not only were Plaintiffs entitled to preserve their rights as explained above, but they would not have been limited to a reasonable royalty even if they had not asserted the 471 patent in this action. The limit on damages under § 271(e)(6)(B) is expressly conditioned on failure to pursue litigation on patents selected by the parties pursuant to 42 U.S.C. § 262(l)(4) or (l)(5)(B). *See* 35 U.S.C. § 271(e)(6)(A)(i). But Defendants *admit* that they did not follow these procedures; instead they declared the process "moot" before getting to them and refused to proceed any further. Compl. ¶¶ 111-113; Carey Decl. ¶ 25 (D.I. 37). As a result, the 471 patent was not on the specified lists of patents, and the § 271(e)(6) limitation on damages does not apply in this case.

Defendants also fail to show that a stay would cause them undue prejudice. Importantly, Defendants do not contend that the threat of owing *any* damages on infringing sales is unduly prejudicial. The alleged unfair prejudice stems from the *incremental* damages they might owe for infringing the 471 patent if a stay is granted versus if Plaintiffs had filed suit later, i.e., the difference between reasonable-royalty damages and lost-profits damages. But 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. *See Body Sci. LLC v. Philips Elec. N. Am. Corp.*, No. 12-md-2357, 2012 U.S. Dist. LEXIS 158835, at *13 (D. Mass. Nov. 2, 2012) (noting that "a stay can cause some prejudice to [the nonmovant] without constituting *undue* prejudice") (emphasis in original). Indeed, under the circumstances of this case, reasonable-royalty damages could approach lost profits. *See, e.g.*, *AstraZeneca AB v. Apotex Corp.*, No. 2014-1221, __ F.3d __, 2015 U.S. App. LEXIS 5543, at *28 (Fed. Cir. Apr. 7, 2015) (50% royalty on pharmaceutical) (Ex. 1)[1]; *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1554-55 (Fed. Cir. 1995) (en banc) (50% royalty).

Defendants' assertion that a stay might "delay competition" lacks any evidentiary basis. Defendants never state that they intend to delay launch of their biosimilar if the 471 patent is stayed. Instead, Defendants assert that the "chance" that they will have to pay any type of damages is "slim" (Opp. Br. at 11-12). Indeed, the whole premise of Defendants' argument is that Defendants *will* launch at risk. All they want is a guarantee of the measure of damages for which they will be liable. There is no basis to conclude that a stay would impact competition.

Finally, Defendants imply that they will be prejudiced because they spent over $110 million in developing their biosimilar product. But they have failed to show that they cannot

[1] Exhibits 1-3 are attached to the Declaration of Andrew D. Cohen in Support of Plaintiff's Motion to Stay being filed herewith.

recover that investment, and earn ample profits, whether they await the expiration of the 471 patent in 2018 or not. Moreover, since Defendants apparently intend to launch upon FDA approval in any event, they will have an opportunity to make sales, which will either go to recovering their investment or paying Plaintiffs' damages. In any event, there is no reason to believe that Defendants have not already recouped their investment through sales in other jurisdictions, including in Europe and Canada.

D. Proceeding While the Reexamination Is Ongoing Would Be Unjust

Defendants fail to address the potentially immense prejudice – and inequity – that the denial of a stay could cause Plaintiffs. As discussed in Plaintiffs' opening brief, the primary underpinning for the PTO's rejection of the 471 patent claims in reexamination is a procedural technicality. The PTO issued double-patenting rejections for the 471 patent claims over a related patent, U.S. Patent 5,698,195 (the "195 patent") (Opening Br. at 7-8 (D.I. 9)). But as Plaintiffs explained to the PTO, the 471 and 195 patents were filed as a result of a restriction requirement – meaning that they were *required* to be prosecuted separately – and they therefore should be protected from double-patenting rejection by a statutory safe harbor. 35 U.S.C. § 121. The examiner initially refused to apply the safe harbor because, in part, the 471 patent was not explicitly identified as a "divisional," which she considered a technical requirement for the safe harbor. Although Plaintiffs disagreed, to avoid any doubt they amended the patent specification explicitly to designate the 471 patent as a divisional. *That amendment has been accepted by the Patent Office, but will not take effect outside of the Patent Office until the reexamination certificate issues.* Casey Decl. Ex. 3, at 2 (D.I. 13); 37 C.F.R. § 1.530(k). Thus, until the 471 patent emerges from the reexamination, its specification will not explicitly reflect that it is a divisional.

Although Defendants argue incorrectly that the 471 patent is invalid in its current form, it is true that Plaintiffs' validity defenses will be strengthened if the patent emerges from reexamination with an amended specification that accurately reflects that the 471 patent was prosecuted as a divisional. Litigating the same validity issues based on the unamended patent would be unfair. Rather than being able to rely upon an unchallengeable amended patent specification, Plaintiffs would be forced to make the same arguments about whether the patent is a divisional that the PTO has already accepted and Defendants would dispute them because the amendment has not yet take effect. Plaintiffs would thus litigate the validity of the 471 patent with one hand tied behind their back. A stay would cause no analogous prejudice to the merits of Defendants' case. Granting a stay is therefore necessary to the full and fair determination of the merits of Plaintiffs' claims. *See In re Columbia Univ. Patent Litig.*, 330 F. Supp. 2d 12, 16 (D. Mass. 2004) (Wolf., J.) (an "important[]" consideration in whether to grant a stay is which forum allows for a "complete inquiry" into the merits of the parties' claims and defenses).[2]

Defendants are eager to take advantage of this inequity. Citing *Senju Pharm. Co. v. Apotex Inc*., 746 F.3d 1344 (Fed. Cir. 2014), and *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335 (Fed. Cir. 2012), they claim the right to challenge the validity of the 471 patent now, and to use that adjudication to "moot[] any patent that may emerge from reexamination" (Opp. Br. at 13-14). In other words, Defendants contend that Plaintiffs should *never* have the opportunity to litigate the 471 patent based on the amendment that has already been approved by the PTO. But *Senju* and *Aspex* were not stay cases. Rather, they were cases where the patent owner litigated its claims and lost, and then attempted to litigate them again on the basis of a

[2] Although this Court ultimately denied a stay in the cited case, the circumstances were quite different. That case involved a patent just issuing after 22 years of prosecution where the reexamination was in its early stages and had not been initiated by one of the defendants. *See Columbia Univ.*, 330 F. Supp. 2d at 14 & n.1.

reexamined patent. Those cases support a policy against piecemeal litigation, a policy which counsels in favor of a stay here, rather than against one. If the 471 patent is to be litigated, fairness dictates that it be litigated only once, and only after its specification has been amended, as permitted by the PTO, to reflect the reality of its prosecution. It would be unjust for this Court to deny a stay so that Defendants may challenge the validity of the patent based on the existence of a technical flaw that, if it needed to be corrected at all, has already been cured within the PTO.

E. A Stay Will Simplify Litigation of the 471 Patent

It is evident that awaiting the outcome of the reexamination will simplify resolution of the 471 patent issues, and Defendants do not deny that. Instead, Defendants point to other issues in this case that will still be litigated, specifically those concerning a related patent, U.S. Patent No. 7,223,396 (the "396 patent"). Of course, the 396 patent will be at issue only if FDA approves Defendants' biosimilar for Crohn's disease, an uncertain proposition at the moment. *See* Plaintiffs' S.J. and P.I. Br., at 15-16 (D.I. 34-1). But if the 396 patent remains in dispute, Plaintiffs agree that fact discovery on the 396 patent will overlap with fact discovery on the 471 patent. In that event, Plaintiffs have no objection to completing fact discovery (document production and deposition discovery) on both patents at the same time. However, pretrial proceedings specific to the 471 patent – including expert reports, claim construction and dispositive motions – should be postponed until the reexamination is completed.

F. The Early Stage of This Case and Advanced Stage of the Reexamination Proceeding Strongly Favor a Stay

Defendants argue that the early stage of this case does not *require* a stay, but they cannot deny that it favors a stay. Even more important here, the advanced stage of the reexamination strongly favors a stay. After two years of reexamination, Janssen has just received an Advisory Action that is the final action at the examiner level in the reexamination (Ex. 2). Janssen will be

filing its notice of appeal to the Patent Trial and Appeal Board shortly. Moreover, if an appeal to the Federal Circuit is needed, it would resolve many issues that would otherwise need to be considered by this Court. The concern some courts have expressed about staying litigation for a recently initiated reexamination does not apply here. *See, e.g.*, *JuxtaComm-Texas Software, LLC v. Lanier Parking Sys. of Va., Inc.*, No. 11-cv-299, 2011 U.S. Dist. LEXIS 84924, at *7-8 (E.D. Va. Aug. 1, 2011) (staying case in light of early stage of litigation compared to advanced stage of reexamination) (Ex. 3).

III. THERE IS NO LEGITIMATE BASIS FOR FORCING PLAINTIFFS TO AGREE TO LIMIT THEIR DAMAGES CLAIM

Defendants end their brief with the suggestion that, in exchange for a stay, Plaintiffs should stipulate to seek only reasonable royalty damages. Defendants thus effectively admit that they *will* launch at risk and that their opposition to this stay motion is in reality just an effort to obtain an insurance policy, an unwarranted cap on the amount of damages they will face. But as noted above, Defendants have no basis under the BPCIA to limit Plaintiffs to reasonable-royalty damages. Plaintiffs have sought a stay pending reexamination and they are entitled to one under the law. They do not have to negotiate with Defendants over the amount of potential damages as the price of stay.

IV. CONCLUSION

This Court should stay Court action on the 471 patent.

Dated: January 13, 2016

Respectfully submitted,

/s/ *Heather B. Repicky*

Heather B. Repicky (BBO # 663347)
hrepicky@nutter.com
Alison C. Casey (BBO # 688253)
acasey@nutter.com
NUTTER MCCLENNEN & FISH LLP
Seaport West
155 Seaport Boulevard
Boston, MA 02210
617-439-2000
FAX: 617-310-9192

Of Counsel:
Dianne B. Elderkin (admitted *pro hac vice*)
delderkin@akingump.com
Barbara L. Mullin (admitted *pro hac vice*)
bmullin@akingump.com
Angela Verrecchio (admitted *pro hac vice*)
averrecchio@akingump.com
Jason Weil (admitted *pro hac vice*)
jweil@akingump.com
AKIN GUMP STRAUSS HAUER & FELD LLP
Two Commerce Square
2001 Market Street, Suite 4100
Philadelphia, PA 19103-7013
215-965-1200
FAX: 215-965-1210

Gregory L. Diskant (admitted *pro hac vice*)
gldiskant@pbwt.com
Irena Royzman (admitted *pro hac vice*)
iroyzman@pbwt.com
Aron Fischer (admitted *pro hac vice*)
afischer@pbwt.com
Andrew D. Cohen (admitted *pro hac vice*)
acohen@pbwt.com
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
212-336-2000
FAX: 212-336-2222

Attorneys for Janssen Biotech, Inc. and New York University

CERTIFICATE OF SERVICE

I certify that on January 13, 2016, this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing and if not so registered, that copies will be electronically mailed to such parties or their counsel.

/s/ *Alison C. Casey*

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action No. 1:15-cv-10698**
	)	
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC.	)	
Defendants.	)	
	)	

DECLARATION OF ANDREW D. COHEN IN SUPPORT OF
PLAINTIFF'S MOTION TO STAY

I, Andrew D. Cohen, declare and state as follows:

1. I am an associate attorney at the law firm Patterson Belknap Webb & Tyler LLP, counsel for Janssen Biotech, Inc. and New York University, and as such I am familiar with the facts stated herein.

2. Attached hereto as Exhibit 1 is a true and correct copy of *AstraZeneca AB v. Apotex Corp.*, No. 2014-1221, 782 F.3d 1324, 2015 U.S. App. LEXIS 5543 (Fed. Cir. Apr. 7, 2015).

3. Attached hereto as Exhibit 2 is a true and correct copy of an Advisory Action issued by the United States Patent and Trademark Office in Reexamination Control No. 90/012,851 dated April 29, 2015.

4. Attached hereto as Exhibit 3 is a true and correct copy of *JuxtaComm-Texas Software, LLC v. Lanier Parking Sys. of Va., Inc.*, No. 11-cv-299, 2011 U.S. Dist. LEXIS 84924 (E.D. Va. Aug. 1, 2011).

I declare under penalty of perjury that the foregoing is true and correct.

Dated: January 13, 2016

/s/ Andrew D. Cohen

Andrew D. Cohen (admitted *pro hac vice*)
acohen@pbwt.com
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
212-336-2000
FAX: 212-336-2222

CERTIFICATE OF SERVICE

I certify that on January 13, 2016, this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing and if not so registered, that copies will be electronically mailed to such parties or their counsel.

/s/ *Alison C. Casey*

EXHIBIT 1

LEXSEE

Analysis
As of: May 05, 2015

ASTRAZENECA AB, aka ASTRA ZENICA AB, AKTIEBOLAGET HASSLE, KBI-E INC., KBI INC., ASTRAZENECA LP, Plaintiffs-Appellees v. APOTEX CORP., APOTEX INC., TORPHARM INC., Defendants-Appellants

2014-1221

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2015 U.S. App. LEXIS 5543

April 7, 2015, Decided

PRIOR HISTORY: [*1] Appeal from the United States District Court for the Southern District of New York in No. 1:01-cv-09351-DLC, Senior Judge Denise Cote.
Astrazeneca AB v. Apotex Corp., 985 F. Supp. 2d 452, 2013 U.S. Dist. LEXIS 170188 (S.D.N.Y., 2013)

DISPOSITION: AFFIRMED IN PART, REVERSED IN PART, and REMANDED.

CASE SUMMARY:

OVERVIEW: HOLDINGS: [1]-A calculation of a reasonable royalty rate for infringement of patents for a prescription drug did not overcompensate the patent holders since it was properly determined that the infringer's benefits and holders' costs for a license would have been considerable, the infringer had little chance of developing a non-infringing product, and negotiations with other sellers were properly weighed; [2]-Exclusion of the value of the active ingredient of the drug for which the patent had expired was properly denied since the patents created a new, commercially viable drug which covered the infringing product as a whole; [3]-The royalty rate was improperly applied during the pediatric exclusivity period after expiration of the patents barring government approval of competing products, since exclusivity period did not extend the terms of the patents which could no longer be infringed.

OUTCOME: Judgment affirmed in part and reversed in part, and case remanded.

CORE TERMS: patent, omeprazole, generic, royalty, infringement, license, exclusivity, non-infringing, pediatric, royalty rate, manufacturer, negotiation, settlement, infringing, ingredient, patentee, patented, prescription, expiration, invention, hypothetical, enteric, coating, generic drug, pharmaceutical, infringer, market value, subcoating, licensing, patient

LexisNexis(R) Headnotes

Patent Law > Remedies > Damages > Reasonable Royalties
Patent Law > Remedies > Damages > Infringer Profits
Patent Law > Remedies > Damages > Measures
[HN1]Upon a finding of patent infringement, the patentee is entitled to damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer. 35 U.S.C.S. § 284. The two alternative categories of infringement compensation under § 284 are the patentee's

lost profits and the reasonable royalty he would have received through arms-length bargaining.

Patent Law > Remedies > Damages > General Overview
Patent Law > Jurisdiction & Review > Standards of Review > Clearly Erroneous Review
Patent Law > Jurisdiction & Review > Standards of Review > Abuse of Discretion
[HN2]The amount of damages awarded to a patentee for infringement, when fixed by the district court, is a factual finding reviewed for clear error, while the methodology underlying the court's damages computation is reviewed for abuse of discretion.

Patent Law > Remedies > Damages > Reasonable Royalties
[HN3]The reasonable royalty theory of damages for patent infringement seeks to compensate the patentee not for lost sales caused by the infringement, but for its lost opportunity to obtain a reasonable royalty that the infringer would have been willing to pay if it had been barred from infringing.

Patent Law > Remedies > Damages > Reasonable Royalties
[HN4]When an infringer can easily design around a patent and replace its infringing goods with non-infringing goods, the hypothetical royalty rate for the product is typically low. There is little incentive in such a situation for the infringer to take a license rather than side-step the patent with a simple change in its technology. By the same reasoning, if avoiding the patent would be difficult, expensive, and time-consuming, the amount the infringer would be willing to pay for a license is likely to be greater.

Patent Law > Remedies > Damages > Reasonable Royalties
[HN5]While the fact that a settlement or settlement offer comes in the midst of litigation may affect the relevance of the settlement or offer for purposes of determining a reasonable royalty rate for patent infringement, there is no per se rule barring reference to settlements simply because they arise from litigation.

Patent Law > Remedies > Damages > Measures
[HN6]When small elements of multi-component products are accused of infringement, a patentee may assess damages based on the entire market value of the accused product only where the patented feature creates the basis for customer demand or substantially creates the value of the component parts.

Patent Law > Remedies > Damages > Measures
[HN7]A patentee must in every infringement case give evidence tending to separate or apportion the defendant's profits and the patentee's damages between the patented feature and unpatented features, and such evidence must be reliable and tangible, and not conjectural or speculative. Even when the accused infringing product is the smallest salable unit, the patentee must do more to estimate what portion of the value of that product is attributable to the patented technology if the accused unit is a multi-component product containing several non-infringing features with no relation to the patented feature. Thus, the entire market value rule applies when the accused product consists of both a patented feature and unpatented features; the rule is designed to account for the contribution of the patented feature to the entire product.

Patent Law > Remedies > Damages > Measures
[HN8]When a patent covers an infringing product as a whole, and the claims recite both conventional elements and unconventional elements, the court must determine how to account for the relative value of the patentee's invention in comparison to the value of the conventional elements recited in the claim, standing alone.

Patent Law > Remedies > Damages > Measures
Patent Law > Claims & Specifications > Claim Language > Combination Claims
[HN9]In practice, all inventions are for improvements; all involve the use of earlier knowledge; all stand upon accumulated stores of the past. Yet it has long been recognized that a patent that combines old elements may give the entire value to the combination if the combination itself constitutes a completely new and marketable article.

Patent Law > Remedies > Damages > Measures
[HN10]It is not the case that the value of all conventional elements must be subtracted from the value of the patented invention as a whole when assessing damages.

For a patent that combines old elements, removing the value of all of those elements would mean that nothing would remain. In such cases, the question is how much new value is created by the novel combination, beyond the value conferred by the conventional elements alone.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[HN11]Under 21 U.S.C.S. § 355a, the Food and Drug Administration (FDA) is authorized to make a written request to the holder of an approved New Drug Application (NDA) for the holder to perform pediatric studies. If the NDA holder agrees to the request and performs the pediatric studies, and if the FDA considers the results of the studies acceptable, the statute extends the period during which the FDA is barred from approving Abbreviated NDAs filed by competing drug manufacturers for six months beyond the patent's expiration date. § 355a(b)-(c). That six-month extension is known as the pediatric exclusivity period.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

[HN12]When a generic drug manufacturer files an Abbreviated New Drug Application (ANDA) with a Paragraph IV certification, a patent holder may then initiate a patent infringement suit against the ANDA applicant. 21 U.S.C.S. § 355(j)(2)(A)(vii); 35 U.S.C.S. § 271(e)(2)(A). If the district court determines that the patent is both valid and infringed, the court is required to order the effective date of the ANDA approval to be a date not earlier than the expiration date of the patent. § 271(e)(4)(A). If the Food and Drug Administration (FDA) has not approved the ANDA at the time of the district court's decision, the FDA may not approve the ANDA (and the generic may not sell its drug) until after the patent expires. If the FDA has already approved the ANDA, the district court's order alters the effective date of that approval.

Patent Law > Remedies > General Overview

[HN13]For an act of infringement, as defined in 35 U.S.C.S. § 271(e)(2), the Patent Act provides three types of remedies. They are as follows: (A) the court shall order the effective date of any approval of the drug involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed; (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug; and (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug. 35 U.S.C.S. § 271(e)(4).

Patent Law > Remedies > Damages > Reasonable Royalties

Patent Law > Remedies > Damages > Measures

[HN14]When there has been commercial manufacture, use, or sale of an approved drug, the patentee is entitled to damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer. 35 U.S.C.S. §§ 271(e)(4)(C), 284.

Patent Law > Infringement Actions > General Overview

[HN15]There can be no infringement once a patent expires, because the rights flowing from a patent exist only for the term of the patent.

Patent Law > Remedies > Damages > Reasonable Royalties

[HN16]The royalty base for reasonable royalty damages cannot include activities that do not constitute patent infringement, as patent damages are limited to those adequate to compensate for the infringement. 35 U.S.C.S. § 284.

Patent Law > Remedies > Damages > Reasonable Royalties

[HN17]The royalty due for patent infringement should be the value of what was taken--the value of the use of the patented technology.

COUNSEL: CONSTANTINE L. TRELA, JR., Sidley Austin, LLP, Chicago, IL, argued for plaintiffs-appellees. Also represented by JOHN W. TREECE, DAVID C. GIARDINA; JOSHUA EUGENE ANDERSON, Los Angeles, CA; PAUL ZEGGER, Washington, DC.

JAMES F. HURST, Winston & Strawn LLP, Chicago, IL, argued for defendants-appellants. Also represented by STEFFEN NATHANAEL JOHNSON, EIMERIC REIG-PLESSIS, CHRISTOPHER ERNEST MILLS,

Washington, DC.

JUDGES: Before O'MALLEY, CLEVENGER, and BRYSON, Circuit Judges.

OPINION BY: BRYSON

OPINION

Bryson, *Circuit Judge*.

Apotex Corp., Apotex Inc., and TorPharm Inc., (collectively, "Apotex") appeal from a final judgment entered against them by the United States District Court for the Southern District of New York. We previously affirmed the district court's decision in an earlier phase of the same litigation holding that Apotex had infringed certain patents held by AstraZeneca AB and related parties (collectively, "Astra"). *In re Omeprazole Patent Litig.*, 536 F.3d 1361 (Fed. Cir. 2008). In the portion of the proceeding now under review, the district court awarded damages to Astra on a reasonable [*2] royalty theory of recovery. We affirm in part, reverse in part, and remand.

I

A

The patents at issue in this case are U.S. Patent No. 4,786,505 ("the '505 patent") and U.S. Patent No. 4,853,230 ("the '230 patent"). The two patents relate to pharmaceutical formulations containing omeprazole, the active ingredient in Astra's highly successful prescription drug, Prilosec.

Omeprazole is a "proton pump inhibitor" ("PPI"). It inhibits gastric acid secretion and for that reason is effective in treating acid-related gastrointestinal disorders. However, the omeprazole molecule can be unstable in certain environments. In particular, it is susceptible to degradation in acidic and neutral media. Its stability is also affected by moisture and organic solvents.

To protect the omeprazole in a pharmaceutical dosage from gastric acid in the stomach, formulators have tried covering the omeprazole with an enteric coating. Enteric coatings, however, contain acidic compounds, which can cause the omeprazole in the drug core to decompose while the dosage is in storage, resulting in discoloration and decreasing omeprazole content in the dosage over time. To enhance the storage stability of a pharmaceutical dosage, alkaline reacting compounds ("ARCs") must be added to the drug core. The addition of [*3] ARCs, however, can compromise a conventional enteric coating. Ordinarily, an enteric coating allows for some diffusion of water from gastric juices into the drug core. But when water enters the drug core, it dissolves parts of the core and produces an alkaline solution near the enteric coating. The alkaline solution in turn can cause the enteric coating to dissolve.

The inventors of the '505 and '230 patents solved that problem by adding a water-soluble, inert subcoating that separates the drug core, and thus the alkaline material, from the enteric coating. The resulting formulation, consisting of an active ingredient core with ARCs, a water-soluble subcoating, and an enteric coating, provides a dosage form of omeprazole that has both good storage stability and sufficient gastric acid resistance to prevent the active ingredient from degrading in the stomach. Once the dosage reaches the small intestine, where the drug can be effectively absorbed, the solubility of the subcoating allows for rapid release of the omeprazole in the drug core.

Astra held patents on both the active ingredient, omeprazole, and the formulation for delivering it. The active ingredient patents expired in 2001, but several patents [*4] covering the formulation, including the patents at issue in this case, did not expire until April 20, 2007.

Starting in 1997, anticipating the expiration of the active ingredient patents, eight generic drug manufacturers, including Apotex, filed Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration ("FDA"), seeking permission to manufacture and sell omeprazole. Those applications were accompanied by what are known as "Paragraph IV certifications," in which the generic drug manufacturers asserted that their formulations did not infringe the '505 and '230 patents and that the patents were invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Astra subsequently sued all eight generic drug companies in the same district court. The lawsuits were divided into two groups, each involving four defendants.

In the "first wave" litigation, the district court found that the '505 and '230 patents were not invalid and that three of the first wave defendants--all except Kremers Urban Development Co. and Schwarz Pharma, Inc.

(collectively, "KUDCo")--infringed the patents. We affirmed the district court's decision in *In re Omeprazole Patent Litig.*, 84 F. App'x 76 (Fed. Cir. 2003) ("*Omeprazole I*"), and *In re Omeprazole Patent Litig.*, 483 F.3d 1364 (Fed. Cir. 2007) ("*Omeprazole II*").

On May 31, 2007, during the "second wave" litigation, the district court issued an opinion [*5] holding that the generic version of omeprazole manufactured by Mylan Laboratories, Inc., and Mylan Pharmaceuticals, Inc., (collectively, "Mylan") did not infringe the patents. The district court also held that the generic version of omeprazole manufactured by Lek Pharmaceutical and Chemical Company D.D. and Lek USA, Inc., (collectively, "Lek") did not infringe Astra's patents. The court, however, entered judgment of infringement against Apotex. We affirmed the judgment in favor of Mylan in *In re Omeprazole Patent Litig.*, 281 F. App'x 974 (Fed. Cir. 2008) ("*Omeprazole III*"). We affirmed the judgment of infringement against Apotex in *In re Omeprazole Patent Litig.*, 536 F.3d 1361 (Fed. Cir. 2008) ("*Omeprazole IV*").

Apotex started selling its generic omeprazole product in November 2003, during the pendency of the second wave litigation. It continued selling its generic product until 2007, when the district court held that Apotex's formulation infringed Astra's patents. After we affirmed the district court's judgment of liability against Apotex, the district court held a bench trial to determine Astra's damages.

B

[HN1]Upon a finding of infringement, the patentee is entitled to "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer." [*6] 35 U.S.C. § 284. The two "alternative categories of infringement compensation" under section 284 are "the patentee's lost profits and the reasonable royalty he would have received through arms-length bargaining." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009).

The parties in this case agreed that damages were to be assessed based on a reasonable royalty theory. The district court sought to determine the reasonable royalty by analyzing the royalty that would have been reached through a hypothetical negotiation between the parties in November 2003, when Apotex began to infringe. Following the bench trial, the court held that Astra was entitled to 50 percent of Apotex's gross margin from its sales of omeprazole between 2003 and 2007.

In the course of its analysis, the court made detailed findings of fact. In summary, the court's findings were as follows:

Three generic companies launched their generic omeprazole products after the district court's first wave opinion in 2002 and before Apotex launched its generic product. KUDCo, whose formulation had been found to be non-infringing, was first on the market, but it did not have the manufacturing capacity to supply the full needs of the market immediately, and it kept the price of its omeprazole product high. Lek [*7] and Mylan were second wave defendants, and at that time the district court had not yet ruled on Astra's infringement claims against them. Nonetheless, they made the decision to launch their products in August 2003, knowing that they were at risk of later being held to infringe. In light of the risk that they might be held to be infringing Astra's patents, Mylan and Lek did not cut their prices aggressively.

The district court found that after those generic manufacturers entered the market, the price of generic omeprazole declined, but not significantly. However, the court found that the sales of Prilosec, Astra's prescription PPI drug, declined precipitously, both before 2002, when Prilosec was being replaced by Astra's newer prescription PPI drug, Nexium, and after 2002, when the generic manufacturers entered the market. Nonetheless, Astra continued to reap substantial revenues from Prilosec, which had net sales of $865 million in 2003, and $361 million in 2004.

After surveying the relevant data, the district court concluded that the price of generic omeprazole remained "relatively and uncharacteristically high" as of November 2003, due to the fact that only KUDCo was operating "freely [*8] and without the threat of litigation hanging over it." The district court therefore concluded that if Apotex had obtained a license from Astra in November 2003, it would have had "a golden opportunity to take significant market share away from both other generic manufacturers and perhaps even branded PPIs by launching at a lower price."

The district court found that Astra had anticipated the expiration of its patent on omeprazole, and that before the omeprazole patent expired, it had introduced Nexium,

which it hoped would take the place of Prilosec over time. Nexium quickly developed into a highly successful drug. In 2003, Astra's net sales of Nexium totaled $2.5 billion.

Astra's strategy was to extend the period of market dominance for Prilosec through the strategic use of its patents and to attempt to transition Prilosec patients to Nexium, which was marketed as a superior drug that would offer relief to some patients who failed on Prilosec. Astra believed that patients who remained on Prilosec were more likely to transition to Nexium than patients who switched to generic omeprazole.

At that time, the district court found, Astra was intent on seeing that Nexium remained an approved [*9] drug with a favorable reimbursement formula from third-party payers ("TPPs"), such as health insurance providers, who paid a share of patients' prescription drug costs. Astra was already effectively reducing the price of Nexium by offering rebates to the TPPs to ensure that the TPPs would continue to approve prescriptions for Nexium. In fact, between December 2002 and November 2003, the cost of Nexium therapy to the TPPs was actually lower than the cost of omeprazole therapy, both because of the rebates the TPPs received from Astra and because the price of generic omeprazole remained relatively high. Importantly, the modest decline in the price of omeprazole after Mylan and Lek entered the market in August 2003 was not sufficient to cause the TPPs to take steps to promote the use of generic omeprazole over Prilosec or Nexium.

The district court found that Astra had "every reason to expect that the launch of a fourth generic, particularly for a licensed product, would swiftly accelerate the decline in omeprazole prices" and would lead to the destruction of the remaining Prilosec market. In addition, the district court found, Astra would have been very concerned about the effect that [*10] the entry of a fourth generic product would have on the TPPs' willingness to continue to support Prilosec and Nexium.

In fact, after Apotex entered the market in November 2003, Astra had to increase its Nexium rebates to the TPPs to cope with pricing pressures from generic omeprazole. While prices declined even with Apotex's "at risk" entry into the market, the district court found that Astra would have been concerned that with a licensed product Apotex would have felt freer to cut prices in order to gain market share. That, in turn, would have caused an even more dramatic reduction in omeprazole prices, with the accompanying threat to Prilosec and, especially, Nexium.

Previously, in an agreement reached in 1997, Astra had licensed Procter & Gamble ("P&G") to market an over-the-counter version of Prilosec, known as Prilosec OTC, which was launched in September 2003. Because the market for over-the-counter drugs is largely separate from the market for prescription drugs, Astra viewed the introduction of Prilosec OTC as a way to continue to sell Prilosec in the event the market for prescription omeprazole were to be completely "genericized."[1] In addition, Astra believed that the availability [*11] of Prilosec OTC could also help promote Nexium because, if a patient failed on Prilosec OTC, the patient would naturally proceed to Nexium, since it was the only PPI that had been shown to be superior to Prilosec.

1 A market is considered "genericized" when the TPPs impose a "maximum allowable cost," which is the maximum amount they will pay for a particular prescription drug. Typically, the maximum allowable cost is based on the generic price of the drug.

The introduction of Prilosec OTC caused a reduction in the market share of both Prilosec and the generic omeprazole products. Significantly, however, the court found that the introduction of Prilosec OTC did not have any effect on omeprazole pricing, "because the systems through which prescription and OTC drugs are paid for are largely separate."

Viewing the matter from Apotex's perspective, the district court found that, as Apotex prepared to enter the market in 2003, it expected to experience roughly $581 million in sales during its first five years on the market, and that in the first year it expected to earn profits of $27 million at a profit margin of 92.5 percent. Moreover, the court found that Apotex knew that sales of its generic [*12] omeprazole would help Apotex sell its other pharmaceutical products. Accordingly, the court found that because Apotex "expected to (and did) make substantial profits from its sale of omeprazole, it would have been willing to pay a large share of those profits for the right to use [Astra's formulation] patents in 2003."

Contrary to Apotex's argument at trial, the court found that as of November 2003, it was not likely that Apotex would be able to develop a non-infringing version

of an omeprazole formulation within a reasonable period of time. Nor, the court found, would Apotex have been able to copy the formulations of others. As of November 2003, only KUDCo's patented formulation had been held not to infringe Astra's patents; the formulations used by Mylan and Lek had not yet been adjudged non-infringing. Moreover, the district court found that if Apotex had tried to copy either of those formulations, it would have incurred considerable time and expense in research and development, because of the very different technical approaches taken by Mylan and Lek.[2]

> 2 In addition, by 2003 Lek had already obtained a patent relating to its formulation. Mylan obtained patent protection for its formulation [*13] the following year.

With the background of those factual findings, the district court set about to determine what royalty rate Astra and Apotex would have agreed to if they had negotiated a license to Astra's patents in November 2003. In doing so, the court employed the so-called *Georgia-Pacific* factors, the set of 15 factors drawn from the frequently cited opinion in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970).

The court concluded that the parties would have settled on a royalty rate of 50 percent of Apotex's gross margin from the sales of its omeprazole product. The court based that conclusion principally on these considerations:

First, in November 2003 Apotex expected a gross margin on sales of its omeprazole product more than twice as large as the average gross margin on other generic products that it sold in the United States. The district court found that Apotex's estimates of its profits would have been even higher if it had had a license to Astra's patents, since the litigation would have ended and Apotex would not have had to act "with the caution in pricing its generic product that is customary for 'at risk' entrants into the generic market."

Second, Apotex's prospects of finding a non-infringing omeprazole formulation [*14] were not good. Delays in entering the market and obtaining governmental approval for a new formulation, moreover, would have put Apotex at risk of being shut out of the generic market altogether. That risk was enhanced, the district court noted, because of the practice among pharmacies of carrying only one generic version of a drug, a practice that could have severe consequences for late entrants into the market.

Third, Astra did not license generic manufacturers of prescription omeprazole, and it would have been especially reluctant to license Apotex in 2003, because Apotex's entry would have altered the dynamics of the PPI market, damaged Astra financially, and disrupted its long-term PPI strategy. In particular, the entry of a licensed generic manufacturer would have risked the "genericization" of the prescription omeprazole market, since the entry of low-priced generic drugs could have caused the TPPs to adopt a maximum allowable cost for prescription omeprazole or otherwise to restrict patients' use of branded drugs such as Prilosec and Nexium.

Fourth, the district court examined other licenses and settlements entered into by Astra relating to omeprazole and determined that those [*15] settlements, although not a "perfect benchmark" for the outcome of a hypothetical negotiation between Astra and Apotex in November 2003, nonetheless provided support for the 50 percent royalty rate selected by the court in this case.

Based on its conclusion as to the likely effects of the hypothetical negotiation, the court entered final judgment against Apotex in the amount of $76,021,994.50 plus prejudgment interest. This appeal followed.

II

The issue before us is whether the district court committed legal or factual error in concluding that, in a hypothetical negotiation, Astra and Apotex would have agreed upon a license to Astra's patents in exchange for a royalty rate of 50 percent of Apotex's profits from the sales of its infringing omeprazole product during the period of its infringement, 2003 to 2007. [HN2]The amount of damages awarded to a patentee, when fixed by the district court, is a factual finding reviewed for clear error, while the methodology underlying the court's damages computation is reviewed for abuse of discretion. *Aqua Shield v. Inter Pool Cover Team*, 774 F.3d 766, 770 (Fed. Cir. 2014); *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1345 (Fed. Cir. 2003).

A

Apotex first contends that the district court's damages award overcompensated Astra because the court

"lost sight of the essential purpose of the exercise: [*16] to compensate Astra for harm actually suffered." According to Apotex, the court's analysis (1) improperly discounted evidence that by November 2003 the market for omeprazole was "well on its way to full genericization"; (2) placed undue emphasis on Astra's ability to keep Apotex temporarily off the market by refusing to grant a license; and (3) gave "short shrift to contemporaneous licensing agreements that Astra entered with other companies" for royalty rates lower than 50 percent.

With respect to the first issue, Apotex argues that it was the fourth generic manufacturer to enter the omeprazole market, and therefore its entry caused little marginal injury to Astra. Because Astra suffered "negligible harm" from Apotex's infringement, according to Apotex, the damages award granted by the district court substantially overcompensated Astra for its loss.

Apotex's argument ignores many of the detailed findings made by the district court in support of the court's determination of the reasonable royalty in this case. For example, Apotex challenges the court's finding that in November 2003, Astra would have been concerned that Apotex's licensed entry would cause the price of generic omeprazole [*17] to plummet, thereby triggering a "genericization" of the omeprazole market. Apotex points to the fact that, in reality, it did not aggressively cut prices. The district court, however, explained that a licensed generic drug manufacturer would be able to launch at a lower price while an "at-risk" entrant, with the threat of litigation hanging over it, would be forced to set an "uncharacteristically high" price on its generic product. Based on that distinction, the district court correctly concluded that Apotex's actual pricing history sheds little light on how Apotex would have priced its omeprazole if it had obtained a license from Astra.

Moreover, Apotex's focus on what it refers to as "the harm that Astra actually suffered" is more suited to a case involving lost profits. Apotex argues, for example, that "if Apotex's entry caused Prilosec sales to implode, that would be evidence of significant harm for which Astra would be entitled to a higher royalty."

That argument would be relevant in a lost profits case. [HN3]The reasonable royalty theory of damages, however, seeks to compensate the patentee not for lost sales caused by the infringement, but for its lost opportunity to obtain a reasonable [*18] royalty that the infringer would have been willing to pay if it had been barred from infringing. *Lucent Techs.*, 580 F.3d at 1325. In determining what such a reasonable royalty would be, the district court was required to assess Astra's injury not according to the number of sales Astra may have lost to Apotex, but according to what Astra could have insisted on as compensation for licensing its patents to Apotex as of the beginning of Apotex's infringement, in November 2003.[3]

> 3 Apotex's intermingling of the lost profits and the reasonable royalty methods of calculating damages is illustrated by its reliance on this court's decision in *Grain Processing Corp. v. American Maize-Products Co.*, 185 F.3d 1341 (Fed. Cir. 1999). The statement in *Grain Processing* that a district court must reconstruct the market "as it would have developed absent the infringing product, to determine what the patentee would have made," is directed to a lost profits analysis, not to a reasonable royalty analysis, as the portion of the district court opinion quoted by the *Grain Processing* court makes clear. *See id.* at 1350 (citing *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 979 F. Supp. 1233, 1236 (N.D. Ind. 1997)). The reasonable royalty analysis does not look to what would have happened absent the infringing product, but to what the parties would have agreed upon as a reasonable royalty on the sales made by the infringer. [*19]

As the district court explained in detail, the benefits to Apotex, and the costs to Astra, of a license to the formulation patents would have been considerable. For its part, Apotex stood to (and did) garner immense profits from selling its generic omeprazole product. The district court found that even after a 50 percent royalty payment to Astra, Apotex would be left with a profit margin of 36 percent, which was "solidly in the range of 31 to 48% margins [Apotex] typically earned on its products at the time."

For Astra, on the other hand, a license would have entailed risks to both of its highly successful branded PPIs, Prilosec and Nexium. As the district court found, Astra would reasonably have expected that Apotex's entry into the market, armed with a license, "would swiftly accelerate the decline in omeprazole prices and lead to the destruction of the remaining Prilosec market"

as well as a decrease in Nexium sales or a forced increase in Nexium rebates to the TPPs. Under those circumstances, the district court was justified in concluding that a reasonable royalty rate of 50 percent would not overcompensate Astra for Apotex's infringement.

Apotex's second "overcompensation" argument [*20] is that a royalty rate that depends on the obstacles that would have "ke[pt] a competitor off the market, regardless of the actual harm the patentee suffers," is not reasonable. To the extent Apotex means to say that the costs the infringer would incur to produce a non-infringing product are not relevant to the reasonable royalty for a license to sell a product covered by the patent, we disagree.

[HN4]When an infringer can easily design around a patent and replace its infringing goods with non-infringing goods, the hypothetical royalty rate for the product is typically low. *See* *Grain Processing*, 185 F.3d at 1347; *see also* *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1312 (Fed. Cir. 2002) ("The economic relationship between the patented method and non-infringing alternative methods, of necessity, would limit the hypothetical negotiation."). There is little incentive in such a situation for the infringer to take a license rather than side-step the patent with a simple change in its technology. By the same reasoning, if avoiding the patent would be difficult, expensive, and time-consuming, the amount the infringer would be willing to pay for a license is likely to be greater.

The district court found that Apotex would have faced substantial technical and practical obstacles to marketing a non-infringing [*21] generic omeprazole formulation. Based on that finding, it was proper for the court to hold that the difficulties Apotex would have encountered upon attempting to enter the omeprazole market with a non-infringing product are relevant to the royalty rate a party in Apotex's position would have been willing to pay for a license to Astra's patents.

Apotex takes issue with the district court's consideration of the FDA regulatory delay as one factor affecting the result of the hypothetical negotiation. The district court found that Apotex would have faced considerable difficulties in marketing a non-infringing product of its own, because Apotex's proposed changes to its existing infringing formulation either had been rejected for technical reasons or were unlikely to result in a non-infringing product. In the alternative, the court found that even if Apotex could have successfully created an alternative, non-infringing formulation that would have received FDA approval, the process of development and approval would have resulted in a delay of at least two years before Apotex would have been able to market its new, non-infringing product. That two-year period, according to the district court, [*22] would have included approximately a year for the completion of the FDA approval process.

Apotex argues that the district court overcompensated Astra by considering the regulatory delay, which applies to every drug application and bears no relation to the value of Astra's patents. Significantly, however, the district court's principal finding was that as of November 2003 Apotex would have had little chance of developing and marketing a non-infringing product of its own, and the evidence at trial supports that finding. The evidence shows that none of Apotex's proposed changes to its infringing formulation were feasible. Indeed, by the end of the trial, Apotex had "largely abandoned its argument that it could have altered the infringing formulation successfully." Simply put, in November 2003 Apotex's prospect of developing its own non-infringing alternative was bleak, with or without a period of FDA delay. The district court's consideration of the regulatory delay, as an alternative ground for its conclusion that Apotex would not have been able to market a non-infringing formulation within a reasonable period of time, therefore had no effect on the court's damages calculation.

Apotex's [*23] third claim regarding Astra's alleged overcompensation is that the district court's analysis of the evidence regarding settlement and licensing negotiations with omeprazole sellers other than Apotex was fundamentally flawed and that the court abused its discretion in the way it assessed that evidence. We do not agree. The district court analyzed the pertinent settlement and licensing negotiations in detail and with close attention to the similarities and differences between those negotiations and the hypothetical negotiation in this case. We are satisfied that the court fairly weighed those negotiations in reaching its ultimate determination as to the reasonable royalty rate for damages purposes.

With regard to the settlement and license negotiations, Apotex focuses principally on Astra's license to P&G for the rights to sell Prilosec OTC.

Although the royalty formula in that case was complex, the district court found that the royalty rate turned out to be a blended rate of approximately 20 percent of P&G's net sales, or 23 percent for the first three years of the license, counting P&G's initial payment. Apotex argues that because that rate is significantly below the 50 percent rate [*24] assessed by the district court, the district court's royalty rate was plainly too high.

As the district court explained, and as Astra underscores in its brief, the P&G license for Prilosec OTC had an economic impact on Astra very different from the impact a license to a generic manufacturer such as Apotex would have had. For reasons explained in detail by the district court, the over-the-counter drug market is largely distinct from the prescription drug market. Astra did not expect Prilosec OTC to have a significant impact on the price and sales of its prescription drug, Prilosec. The risk to Prilosec from prescription generic omeprazole, by contrast, was much greater. Moreover, Astra expected sales of Prilosec OTC to be helpful to it by promoting Nexium as a more effective drug for patients who had not obtained satisfactory results with Prilosec. As the district court summarized the situation, the P&G licensing arrangement was especially favorable to Astra because Astra "received a handsome royalty for a product that was an essential part of its long-term PPI strategy."

Besides criticizing the district court for giving insufficient weight to the P&G license, Apotex complains that the [*25] court gave too much weight to a settlement and offer of settlement between Astra and two other generic manufacturers, Andrx Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc. The court found that the amount of Astra's settlement with Teva represented 54 percent of Teva's net profits on its omeprazole sales, and that the offer of settlement by Andrx was for 70 percent of Andrx's profits on the 40mg omeprazole dosage and 50 percent of its profits on the 20mg and 10 mg dosages. Astra did not accept Andrx's offer.

Apotex contends that the fact that the Teva and Andrx transactions occurred in the midst of litigation makes them irrelevant for purposes of determining a reasonable royalty rate in this case. That contention goes too far. [HN5]While the fact that a settlement or settlement offer comes in the midst of litigation may affect the relevance of the settlement or offer, there is no per se rule barring reference to settlements simply because they arise from litigation. *See* *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 872 (Fed. Cir. 2010) (noting that "the most reliable license in this record arose out of litigation," while also recognizing that in other instances, "litigation itself can skew the results of the hypothetical negotiation"); *see also* [*26] *In re MSTG, Inc.*, 675 F.3d 1337, 1348 (Fed. Cir. 2012).

In this case, Teva's settlement and Andrx's offer both arose only after the district court had held the patents valid and had made a finding of infringement as to both defendants. The setting in which those events took place was therefore similar to the setting of a hypothetical negotiation in which infringement and patent validity are assumed. In that context, Andrx's willingness to take a license for between 50 and 70 percent of its profits, and Teva's agreement to settle the infringement action against it for 54 percent of its net sales, constitute persuasive evidence that a royalty rate in the neighborhood of 50 percent of net sales for a similarly situated party would be reasonable. *See* *Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 862 F.2d 1564, 1570-72 (Fed. Cir. 1988); John M. Skenyon et al., *Patent Damages Law and Practice* § 1:15, at 25 (2013 ed.) ("[L]icenses negotiated to settle a case after a court has established validity and infringement of the patent are very probative of reasonable royalty. Such licenses duplicate the analytical process undertaken by the court in setting reasonable royalty damages in the 'willing licensor-willing licensee' fictional negotiation.").[4]

4 In its reply brief, Apotex argues that Andrx's situation at the time it [*27] made its offer was not comparable to Apotex's situation in 2003 because Andrx would have been the sole generic seller of 40 mg omeprazole for 180 days and because Andrx sought to have Astra drop its claims for willful infringement, past damages, and attorney fees. While those factors distinguish the Andrx offer from a pure license for future sales, the offer nonetheless served "as a marker of the value of licensing rights," as the district court held.

As for the Teva settlement, Apotex points to evidence that the amount paid by Teva was in settlement of claims against both Teva and Impax, and that the settlement actually constituted only 39 percent of the collective profits of those two entities. That number, while lower than the 54

> percent royalty rate referenced by the district court, nonetheless demonstrates that generic manufacturers attached a high premium to the right to sell generic omeprazole. Moreover, generic entrance is often a race to the market, because most pharmacies keep only one generic version of a drug on hand. In light of the fact that Teva/Impax were willing to pay at least a 39 percent rate on profits to become the fifth generic to enter the market, the district [*28] court's finding that Apotex would have paid a 50 percent rate to become the fourth generic entrant is reasonable.
>
> In a footnote, Apotex points to Astra's licensing agreements relating to PPI products other than omeprazole. Because those agreements did not involve omeprazole and contained cross-licenses and other features, the district court properly found them irrelevant to the damages determination.

We therefore reject Apotex's challenges to the district court's evidentiary analysis and its conclusion from that analysis that the 50 percent royalty rate constituted fair compensation to Astra under the reasonable royalty theory of damages.

B

Apotex next contends that the district court improperly based its damages calculation on the value of the omeprazole product as a whole. According to Apotex, because the active ingredient patents had expired at the time of the infringement and the active ingredient had thus become a "conventional element," the district court should have calculated damages by apportioning the relative contribution of value between the active ingredient and the "inventive element" of the patents, i.e., the subcoating.

Apotex predicates its argument on this court's cases [*29] applying the "entire market value rule." The court has held that [HN6]when small elements of multi-component products are accused of infringement, a patentee may "assess damages based on the entire market value of the accused product only where the patented feature creates the basis for customer demand or substantially creates the value of the component parts." *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1318 (Fed. Cir. 2011) (internal quotation marks omitted); *see also. LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 67 (Fed. Cir. 2012).

A threshold question arose below regarding the applicability of the entire market value rule in this case. As an initial matter, the district court noted that "there is little reason to import [the entire market value] rule for multi-component products like machines into the generic pharmaceutical context." While we do not hold that the entire market value rule is per se inapplicable in the pharmaceutical context, we concur with the district court that the rule is inapplicable to the present case.

The entire market value rule is derived from Supreme Court precedent requiring that [HN7]the patentee "must in every case give evidence tending to separate or apportion the defendant's profits and the patentee's damages between the patented feature and unpatented features, and such evidence must [*30] be reliable and tangible, and not conjectural or speculative." *LaserDynamics*, 694 F.3d at 67 (quoting *Garretson v. Clark*, 111 U.S. 120, 121, 4 S. Ct. 291, 28 L. Ed. 371, 1884 Dec. Comm'r Pat. 206 (1884)). We recently reiterated that principle, holding that even when the accused infringing product is "the smallest salable unit," the patentee "must do more to estimate what portion of the value of that product is attributable to the patented technology" if the accused unit is "a multi-component product containing several non-infringing features with no relation to the patented feature." *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1327 (Fed. Cir. 2014). Thus, the entire market value rule applies when the accused product consists of both a patented feature and unpatented features; the rule is designed to account for the contribution of the patented feature to the entire product.

This case does not fit the pattern in which the entire market value rule applies. Astra's formulation patents claim three key elements--the drug core, the enteric coating, and the subcoating. The combination of those elements constitutes the complete omeprazole product that is the subject of the claims. Thus, Astra's patents cover the infringing product as a whole, not a single component of a multi-component product. There is no unpatented or non-infringing feature in the product.

While the entire market value [*31] rule does not apply to this case, the damages determination nonetheless requires a related inquiry. [HN8]When a patent covers the infringing product as a whole, and the claims recite

both conventional elements and unconventional elements, the court must determine how to account for the relative value of the patentee's invention in comparison to the value of the conventional elements recited in the claim, standing alone. *See* *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1233 (Fed. Cir. 2014) ("[T]he patent holder should only be compensated for the approximate incremental benefit derived from his invention.") (citing *Garretson*, 111 U.S. at 121).

Several of the factors set forth in the *Georgia-Pacific* case bear directly on this issue. *Georgia-Pacific* factors nine and ten refer to "the utility and advantages of the patent property over any old modes or devices that had been used" and "the nature of the patented invention, its character in the commercial embodiment owned and produced by the licensor, and the benefits to those who used it," respectively. Factor thirteen, which refers to the "portion of the realizable profit that should be credited to the invention," embodies the same principle. Thus, the standard *Georgia-Pacific* reasonable royalty analysis takes account of the importance of [*32] the inventive contribution in determining the royalty rate that would have emerged from the hypothetical negotiation. However, while it is important to guard against compensation for more than the added value attributable to an invention, it is improper to assume that a conventional element cannot be rendered more valuable by its use in combination with an invention.

[HN9]In practice, "all inventions are for improvements; all involve the use of earlier knowledge; all stand upon accumulated stores of the past." *Cincinnati Car Co. v. N.Y. Rapid Transit Corp.*, 66 F.2d 592, 593 (2d Cir. 1933). Yet it has long been recognized that a patent that combines "old elements" may "give[] the entire value to the combination" if the combination itself constitutes a completely new and marketable article. *Westinghouse Elec. & Mfg. Co. v. Wagner Elec. & Mfg. Co.*, 225 U.S. 604, 614, 32 S. Ct. 691, 56 L. Ed. 1222, 1912 Dec. Comm'r Pat. 641 (1912) (citing *Hurlbut v. Schillinger*, 130 U.S. 456, 472, 9 S. Ct. 584, 32 L. Ed. 1011, 1889 Dec. Comm'r Pat. 459 (1889)); *see also* *Seymour v. Osborne*, 78 U.S. 516, 542, 20 L. Ed. 33 (1870) ("Improvements in machines protected by letters patent may also be mentioned, of a much more numerous class, where all the ingredients of the invention are old, and where the invention consists entirely in a new combination of the old ingredients, whereby a new and useful result is obtained, and many of them are of great utility and value, and are just as much entitled to protection as those of any other class.").

[HN10]It is not the case that the value of all conventional [*33] elements must be subtracted from the value of the patented invention as a whole when assessing damages. For a patent that combines "old elements," removing the value of all of those elements would mean that nothing would remain. In such cases, the question is how much new value is created by the novel combination, beyond the value conferred by the conventional elements alone.[5]

> 5 We recently made the same point in *University of Pittsburgh v. Varian Medical Systems, Inc.*, 561 F. App'x 934, 947-50 (Fed. Cir. 2014). In addressing the proper calculation of the royalty base in a reasonable royalty determination, we declined the defendant's invitation to remove the conventional elements from the overall value of the combination apparatus; we noted that guarding against compensation for more than the added value attributable to the invention "is precisely what the *Georgia-Pacific* factors purport to do." *Id.* at 950.

The district court addressed, and answered, that question. The court rejected Apotex's proposition that the patented formulation constituted only a minor, incremental improvement over the active ingredient. The court found instead that the formulation "substantially create[d] the value" of the entire omeprazole product. That was because, despite the effectiveness of omeprazole in reducing the production [*34] of gastric acid, it is notoriously difficult to formulate. Omeprazole is most effective when absorbed by the small intestine, but it is highly susceptible to degradation in the acidic environment of the stomach. In order to deliver the active ingredient to the part of the human body where it can take effect, scientists had to develop a formulation that would allow the drug to pass through the stomach and be absorbed by the small intestine, while ensuring adequate shelf life in a drug that is sensitive to heat, moisture, organic solvents, and light.

After years of effort, Astra's scientists determined that a water-soluble subcoat helped solve many of these problems and allowed them to formulate a commercially viable drug. The district court found that Astra's prior formulations, which lacked a subcoat, were not commercially viable.

The district court did not clearly err in concluding that the subcoating is so important to the viability of the commercial omeprazole product that it was substantially responsible for the value of the product. A commercially viable omeprazole drug requires both storage stability and gastric acid resistance. The former may be achieved with the addition of ARCs [*35] to the drug core, and the latter with the enteric coating. Without the subcoating, however, storage stability and acid resistance are irreconcilable, because the addition of ARCs would compromise the enteric coating. By inventing a structure in which a subcoating separates the drug core, and thus the ARCs, from the enteric coating, and finding the right subcoating material, Astra was able to achieve both storage stability and acid resistance. That combination of features made it possible for drug manufacturers to commercialize omeprazole.

Astra's formulation thus created a new, commercially viable omeprazole drug. That product was previously unknown in the art and was novel in its own right. Accordingly, the district court permissibly found no reason to exclude the value of the active ingredient when calculating damages in this case.[6]

> 6 In support of its apportionment argument, Apotex relies on a license that Astra granted to Takeda Chemical Industries, Ltd. that included the '230 patent, for Takeda to practice with a different PPI ingredient and formulation. The license enabled Takeda to develop and ultimately market its own formulation. The royalty rates paid by Takeda under that license do not [*36] bear on whether the damages for infringing the omeprazole formulation patents must be apportioned between the active ingredient and the formulation.

C

Taking another tack in challenging the compensation awarded to Astra for Apotex's infringing sales, Apotex argues that the value of the patented formulation must be discounted in light of the non-infringing alternative formulations in existence at the time of the infringement. The district court examined those alleged non-infringing alternatives and concluded that none were available to Apotex as of the beginning of Apotex's infringement in November 2003. Apotex did not have a non-infringing alternative formulation at that time, and KUDCo was the only generic market entrant found to be non-infringing. KUDCo's formulation, however, was covered by its own patents, and the district court found that Apotex had failed to explain how it could copy that formulation without infringing KUDCo's patents. Finally, the district court found that the formulations used by two other generic manufacturers, Lek and Mylan, could not have been regarded as non-infringing alternatives in November 2003, as they launched at risk in 2003 and their formulations [*37] were not found to be non-infringing until 2007.

Apotex does not challenge the finding that it had no non-infringing formulation of its own, and we agree with the district court that the Lek and Mylan formulations, which were launched at risk amid on-going litigation with Astra and were not found to be non-infringing until 2007, would not have been considered as non-infringing alternatives in November 2003. *See* *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1222 (Fed. Cir. 1995) (an accused alternative product offered by a third party could not be considered as a non-infringing alternative before the patentee and the third party voluntarily settled their litigation); *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 824 (Fed. Cir. 1989). The issue is therefore whether the KUDCo formulation was available to Apotex in November 2003.

In the district court, Apotex did not dispute that KUDCo's formulation was covered by KUDCo's own patents. Apotex argues that it was not shown that the KUDCo formulation was unavailable at the time of the infringement because Astra did not prove that using the KUDCo formulation would have infringed the KUDCo patents. We disagree.

The patents held by KUDCo were designed to protect its formulation. From that fact, the district court could reasonably infer that the KUDCo formulation was not available [*38] to Apotex as a non-infringing alternative. Apotex's conclusory assertion that it could have used KUDCo's formulation without infringing KUDCo's patents does not suffice to overcome that inference. *See* *Grain Processing*, 185 F.3d at 1353. Therefore, the district court did not clearly err by refusing to discount the value of Astra's patents based on the existence of alternatives to the infringing formulation that Apotex actually used.

III

Finally, Apotex objects to the district court's decision

to award damages for sales of its generic omeprazole during the "pediatric exclusivity" period of the asserted patents. [HN11]Under 21 U.S.C. § 355a, the FDA is authorized to make a written request to the holder of an approved New Drug Application ("NDA") for the holder to perform pediatric studies. *See* *Omeprazole IV*, 536 F.3d at 1368. If the NDA holder agrees to the request and performs the pediatric studies, and if the FDA considers the results of the studies acceptable, the statute extends the period during which the FDA is barred from approving ANDAs filed by competing drug manufacturers for six months beyond the patent's expiration date. 21 U.S.C. § 355a(b)-(c); *Omeprazole IV*, 536 F.3d at 1368. That six-month extension is known as the pediatric exclusivity period.

[HN12]When a generic drug manufacturer files an ANDA with a Paragraph IV [*39] certification, the patent holder may then initiate a patent infringement suit against the ANDA applicant. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 35 U.S.C. § 271(e)(2)(A). If the district court determines that the patent is both valid and infringed, the court is required to order the effective date of the ANDA approval to be a date "not earlier than" the expiration date of the patent. 35 U.S.C. § 271(e)(4)(A). If the FDA has not approved the ANDA at the time of the district court's decision, the FDA may not approve the ANDA (and the generic may not sell its drug) until after the patent expires. *Omeprazole IV*, 536 F.3d at 1367. If the FDA has already approved the ANDA, the district court's order alters the effective date of that approval. *Id.* at 1367-68.

Astra obtained the right to a six-month pediatric exclusivity before the district court's liability decision. Thus, although the asserted patents expired on April 20, 2007, the district court ordered that the effective date of Apotex's ANDA approval be set six months later, on October 20, 2007. *See* *Omeprazole IV*, 536 F.3d at 1376 (affirming the district court's order resetting Apotex's ANDA effective date). On June 28, 2007, pursuant to the district court's order, the FDA revoked its earlier approval of Apotex's ANDA, forcing Apotex to cease distribution of its generic drug until the FDA [*40] re-approved its ANDA on October 22, 2007. *See* *Apotex Inc. v. U.S. Food & Drug Admin.*, 508 F. Supp. 2d 78, 80 (D.D.C. 2007). Apotex made some sales between April 20, 2007, and June 28, 2007, i.e., during the pediatric exclusivity period and before the FDA's revocation order. The district court allowed Astra to recover a reasonable royalty on those sales, even though the sales had occurred after the expiration date of the patents.

The district court reasoned that the effect of the pediatric exclusivity period, like that of the patent term, is to bar the sale of a generic product until after the expiration of the exclusivity period. The court further noted that the FDA allows a party holding statutory exclusivity rights to waive those rights in favor of another drug manufacturer. *See* *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 2 (D.D.C. 1997). The district court therefore concluded that if Apotex had obtained a license from Astra in 2003, the license would have included the right to sell omeprazole both during the original term of the asserted patents and during Astra's pediatric exclusivity period. In exchange, Astra would have received both a royalty payment for sales made during the original patent term and a payment for its waiver of its pediatric exclusivity rights for sales made during the pediatric exclusivity [*41] period.

Apotex contends that the district court's award of damages for the period after the expiration of Astra's patents runs counter to the Supreme Court's decision in *Brulotte v. Thys Co.*, 379 U.S. 29, 85 S. Ct. 176, 13 L. Ed. 2d 99 (1964). In that case, the Court held that a royalty agreement that projects beyond the expiration date of the patent is unlawful per se. *Id.* at 32.

We do not agree with Apotex that *Brulotte* controls the outcome in this case. In *Brulotte*, the Supreme Court barred a patentee from using a licensing agreement to extract royalties after the patent had expired because the Court deemed such a practice to be a wrongful leverage of the patent monopoly, "analogous to an effort to enlarge [that] monopoly" beyond its lawful duration. *Brulotte*, 379 U.S. at 32-33. The Court's analysis in *Brulotte*, however, does not apply to a situation such as this one, in which Congress, by creating the pediatric exclusivity period, explicitly authorized additional market exclusivity to be granted to the patent owner beyond the life of the patent. In *Brulotte*, anyone was free to use the patented technology after the patent expired. In this case, by contrast, absent a waiver from Astra the FDA was not free to authorize the sale of a generic drug using the patented technology until the [*42] end of the pediatric exclusivity period. Thus, Astra's demand for royalty payments for post-expiration sales does not rest on its patent monopoly; the demand is based on the fact of Astra's legal entitlement to a pediatric exclusivity period.

The only issue here is whether the period during which damages are to be measured under section 284 may include the post-expiration pediatric exclusivity period.[7] We hold that it may not.

> 7 We do not decide whether the pediatric exclusivity period may be considered in determining the royalty *rate* that might be employed in a hypothetical negotiation. Neither party has raised that argument, and the district court made no finding regarding the relationship between the royalty rate and the pediatric exclusivity period.

[HN13]For an act of infringement, as defined in 35 U.S.C. § 271(e)(2), the Patent Act provides three types of remedies. They are as follows:

> (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
>
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within [*43] the United States or importation into the United States of an approved drug . . . [and]
>
> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . . .

35 U.S.C. § 271(e)(4).

While the remedy under subparagraph (A) is unique to section 271(e)(2) infringement, subparagraphs (B) and (C) provide the "typical remedies" for patent infringement: injunctive relief and money damages. *Omeprazole IV*, 536 F.3d at 1367. [HN14]When there has been "commercial manufacture, use, or sale of an approved drug," the patentee is entitled to "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer." 35 U.S.C. §§ 271(e)(4)(C), 284; *see Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 678, 110 S. Ct. 2683, 110 L. Ed. 2d 605 (1990) (section 271(e)(2) created a "highly artificial act of infringement" to enable "judicial adjudication" upon which the ANDA and paper NDA schemes depend; monetary damages, however, are permitted only if there has been "commercial manufacture, use, or sale" of the patented invention).

The district court found that in November 2003, the parties would have agreed to a license that would extend beyond the expiration date of the patent, [*44] because the FDA allows Astra to monetize its exclusivity right by waiving it in favor of a generic drug manufacturer, much as a patentee may license the right to use its patent for a payment of royalty. Indeed, when Andrx, one of the "first wave" defendants, attempted to settle its dispute with Astra in 2005, it offered precisely such a royalty payment covering both the original patent term and the pediatric exclusivity period. Thus, the post-expiration royalty that the district court envisioned resulting from a hypothetical negotiation reflects what a generic drug manufacturer in Apotex's position would have agreed to in a real licensing negotiation. Nevertheless, on the facts of this case it was error for the court to award that amount as part of Astra's patent infringement damages under sections 271(e)(4)(C) and 284.

We have long held that [HN15]"there can be no infringement once the patent expires," because "the rights flowing from a patent exist only for the term of the patent." *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1550 (Fed. Cir. 1994) (citing *Kinzenbaw v. Deere & Co.*, 741 F.2d 383, 386 (Fed. Cir. 1984); *Standard Oil Co. v. Nippon Shokubai Kagaku Kogyo, Ltd.*, 754 F.2d 345, 347 (Fed. Cir. 1985)). The pediatric exclusivity period is not an extension of the term of the patent. *See* 21 U.S.C. 355a(o)(1) (distinguishing patent exclusivity from non-patent exclusivity); *see also* FDA, *Guidance for Industry Qualifying for Pediatric Exclusivity* [*45] *Under Section 505A of the Federal Food, Drug, and Cosmetic Act* (Sept. 1999) ("FDA Guidance"), at 13 ("Pediatric exclusivity . . . is not a patent term extension under 35 U.S.C. § 156."); *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1280, 363 U.S. App. D.C. 440 (D.C. Cir. 2004) (giving *Chevron* deference to the FDA's interpretation of the pediatric exclusivity statute). For that reason, it is clear that Apotex did not infringe Astra's patents during the exclusivity period, since those patents had expired; if Apotex had launched its generic product

during the exclusivity period, Astra could not have sued Apotex for patent infringement based on those sales.

[HN16]The royalty base for reasonable royalty damages cannot include activities that do not constitute patent infringement, as patent damages are limited to those "adequate to compensate for the infringement." 35 U.S.C. § 284; *see* *Hoover Grp., Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 304 (Fed. Cir. 1995) ("[A patentee] may of course obtain damages only for acts of infringement after the issuance of the [] patent."); *cf.* *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1366 (Fed. Cir. 1998) (the district court abused its discretion in ordering the repatriation of the exported vials under section 283, because the injunction was directed at activities that did not constitute infringement).

For example, in *Gjerlov v. Schuyler Lab., Inc.*, 131 F.3d 1016 (Fed. Cir. 1997), the patent owner and the defendant had reached a settlement agreement under which the defendant agreed not to manufacture [*46] or sell certain products, including certain non-infringing products, in exchange for a release from patent infringement liability. Upon a request of the patent owner to enforce the settlement agreement, the district court awarded reasonable royalty damages under section 284 for the defendant's sales of a non-infringing product that were prohibited under the contract. We reversed and vacated that portion of the district court's judgment because the reasonable royalty award included damages for the sale of non-infringing products. If the defendant had breached the contract by selling an infringing product, reasonable royalty damages under section 284 would have been the proper remedy. *Gjerlov*, 131 F.3d at 1022-23. We held, however, it was improper to award reasonable royalty damages for the defendant's sale of the prohibited non-infringing products, because acts that do not constitute patent infringement cannot provide a proper basis for recovery of damages under section 284. *Id.* at 1024.

That proposition follows from the familiar principle that [HN17]the royalty due for patent infringement should be the "'value of what was taken'--the value of the use of the patented technology." *Aqua Shield*, 774 F.3d at 770 (quoting *Dowagiac Mfg. Co. v. Minn. Moline Power Co.*, 235 U.S. 641, 648, 35 S. Ct. 221, 59 L. Ed. 398, 1915 Dec. Comm'r Pat. 320 (1915) ("As the exclusive right conferred by the patent was property, and the [*47] infringement was a tortious taking of a part of that property, the normal measure of damages was the value of what was taken.")); *Ericsson*, 773 F.3d at 1226 ("As a substantive matter, it is the 'value of what was taken' that measures a 'reasonable royalty' under 35 U.S.C. § 284.").

In this case, what was taken by Apotex was the exclusive right conferred by Astra's patents up to the date that they expired. The damages determination should not include Apotex's sales during the post-expiration period of pediatric exclusivity, because Astra's rights during that period were not attributable to its patents and were not invaded by Apotex's infringement. Therefore, even though a party in Apotex's position would have agreed to a license covering both the patent term and the pediatric exclusivity period, determining damages adequate to compensate Astra for Apotex's infringement requires that we focus solely on those activities that constitute actual infringement, i.e., Apotex's pre-expiration sales. Apotex's sales during the pediatric exclusivity period cannot support Astra's claim for reasonable royalties under section 284, because those sales did not infringe Astra's patents.[8]

> 8 Astra also argues that reasonable royalties are recoverable for Apotex's [*48] post-expiration sales under the so-called "accelerated market entry" theory. The cases cited by Astra, however, were all directed at lost profits analysis and are therefore inapposite.

Nor can the award of damages for post-expiration sales be justified on the ground that those damages can be treated as "'waiver' payments made in exchange for Astra's waiver of the pediatric exclusivity period," as the district court held. Astra did not assert a claim under the Federal Food, Drug, and Cosmetic Act; its sole claim for relief was predicated on 35 U.S.C. § 271(a), and the scope of recoverable damages under that section is defined by section 284. Even if it had asserted such a claim, the statute provides no such remedy. *See* 21 U.S.C. § 337(a) ("Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.").

By prohibiting the FDA from approving an ANDA for six months after the expiration of the patent, section 355a in effect gives an NDA holder in Astra's situation six additional months free from competition from ANDA applicants. *See* 21 U.S.C. § 355a(b)-(c); FDA Guidance, at 13 ("Pediatric exclusivity . . . extends the period during

which the approval of an abbreviated new drug [*49] application (ANDA) or 505(b)(2) application may not be made effective by FDA."). But the statute does not create a damages remedy against an ANDA applicant who was authorized by the FDA to make sales during that period, as Apotex was for the first two months following the expiration of Astra's patents.

The problem that arose in this case resulted from the timing of the district court's infringement ruling. If the liability determination had been made before the expiration date of the patents, the FDA would have revoked the approval of Apotex's ANDA in time so that Apotex would have been barred from selling its generic product during the entire pediatric exclusivity period. However, because the district court's ruling was issued after the expiration date of the patent, there was a two-month period during which Apotex was authorized to sell its generic products before the FDA withdrew its approval of Apotex's ANDA. Although the sales that Apotex was authorized to make during that two-month period may have benefited Apotex and injured Astra, section 284 is not designed to compensate for those post-expiration sales.

Given that section 284 fails to support Astra's claim for royalty payments on Apotex's post-expiration [*50] sales, we reverse the portion of the district court's damages award relating to the pediatric exclusivity period, and we remand for a recalculation of damages.

Costs to Astra.

AFFIRMED IN PART, REVERSED IN PART, and REMANDED

EXHIBIT 2

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/012,851	04/29/2013	6284471	0975.0017-000CEN0095USREX	4111

114501 7590 04/29/2015

Hamilton, Brook, Smith & Reynolds, P.C.
530 Virginia Rd.
Concord, MA 01742

EXAMINER	
PONNALURI, PADMASHRI	

ART UNIT	PAPER NUMBER
3991	

MAIL DATE	DELIVERY MODE
04/29/2015	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

DO NOT USE IN PALM PRINTER

(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

MILLER, MATTHIAS & HULL, LLP

ONE NORTH FRANKLIN STREET

SUITE 2350

CHICAGO, IL 60606

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/012,851*.

PATENT NO. *6284471*.

ART UNIT *3991*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Ex Parte Reexamination Advisory Action *Before the Filing of an Appeal Brief*	**Control No.** 90/012,851	**Patent Under Reexamination** 6284471	
	Examiner PADMASHRI PONNALURI	**Art Unit** 3991	**AIA (First Inventor to File) Status** No

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

THE PROPOSED RESPONSE FILED *JUPITERS CIRCLE #1 13 April 2015* FAILS TO OVERCOME ALL OF THE REJECTIONS IN THE FINAL REJECTION MAILED *12 February 2015*.

1. ☐ Unless a timely appeal is filed, or other appropriate action by the patent owner is taken to overcome all of the outstanding rejection(s), this prosecution of the present *ex parte* reexamination proceeding WILL BE TERMINATED and a Notice of Intent to Issue *Ex Parte* Reexamination Certificate will be mailed in due course. Any finally rejected claims, or claims objected to, will be CANCELLED.

   THE PERIOD FOR RESPONSE IS EXTENDED TO RUN *4* MONTHS FROM THE MAILING DATE OF THE FINAL REJECTION. Extensions of time are governed by 37 CFR 1.550(c).

NOTICE OF APPEAL

2. ☐ An Appeal Brief is due two months from the date of the Notice of Appeal filed on _____ to avoid dismissal of the appeal. See 37 CFR 41.37(a). Extensions of time are governed by 37 CFR 1.550(c). See 37 CFR 41.37(e).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final action, but prior to the date of filing a brief, will not be entered because:
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the proceeding in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____ (See 37 CFR 1.116 and 41.33(a)).

4. ☒ Patent owner's proposed response filed *12 April 2015* has overcome the following rejection(s):*See Continuation Sheet*

5. ☐ The proposed new or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

6. ☒ For purposes of appeal, the proposed amendment(s) a)☐ will not be entered, or b)☒ will be entered and an explanation of how the new or amended claim(s) would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) patentable and/or confirmed: _____
   Claim(s) objected to: _____
   Claim(s) rejected: *1-7*
   Claim(s) not subject to reexamination: _____

AFFIDAVIT OR OTHER EVIDENCE

7. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because patent owner failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence fails to overcome all rejections under appeal and/or appellant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

12. ☐ Note the attached Information Disclosure Statement(s), PTO/SB/08, Paper No(s) _____.

13. ☐ Other:_____.

/Padmashri Ponnaluri/	/Evelyn Huang/	/Stephen Stein/
Patent Reexamination Specialist	Patent Reexamination Specialist	SPE
CRU-3991	CRU-3991	CRU-3991

cc: Requester (if third party requester)

Continuation of 4. Patent owner's response filed has overcome the following rejection(s): Patent Owner amended the specification and the drawings; and amended the specification to include the deposit information of the cell line c134 A that produces mAb A2; and provided the statements to comply with 37 CFR 1.804,1.806 and 1.808. Thus, the lack of written description rejection and enablement rejection of claim 1-7 set forth in the final rejection mailed on 2/12/15 are hereby withdrawn.

Continuation of 10. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: the ODP rejections of claims 1-7 set forth in the final rejection mailed on 2/15/15 are maintained for the reasons of record.

Patent Owner has reiterated the previous arguments and argued that the ODP rejections based on the `195 and `272 patents should be withdrawn.

In the final rejection mailed on 2/12/15, the examienr has addressed these arguments. The `195 and the `272 patent applications were filed as Continuation-in-part of applications of the parent `413 application.

The specification of the `195 and `272 patent applications were different from the parent `413 application; the original claims which were subjected to the resriction requirement in the parent application were not present (at the time of the filing of the application) in these applications. Since the `195 and `272 patent applications were filed as CIP applications and include different specification (new matter as compared to the parent `413 application) and claim priority to more than one prior application, the safe harbor provision of 37 CFR 121 does not apply.

Further, the present `471 patent application was originally (2/4/94) filed as continuation-in-part application of parent `413 application (with a different specification as compared to the parent), thus the present `471 patent application was not filed "as divisional application as a result of restriction requirement." The 10/10/14 amendment corrected the relationship of the `471 patent to the `413 application as "Divisional", which would not read on the third sentence of the 37 CFR 121, which refers to a "patent issuing on an application filed as a result of restriction requirement." The `471 patent application was not filed (2/4/94) as divisional as a result of restriction requirement. Thus, for the reasons of record the safe harbor provisions of 37 CFR 121 are not applicable for the present `471 patent and for the reasons of record set forth in the final office action, the ODP rejections are maintained.

.

EXHIBIT 3

LEXSEE

Analysis
As of: May 04, 2015

JUXTACOMM-TEXAS SOFTWARE, LLC, Plaintiff, v. LANIER PARKING SYSTEMS OF VIRGINIA, INC. et al., Defendants.

Civil Action No. 3:11-CV-299

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA, RICHMOND DIVISION

2011 U.S. Dist. LEXIS 84924

August 1, 2011, Decided
August 2, 2011, Filed

SUBSEQUENT HISTORY: Judgment entered by Juxtacomm-Texas Software, LLC v. Lanier Parking Sys. of Va., 2013 U.S. Dist. LEXIS 64631 (E.D. Va., May 6, 2013)

PRIOR HISTORY: JuxtaComm-Texas Software, LLC v. Axway, Inc., 2010 U.S. Dist. LEXIS 125352 (E.D. Tex., Nov. 29, 2010)

CORE TERMS: reexamination, discovery, initiated, lawsuit, software, simplify, patent, early stages, expert witness, trial date, pendency, stay proceedings, ex parte, prior to trial, monetary damages, patentability, infringement, invalidity, expertise, licensing, investors, serving, vendors, cloud, joined

COUNSEL: [*1] For JuxtaComm-Texas Software, LLC, a Texas Limited Liability Company, Plaintiff: Anthony Tobias Pierce, LEAD ATTORNEY, Akin Gump Strauss Hauer & Feld LLP, Washington, DC; Cassandra Danielle Garza, Kirt S. O'Neill, Melanie G. Cowart, Richard Laurence Macon, PRO HAC VICE, Akin Gump Strauss Hauer & Feld, LLP (TX-NA), San Antonio, TX.

For Lanier Parking Systems of Virginia, Inc., a Georgia Corporation, Defendant: David Evan Finkelson, LEAD ATTORNEY, McGuireWoods LLP, Richmond, VA; Frank Garrett Smith , III, Alston & Bird LLP, Atlanta, GA; George Douglas Medlock , Jr., Kamran Jivani, PRO HAC VICE, Alston & Bird LLP (GA-NA), Atlanta, GA.

For Hines Riverfront Plaza, LP, a Delaware Limited Partnership, Defendant: Ali Dhanani, Paul Morico, PRO HAC VICE, Baker Botts LLP (Houston-NA), Houston, TX; Mark L. Whitaker, Baker Botts LLP, Washington, DC; Nicholas Carlson Margida Thomas Chisman Martin,, Baker Botts LLP (DC), Washington, DC.

For First States Investors 3500 LLC, a Delaware Limited Liability Company, Defendant: Maya Miriam Eckstein, LEAD ATTORNEY, Hunton & Williams LLP, Richmond, VA; Brian Mark Buroker, Hunton & Williams, Washington, DC; Paul Thomas Nyffeler, Hunton & Williams LLP (Richmond), [*2] Richmond, VA.

For James Center Property LLC, a Delaware Limited Liability Company, Defendant: David Blaine Sanders, PRO HAC VICE, Robinson Bradshaw & Hinson PA, Charlotte, NC; Eric Lloyd Yaffe, PRO HAC VICE, Gray, Plant, Mooty, Mooty & Bennett, P.A., Washington, DC; Maisa Jean Frank, Gray Plant Mooty Mooty & Bennett, P.A., Washington, DC.

For Dominion Tower Financial Associates LLC, a Delaware Limited Liability Company, First Tower Associates LP, a Virginia Limited Partnership, Defendants, Counter Claimants: Robert Thomas Hicks, LEAD ATTORNEY, Holland & Knight LLP, McLean, VA; Benjamin Michael Stern, PRO HAC VICE, Joshua C. Krumholz, Holland & Knight LLP (MA-NA), Boston, MA.

For Direct Invest-500 East Main, LLC, a Delaware Limited Liability Company, Defendant: Kenneth Reed Mayo, LEAD ATTORNEY, Reed Mayo Law Firm PC, Virginia Beach, VA.

For JuxtaComm-Texas Software, LLC, a Texas Limited Liability Company, Counter Defendant: Anthony Tobias Pierce, LEAD ATTORNEY, Akin Gump Strauss Hauer & Feld LLP, Washington, DC; Cassandra Danielle Garza, Kirt S. O'Neill, Melanie G. Cowart, Richard Laurence Macon, Akin Gump Strauss Hauer & Feld, LLP (TX-NA), San Antonio, TX.

For Hines Riverfront Plaza, LP, [*3] a Delaware Limited Partnership, Counter Claimant: Ali Dhanani, Paul Morico, Baker Botts LLP (Houston-NA), Houston, TX; Mark L. Whitaker, Baker Botts LLP, Washington, DC; Nicholas Carlson Margida Thomas Chisman Martin, Baker Botts LLP (DC), Washington, DC.

JUDGES: James R. Spencer, Chief United States District Judge.

OPINION BY: James R. Spencer

OPINION

MEMORANDUM OPINION

THIS MATTER is before the Court on a Motion to Stay Case Pending Reexamination filed by Defendant Lanier Parking Systems of Virginia, Inc. ("Lanier"). (ECF No. 39). Defendants Dominion Tower Financial Associates LLC, First Tower Associates LLC, First States Investors 3500 LLC, James Center Property LLC, and Hines Riverfront Plaza, LP, have joined the motion, (ECF Nos. 55, 57, 65, 71), which Plaintiff JuxtaComm-Texas Software, LLC, opposes. The Court held a hearing on this matter on July 20, 2011. For the reasons discussed below, the Court has granted the motion.

I. BACKGROUND

Plaintiff JuxtaComm is the exclusive licensee of U.S. Patent No. 6,195,662 ("the '662 Patent"). The patent was issued in February 2001 and has 19 claims. This is the third lawsuit JuxtaComm has filed seeking to enforce the '662 patent. The Plaintiff initiated the first lawsuit, [*4] *JuxtaComm I*, in August 2007 in the Eastern District of Texas. The twenty-one *JuxtaComm I* defendants included the Microsoft Corporation and IBM. Six months before trial, Microsoft initiated an *ex parte* reexamination proceeding before the United States Patent and Trademark Office (PTO). The PTO issued an Office Action confirming the patentability of all but one of the claims of the '662 Patent.

The Plaintiff initiated the second lawsuit, *JuxtaComm II*, in January 2010, again in the Eastern District of Texas. The defendants in this action were additional software vendors. Tenth months after JuxtaComm initiated the lawsuit, two of the defendants filed an *ex parte* request for reexamination questioning the patentability of the '662 Patent. This second reexamination relied on allegedly prior new art (DBMS Copy Plus), alone and in combination with another system (DAISy) that was rejected as publicly accessible prior art in the first reexamination. On May 12, 2011, the PTO issued a Final Office Action invalidating Claims 1-11 and 14-19 of the '662 Patent. [1] JuxtaComm then requested that the examiner reconsider certain evidence. She agreed to do so and on June 7 withdrew her final rejection of [*5] the claims as obvious over the combination of DBMS Copy Plus and DAISy; however, she left intact the rejection of the claims as anticipated by DBMS Copy Plus. JuxtaComm will file a request for reconsideration and appeal the decision, if necessary.

1 Of the 19 claims in the '662 Patent, 17 were at issue in the reexamination. Of the two not at issue, one was canceled (Claim 13) and the other (Claim 12) was not asserted in *JuxtaComm I* or *II* and is dependent on three other claims (Claims 1, 10, and 11), all of which the PTO rejected.

JuxtaComm filed the Complaint in this lawsuit on May 6, 2011, and began serving the Defendants on May 13. Defendant Lanier, joined by five other Defendants, has requested that the Court stay this litigation pending reexamination.

II. LEGAL STANDARD

A court's "power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254, 57 S. Ct. 163, 81 L. Ed. 153 (1936). "It is well-settled law that a district court may exercise its discretion when ruling on a motion to stay proceedings pending reexamination of the patents-in-suit [*6] by the PTO." *NTP, Inc. v. Research In Motion, Ltd.*, 397 F. Supp. 2d 785, 787 (E.D. Va. 2005). Courts deciding motions to stay patent litigation pending reexamination consider "(1) whether discovery is complete and a trial date is scheduled; (2) whether a stay would simplify the matters at issue; and (3) whether a stay would unduly prejudice or clearly disadvantage the non-moving party." *ePlus, Inc. v. Lawson Software*, No. 3:09-CV-620, 2010 U.S. Dist. LEXIS 31322, 2010 WL 1279092, at *2 (E.D. Va. Mar. 31, 2010).

III. DISCUSSION

A. Discovery and Trial Date

This litigation is in its early stages. Discovery has not yet begun and the Court has not yet established a case schedule, *Markman* hearing date, or trial date. Thus, the parties have expended relatively small amounts of time and resources at this point. The Defendant is not entitled to a stay simply because the litigation is its early stages, however. Rather, the proper inquiry considers "the stage of the litigation in comparison to the stage of the PTO reexaminations." *MercExchange, L.L.C. v. eBay Inc.*, 500 F. Supp. 2d 556, 565 (E.D. Va. 2007). That inquiry favors staying the litigation.

The posture of this case is somewhat distinct from other cases where courts have [*7] denied motions to stay pending reexamination. In many of those cases, a party filed a motion to stay in the latter stages of litigation or initiated a reexamination during the pendency of the litigation. *E.g.*, *Osmose, Inc. v. Arch Chems., Inc.*, No. 2:10-CV-108, 2011 U.S. Dist. LEXIS 41533 (E.D. Va. Jan. 28, 2011) (denying stay after *Markman* hearing and three months prior to trial); *Sunbeam Prods., Inc. v. Hamilton Beach Brands, Inc.*, No. 3: 09-CV-791, 2010 U.S. Dist. LEXIS 45654, 2010 WL 1946262, at *5 (E.D. Va. May 10, 2010) (denying stay where request for reexamination was filed three months after litigation commenced and "discovery [was] well underway"); *ePlus, Inc.*, 2010 U.S. Dist. LEXIS 31322, 2010 WL 1279092, at *2 (E.D. Va. Mar. 31, 2010) (denying stay requested two months prior to close of discovery period and six months prior to trial); *NTP, Inc. v. Research In Motion, Ltd.*, 397 F. Supp. 2d at 787-88 (denying stay on remand where a jury found infringement but the PTO had not issued first office actions against all patents at issue). In contrast, defendants in other JuxtaComm litigation initiated reexamination prior to this litigation. Furthermore, JuxtaComm began serving the Defendants with the Complaint in this lawsuit *after* the PTO's Final Office Action.

Comparing [*8] the early stage of litigation with the advanced stage of reexamination favors granting the Defendant's motion to stay.

B. Simplifying the Matters at Issue

Lanier argues that a stay would simplify the matters at issue in this litigation by determining whether JuxtaComm can assert the claims against the Defendants. JuxtaComm contends that reexamination is a slower and less focused process than the district court procedure for determining validity and that the PTO's expertise is not needed to proceed with this litigation.

"It is little more than a tautology to state that reexamination will simplify the matters at issue . . . because the Patent Office's expertise as provided during reexamination will always inform the underlying issues that the Court would consider after the reexamination process was complete." *Sunbeam Products*, 2010 U.S. Dist. LEXIS 45654, 2010 WL 1946262, at *3. Nonetheless, simplification would be a benefit in this matter because as it currently stands, the PTO has deemed virtually all of the claims of the '662 Patent invalid. If litigation were to proceed under this "cloud of invalidity," the scope and validity of the claims at issue will likely be in constant flux. Given the PTO's Final Office Action, [*9] it appears likely that reexamination will significantly simplify the underlying issues.

C. Prejudice to JuxtaComm

JuxtaComm has alleged numerous sources of prejudice, including the length of time it will take to complete the reexamination and appeals process, the loss of discovery information, the potential unavailability of the named inventors and an expert witness, and negative effects on its licensing program. None of these alleged sources of prejudice favors denying the motion to stay.

First, although JuxtaComm's estimate that the reexamination and appeals process may take an additional forty-five months is reasonable, it does not necessarily favor denying the requested stay. Doing so would permit JuxtaComm to race to the finish line in litigation it pursued after learning that the PTO had rejected virtually all its claims. Additionally, as Lanier notes, the Defendants do not make software and are not in the software business. Therefore, the relevant discovery information they possess is limited--namely the identities of software vendors and the number of cars that park in a given garage. They can easily maintain that information during a stay. Next, JuxtaComm's arguments concerning [*10] the availability of the named investors and its expert witness are speculative at best. If, however, the expert witness becomes unwilling or unable to participate in this litigation, JuxtaComm can rely on a different expert witness. Finally, any harms that JuxtaComm experiences during the pendency of a stay, including harms to its licensing program, are recoverable through monetary damages. *See* *NTP, Inc. v. T-Mobile, USA, Inc.*, No. 3:07-CV-548, 2007 U.S. Dist. LEXIS 82063, 2007 WL 3254796, at *3 (E.D.Va. Nov. 2, 2007) (finding a stay would not harm the plaintiff where monetary damages are available for infringement during the pendency of the stay). Thus, a stay would not prejudice JuxtaComm.

IV. CONCLUSION

Considering the advanced stage of reexamination juxtaposed with the early stage of litigation, the likelihood that the outcome of reexamination will greatly simplify the issues in this case, and the lack of prejudice to JuxtaComm, the Court finds that the Defendant's request for a stay is not a dilatory litigation tactic but a reasonable request to prevent this litigation from proceeding under a "cloud of invalidity." Accordingly, the Court GRANTS the Defendant's motion to stay.

Let the Clerk send a copy of this [*11] Memorandum Opinion to all counsel of record.

An appropriate Order has issued.

/s/

James R. Spencer

Chief United States District Judge

ENTERED this 1st day of August 2011.