

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 10-10951-RWZ

SMITH & NEPHEW, INC.

v.

INTERLACE MEDICAL, INC. and HOLOGIC, INC.

MEMORANDUM OF DECISION

June 27, 2013

ZOBEL, D.J.

Plaintiff Smith & Nephew, Inc. (“S&N”), sued defendants Interlace Medical, Inc., and Hologic, Inc. (collectively “Hologic”),<sup>1</sup> for infringing two patents: U.S. Patent No. 7,226,459 (“the ‘459 patent”), relating to an arthroscopic surgical instrument, and U.S. Patent No. 8,061,359 (“the ‘359 patent”), relating to a surgical endoscopic cutting device and method for its use. After a ten-day trial, the jury found all the asserted patent claims valid and infringed. The case then proceeded to a two-day bench trial on whether S&N procured the ‘359 patent by inequitable conduct. This opinion resolves Hologic’s pending motions for judgment as a matter of law on the issues tried to the jury, and decides the inequitable conduct claim from the bench trial. The opinion also addresses S&N’s motion for a permanent injunction and certain questions regarding

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<sup>1</sup> Interlace Medical, Inc., is a wholly-owned subsidiary of Hologic, Inc.

damages.

## **I. Judgment as a Matter of Law**

Hologic filed one motion for judgment as a matter of law after S&N rested its case, and a second such motion at the close of all the evidence. Together, these two motions cover practically every issue tried in the case.

The jury found that Hologic had directly infringed the '459 patent, and had induced infringement and contributed to infringement of the '359 patent. It also concluded that none of the asserted patent claims were invalid for anticipation or obviousness, that the '359 patent was entitled to an earlier priority date than its filing date, and that the asserted claims of the '359 patent met the enablement and written description requirements. After reviewing the record, I am persuaded that the jury had a legally sufficient evidentiary basis for the factual determinations that underlie these conclusions. See Fed. R. Civ. P. 50(a); cf. Function Media, LLC v. Google, Inc., 708 F.3d 1310, 1329 (Fed. Cir. 2013) (juries may return general verdicts on legal questions that rest on underlying factual questions). The motions for judgment as a matter of law are therefore denied.

## **II. Inequitable Conduct**

On December 10 and December 11, 2012, I held a two-day bench trial on Hologic's claim that S&N obtained the '359 patent by inequitable conduct. Based on the evidence adduced at that bench trial and in the previous jury trial, I find the following facts and reject Hologic's inequitable conduct claim.

## **A. Background<sup>2</sup>**

In about 1996, Dr. Marc Hans Emanuel combined a surgical cutting instrument with an endoscope to create an endoscopic cutting device. In his prototype of the device, he used a commercially available endoscope manufactured by a company named Olympus.

After obtaining several related European patents, Emanuel filed his first U.S. patent application on the invention in 2000. The application was eventually granted, and a patent issued as U.S. Patent No. 7,249,602 (“the ‘602 patent”). The original patent application claimed a surgical endoscopic cutting device including both a viewing part (the endoscope) and a cutting part. Figure 1 of the application showed the entire, assembled device, while Figure 2 showed just the viewing part of the device.<sup>3</sup> The latter figure was drawn based on an unmodified Olympus endoscope. Moreover, the application emphasizes that one important part of the invention was a further outlet channel on the viewing part of the device; that further outlet channel already existed on the Olympus endoscope. However, the patent application did not disclose the Olympus endoscope as relevant prior art.

Emanuel assigned his rights in the invention to S&N, which prosecuted the ‘602 patent through its issuance. In July 2007, S&N filed a continuation application based on the ‘602 patent; that continuation led to the issuance of the ‘359 patent, which claims

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<sup>2</sup> S&N has moved to strike certain exhibits to Hologic’s brief regarding inequitable conduct. See Docket # 290. That motion is denied.

<sup>3</sup> These same figures also appeared in the issued patent.

methods of using Emanuel's device to remove tissue from the uterus. The '359 patent was prosecuted by S&N's in-house attorney Norman Hainer, and by S&N's outside counsel Phyllis Kristal of the law firm Fish & Richardson. The '359 patent application did not disclose the Olympus endoscope. However, it did disclose U.S. Patent No. 4,606,330 to Bonnet ("the Bonnet reference"), another device similar to the Olympus endoscope.

Hologic asserts inequitable conduct by Emanuel in affirmatively misrepresenting the Olympus endoscope as his own invention. It also asserts inequitable conduct by both Emanuel and Hainer in failing to disclose the Olympus endoscope as relevant prior art.

## **B. Analysis**

All patent applicants have a duty of candor and good faith towards the Patent and Trademark Office ("PTO"). See 37 C.F.R. § 1.56(a). That duty extends not only to the inventor, but to all other persons "substantively involved" in the prosecution of the patent. Id. § 1.56(c)(3). Failure to observe that duty of candor constitutes inequitable conduct, which renders any resulting patent unenforceable. Fox Indus. v. Structural Pres. Sys., 922 F.2d 801, 804 (Fed. Cir. 1990).

The Federal Circuit has recently clarified the law regarding inequitable conduct in patent prosecution. See Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (2011). Addressing "the problems created by the expansion and overuse of the inequitable conduct doctrine," the Federal Circuit in Therasense "tighten[ed] the standards for finding both intent and materiality in order to redirect a doctrine that has

been overused to the detriment of the public.” Id. at 1285, 1290.

Under Therasense, the party asserting inequitable conduct must prove by clear and convincing evidence that the patentee “acted with the specific intent to deceive the PTO,” something more than mere negligence or even gross negligence. Id. at 1290. In addition, it must prove either that the misconduct at issue was affirmative and egregious, or that it was material to the patent’s issuance—in other words, that the patent would not have issued but for the patentee’s deceptive conduct. Id. at 1291-93.

### **1. Affirmative Egregious Misconduct**

First, Hologic claims that Emanuel engaged in affirmative egregious misconduct by misrepresenting aspects of the Olympus endoscope as his invention. Affirmative egregious misconduct, as described in Therasense, is a relatively narrow category; the examples given in that opinion include truly extreme misdeeds, such as filing unmistakably false affidavits, suborning perjury, bribing witnesses, and actively suppressing evidence. See id. at 1292-93; see also id. at 1285-87 (describing the Supreme Court cases that laid the basis for the inequitable conduct doctrine). It does not include “mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit.” Id. at 1293.

Hologic emphasizes one sentence in the ‘602 patent application to show that Emanuel affirmatively and egregiously misrepresented his invention. In that sentence, Emanuel states: “By means of the invention a further outlet channel is provided, the function of which channel is independent of whether or not detached tissue has been released.” Docket # 289, Ex. 13, at D406-014; see also id., Ex. 22, at 2:18-20. That

sentence implies that the further outlet channel is new to the invention, when in fact the pre-existing Olympus endoscope already included such a channel. Hologic also points to several other sentences emphasizing the benefits of the further outlet channel, as well as diagrams in the '602 patent application that depict the Olympus endoscope as part of the claimed invention.

Emanuel's description of his invention in the '602 patent application is certainly somewhat misleading, and he would have been better advised to explain more carefully what his invention contributed over the prior art. The invention combines a cutter and an endoscope to create an endoscopic cutting device. Naturally, the application emphasizes aspects of the endoscope that make the endoscopic cutting device more useful. That emphasis could lead a reader to believe that Emanuel invented those aspects of the endoscope, rather than finding them in a preexisting product. But the ambiguous misrepresentations here simply do not present the "extraordinary circumstances" of affirmative egregious misconduct. Therasense, 649 F.3d at 1293. Hologic has not pointed to any explicitly false statements, manufactured evidence, or other blatant deceit rising to the level that Therasense requires. See id. As such, Hologic's assertion of affirmative egregious misconduct must fail.<sup>4</sup>

Moreover, I find that Hologic has failed to prove by clear and convincing evidence that Emanuel had the specific intent to deceive the PTO through his

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<sup>4</sup> Hologic refers repeatedly in its argument regarding affirmative egregious misconduct to the fact that Emanuel failed to disclose the Olympus endoscope in the '602 application. But the failure to disclose a prior art reference cannot constitute affirmative egregious misconduct. See Therasense, 649 F.3d at 1292-93. At best, it only contributes to the misleading nature of Emanuel's statements—but even so, the misstatements are not so extreme as to constitute affirmative egregious misconduct.

statements. Hologic has presented no direct evidence of deceptive intent on Emanuel's part. And while deceptive intent may be inferred from circumstantial evidence, the clear and convincing evidence standard requires that the specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence." Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008). "[W]hen there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." Therasense, 649 F.3d at 1290-91. In this case, the facts do raise a reasonable inference that Emanuel acted with the specific intent to deceive the PTO. But they raise an equally reasonable inference that Emanuel was merely negligent (or perhaps grossly negligent) in preparing his application—that he unintentionally did a poor job of describing why his new device was inventive. Thus, Hologic has failed to carry its burden to show inequitable conduct based on Emanuel's misleading statements in the patent application.

## **2. Failure to Disclose**

Hologic also argues that both Emanuel and Hainer failed to disclose the Olympus endoscope. To show inequitable conduct based on a patent applicant's failure to disclose a prior reference, Hologic "must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." Therasense, 649 F.3d at 1290. Moreover, it must prove but-for materiality—i.e., that the patent would not have issued if the reference had been disclosed. Id. at 1291.

As to Emanuel, Hologic has conclusively established that he knew of the

Olympus endoscope and knew it was an important part of his invention. But it has not proven by clear and convincing evidence that Emanuel made an intentional decision to withhold the Olympus endoscope from the PTO. Once again, Hologic presents no direct evidence that Emanuel deliberately decided to hide this prior art. Hologic rests instead on circumstantial evidence: (1) the fact that Emanuel failed to disclose the Olympus endoscope, even though he used it in his prototype device; (2) the fact that he used drawings of the Olympus scope in his application without acknowledging their source; and (3) the fact that Emanuel emphasized features of his invention that already existed in the Olympus endoscope. In addition, Emanuel did disclose the Olympus scope to the Dutch patent office in a prior patent application; that application focused on the cutter (rather than the entire endoscopic cutting device) as his invention.

This circumstantial evidence surely raises a reasonable inference, even a strong inference, that Emanuel deliberately withheld the Olympus endoscope reference. But I find that the evidence is not “sufficient to require a finding of deceitful intent in the light of all the circumstances.” Kingsdown Med. Consultants v. Hollister Inc., 863 F.2d 867, 873 (Fed. Cir. 1988). The record permits an equally reasonable inference that Emanuel’s failings were only negligent, not deceitful. Emanuel failed to provide important information to the PTO by failing to specifically mention the Olympus endoscope, and by failing to cite his diagrams properly. But the mere fact that Emanuel omitted important information is not enough to prove that he did so intentionally. See Therasense, 649 F.3d at 1290 (“[A] district court may not infer intent solely from materiality.”). The additional evidence of deliberate intent—particularly Emanuel’s



somewhat misleading description of his invention—is not enough to negate the reasonable inference that Emanuel was simply careless in failing to cite the Olympus endoscope as relevant prior art. Because Hologic has not shown that specific intent to deceive is “the single most reasonable inference,” Star Scientific, 537 F.3d at 1366, it has failed to show clear and convincing evidence of inequitable conduct by Emanuel.

As to Hainer, the alleged inequitable conduct stands on a slightly different basis. Hainer testified at the bench trial that he was not substantively involved in the prosecution of the ‘602 patent; on this point, I find him credible, despite a few emails in S&N’s privilege log bearing Hainer’s name and addressing that patent. Instead, Hainer was only substantively involved in S&N’s application for the ‘359 patent. If he committed inequitable conduct, it must be in connection with that application.

Hainer testified at the bench trial that he had no knowledge of the Olympus endoscope during his prosecution of the ‘359 patent. That testimony is not credible. Hologic introduced substantial evidence that employees in S&N’s gynecology department were well aware that Emanuel had used an Olympus endoscope in his prototype of the ‘602 device. Moreover, Emanuel published an article in 2005 describing a prototype of his invention, and specifically cited the Olympus endoscope as one of its component parts. That article was subsequently emailed out to S&N affiliates for marketing purposes. As the in-house counsel responsible for S&N’s patents in this field, Hainer’s employment responsibilities specifically entailed having some basic knowledge of what S&N’s innovations were based on and what prior art they competed with. His claim that he was not aware of the Olympus endoscope is not

believable.

Hainer's testimony is further discredited by his regrettable performance at the bench trial and at his deposition. At the trial, Hainer's uncooperative demeanor on the stand raised serious doubts regarding his truthfulness. As to his deposition, although Hainer was specifically designated to testify on behalf of S&N about its knowledge of prior art related to the '359 patent, he apparently reviewed no documents in preparation for his testimony. He also did not speak to anyone other than litigation counsel to learn relevant information. Moreover, S&N's counsel repeatedly instructed Hainer at his deposition not to answer certain pertinent questions, on the basis of rather flimsy privilege objections. Considering this record as a whole, I find that Hologic has proven by clear and convincing evidence that Hainer knew of the Olympus endoscope during his prosecution of the '359 patent.

Nevertheless, I find that Hologic has failed to show materiality. To prove the Olympus endoscope was material, Hologic had to prove by a preponderance of the evidence that the PTO would not have allowed the '359 patent if the Olympus endoscope had been disclosed. Therasense, 649 F.3d at 1292. "It is well-established, however, that information is not material if it is cumulative of other information already disclosed to the PTO." Star Scientific, 537 F.3d at 1367. Here, the relevant features of the Olympus endoscope were also present in the Bonnet reference, which S&N did disclose during the prosecution of the '359 patent. Hologic has not pointed out any relevant aspect of the Olympus endoscope that was not present in the Bonnet reference or in other endoscopes cited during the prosecution. Indeed, Hologic

emphasizes the similarity of the Olympus endoscope and the Bonnet reference; it argues that as the PTO rejected the relevant claims on reexamination based on the Bonnet reference, it would have rejected them in the original prosecution if shown the Olympus endoscope. But the Bonnet reference was disclosed in the original prosecution; and Hologic advances no convincing reason why adding the Olympus endoscope should have made a difference. Therefore, Hologic has failed to prove that the Olympus reference was material and not cumulative.

Hologic raises two counterarguments. First, it argues that the Olympus endoscope is not cumulative of the Bonnet reference (or other prior art patents) because a physical device provides more information than a written patent description. It cites trial testimony by S&N's expert that a person of ordinary skill in the art would know how to use the Olympus endoscope in the uterus just by looking at it, but would not know how to use a different prior art patent in the uterus just by its written description. Of course, that trial testimony regarding a different prior art patent is only tangentially relevant. And in any case, I am not persuaded that the PTO would allow the '359 patent over the written Bonnet reference, but would have denied the patent if shown a physical device with the same relevant features as the Bonnet reference.

Second, Hologic argues the very fact that Emanuel used the Olympus endoscope in his prototype is itself material. But Hologic has not pointed to any evidence to show the PTO would have denied the patent if it knew the Olympus endoscope was part of the prototype. Naturally, it would have been preferable to cite the prior art used in the actual working prototype, and it certainly would have been

preferable to cite the diagrams showing parts of the invention that already existed in the prior art. But given that the patent application disclosed at least one prior art reference substantially similar to the Olympus endoscope, I find Hologic has not shown by a preponderance of the evidence that the omitted information was material.

### **3. Conclusion**

Hologic has failed to carry its burden to show inequitable conduct by either Emanuel or Hainer.

### **III. Permanent Injunction**

S&N has also moved for a permanent injunction barring Hologic from further infringement. According to the traditional four-factor test, a plaintiff seeking a permanent injunction must show:

- (1) that it has suffered an irreparable injury;
- (2) that monetary damages are inadequate to compensate for that injury;
- (3) that an equitable remedy is warranted given the balance of hardships; and
- (4) that the public interest will not be disserved.

eBay Inc. v. MercExchange, LLC, 547 U.S. 388, 391 (2006). “From at least the early 19th century, courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases.” Id. at 395 (Roberts, C.J., concurring).<sup>5</sup>

#### **A. Irreparable Injury**

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<sup>5</sup> Hologic submitted four affidavits along with its opposition to the motion for a permanent injunction, one from the general manager of its gynecologic surgical products division and three from practicing physicians. S&N has moved to strike all four affidavits. Those motions to strike are denied. However, I afford relatively little weight to the parts of the affidavits that contain only anecdotal evidence and general assertions.

The first part of the eBay test asks whether the plaintiff has suffered irreparable injury from the defendant's actions. Given "the fundamental nature of patents as property rights granting the owner the right to exclude," Robert Bosch LLC v. Pylon Mfg. Corp., 659 F.3d 1142, 1149 (Fed. Cir. 2011), courts often find that continued infringement constitutes an irreparable injury, since it impairs the monopoly to which the patentee is entitled. Cf. Presidio Components, Inc. v. Am. Technical Ceramics Corp., 702 F.3d 1351, 1362 (Fed. Cir. 2012) ("[T]he axiomatic remedy for trespass on property rights is removal of the trespasser.").

S&N is particularly likely to suffer irreparable injury from Hologic's infringement because Hologic's product competes directly with S&N's. "Direct competition in the same market . . . suggest[s] strongly the potential for irreparable harm without enforcement of the right to exclude." Presidio Components, 702 F.3d at 1363. Of course, the relevant market includes more than just two players; the products manufactured by S&N and Hologic are not the only treatment options available, since other procedures such as loop resection can also be used to remove tissue from the uterus. The jury's verdict also confirms that the relevant market contains more than two players, since the jury awarded S&N a smaller amount in lost profits than Hologic's total profits on its sales; assuming that S&N could increase its output to meet demand, the partial lost profits award implies that the jury found consumers had some options other than just S&N's and Hologic's products. Nevertheless, direct competition still weighs in favor of irreparable harm even in the absence of a two-player market. See Robert Bosch, 659 F.3d at 1151-53.

S&N further argues that it has lost market share based on Hologic's infringement. S&N has presented evidence of the increased sales costs it was forced to incur to compete with Hologic's products; it also presents persuasive evidence that Hologic's sales have interfered with S&N's relationship with particular customers, showing some irreparable harm from lost business opportunities. Those lost opportunities are a paradigmatic example of irreparable injury. See Robert Bosch, 659 F.3d at 1155.

Hologic counters that it actually benefitted S&N by growing the market as a whole; it points to the fact that S&N's sales have consistently increased each year since Hologic's product came on the market. Of course, it is impossible to know for sure whether S&N's total sales would have been even larger without Hologic's infringement; but Hologic presents a persuasive argument that its advertising and marketing increased the size of this market for both parties. That weighs somewhat against finding irreparable injury from Hologic's infringement.

Hologic also persuasively rebuts S&N's argument that Hologic's product caused price erosion in the relevant market. Hologic's product has consistently sold at a higher price than S&N's, and S&N has in fact raised its prices over time. On the record presented, it does not appear that S&N has suffered irreparable injury specifically from price erosion.<sup>6</sup>

Finally, Hologic argues that S&N's showing of irreparable injury is undermined

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<sup>6</sup> I also am not convinced that S&N has suffered irreparable injury from loss of reputation or from diverting its research budget to cover legal fees. There is practically no evidence of harm to S&N's reputation, and no evidence at all that S&N diverted money from its research budget into its legal budget. Moreover, litigation costs "are not an irreparable harm in the injunction calculus." ActiveVideo Networks, Inc. v. Verizon Commc'ns, 694 F.3d 1312, 1337 (Fed. Cir. 2012).

by the ongoing reexamination of the asserted patents by the PTO. Both the '459 patent and the '359 patent are in the midst of reexamination proceedings; and all of the claims asserted here (claim 32 of the '459 patent, and claims 5-8 of the '359 patent) currently stand rejected in those proceedings. Although the PTO has not yet issued a final action on these patents, its preliminary rejection does weaken S&N's showing of irreparable harm, since S&N has not suffered any cognizable harm at all if its patents were improvidently granted. See MercExchange, LLC v. eBay, Inc., 500 F. Supp. 2d 556, 575 n.15 (E.D. Va. 2007).

Considering all of these circumstances, it appears that S&N has suffered some injury from Hologic's infringement based on the injury to its right to exclude, the harm from direct competition, and its lost customers and lost opportunities. These injuries are irreparable and favor granting a permanent injunction. However, I find the weight of this factor is somewhat diminished by the possibility that S&N's asserted patent claims will be invalidated upon reexamination, and by the fact that Hologic apparently increased the total size of the market.

### **B. Inadequacy of Monetary Damages**

The second part of the eBay test asks whether monetary damages can adequately compensate the plaintiff's injury. In general, monetary damages are often insufficient to fully compensate a patentee for lost market share and lost business opportunities. See Robert Bosch, 659 F.3d at 1155. That is particularly true because such damages can be difficult to quantify precisely. See i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 862 (Fed. Cir. 2010), *aff'd on other grounds*, 131 S. Ct. 2238

(2011). Likewise, monetary damages cannot perfectly substitute for the loss a patentee suffers when it is deprived of its right to exclude others from its invention. Finally, monetary damages raise the risk of strategic behavior by defendants, since “a calculating infringer may . . . decide to risk a delayed payment to obtain use of valuable property without prior negotiation or the owner’s permission.” Presidio Components, 702 F.3d at 1362-63.

On the other hand, the law often relies on monetary damages to partially recompense a loss even when those damages cannot perfectly repair the damage done. Cf., e.g., Carey v. Piphus, 435 U.S. 247, 254-59 (1978) (monetary damages appropriate to compensate injuries caused by the deprivation of constitutional rights); Aponte-Rivera v. DHL Solutions (USA), Inc., 650 F.3d 803, 811-12 (1st Cir. 2011) (reviewing cases awarding monetary damages for emotional distress). Even in the patent realm, monetary damages can be sufficient to adequately compensate for future infringement in some circumstances. See, e.g., Voda v. Cordis Corp., 536 F.3d 1311, 1329 (Fed. Cir. 2008).

Here, S&N has shown evidence that it has lost market share and lost business opportunities as the result of Hologic’s infringement. In addition, it has suffered the intangible harm associated with the violation of its right to exclusivity. See Douglas Dynamics, LLC v. Buyers Prods. Co., 2013 WL 2158423, at \*6 (Fed. Cir. May 21, 2013). Monetary damages are not adequate to fully compensate these injuries, and so this second part of the eBay test also favors entering a permanent injunction. At the same time, although such damages cannot fully repair the harm S&N will suffer from



continued infringement, they can nevertheless substantially mitigate S&N's losses.<sup>7</sup> Moreover, it should be easy to calculate an appropriate ongoing royalty because Hologic tracks the sales of its infringing products separately. So although the inadequacy of monetary damages weighs in favor of a permanent injunction, it does not weigh heavily.

### **C. Balance of Hardships**

The third part of the eBay test balances the potential hardship to either party from granting or denying an injunction. The harms S&N will suffer if a permanent injunction is denied are described above; they include ongoing losses of revenue, market share, and business opportunities from Hologic's infringement. Of course, these harms can be somewhat mitigated (though not entirely repaired) by monetary damages.

On the other hand, Hologic asserts that if its infringing products are enjoined, it will be forced to lay off 159 employees and will lose its investment of over \$266 million in the products at issue. S&N argues that I should disregard these hardships because they stem from Hologic's investment in an infringing product, and "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected."

Windsurfing Int'l v. AMF, Inc., 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986). But that argument goes too far, particularly since there is no claim that Hologic willfully infringed S&N's patents. The hardships Hologic faces are partly the result of investing in technology that was later found to be infringing; that may be a reason to weigh those

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<sup>7</sup> I note that Hologic appears financially stable and capable of paying any damages awarded. Cf. Robert Bosch, 659 F.3d at 1155-56.

hardships less heavily in the injunction calculus, but it is not a reason to disregard them altogether.

More importantly, as noted above, all the asserted claims currently stand rejected in the ongoing PTO reexaminations. The PTO proceedings are not yet final, of course; but the possibility that the claims may be amended or invalidated tends to discount the potential hardship to S&N and heighten the potential hardship to Hologic. See Beldon Techs. v. Superior Essex Commc'ns, 802 F. Supp. 2d 555, 579 (D. Del. 2011) (in the context of ongoing reexamination proceedings, “the harm to defendants if the injunction were to issue on invalid patents is much greater than the harm to plaintiffs should the injunction not issue at all”). But see ePlus, Inc. v. Lawson Software, Inc., Civil Action No. 3:09-620, 2011 U.S. Dist. LEXIS 54957, at \*54-55 (E.D. Va. May 23, 2011). If a permanent injunction were to issue now, it might well be invalidated if the PTO reexaminations void S&N’s patents. In that scenario, Hologic would incur costs in excess of \$38 million to restart its product line. That potential hardship certainly weighs against issuing an injunction.

Under these circumstances, I find that the balance of hardships weighs against a permanent injunction. While S&N will suffer if a permanent injunction is denied, its injuries can be at least partially remedied by monetary damages. On the other hand, if a permanent injunction issues, Hologic will immediately lose its \$266 million investment—and 159 of its employees will lose their jobs. That hardship is substantially more severe than any faced by S&N. Even considering the fact that Hologic’s investment was (unintentionally) built on infringement, the equities here favor

compensating S&N with damages rather than destroying Hologic's intrauterine device business.

#### **D. Public Interest**

The final part of the eBay test looks to whether a permanent injunction would disserve the public interest. On the one hand, the public interest generally favors protecting the rights of patentees and enforcing the patent system. See ActiveVideo Networks, Inc. v. Verizon Commc'ns, 694 F.3d 1312, 1341 (Fed. Cir. 2012); see also Douglas Dynamics, 2013 WL 2158423 at \*7. But here, there is a strong countervailing public interest in making Hologic's device available for medical treatment. Hologic has presented evidence showing that at least some doctors consider its product more effective than S&N's for intrauterine tissue removal. Of course, S&N disputes that evidence; it correctly points out that there is no controlled clinical study showing any advantage for Hologic's product over S&N's, and emphasizes that anecdotal evidence about physician preference is not enough to prove an issue of patient safety. See Mallinckrodt, Inc. v. Masimo Corp., 147 F. App'x 158, 177-78 (Fed. Cir. 2005). I am nevertheless convinced that at least some doctors and their patients will suffer a negative impact if Hologic is enjoined from selling its medical device. Because different doctors may find one device or the other more suitable for particular intrauterine tissue procedures, health providers and patients benefit substantially from having both products available in the market. Given the importance of optimal patient care, the public interest weighs against granting a permanent injunction here.

#### **E. Conclusion**

The decision here is extremely close. The first two factors of the eBay test weigh somewhat in favor of a permanent injunction, while the third and fourth factors each weigh against it. Importantly, the balance among the four factors is substantially affected by the ongoing reexamination proceedings, which weaken the arguments favoring an injunction and strengthen the arguments against it.<sup>8</sup> Balancing the eBay factors as detailed above, I find that S&N will be entitled to a permanent injunction if the reexamination proceedings and any subsequent appeals are eventually resolved in S&N's favor.<sup>9</sup> At present, however, the unresolved PTO reexaminations tip the balance against immediately enjoining Hologic. I therefore allow S&N's motion for a permanent injunction, but stay that injunction until the reexaminations and any subsequent appeals therefrom are concluded. See Standard Haven Prods. v. Gencor Indus., 996 F.2d 1236, 1993 WL 172432 (Fed. Cir. 1993) (table).<sup>10</sup> The parties shall confer and agree on an appropriate sunset royalty rate for Hologic to pay S&N while the permanent injunction is stayed. If the parties are unable to agree, the court will determine an appropriate rate.

#### **IV. Damages**

Finally, the parties raise various issues regarding the proper calculation of

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<sup>8</sup> Hologic also argues that S&N should be barred from obtaining equitable relief by its "unclean hands." See Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240 (1933). Specifically, Hologic asserts that S&N obtained its patents through inequitable conduct before the PTO, and that it engaged in litigation misconduct by blocking key discovery during depositions. I have already rejected Hologic's inequitable conduct arguments above; as to the alleged litigation misconduct, I find that it is not so egregious as to bar equitable relief.

<sup>9</sup> If the reexamination proceedings find S&N's patents invalid, of course, then S&N will not be entitled to any relief whatsoever.

<sup>10</sup> Hologic has also indicated that it may seek a separate stay of the permanent injunction pending appeal of the judgment in the present case. That question, however, is not yet before me.

damages.

### **A. Damages in the Jury Verdict**

The jury's verdict form included four questions regarding damages (questions 8 through 11). The first question asked the jury whether S&N was entitled to lost profits; the second asked what amount S&N was entitled to in lost profits; and the third asked what a reasonable royalty rate on these patents would equal. The fourth and final question asked: "For those sales infringing one or both patents for which plaintiff is not entitled to lost profits, what is the dollar amount of the damages based on a reasonable royalty?" Docket # 241 at 6. Because the parties had both presented theories under which lost profits might be available on some sales and a reasonable royalty on others, the parties asked me to instruct the jury that it could answer all four questions if it intended to award partial damages in lost profits and partial damages in royalties.

During its deliberations, the jury sent the following question: "We have come to a royalty rate, but are unable to come to a dollar figure due to inability to find financial information. We request advice from Judge Zobel." Docket # 270 at 5. The parties agreed that there was no dispute as to the royalty base, which equaled Hologic's revenue base, and that the total damages could be easily calculated by multiplying the royalty rate by Hologic's revenue base. Id. at 4. The parties therefore agreed that I should instruct the jury that if it had answered all of the questions except the final one, then it should return its verdict. Id. at 6.

The jury returned a verdict awarding S&N \$4 million in lost profits and a reasonable royalty rate of 16%. Taking advantage of its instructions, the jury left the

final question blank—that is, it did not determine an exact dollar amount of the damages owed under a reasonable royalty.

That mixed award was unexpected. In answering the jury's question, the parties assumed that the jury intended only to award damages under a reasonable royalty. In that situation, the reasonable royalty damages would equal the 16% royalty rate multiplied by the total amount of Hologic's revenue base (about \$32.8 million), for a total of about \$5.2 million. But the jury did not only award reasonable royalty damages; instead, it also awarded \$4 million in lost profits. That \$4 million necessarily represents profits on some portion of Hologic's sales. As to any individual infringing item, however, S&N is only entitled to either its lost profit on that item or a reasonable royalty on that item. S&N therefore cannot be entitled to both the \$4 million in lost profits and an additional 16% reasonable royalty on all of Hologic's sales; that would double count S&N's damages as to the portion of Hologic's sales covered both by the lost profits award and by the reasonable royalty award. Instead, S&N is entitled to \$4 million in lost profits as compensation for some fraction of Hologic's sales, and a 16% royalty on the remainder of Hologic's sales.

The problem is that it is impossible to determine from the jury's verdict what fraction of Hologic's sales the award of \$4 million in lost profits was intended to cover. For example, if the lost profits were intended to cover one quarter of Hologic's infringing sales, then S&N would additionally be entitled to about \$3.9 million in reasonable royalties on the other three quarters of Hologic's sales (a 16% royalty on \$24.6 million, which is three-quarters of Hologic's \$32.8 million revenue base). On the

other hand, if the lost profits award was intended to cover one half of Hologic's sales, then the reasonable royalty damages would only be about \$2.6 million (a 16% royalty on \$16.8 million, which is the other half of Hologic's revenue base). The mixed award returned by the jury is thus hopelessly ambiguous.

S&N proposes to resolve the ambiguity by assuming that the jury accepted S&N's total claim for lost profits, about \$17.1 million, as the correct figure to cover all Hologic's sales. Since the jury awarded \$4 million in lost profits, about a quarter of that claim, S&N concludes that the \$4 million represents about a quarter of all Hologic's sales (meaning S&N is entitled to royalty damages on the other three quarters). But that argument rests on pure speculation. There is no reason to believe that the jury blindly accepted S&N's calculation of the total profits it would have earned on all Hologic's sales, and S&N does not explain why (if the jury had accepted that calculation) it would have awarded only a quarter of those lost profits. A damages award cannot be based on such speculation and guesswork. See Interactive Pictures Corp. v. Infinite Pictures, Inc., 274 F.3d 1371, 1376 (Fed. Cir. 2001).

Unfortunately, I am left without any measure of what damages to award. To rectify the situation, three options present themselves. First, the parties could simply agree on an appropriate measure of damages; second, the court could hold a bench trial limited to determining the correct amount of damages; or third, the court could hold a jury trial limited to determining the correct amount of damages. The parties shall confer on this issue and report on how they wish to proceed.<sup>11</sup>

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<sup>11</sup> In light of this situation, I need not decide now whether S&N is entitled to royalties on products that Hologic provided to its customers free of charge.

## **B. Pre-Verdict Sales**

S&N has also moved for an accounting of Hologic's infringing sales between July 1, 2012 and the entry of judgment, so that it can recover a reasonable royalty on those sales. Hologic opposes that motion on the ground that the jury's verdict adequately compensates S&N for all of its pre-verdict damages.

As a general rule, a verdict of lost profits is presumed to include all of the plaintiff's lost profits up to the date the verdict is rendered. See, e.g., Presidio Components, Inc. v. Am. Technical Ceramics Corp., Civil Action No. 08-335-IEG (NLS), 2010 WL 3070370, at \*2 n.1 (S.D. Cal. Aug. 5, 2010), aff'd in part and vacated in part, 702 F.3d 1351 (Fed. Cir. 2012); Oscar Mayer Foods Corp. v. Conagra, Inc., 869 F. Supp. 656, 668 (W.D. Wis. 1994). On the other hand, where the jury awards damages based on a determinable royalty rate, then courts will generally allow motions for further accounting and apply that royalty rate to periods of infringing activity that the jury did not consider. See Itron, Inc. v. Benghiat, Civil Action No. 99-501 (JRT/FLN), 2003 U.S. Dist. LEXIS 15039, at \*48-49 (D. Minn. Aug. 29, 2003). That practice corresponds with the general rule that patentees are 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." 35 U.S.C. § 284.

Because the correct measure of damages is not yet settled, as described above, it is not clear whether S&N will be compensated for Hologic's infringement by a lump-sum award of lost profits or by a reasonable royalty on sales (or by a mixed award). I therefore cannot determine at this point whether an additional accounting is



appropriate. S&N's motion is consequently denied as premature.

### **C. Prejudgment Interest**

Finally, S&N moves for an award of prejudgment interest under 35 U.S.C. § 284. Once again, because the correct measure of damages is not yet settled, this motion is denied as premature.

### **V. Conclusion**

Hologic's motions for judgment as a matter of law (Docket ## 227, 240) are DENIED.

S&N's motion for judgment against Hologic on its inequitable conduct claim (Docket # 283) is ALLOWED. S&N's motion to strike exhibits relevant to that claim (Docket # 290) is DENIED.

S&N's motion for a permanent injunction (Docket # 254) is ALLOWED; however, the injunction is STAYED until the PTO reexamination proceedings, and any subsequent appeals, are concluded. The parties shall confer and agree on an appropriate sunset royalty rate to be paid while the permanent injunction is stayed, or shall inform the court if they are unable to set an agreed rate. S&N's motions to strike certain affidavits (Docket ## 273, 275) are DENIED.

S&N's motion for calculation of damages (Docket # 260) is DENIED. As described above, the parties are ORDERED to report on how they wish to determine the correct amount of damages. S&N's motion to supplement the record (Docket # 277) is DENIED AS MOOT since the transcript is already part of the record.

S&N's motion for an accounting and for prejudgment interest (Docket # 263) is

DENIED as premature.

June 27, 2013

DATE

/s/Rya W. Zobel

RYA W. ZOBEL  
UNITED STATES DISTRICT JUDGE