IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SENORX, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. 12-173-LPS-CJB
HOLOGIC, INC.,	)	
Defendant.	)	

DEFENDANT'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO BIFURCATE AND STAY DISCOVERY ON DAMAGES AND WILLFULNESS

Karen L. Pascale (#2903)
James L. Higgins (#5021)
YOUNG CONAWAY STARGATT & TAYLOR LLP
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600

OF COUNSEL
Matthew M. Wolf
John E. Nilsson
Amy L. DeWitt
ARNOLD & PORTER LLP
555 Twelfth Street, NW
Washington, D.C. 20004
(202) 942-5000

Attorneys for Defendant Hologic, Inc.

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Defendant Hologic, Inc. ("Hologic") respectfully submits this Reply Brief in further support of its motion to bifurcate liability issues from damages and willfulness issues pursuant to Fed. R. Civ. P. 42(b) (D.I. 15, 16), and to stay damages- and willfulness-related discovery pending resolution of liability issues.

PRELIMINARY STATEMENT

Plaintiff SenoRx, Inc. ("SenoRx") cannot dispute the following:

- This case involves two separate patents with 100 claims possibly asserted;
- The patents concern complex radioactive brachytherapy technology, with which the jury is not likely to be familiar;
- Liability issues include the infringement of up to 100 patent claims, literally or under the doctrine of equivalents, and the validity and/or unenforceability of those claims in light of numerous prior art references and other requirements of the patent code; and
- Whether SenoRx asserts damages based on lost profits, lost market share, price erosion, reasonably royalty, or another theory, its damages and willfulness cases will be similarly complex, and will require additional fact and expert discovery that will not otherwise be required in the liability phase.

As explained in Hologic's Opening Brief (D.I. 16) ("Opening Br."), these are precisely the sort of factors in patent cases that weigh in favor of bifurcation. Contrary to SenoRx's characterizations, Hologic asserts that bifurcation in patent cases in the District of Delaware is a presumption, *not* a categorical rule. (Opening Br. at 4-5.) Nonetheless, it cannot be refuted that courts in this District have taken the position that bifurcation is "appropriate, if not necessary, in all but exceptional patent cases." *Dutch Branch of Streamserve Dev. AB v. Exstream Software, LLC*, Civ. No. 08-343-SLR, 2009 U.S. Dist. LEXIS 76006, at *2 (D. Del. Aug. 26, 2009); *Robert Bosch LLC v. Pylon Mfg. Corp.*, Civ. No. 08-542-SLR, 2009 U.S. Dist. LEXIS 76010, at *2 (D. Del. Aug. 26, 2009) (same). The *Dutch Branch* and *Robert Bosch* rulings remain good law, despite SenoRx's attempt to minimize them in a footnote. (D.I. 24, Opp. at 5 n. 1.) For the

reasons that bifurcation is "appropriate, if not necessary, in all but exceptional patent cases," it is equally appropriate here.

ARGUMENT

SenoRx argues that this case is not sufficiently complex to merit bifurcation, which it contends would create judicial inefficiency and prejudice to SenoRx. (Opp. at 9-13.) In so doing, SenoRx vastly understates the complexity of the patents-in-suit and underlying technologies, as well as the potential benefits to this Court of separating issues that may never need to be tried at all. SenoRx also ignores the substantial prejudice to Hologic that would result from proceeding with damages- and willfulness-related discovery at this stage.

A. The Complexity Of Liability Issues In This Case Merits Bifurcation

Despite SenoRx's attempts to oversimplify the numerous technological, liability-related, and damages-related issues in play (Opp. at 7-9), this case, as presently framed, promises to be highly complex for a lay jury. As Hologic explained in its Opening Brief, this case will require expert explanation of a variety of complex technical issues that will almost certainly be unfamiliar to the jury, including medical device design and engineering, brachytherapy treatment methods, and radiation therapy. (Opening Br. at 5.) For example, independent claim 66 of U.S. Patent No. 8,079,946 ("the '946 patent") is directed to

> [a] device for delivering radiation to tissue around at least a portion of a body cavity of a patient, comprising: (a) an elongated shaft which has a proximal shaft portion, a distal shaft portion spaced apart from the proximal portion along a longitudinal direction and a central longitudinal axis; (b) an expandable member on the distal portion of the shaft which has a contracted and expanded configuration and which defines at least in part a volume proximate the distal shaft portion; (c) a guide member within the volume proximate the distal shaft portion which is configured to slidably retain a moveable radiation source along a path within said volume such that the moveable radiation source can be slidably advanced along the guide member and can be positioned at a plurality of distances off-set from the central longitudinal axis and is spaced from and unsecured to the expandable member in the expanded configuration.

(D.I. 1 at 26, 16:7-26.) In contrast, many of the cases relied upon by SenoRx involved technologies that were familiar and easy for juries to comprehend. *See, e.g., Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 498 F. Supp. 2d 734, 736, 738 (D. Del. 2007) (cited in Opp. *passim*) (denying bifurcation of counterclaims where technology involved a "common beverage can," which is "[n]o doubt an item . . . with which most, if not all jurors, have some familiarity"); *Computer Assocs. Int'l, Inc. v. Simple.com, Inc.*, 247 F.R.D. 63, 68 (E.D.N.Y. 2007) (cited in Opp. at 6, 10) (case "involves computer software and computers are a topic, in this day and age, that a large portion of the population have at least some familiarity with as opposed to other, more esoteric types of patent litigation"); *Innovative Office Prods. v. SpaceCo, Inc.*, Civil No. 05-04037, 2006 U.S. Dist. LEXIS 29439, at *7 (E.D. Pa. May 15, 2006) (cited in Opp. at 8) (noting that "each of these patents relates to a relatively simple mechanical device with which many jurors may have personal experience, as opposed to more complex chemical or electrical patents"); *Datastrip (IOM) Ltd. v. Symbol Techs., Inc.*, Civ. No. 97-70-JJF, 1998 WL 35287850, at *1 (D. Del. Jan. 7, 1998) (cited in Opp. at 5, 6, 9, 13) (denying motion to bifurcate where plaintiff's patent covered a two-dimensional bar code).[1]

Moreover, claim 66 of the '946 patent is just one of the 100 claims (including 13 independent claims) possibly at issue. Many of the other claims potentially to be asserted are method of treatment claims that may only be infringed, if at all, by physicians using the accused

[1] Numerous cases cited by SenoRx in its Opposition likewise offer justifications for bifurcation, even where the Court opted not to bifurcate liability from damages and willfulness issues. *See, e.g., Masimo Corp. v. Philips Elecs. N. Am. Corp.*, 742 F. Supp. 2d 492, 496 (D. Del. 2010) (trial on damages is "often difficult and expensive, while being easily severed from the trial of the questions of validity and infringement of the patent") (internal quotations and citation omitted); *Johns Hopkins Univ. v. Cellpro*, 160 F.R.D. 30, 33 (D. Del. 1995) (cited in Opp. *passim*) ("Historically, courts have found it worthwhile to hold separate trials on liability and damage issues in patent cases. They have also apparently found it can be more efficient to defer discovery and trial on damage issues until after liability has been resolved at trial and on appeal."); *Datastrip (IOM) Ltd.*, 1998 WL 35287850, at *2 (cited in Opp. at 5, 6, 9, 13) (same).

technology.[2] Thus, resolution of infringement issues potentially involves not only direct infringement analyses under 35 U.S.C. § 271(a) but also indirect infringement analyses under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c). (D.I. 1 at 3-5.) This is not to mention the defenses that Hologic intends to raise (defenses ignored by SenoRx in its Opposition). For example, should this case proceed past the discovery stage, Hologic intends to present compelling evidence to the Court and, if necessary, the jury that the claims are invalid under 35 U.S.C. §§ 102-103 in light of the disclosures of virtually identical prior art technologies disclosed in references such as U.S. Published Application No. 2005/0101823, U.S. Patent No. 7,662,082, and U.S. Published Application No. 2007/0270627. In assessing defenses under 35 U.S.C. § 102, jurors will need to make complicated findings of fact on whether or not the asserted claims are anticipated by these and other prior art references. *See Voda v. Cordis Corp.*, 536 F.3d 1311, 1323 (Fed. Cir. 2008) (anticipation requires disclosure of each and every claim limitation in a prior art reference, either explicitly or inherently) (internal citation omitted). In assessing defenses under 35 U.S.C. § 103, jurors will be required to make factual findings regarding: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, (3) the level of ordinary skill in the pertinent art, and (4) secondary considerations of non-obviousness. *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1327 (Fed. Cir. 2009).

SenoRx has also oversimplified the damages issues that the jury will potentially face without bifurcation. As a direct competitor of Hologic, SenoRx will likely attempt to present both "reasonable royalty" and "lost profits" damages theories. A "reasonable royalty"

[2] For instance, claim 1 of U.S. Patent No. 8,075,469 (the '469 patent) is a method claim directed to "[a] method of delivering radiation therapy to tissue around at least a portion of a cavity formed by tissue removal in a patient's breast. . . ." (D.I. 1 at 45, 11:37-38.)

calculation requires an analysis of "15 different factors, ***each of which is complex***." *Yamaha Hatsudoki Kabushiki Kaisha v. Bombardier Inc.*, 59 U.S.P.Q. 2d (BNA) 1088, 1089-90 (C.D. Cal. 2001) (emphasis added) (citing *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970)). A "lost profits" analysis is similarly complex, as set forth in Hologic's Opening Brief.[3] (Opening Br. at 6-7.)

Thus, notwithstanding SenoRx's assurances, this case is far more complex than "a straightforward infringement claim." (Opp. at 7.)

B. Bifurcation Will Promote Efficiency

Like the jury, the Court will benefit from taking on these complex issues in sequence, rather than all at once. *See General Patent Corp., Int'l v. Hayes Microcomputer Prods.*, 44 U.S.P.Q. 2d (BNA) 1954, 1956 (C.D. Cal. 1997) ("[I]t will almost certainly be efficient for this court to first address the issues of validity and enforceability before turning to the other claims."). In arguing that bifurcation would be inefficient (Opp. at 9-12), SenoRx overlooks the likelihood that this case may be resolved even prior to a liability trial, thus making a damages and willfulness trial unnecessary. Indeed, one of the primary benefits of bifurcation is that it facilitates the efficient resolution of disputes without necessitating trial of all issues. *See Smith v. Alyeska Pipeline Serv. Co.*, 538 F. Supp. 977, 982-83 (D. Del. 1982) ("[S]eparate trial on the issue of liability may present counsel the opportunity to obtain final settlement of that issue or appeal without having reached the often time-consuming and difficult damages question.");

[3] In contrast, in *Kos Pharms., Inc. v. Barr Labs., Inc.*, 218 F.R.D. 387, 391 (S.D.N.Y. 2003), on which SenoRx relies, damages were not even at issue. Indeed, the court noted that damages issues are "a complication that generally raises sufficiently independent issues to support bifurcation." *Id.* And in *Johns Hopkins Univ. v. CellPro*, on which SenoRx also relies, bifurcation was denied on the grounds that, *inter alia*, "[Defendant] has not shown that the damage issues in this case are particularly difficult or complex." 160 F.R.D. at 35. Indeed, in *Johns Hopkins*, the Defendant's product did not even have any commercial sales. *Id.* at 32.

Johns Hopkins, 160 F.R.D. at 33 (cited in Opp. *passim*) (courts "have [ ] apparently found it can be more efficient to defer discovery and trial on damage issues until after liability has been resolved at trial and on appeal"); *Masimo Corp.*, 742 F. Supp. 2d at 496 (cited in Opp. at 5) ("[o]ther courts have found that a finding on the question of liability may obviate the necessity for a damages inquiry or encourage a settlement," and "separation of damages from liability allows the parties to obtain final resolution of the liability issue on appeal without reaching the often time-consuming and difficult damages question") (citation omitted). Further, assuming that the outcome of the liability trial does not obviate the need for a damages trial, a separate liability trial would likely narrow the relevant damages issues, creating even greater efficiency and saving both parties' time and resources and minimizing judicial resources devoted to damages issues. *Cf. Robert Bosch LLC*, 2009 U.S. Dist. LEXIS 76010, at *3-4 (bifurcating damages from liability because, among other things, "discovery disputes related to document production on damages and the *Daubert* motion practice related to damages experts are a drain on scarce judicial resources").

Notwithstanding SenoRx's protests (Opp. at 10-11), the mere fact that there may be some evidentiary overlap between the liability and damages phases of the cases does not outweigh the advantages of bifurcation. Numerous courts have held that a plaintiff in a patent infringement action cannot avoid bifurcation merely by pointing to areas of potential overlap between liability and damages. *See, e.g.*, *Princeton Biochemicals, Inc. v. Beckman Instruments, Inc.*, 180 F.R.D. 254, 259 (D.N.J. 1997) (bifurcating damages despite some overlap between the issue of commercial success, which figures in an obviousness determination, and the damages case).[4]

[4] *See also Sage Prods. v. Devon Indus.*, No. CV 93-2403 RG, 1994 U.S. Dist. LEXIS 21634, at *9 (C.D. Cal. Jan. 24, 1994) (same); *In re Recombinant DNA Tech. Patent and Contract Litig.*,

Indeed, "[t]he criteria is not whether the ***same evidence*** is presented at both trials, but rather whether the ***same essential issues will be decided***." *F&G Scrolling Mouse L.L.C. v. IBM Corp.*, 190 F.R.D. 385, 388 (M.D.N.C. 1999) (emphasis added). The "essential issues" in the liability phase are those related to infringement and validity. Those issues are distinct from those of damages and willfulness.[5]

C. SenoRx Ignores The Prejudice To Hologic Absent Bifurcation

SenoRx argues that it would suffer prejudice through bifurcation and thus that the equities weigh against bifurcation. (Opp. at 12-13.) This is in stark contrast to the position it adopted as defendant in Hologic's patent infringement suit against it. *Hologic, Inc. v. SenoRx, Inc.*, 5:08-CV-00133-RMW (N.D. Cal.). In that case, which is scheduled to be retried in 2013, the parties agreed to bifurcate the issue of damages until after liability is determined. Thus, despite the fact that the original complaint was filed in 2008, SenoRx has yet to be required to produce the sort of damages-related discovery that it is demanding of Hologic in this case.

SenoRx fails, moreover, even to address the substantial prejudice to Hologic that would result from proceeding with discovery and trial on damages and willfulness. Hologic and SenoRx are direct competitors in the breast brachytherapy field, with SenoRx's Contura® Multi-Lumen Balloon ("Contura") and Hologic's accused device, the MammoSite® Multi-Lumen ("MammoSite ML"). Damages discovery, particularly in the case of a "lost profits" claim by a competitor, typically requires the production of sensitive commercial and financial information concerning the revenues, profit margins, costs, and manufacturing capacities. *See Standard*

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30 U.S.P.Q. 2d (BNA) 1881, 1899 (S.D. Ind. 1994) (same); *Avia Grp. Int'l, Inc. v. Nike, Inc.*, 22 U.S.P.Q. 2d (BNA) 1475, 1477 (D. Or. 1991) (same).

[5] As explained in Hologic's Opening Brief, willfulness "is a damages issue, not a liability issue" that "requires quantitatively and qualitatively different proof than does infringement." *Robert Bosch LLC*, 2009 U.S. Dist. LEXIS 76010, at *4.

Havens Prods. v. Gencor Indus., 953 F.2d 1360, 1373 (Fed. Cir. 1991) (explaining lost profits factors).[6] Indeed, SenoRx has already sought documents related to, *inter alia*, "revenue forecasts, profit forecasts, market share projections, pricing and distribution strategies, advertising materials, consumer analyses, customers or proposed customers and use or expected use of or for the MammoSite ML" (Request No. 21); and Hologic's "strategies, practices, and/or plans relating to how [MammoSite ML] is (1) priced, (2) discounted, (3) promoted to prospective customers (including the use of any incentives), and (4) sold to customers" (Request No. 14). (D.I. 24-1, Ex. A at 5-6.) Furthermore, the discovery needed to support these types of damages claims is typically burdensome and costly for both parties. All of these factors, ignored by SenoRx in its opposition, militate in favor of bifurcation.

CONCLUSION

For the foregoing reasons, Hologic respectfully requests that the Court issue an order that all issues relating to damages and willfulness be tried, if necessary, separately from and after the liability trial in this case. Hologic also request that the Court stay any discovery regarding damages and willfulness issues until after a final determination of liability.

[6] Alternatively, in a "market share" analysis, courts look to evidence concerning the relevant market and the participants' relative market shares. *See State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989).

YOUNG CONAWAY STARGATT & TAYLOR LLP

/s/ Karen L. Pascale

Karen L. Pascale (#2903) [kpascale@ycst.com]
James L. Higgins (#5021) [jhiggins@ycst.com]
Rodney Square
1000 North King Street
Wilmington, DE 19801
Telephone: (302) 571-6600
Attorneys for Defendant Hologic, Inc.

OF COUNSEL:

Matthew M. Wolf
John E. Nilsson
Amy L. DeWitt
ARNOLD & PORTER LLP
555 Twelfth Street, NW
Washington, DC 20004
Telephone: (202) 942-5000

CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on August 23, 2012, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF (which will send notification that such filing is available for viewing and downloading to all registered counsel), and in addition caused true and correct copies of the foregoing document to be served upon the following counsel of record in the manner indicated:

By E-Mail

Jack B. Blumenfeld [jblumenfeld@mnat.com]
Regina S.E. Murphy [rmurphy@mnat.com]
MORRIS, NICHOLS, ARSHT & TUNNELL, LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19801

Bruce R. Genderson [bgenderson@wc.com]
Aaron P. Maurer [amaurer@wc.com]
Adam D. Harber [aharber@wc.com]
Patricia L. Richman [prichman@wc.com]
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
Attorneys for Plaintiff SenoRx, Inc.

YOUNG CONAWAY STARGATT & TAYLOR LLP

/s/ Karen L. Pascale

Karen L. Pascale (#2903) [kpascale@ycst.com]
James L. Higgins (#5021) [jhiggins@ycst.com]
Rodney Square
1000 North King Street
Wilmington, DE 19899-0391
Telephone: 302-571-6600
Attorneys for Defendant Hologic, Inc.