NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE BIOGEN '755 PATENT LITIGATION	**Civil Action No.: 10-2734 (CCC)(JBC) (consolidated)** **OPINION**

CECCHI, District Judge.

Before the Court are the motions for severance by Bayer Healthcare Pharmaceuticals Inc. ("Bayer") and by EMD Serono, Inc. and Pfizer Inc. ("Serono"). ECF Nos. 433, 435. Novartis Pharmaceuticals Corp. ("Novartis") joined Bayer's motion. ECF No. 434. The Court heard oral argument on November 22, 2016. Having considered the parties' written submissions and oral presentations, for the reasons discussed below the Court grants both motions.

I. FACTUAL BACKGROUND

In this consolidated patent infringement action, Biogen MA, Inc. ("Biogen") has asserted claims from U.S. Patent No. 7,588,755 (the "'755 patent") against Bayer, Serono, and Novartis. The '755 patent claims a method for immunomodulation, or treating viral diseases, cancers, or tumors, by administering to a patient a recombinant polypeptide—human interferon beta ("interferon-β")—that is produced by a non-human host transformed by a recombinant DNA molecule.

Biogen's infringement claims against Bayer are based on the sale of interferon-β products Betaseron® and Extavia® in the United States for the treatment of multiple sclerosis ("MS") via

immunomodulation.[1] C.A. No. 10-2760, ECF No. 1 at ¶¶ 50-65, ECF No. 61 at ¶¶ 60-75. Biogen's infringement claims against Serono are based on the sale of interferon-β product Rebif® in the United States for the treatment of MS via immunomodulation. C.A. No. 10-2760, ECF No. 1 at ¶¶ 32-49, ECF No. 61 at ¶¶ 42-59.

II. PROCEDURAL HISTORY

On May 27, 2010, Bayer filed suit against Biogen seeking a declaration that Bayer does not infringe the '755 patent claims and that the '755 patent claims are invalid. ECF No. 1. On May 28, 2010, Biogen initiated a separate proceeding by filing suit against Bayer, Serono, and Novartis. C.A. No. 10-2760, ECF No. 1. Biogen asserts that Bayer infringes claim 1 of the '755 patent by making, using, selling, and/or offering to sell Betaseron® and Extavia® in the United States. In addition, Biogen asserts that Serono infringes claims 1 and 2 of the '755 patent by making, using, selling, and/or offering to sell Rebif® in the United States. Bayer and Serono claim that the '755 patent is invalid, not infringed, and/or unenforceable. On October 1, 2010, the previous Magistrate Judge entered a Pretrial Scheduling Order consolidating Bayer's declaratory judgment action with Biogen's patent infringement suit. ECF No. 37. The Pretrial Scheduling Order also sets deadlines through the close of expert discovery but is silent as to summary judgment and trial.

The present motions were filed on August 2, 2016. ECF Nos. 433, 435. Biogen opposes both motions. ECF No. 445. Briefing was completed on September 22, 2016. The Court heard

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[1] Novartis, whose product Extavia® is manufactured by Bayer, joined Bayer's motion. ECF No. 434. Extavia® is essentially rebranded Betaseron®. *Id.*; ECF No. 433 at 3. Accordingly, all references to Betaseron® in this Opinion include Extavia®, and the Court's ruling in this Opinion pertaining to Bayer applies to Novartis.

oral argument on November 22, 2016.[2] The parties also submitted letters subsequent to oral argument, (*see* ECF Nos. 475, 476, 477), and the Court conducted several telephone conferences with the parties.

III. LEGAL STANDARD

Federal Circuit law governs questions of joinder and severance in patent cases. *In re EMC Corp.*, 677 F.3d 1351, 1354 (Fed. Cir. 2012). The Federal Circuit has prescribed that courts considering a motion to sever under Federal Rule of Civil Procedure 21 look to Rule 20 for guidance. *Id.* at 1356. Pursuant to Rule 20, Defendants may be joined in a single action if two independent requirements are met: (1) "any right to relief is asserted against them jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences," and (2) "any question of law or fact common to all defendants will arise in the action." Fed. R. Civ. P. 20.[3]

The Federal Circuit has definitively stated that "[j]oinder of independent defendants is ***only*** appropriate where the accused products . . . are the same in respects relevant to the patent." *EMC*, 677 F.3d at 1359 (emphasis added). Rule 20's transaction-or-occurrence requirement is not satisfied simply by asserting the "same claims of the same patent" against independent defendants, "even though the claims would raise common questions of claim construction and patent invalidity." *Id.* at 1357. The transaction-or-occurrence requirement instead requires a "logical relationship" between the causes of action, such that "the defendants' allegedly infringing acts . . . ***share*** an aggregate of operative facts." *Id.* at 1358. Those overlapping, operative facts must

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[2] All references to "11/22 Tr." in this Opinion refer to the November 22, 2016 hearing transcript.
[3] This action was commenced prior to September 16, 2011, the date the America Invents Act ("AIA") was signed into law. Accordingly, 35 U.S.C. § 299(a), the AIA's joinder provision, does not control the analysis in this case. *EMC*, 677 F.3d at 1355-56.

be more than "coincidentally identical;" that the accused products of independent defendants are the "same" is not enough to establish that claims of infringement arise from the "same transaction." *Id.* at 1359. Therefore, "[u]nless there is an actual link between the facts underlying each claim of infringement, ***independently developed products*** using ***differently sourced parts*** are not part of the same transaction, even if they are otherwise coincidentally identical." *Id.* (emphasis added).

In assessing whether an actual link between different products exists, the Court weighs "pertinent factual considerations" including "whether the alleged acts of infringement occurred during the same time period, the existence of some relationship among the defendants, the use of identically sourced components, licensing or technology agreements between the defendants, overlap of the products' or processes' development and manufacture, and whether the case involves a claim for lost profits." *Id.* at 1359-60. The Court "enjoys considerable discretion in weighing" these factors. *Id.* at 1360.

Even if joinder under Rule 20 is impermissible, the Court retains discretion to consolidate cases for trial under Rule 42, so long as venue is proper and there is "a common question of law or fact." Fed. R. Civ. P. 42(a); *see also EMC*, 677 F.3d at 1360. "On the other hand, even if a plaintiff's claims arise out of the same transaction and there are questions of law and fact common to all defendants, 'district courts have the discretion to refuse joinder in the interest of avoiding prejudice and delay, ensuring judicial economy, or safeguarding principles of fundamental fairness.'" *EMC*, 677 F.3d at 1360 (citation omitted).

IV. DISCUSSION

The first question to consider is whether the accused products are "the same in respects relevant to the patent." *EMC*, 677 F.3d at 1359. It is undisputed that Bayer's Betaseron® and Serono's Rebif® are separately developed products manufactured and sold by unrelated parties.

The active ingredients in Betaseron® and Rebif® are distinct polypeptides wherein their amino acid sequences, and the DNA sequences that encode them, are different. ECF No. 433-1 at 4, 10. Bayer and Serono contend that Biogen has asserted dependent claim 2 against Serono but not against Bayer precisely because the accused products are chemically different. *Id.* at 4-6, 10; ECF No. 436-13 at 12-13. Betaseron® and Rebif® also differ in the way they are formulated and administered. ECF. No. 436-13 at 8, 14. Moreover, Bayer and Serono have asserted that they engaged different experts to offer non-infringement opinions unique to each defendant. *See Vehicle IP, LLC v. AT&T Mobility LLC*, No. 09-1007, 2016 WL 6404093, at *2 (D. Del. Oct. 20, 2016) (finding that the "accused products differ[ed] in respects relevant to the patent" where "Defendants engaged different infringement experts").

Biogen argues that, although there are differences between the accused products, Rule 20 nevertheless is satisfied because those differences "have no bearing on the infringement issues in this case." ECF No. 445 at 2.[4] In particular, Biogen asserts that Bayer and Serono "share the same non-infringement defenses" and will advance largely identical infringement arguments and proofs at trial. *Id.* at 2, 15-18. Biogen has not pointed to any "actual link," however, between the facts underlying its infringement claims against Bayer and its infringement claims against Serono. *See*

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[4] Biogen also argues that the defendants consented to having a consolidated trial by virtue of the previous Magistrate Judge's October 1, 2010 Pretrial Scheduling Order. ECF No. 445 at 8-9. The Court finds this argument unpersuasive and agrees with Bayer's and Serono's interpretation of the Pretrial Scheduling Order. Consolidation of Bayer's declaratory judgment action and the Biogen patent infringement action at the early stages of the cases was merely intended to avoid the redundancy of engaging in pretrial fact and expert discovery separately in those two actions. The Pretrial Scheduling Order does not address the scheduling of trial and does not appear to reflect a binding agreement by the defendants with respect to joinder or consolidation for trial. *See* ECF No. 477 at 2. In any event, the Court has the authority to modify pretrial orders if the Court deems it appropriate to do so. *See* Fed. R. Civ. P. 16(d); *see also* Rule 16 Advisory Committee Notes–1983 Amendment (acknowledging that Rule 16 does "not impos[e] any limitation on the ability to modify a pretrial order").

EMC, 677 F.3d at 1359 ("Unless there is an actual link between the facts underlying each claim of infringement, independently developed products using differently sourced parts are not part of the same transaction, even if they are otherwise coincidentally identical."). The infringement analysis for Bayer centers on the specifics of Betaseron®, and the infringement analysis for Serono centers on the specifics of Rebif®—an independently developed product comprised of differently sourced components. Indeed, Biogen's infringement expert reports disclosed results of two distinct hybridization experiments—one for the DNA encoding Betaseron® and the other for the DNA encoding Rebif®. (*See* ECF No. 433-1 at 11; 11/22 Tr. at 174:5-14.) Accordingly, the Court finds that the accused products differ in respects relevant to the '755 patent.

Even assuming the accused products are the "same" in relevant respects, the six-factor test set out in *EMC* weighs against joinder. Biogen has neither argued that there is any relationship between Bayer and Serono nor accused Bayer and Serono of joint liability. Indeed, Bayer and Serono are direct competitors in the market for MS treatments, which weighs heavily against joinder. *See Vehicle IP*, 2016 WL 6404093, at *2; *see also Richmond v. Lumisol Elec. Ltd.*, No. 13-1944, 2014 WL 1716447, at *5 (D.N.J. Apr. 30, 2014) ("Logically, competitors, absent a conspiracy, are not part of the same transaction.").[5] Other factors weighing against joinder include the fact that Biogen has not asserted that the accused products use identically sourced components or that Bayer and Serono entered into any licensing or technology agreements with each other. In addition, as stated above, Betaseron® and Rebif® were developed independently and are manufactured by unaffiliated, competing companies. While Biogen has raised a claim for lost

[5] The *Richmond* court held that "direct competitors may not be joined in a patent infringement action pursuant to § 299, absent allegations of concerted action." *Id.* While the joinder analysis in that case was governed by 35 U.S.C. § 299, unlike here, this Court views the *Richmond* court's reasoning regarding direct competitors as instructive.

profits against Bayer and Serono,[6] this factor does not outweigh the other considerations weighing in favor of severance. In addition, the fact that the alleged infringing acts occurred during the same time period—here, 2009 to the present—is merely due to the fact that the '755 patent issued in 2009, years after the accused products were on the market. Thus, this factor does not weigh in favor of joinder. On the whole, the Court finds the *EMC* factors to weigh in favor of severance. Accordingly, the Court finds that the transaction-or-occurrence requirement of Rule 20 is not satisfied and, therefore, severance under Rule 21 is appropriate.

Since the Court has concluded that the first requirement of Rule 20 has not been satisfied, the Court need not decide whether "any question of law or fact common to all defendants will arise in the action." Fed. R. Civ. P. 20; *see EMC*, 677 F.3d at 1356 (indicating that both of the "two independent requirements of Rule 20" must be satisfied to join defendants in a single action). For the sake of completeness, however, the Court will briefly address the second requirement of Rule 20. While the Court recognizes that there may be common questions of law and fact in this case, those commonalities are insufficient to warrant a joint trial. As discussed above, while Biogen has accused both Serono and Bayer of infringing claims of the same patent, Biogen has asserted different patent claims against Serono and Bayer. Although some grounds for invalidity may apply to all asserted claims, Serono asserts that an analysis of the validity of claim 2 will require consideration of different evidence and a legal determination separate from that of claim 1. *See* ECF No. 436-13 at 19. In addition, Biogen's willful infringement and damages claims against Serono and Bayer differ, and Serono and Bayer have each raised distinct defenses to such claims.

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[6] Serono filed a motion for summary judgment as to Biogen's claim to lost profits (ECF No. 271), and Bayer filed a response to that motion (ECF No. 275). The Court does not decide the lost profits issue as part of this Opinion.

See id. at 19-21; *see also* ECF No. 448 at 11-13. Moreover, Serono has indicated that, unlike Bayer, it intends to present an unenforceability case at trial. *See* ECF No. 449 at 9. Accordingly, the Court concludes that severance is appropriate despite any common questions of law or fact.

Although the Court finds that joinder under Rule 20 is impermissible and, therefore, severance under Rule 21 is appropriate, the Court may nevertheless exercise its discretion to consolidate the cases under Rule 42. The Court declines to exercise its discretion to consolidate the cases for trial under Rule 42. The Court agrees with Bayer and Serono that a joint trial would likely result in jury confusion and present a number of logistical and practical challenges. As of the oral argument date, it appears that three dozen expert witnesses (and many more fact witnesses) are expected to testify on behalf of different parties on a variety of complex issues in a case involving complicated technology. (ECF No. 436-13 at 23; 11/22 Tr. at 140:14-22.) This is not a case where the defendants engaged the same infringement or invalidity experts as a united front. Rather, Bayer and Serono have retained separate teams of experts that will offer opinions based on their own sets of evidence. In a consolidated trial, the jury would be presented with and need to sort out evidence regarding complex technical and financial subjects from multiple fact and expert witnesses and numerous documents from different parties. As a result, a joint trial would carry a significant risk that the jury would confuse the differences between the accused products or inadvertently apply evidence or testimony relating to Bayer to their decision regarding Serono, or vice versa. The risks of jury confusion and inefficiency are compounded by the fact that Bayer and Serono are direct competitors and cannot (pursuant to the terms of the governing protective order) see one another's confidential information, necessitating the Court to repeatedly open and close the courtroom before certain evidence is presented to the jury, thereby disrupting proceedings. *See Vehicle IP*, 2016 WL 6404093, at *3; ECF No. 436-13 at 23. The purposes of

efficiency and judicial economy will best be served by severing the Bayer and Serono actions. Accordingly, the Court declines to exercise its discretion under Rule 42 to consolidate the cases for trial.

The Court further concludes that the Biogen-Serono action should proceed to trial first. All sides have indicated that, in the event of severance, a Biogen-Serono trial before a Biogen-Bayer trial is the more logical and efficient order of proceeding. (*See* 11/22 Tr. at 145:2-17; *see also* ECF No. 436-13 at 24-25; ECF No. 445 at 26-27.)

V. CONCLUSION

For the reasons discussed above, the Court grants Bayer's and Serono's motions for severance (ECF Nos. 433, 435). An appropriate Order will accompany this Opinion.

Date: October 27, 2017

HON. CLAIRE C. CECCHI
United States District Judge