

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and)	
AMGEN MANUFACTURING, LIMITED,)	
)	
Plaintiffs,)	C.A. No. 15-839 (RGA)
)	
v.)	JURY TRIAL DEMANDED
)	
HOSPIRA, INC.,)	REDACTED
)	PUBLIC VERSION
Defendant.)	

AMGEN’S MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT

Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, “Amgen”) move to file the attached Second Amended Complaint under Fed. R. Civ. P. 15 and Local Rule 15.1 to add three additional defendants— [REDACTED]

[REDACTED]

[REDACTED] have directly or indirectly infringed Amgen’s patent-in-suit, United States Patent No. 5,756,349 (“the ’349 patent”). Joining them as defendants in this case will enable Amgen to obtain more complete relief for infringement of the ’349 patent, and will not unduly prejudice Hospira.

The proposed amended pleading can be found at Exhibit A.¹ A redlined comparison to the Second Amended Complaint can be found at Exhibit B.

During an August 12, 2016, telephone call, counsel for Amgen discussed the grounds for this motion with counsel for Hospira. On August 15, 2016, Amgen forwarded a near-final version of the Second Amended Complaint to counsel for Hospira. Counsel for Hospira indicated

¹ Exhibits are attached to the Declaration of John R. Labbe filed contemporaneously herewith.

Hospira's position that Amgen had not "given Hospira adequate notice and opportunity to review the proposed amended complaint," and that Amgen "cannot represent Hospira's position on the motion to the Court."

I. INTRODUCTION

[REDACTED]

[REDACTED], have directly and/or indirectly infringed the '349 patent by [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

As alleged in the original Complaint and the Amended Complaint, Hospira infringed the '349 patent (and United States Patent No. 5,856,298 ("the '298 patent")) in making the Hospira Biosimilar Epoetin Product at issue in this case. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

II. RELEVANT FACTUAL BACKGROUND

A. Amgen's EPOGEN[®] and the '349 patent

The active ingredient in Amgen's innovative drug EPOGEN[®] (epoetin alfa) is recombinant human erythropoietin, a 165-amino-acid glycoprotein that is produced by genetically modified animal cells grown in culture vessels. Amgen's '349 patent is directed to vertebrate cells capable of producing such recombinant human erythropoietin, as well as processes for producing recombinant human erythropoietin using such cells.

B. Hospira's infringement of the '349 patent

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

C. Procedural History

On September 18, 2015, Amgen filed its original Complaint in this case, asserting infringement under 35 U.S.C. §§ 271(a) of the '349 patent (and infringement of the '298 patent).

On October 13, 2015, Hospira filed a motion to dismiss two counts in the original Complaint directed to Hospira's obligation to comply with certain provisions of the BPCIA. (D.I. 8.) On November 6, 2015, Amgen filed a First Amended Complaint. (D.I. 11.) On November 12, 2015, Hospira filed a second motion to dismiss one count in the First Amended Complaint directed to Hospira's obligation to comply with the notice-of-commercial-marketing requirement under 42 U.S.C. § 262(D)(8)(A). (D.I. 15.) On August 5, 2016, the Court denied Hospira's second motion to dismiss. (D.I. 68 and 69.)

[REDACTED]

[REDACTED]

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III. ARGUMENT

A. The Federal Rules of Civil Procedure favor liberally granting leave to amend pleadings

Fed. R. Civ. P. 15(a) provides that leave to amend a complaint should be “freely give[n] leave when justice so requires.” The liberal amendment policy embodied in Rule 15(a) is a “mandate to be heeded,” and leave should be granted unless the opposing party can demonstrate extraordinary circumstances, such as excessive delay in the resolution of the case, bad faith on the part of the movant, or undue prejudice to the non-movant. *Foman v. Davis*, 371 U.S. 178, 182 (1962).

The Third Circuit has “interpreted these factors to mean that ‘prejudice to the nonmoving party is the touchstone for the denial of an amendment.’” *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1413-14 (3rd Cir. 1993) (citing *Cornell & Co. v. Occupational Safety & Health Review Comm’n*, 573 F.2d 820, 823 (3rd Cir. 1978)). To establish prejudice, the non-moving party “must do more than merely claim prejudice; it must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the amendments been timely.” *Cordance Corp. v. Amazon.com, Inc.*, 255 F.R.D. 366, 371 (D. Del. 2009) (quoting *Bechtel v. Robinson*, 866 F.2d 644, 652 (3rd Cir. 1989)). “In the absence of substantial or undue prejudice, denial instead must be based on bad faith or dilatory motives, truly undue or unexplained delay, repeated failure to cure the deficiency by amendments previously allowed, or futility of amendment.” *Lorenz*, 1 F.3d at 1414. “Delay alone, however, is an insufficient reason to deny leave to amend. Rather, any delay in seeking leave to amend must be coupled with either a burden on the Court or undue prejudice to the non-moving party if the amendment is allowed.” *St. Clair Intellectual Property Consultants, Inc. v. Samsung Elecs. Co., Ltd*, No. 04-1436-JJF-LPS, 2009 WL 395223, at *2 (D. Del. Feb. 17, 2009).

B. Leave to amend will not unduly prejudice Hospira

For Hospira to prove that amending the complaint will cause it undue prejudice, it must show that its “ability to present its case would be seriously impaired were [the] amendment allowed.” *Dole v. Arco Chem. Co.*, 921 F.2d 484, 488 (3d. Cir. 1990) (citing *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d. Cir. 1989)).

Hospira cannot show any such impairment here, as joining the proposed defendants will not affect Hospira’s ability to present its case.

[REDACTED]

First, Hospira has yet to file an Answer to the First Amended Complaint.

Second, fact discovery is still underway. Although the parties’ document productions were required to be substantially complete by July 15, 2016, Hospira has continued to produce documents as recently as July 29. And no depositions have been scheduled. [REDACTED]

[REDACTED]

Third, the *Markman* hearing on claim construction has not yet occurred. Hospira and Amgen are currently briefing claim construction, but do not dispute construction of any term in

the '349 patent, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Certainly, nothing will need to be re-briefed, because the current briefing does not address the '349 patent. In any event, Amgen is amenable to postponing the claim-construction hearing if necessary.

Finally, trial is more than a year away.

[REDACTED]

[REDACTED]

“The passage of time, without more, does not require that a motion to amend a complaint be denied . . .” *Adams v. Gould Inc.*, 739 F.2d 858, 868 (3rd Cir. 1984).

The Scheduling Order sets August 15, 2016, as the deadline for a party to move to amend the pleadings or join parties, so this motion is timely. And any delay here resulted from Hospira’s obstruction of discovery. *St. Clair*, 2009 WL 395223, at *2. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED] The Federal Circuit has said that the only real inquiry for joinder is whether the claims are logically related. *In re EMC Corp.*, 677 F.3d 1351, 1357-58 (Fed. Cir. 2012) (setting aside the district court’s ruling and outlining the “proper standard” for joinder).

When third parties to be joined as defendants are independent actors, the logical relationship is satisfied when there a “sameness” of the accused products or processes, and “an aggregate of operative facts” that “[give] rise to the cause of action against each defendant.” *Id.* at 1358. The Federal Circuit has held that the aggregate of operative facts may include: 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; and overlap in development or manufacture of the accused products or processes. The district court enjoys “considerable discretion” in weighing these facts. *Id.* at 1359–60.

In addition to Rule 20, Congress addressed the issue of joinder in patent cases in section 19 of the Leahy–Smith America Invents Act, 35 U.S.C. § 299, which took effect September 16, 2011 (providing in relevant part that accused infringers may be joined in one action if the allegations of infringement “aris[e] out of the same transaction, occurrence, or series of transactions or occurrences,” and relate to the same product or process). *EMC*’s “sameness” of accused products and processes and “aggregate of operative facts” approach is consistent with the AIA’s joinder provision, and the two have consistently been interpreted the same.²

² In *EMC*, the Federal Circuit did not address the AIA provision on joinder, 35 U.S.C. § 299, because the case was not covered by the new legislation, and in any event did not find it necessary to “decide whether the sameness test in the new legislation is identical to the sameness

IPVenture, Inc. v. Acer, Inc., 879 F. Supp. 2d 426, 429 (D. Del. 2012) (Andrews, J.) (interpreting joinder issue under both § 299 and Rule 20, finding the outcome would “likely be the same”).

Under facts similar to those here, joinder has been found to be proper. For example, in *Novartis Vaccines & Diagnostics, Inc. v. MedImmune, LLC*, Civ. 11-084-SLR, 2012 WL 3150524 (D. Del. Aug. 2, 2012), the court denied a motion to dismiss and found the defendants to be properly joined because there was “some degree of overlap” in their development and manufacturing. *Id.* at *3. There, the defendants acquired the same expression vector from a non-party manufacturer, then modified and used that vector to produce their own specific recombinant protein products in a mammalian cell line. *Id.* The court found this use of an “identically sourced component” and overlap in the manufacturing process to add to the aggregate of operative facts and the logical relationship between the actions. *Id.*

[REDACTED]

[REDACTED] The '349 patent claims are directed to vertebrate cells capable of producing, and the use of those cells to produce, recombinant human erythropoietin. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

test we adopt.” *EMC* at 1360, FN4. Since then, in similar circumstances, district courts have likewise found no reason to interpret AIA joinder and Rule 20 differently. *Richmond v. Lumisol Elec. Ltd.*, C.A. No. 13-1944 MLC, 2014 WL 1716447, at *3 (D.N.J. Apr. 30, 2014); *MGT Gaming, Inc. v. WMS Gaming, Inc.*, 978 F. Supp. 2d 647, 657-58 (S.D. Miss. 2013); *Digitech Image Techs., LLC v. Agfaphoto Holding GMBH*, C.A. No. 12-1153, 2012 WL 4513805, at *3 (C.D. Cal. Oct. 1, 2012); *Omega Patents, LLC v. Skypatrol, LLC*, C.A. No. 11-cv-24201, 2012 WL 2339320, at *1-*2 (S.D. Fla. June 19, 2012); ; *Golden Bridge Tech. v. Apple Inc.*, C.A. No. 12-cv-4014-ODW, 2012 WL 3999854, at *2 (C.D. Cal. Sept. 11, 2012); *Swipe Innovations LLC v. Elavon Inc.*, C.A. No. 12-cv-40, D.I. 134 at *3-4 (E.D. Tex. Aug. 14, 2012); *Smartfit Solutions LLC v. Pacemaster LLC*, C.A. No. 11-cv-487-LED, D.I. 243 at *3-4, FN4 (E.D. Tex. Sept. 27, 2012).

[REDACTED]

Even if 35 U.S.C. § 299 were to be applied here, the analysis is the same, and joinder would be appropriate. Under the statute, joinder is appropriate where relief is sought regarding the “same accused product or process,” just as in *EMC*’s “sameness” test. *EMC* at 1358. Here,

[REDACTED]

[REDACTED] In contrast, this case is *not* “based solely on allegations that [the defendants] have each infringed the patent” with respect to completely different products or transactions. § 299(b) (defining allegations insufficient for joinder). Here, there is “an actual link between the facts underlying each claim of infringement.” *IPVenture*, 879 F. Supp. 2d at 429 (quoting *EMC*, 677 F.3d at 1359).

[REDACTED]

[REDACTED]

CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2016, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants, and have sent true and correct copies to the following as indicated:

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