IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

NOVARTIS VACCINES & DIAGNOSTICS, INC.,	)	
Plaintiff,	)	
v.	)	Civ. No. 11-084-SLR
MEDIMMUNE, LLC, BIOGEN IDEC, INC., and ALEXION PHARMACEUTICALS, INC.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 2nd day of August, 2012, having reviewed defendant Alexion Pharmaceuticals, Inc.'s ("Alexion's") motion to dismiss based on improper joinder and the papers submitted therewith;

IT IS ORDERED that said motion (D.I. 20) is denied, for the reasons that follow:

1. **Background.** On January 26, 2011, Novartis Vaccines & Diagnostics, Inc. ("plaintiff") filed a complaint against Alexion, MedImmune, LLC ("MedImmune") and Biogen Idec, Inc. ("Biogen") (collectively, "defendants") alleging infringement of U.S. Patent No. 5,688,688 ("the '688 patent"), entitled "Vector for Expression of a Polypeptide in a Mammalian Cell." (D.I. 1) Defendants separately answered the complaint on July 6, 2011, asserting several affirmative defenses as well as counterclaims seeking declaratory judgment of noninfringement and invalidity of the '688 patent. (D.I. 14, 17, 19) MedImmune additionally seeks declaratory judgment of unenforceability of the '688 patent. (D.I. 14) Also on July 6, 2011, Alexion filed a

motion to dismiss based on improper joinder, which is currently pending before the court. (D.I. 20) On July 22, 2011, plaintiff filed an amended complaint, asserting for the first time defendants' use of a commercial gene expression system manufactured by non-party Lonza Group AG ("Lonza"). (D.I. 27) Defendants answered the amended complaint on August 8, 2011, maintaining their original affirmative defenses and counterclaims. (D.I. 37-39) Plaintiff then filed a "first supplemental complaint to the first amended complaint" on July 18, 2012, adding, inter alia, Novartis Pharma AG as a plaintiff.[1] (D.I. 161)

2. Claim 1 of the '688 patent, reproduced below, describes a vector for expression of proteins (or "polypeptides") in mammalian cells.

> 1. A vector for expression of a polypeptide in a mammalian cell comprising a first polynucleotide sequence that comprises:
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> > a) an upstream SV40 origin of replication;
> > b) a downstream SV40 polyadenylation region; and
> > c) a transcription regulatory region from human cytomegalovirus immediate early region HCMV IE1, wherein the transcription regulatory region includes the first HCMV IE1 intron proximal to the 3' end of the HCMV IE1 promoter, is interposed between the SV40 origin of replication and the SV40 polyadenylation region, and is capable of directing the transcription of a polypeptide coding sequence operably linked downstream from the transcription regulatory region.[2]

('688 patent at col. 75:43-56) In preparation for producing protein using the claimed

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[1] This court entered a scheduling order on August 2, 2010 setting a deadline of July 15, 2012 for joining other parties and filing amended pleadings. (D.I. 36 at ¶ 3) Defendants have not yet filed answers to this second amended complaint.

[2] Plaintiff asserts that claim 1 of the '688 patent contains four elements, the fourth of which is a "polypeptide coding sequence encoding a heterologous polypeptide operably linked downstream of the transcription regulatory region" but the court finds no such requirement in claim 1. (D.I. 32 at 4)

vector, a polypeptide coding sequence is inserted into the vector so that the coding sequence is under the control of the transcription regulatory region. (*Id.* at col. 12:4-6) This personalized vector is then introduced into a host such as a mammalian cell, which replicates and functions as a protein production "factory." (*Id.* at col. 12:11-16; D.I. 32 at 4) The resulting protein is then isolated and may subsequently be used in a wide variety of applications, for example, the generation of monoclonal antibodies. ('688 patent at col. 13:62-65)

3. Lonza manufactures and sells a commercial gene expression system, the Lonza GS Expression System™, which allegedly contains the same expression vector claimed in the '688 patent. (D.I. 27 at ¶ 15) Plaintiff asserts that MedImmune, Biogen and Alexion use the expression vector associated with the Lonza GS Expression System to manufacture the humanized antibodies Synagis®, Tysabri® and Soliris®, respectively. (*Id.* at 3-7) The expression vectors used by defendants purportedly differ only with respect to the polypeptide coding sequence, which varies depending on which protein is selected for production. (D.I. 32 at 5) Plaintiff maintains that this difference is irrelevant to the question of infringement because the '688 patent accommodates any polypeptide coding sequence so long as it is derived from a source other than the human cytomegalovirus genome. (*Id.*) Put another way, plaintiff does not claim that defendants' manufacturing processes and products are identical; rather, plaintiff claims that defendants use the Lonza GS Expression System™ vector as a common step in what may otherwise be divergent manufacturing processes. (D.I. 32 at 2)

4. **Standard.** Federal Rule of Civil Procedure 20(a)(2) allows for the joinder of

defendants if:

> (A) 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
> (B) any question of law or fact common to all defendants will arise in the action.

In patent infringement cases, "motions to sever are governed by Federal Circuit law" as is the issue of proper joinder. *In re EMC Corp.*, 677 F.3d 1351, 1356 (Fed. Cir. 2012) ("joinder in patent cases is based on an analysis of the accused acts of infringement, and this issue involves substantive issues unique to patent law").[3] Under Federal Circuit law, "independent defendants satisfy the transaction-or-occurrence test of Rule 20 when there is a logical relationship between the separate causes of action." *Id.* at 1358; *see also Moore v. N.Y. Cotton Exch.,* 270 U.S. 593, 610 (1926) (holding that two claims arise from the same "transaction" when there is a "logical relationship" between them). However, "joinder is not appropriate where different products or processes are involved," and even "the sameness of the accused products or processes is not sufficient." *In re EMC Corp.*, 677 F.3d at 1359. Rather, "the defendants' allegedly infringing acts, which give rise to the individual claims of infringement, must **share** an aggregate of operative facts." *Id.* at 1358 (emphasis in original).

5. To determine whether there is a shared aggregate of operative facts, the Federal Circuit urges consideration of the following factors: "[1] whether the alleged acts of infringement occurred during the same time period, [2] the existence of some

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[3] *In re EMC Corp.* governs cases which were filed prior to enactment of the Leahy-Smith America Invents Act, which codified a new set of rules governing the joinder of parties in civil actions "arising under any Act of Congress relating to patents." 35 U.S.C. § 299.

relationship among defendants, [3] the use of identically sourced components, [4] licensing or technology agreements between the defendants, [5] overlap of the products' or processes' development and manufacture, and [6] whether the case involves a claim for lost profits." *Id.* at 1359. Ultimately, "[t]he district court enjoys considerable discretion in weighing the relevant factors." *Id.*

6. **Same transaction or occurrence.** The first question at bar is whether defendants' actions arise out of the same transaction, occurrence or series of actions or occurrences by virtue of sharing an aggregate of operative facts. One relevant factor in this analysis is whether there is overlap in the development and manufacture of the product or process. *See In re EMC Corp.*, 677 F.3d at 1359. Alexion argues that "each of [d]efendants' accused products are made by different manufacturing processes and result in different drug products." (D.I. 35 at 2) Alexion relies heavily on a recent case from the Southern District of California in which the court held that "alleging a common manufacturer and infringement of the same patent is not enough to support joinder where defendants are unrelated companies, selling different products." *Sorenson v. DMS Holdings, Inc.*, Civ. No. 08-559, 2010 WL 4909615, at *1 (S.D. Cal. Nov. 24, 2010). In *Sorenson*, the products at issue were entirely manufactured by a non-party, offshore company and were merely sold by defendant. *Id.* Here, although the expression vector is manufactured by Lonza, it is allegedly subsequently modified and incorporated into defendants' own manufacturing processes via insertion into a mammalian cell line. (D.I. 32 at 4) Therefore, there is necessarily some degree of

overlap in defendants' manufacturing processes,[4] even if the overlap exists only during "the first of many steps in manufacturing a monoclonal antibody." (D.I. 35 at 3)

7. Another factor in the "shared aggregate of operative facts" analysis is whether defendants use identically sourced components. *See In re EMC Corp.*, 677 F.3d at 1359. Each defendant allegedly obtained the expression vector from Lonza and used it as a tool for producing antibodies. (D.I. 27 at ¶¶ 16, 21, 26) Therefore, the expression vector is an "identically sourced" component used by defendants in their respective manufacturing processes.

8. Together, these factors compel the finding that a logical relationship exists between the causes of action for each defendant. While defendants' only relationship is their common engagement in the research, development, manufacture and sale of pharmaceutical products (D.I. 38 at ¶ 5; D.I. 37 at ¶ 3; D.I. 39 at ¶ 4), the absence of any tangible business or legal relationship is just one of several considerations when determining whether defendants' actions are part of the same transaction, occurrence, or series of transactions or occurrences. *See In re EMC Corp.*, 677 F.3d at 1358.

9. **Common question of law or fact**. The second issue at bar is whether any question of law or fact common to all defendants will arise in the action. Alexion asserts that "[t]he questions to be determined by the trier of fact will concern issues of infringement and damages that are unique to each defendant" and "each accused product." (D.I. 21 at 6) However, plaintiff's allegation of patent infringement will require

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[4] Alexion's assertion - that defendants' manufacturing processes may differ due to the possibility of spontaneous mutagenesis of the vector once it is inserted into and maintained in a cell line - is not a persuasive one. (D.I. 35 at 4)

the court to hold *Markman* hearings and construe the asserted claims. Moreover, defendants each assert invalidity defenses which will require the court to consider the validity of the asserted patent. (D.I. 14, 17, 19) For the sake of efficiency and conservation of judicial resources, the court declines to construe claims and determine the issue of validity separately for each defendant. *See SRI Intern, Inc. v. Internet Security Systems, Inc.,* Civ. No. 04-1199, 2005 WL 851126, at *4 (D. Del. Apr. 13, 2005) (permitting joinder to avoid duplicitous claim construction and determination of "the date of conception and reduction to practice, the relevance of prior art and the level of ordinary skill in the art" when defendants each asserted invalidity defenses).

10. With respect to prejudice to defendant, Alexion raises the concern that it will be forced to disclose sensitive business information to its co-defendants, who are potential competitors. (D.I. 21 at 7) However, the parties have since addressed this concern by agreeing upon a protective order mandating that "highly confidential" and "confidential" disclosures may not be used "for competitive purposes, research, development, manufacture or regulatory purposes, Citizen's Petitions, other litigation, or the prosecution of intellectual property rights." (D.I. 104 at ¶ 5) *See Helicos Biosciences Corp. v. Pacific Biosciences of California*, Civ. No. 10-735, 2011 WL 6758481, at *3 (D. Del. Dec. 22, 2011) (finding no prejudice when the parties agreed to a protective order and a prosecution bar). Finally, because it appears that the investigation into defendants' manufacturing processes will largely be directed at common questions surrounding incorporation of the accused vector, the court finds,

based on the limited information available at this stage in the proceedings, that the scientific questions are not so radically different as to merit a finding of prejudice.[5]

11. **Conclusion.** For the aforementioned reasons, the court denies Alexion's motion to dismiss for improper joinder.

United States District Judge

[5] The court may revisit the issue of separate trials at the final pre-trial conference when the record is more complete, as argued by defendant Alexion (D.I. 35 at 7), defendant Biogen (D.I. 26) and proposed in the alternative by plaintiff (D.I. 32 at 12). *See MyMail, Ltd. v. America Online, Inc.*, 223 F.R.D. 455, 457 (E.D. Tex., 2004) (finding joinder proper under Rule 20 but concluding "[w]hen discovery is complete, the Court, upon motion of a party, will determine whether the state of the evidence compels severance of some type under Rule 21").