IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CELGENE CORPORATION and, ASTELLAS PHARMA INC.,	:	
Plaintiffs,	:	
v.	:	C. A. No. 14-571-RGA
FRESENIUS KABI USA, LLC,	:	
Defendant.	:	

REPORT AND RECOMMENDATION

I. INTRODUCTION

On July 27, 2015, Astellas Pharma Inc., and Celgene Corporation ("plaintiffs") collectively moved to dismiss under FED. R. CIV. P.12(b)(6), counterclaims five through seven of Fresenius Kabi USA, LLC ("defendant") and to strike the related affirmative defenses pursuant to FED. R. CIV. P. 12(f).[1] On August 13, 2015, defendant responded that plaintiffs' motions should be denied, because its counterclaims and affirmative defenses are proper.[2] Plaintiffs filed their reply brief on August 21, 2015.[3] This decision addresses plaintiffs' pending motions as described.

II. BACKGROUND

Celgene is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in Summit, New Jersey 07901.[4] Astellas

[1] D.I. 123.
[2] D.I. 127 at 1-2.
[3] D.I. 132.
[4] D.I. 1 at 1.

is a Japanese Corporation having its principal place of business in Tokyo Japan.[5] Astellas was formed on April 1, 2005 from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.[6] Defendant is a Delaware limited liability company with its principal place of business in Lake Zurich, Illinois.[7]

Plaintiffs initiated this patent matter on April 30, 2014 alleging infringement of their '280 and '724 patents.[8] On May 9, 2014, defendant filed its answer which included seven affirmative defenses and four counterclaims.

On July 1, 2015, defendant filed a motion to amend its affirmative defenses and counterclaims.[9] On July 8, 2015, plaintiffs responded advising the court they did not oppose defendant's motion as long as they were not precluded from later filing a motion to dismiss pursuant to FED. R. CIV. P. 12(b)(6) to defendant's amended answer.[10] Defendant's motion to amend was granted on July 9, 2015.[11] Defendant filed its amended answer on July 9, 2015, adding five affirmative defenses and three counterclaims. The three new counterclaims (counts five through seven) assert improper continuation application, lack of earlier priority date, and improper inventorship.[12] The new affirmative defenses (counts seven through twelve) assert lack of jurisdiction, improper inventorship, improper continuation application, lack of priority, laches, equitable estoppel and unclean hands.[13]

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[5] *Id*. at 2.
[6] *Id*.
[7] D.I. 9 at 8.
[8] D.I. 1 at 1.
[9] D. I. at 111.
[10] D. I. at 114.
[11] D. I. at 117.
[12] *Id*. at 15-27.
[13] *Id*. at 7-8.

Thereafter, plaintiffs filed the present motions under consideration.

III. JURISDICTION AND VENUE

This court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a), because this action arises under 35 U.S.C. § 1 et seq..[14] Venue is proper under 28 U.S.C. §§ 1391(c) and 1400(b).[15] This Report and Recommendation is issued pursuant to 28 U.S.C. § 636(b)(1)(B), FED. R. CIV. P. 72(b)(1), and D. DEL. LR 72.1. For the reasons stated below, it is recommended that plaintiffs' motions be denied.

IV. GOVERNING LAW

FED. R. CIV. P. 12(b)(6) governs a motion to dismiss for failure to state a claim upon which relief can be granted. The purpose of a motion under Rule 12(b)(6) is to test the sufficiency of the pleading, not to resolve disputed facts or decide the merits of the case.[16] "The issue is not whether a [party] will ultimately prevail, but whether the claimant is entitled to offer evidence to support the claims."[17] A motion to dismiss may be granted only if, after "accepting all well-pleaded allegations . . . as true, and viewing them in the light most favorable" to the non-moving party, the court determines that party is not

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[14] *See* 28 U.S.C. § 1331 (federal question jurisdiction); 28 U.S.C. § 1338(a) ("The district court shall have original jurisdiction of any civil action arising out under any Act of Congress relating to patents . . . .").

[15] 28 U.S.C. § 1391 (c) ('An entity . . ., whether or not incorporated, shall be deemed to reside, if a defendant in any judicial district in which such defendant is subject to the court's personal jurisdiction with respect to the civil action . . . .'); 28 U.S.C. § 1400 (b) ('Any civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.').

[16] *Kost v. Kozakiewicz,* 1 F.3d 176, 183 (3d Cir. 1993).

[17] *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotations and citations omitted); *see also Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 563 n.8 (2007) ("[W]hen a [pleading] adequately states a claim, it may not be dismissed based on a district court's assessment that the [party] will fail to find evidentiary support for his allegations or prove his claim to the satisfaction of the factfinder.").

entitled to relief.[18] While the court draws all reasonable factual inferences in the light most favorable to a claimant, it rejects unsupported allegations, "bald assertions," and "legal conclusions."[19]

To survive a motion to dismiss, a party's factual allegations must be sufficient to "raise a right to relief above the speculative level . . . ."[20] Parties are therefore required to provide the grounds of their entitlement to relief beyond mere labels and conclusions.[21] Although heightened fact pleading is not required, "enough facts to state a claim to relief that is plausible on its face" must be alleged.[22] A claim has facial plausibility when the factual content is sufficient for the court to draw the reasonable inference that a party is liable for the misconduct alleged.[23] Once stated adequately, a claim may be supported by showing any set of facts consistent with the allegations.[24] Courts generally consider only the allegations contained in the pleading, exhibits attached, and matters of public record when reviewing a motion to dismiss.[25]

Pursuant to FED. R. CIV. P. 12(f), "[t]he court may strike from a pleading . . . any

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[18] Maio v. Aetna, Inc., 221 F.3d 472, 481-82 (3d Cir. 2000) (citing Burlington, 114 F.3d at 1420).

[19] *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (citations omitted); *see also Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997) (citations omitted) (rejecting "unsupported conclusions and unwarranted inferences"); *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983) ("It is not . . . proper to assume [plaintiff] can prove facts that it has not alleged or that the defendants have violated the . . . laws in ways that have not been alleged.").

[20] *Twombly*, 550 U.S. at 555 (citations omitted); *see also Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (citing *Twombly*, 550 U.S. at 555).

[21] *See Twombly*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

[22] *Twombly*, 550 U.S. at 570; *see also Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) ("In its general discussion, the Supreme Court explained that the concept of a 'showing' requires only notice of a claim and its grounds, and distinguished such a showing from 'a pleader's bare averment that he wants relief and is entitled to it.'") (quoting *Twombly*, 550 U.S. at 555 n.3).

[23] *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 556).

[24] *Twombly*, 550 U.S. at 563 (citations omitted).

[25] *See, e.g., Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (citations omitted).

redundant, immaterial, impertinent, or scandalous matter."[26] "Immaterial matter is that which has no essential or important relationship to the claim for relief or the defenses being pleaded."[27] "Impertinent matter consists of statements that do not pertain, and are not necessary, to the issues in question."[28] Scandalous matter has been defined as "that which improperly casts a derogatory light on someone, most typically on a party to the action."[29] Although motions to strike "serve to 'clean up the pleadings, streamline litigation, and avoid unnecessary forays into immaterial matters,'"[30] as a general matter, these motions are disfavored.[31] They "ordinarily are denied 'unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties.'"[32] Therefore, even where the challenged material is redundant, immaterial, impertinent, or scandalous, a motion to strike should not be granted unless the presence of the surplusage will prejudice the adverse party.[33] When ruling on a motion to strike, the court must construe all facts in favor of the nonmoving party,[34] and it should not grant a motion to strike unless the allegation is clearly insufficient[35]

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[26] FED. R. CIV. P. 12(f).

[27] *Delaware Health Care, Inc. v. MCD Holding Co.*, 893 F. Supp. 1279, 1291-1292 (D. Del. 1995).

[28] *Id.* at 1292.

[29] *Aoki v. Benihana, Inc.*, 839 F. Supp. 2d 759, 764 (D. Del. 2012) (quoting *Carone v. Whalen*, 121 F.R.D. 231, 233 (M.D. Pa. 1988)).

[30] *Penn Mut. Life Ins. Co. v. Norma Espinosa 2007-1 Ins. Trust*, C.A. No. 09-300-LPS, 2011 U.S. Dist. LEXIS 17172, at *4 (D. Del. Feb. 22, 2011) (quoting *McInerney v. Mayer Lumber & Hardware, Inc.* 244 F. Supp. 2d 393, 402 (E.D. Pa. 2002)).

[31] *O'Gara ex rel. Portnick v. Countrywide Home Loans, Inc.*, C.A. No. 08-113-JJF, 2010 U.S. Dist. LEXIS 77130, at *3 (D. Del. July 30, 2010) (citing *Seidel v. Lee*, 954 F. Supp. 810 (D. Del. 1996)).

[32] *Sun Microsystems, Inc. v. Versata Enters.*, 630 F. Supp. 2d 395, 402 (D. Del. 2009) (quoting *McInerney v. Moyer Lumber and Hardware, Inc.*, 244 F. Supp. 2d 393, 402 (E.D. Pa. 2002)).

[33] *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 359 (D. Del. 2009) (internal quotations omitted).

[34] *Proctor & Gamble Co. v. Nabisco Brands, Inc.*, 697 F. Supp. 1360, 1362 (D. Del 1988) (citations omitted).

[35] *Aoki*, 839 F. Supp. 2d at 764 (quoting *Singleton v. Medearis*, Civ. No. 09-CV-1423, 2009 U.S. Dist. LEXIS 101187, at *2 (E.D. Pa. Oct. 28, 2009)).

V. ANALYSIS

A. Improper Continuation Application

Defendant alleges sufficient underlying facts to support its counterclaim at count five for improper continuation application. Plaintiffs contend that counterclaim five fails, because defendant failed to plead the elements of a claim for "improper continuation application, or identify the statue that support its claim." This assertion is misplaced: defendant relied on 35 U.S.C. § 102(b) to support its contention. Defendant notes that absent the earlier priority date, the patents-in-suit would not have issued, because of the statutory bar under 35 U.S.C. § 102(b), which is based on the 2002 publication of Astellas patent application, that was disclosed and dedicated to the public. Defendant further points out that plaintiffs falsely claimed the prior application had common inventors, which enabled Astellas to prosecute the patents-in-suit as continuation applications. Defendant also alleges that plaintiffs misused the PTO procedures by claiming the inventors were the same to claim an earlier priority date. In the absence of such conduct, defendant reasons the patents would not have issued as continuation applications. Therefore, counterclaim five states a claim consistent with Rule 12(b)(6).

B. Priority Date

Plaintiffs argue defendant's sixth counterclaim fails in the absence of citing the authorizing statute. Defendant identified the statute on which it relies, that is 35 U.S.C. § 120. Plaintiffs also contend that under § 120, a patent is entitled to the priority date of an earlier filed application, if the applications have at least one common inventor. They note as long as a common inventor is named on both applications, they are entitled to an

earlier priority date. Defendant maintains plaintiffs are not entitled to an earlier priority date, because the true inventors were not named in the previous application. It further argues plaintiffs' technical reading of § 120 is flawed since the inventors listed on both applications were not the true inventors, and their recent effort to amend inventorship would result in no actual inventors in common.

Although inventorship may generally be amended at anytime under 35 U.S.C. §256, this does not negate § 120, which requires a named common inventor to obtain an earlier priority date. Plaintiffs contend that § 120 only requires common inventors be identified in the application process and nothing further. Defendant argues plaintiffs' application of the statute would allow gaming of the patent system to access an earlier priority date. Plaintiffs filed an amendment with the PTO, which would result in a change of inventorship. In light of the present stage of the proceedings, defendant alleged sufficient facts to support a claim. Therefore, plaintiffs' motion to dismiss count six should be denied.

C. Improper Inventorship

Plaintiffs contend defendant's counterclaim seven fails because § 256 allows inventorship to be corrected at any time, and requires correction to avoid invalidation. In the instant matter, defendant is alleging that inventorship cannot be corrected under § 256, because the original patent was already disclaimed under 35 U.S.C. § 253 prior to plaintiffs' proposed amendment. Defendant maintains that Astellas dedicated the original patent to the public six years ago, thereby statutorily disclaiming it. As a result, plaintiffs cannot amend or correct inventorship of an already disclaimed patent. "[B]ecause the disclaimer of any issued claim inheres in the original patent, we have interpreted 35

U.S.C. § 253 to mean that after such disclaimer 'the patent is treated as though the disclaimed claims never existed."[36] Under defendant's argument regarding disclaimer, there is no inventorship to correct. At the motion to dismiss stage, the court does not analyze the truth or accuracy of the allegation, but decides whether a defendant made an adequate claim upon which relief can be granted. Here, defendant propounded sufficient facts to support improper inventorship, which warrants discovery on this issue. Therefore, plaintiffs' motion to dismiss counterclaim seven should be denied.

D. Affirmative Defenses counts eight through twelve

Plaintiffs contend defendant's affirmative defenses eight through eleven should be stricken under 12(f), since they are analogous to defendant's counterclaims. Although, defendant's affirmative defenses eight through eleven are similar to the counterclaims, they are neither improperly plead nor redundant. Affirmative defenses differ from counterclaims and are governed by FED. R. CIV. P. 8, rather than Rule 13. Generally affirmative defenses must be initially pled or be subject to waiver of the defense. A counterclaim is governed by Rule 13. The party raising either an affirmative defense or a counterclaim bears the burden of proof. Counterclaims and affirmative defenses that raise the similar contentions are not improper.[37]

Motions to strike under Rule 12(f) require a showing of prejudice. Here, plaintiffs have not alleged nor demonstrated any prejudice due to the analogous nature between defendants' counterclaims and affirmative defenses. The evidence required to prove the

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[36] *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.,* 960 F.2d 1020, 1028-29 (Fed. Cir. 1992); *see also Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.,* 988 F. 3d 1157, 1163 (Fed. Cir. 1993).
[37] *Tyco Fire Prod. v. Victaulic Co,* 777 F. Supp. 2d 893, 903-904 (E.D. Pa. 2011).

counterclaims and the affirmative defenses will likely be similar and would not delay discovery or the litigation.

Plaintiffs also claim that affirmative defense eight should be stricken as insufficient as a matter of law, relying on their amendment to correct inventorship and proper assignment by the proposed inventors of their rights to plaintiffs. Defendant emphasizes plaintiffs lack of standing since their application remains pending before the PTO, therefore, the new inventors have no ownership interests or rights to assign to plaintiffs. Defendant sufficiently pled this affirmative defense.

Plaintiffs' motion to strike defendant's ninth through eleventh affirmative defenses of improper inventorship, improper continuation application and lack of priority date respectively should be denied since there is no suggestion of any prejudice. Defendant properly pled these claims as previously analyzed.

Plaintiffs assert that defendant's claim under count twelve is insufficient, because of the operation of § 256. However, § 256 does not necessarily defeat adequately pled affirmative defenses of laches, equitable estoppel and unclean hands. Defendant alleges plaintiffs' failure to act constituted an "unreasonable or inexcusable delay." In support, it emphasizes that Astellas was clearly aware that the earlier patent listed the wrong inventors, but waited more than six years after issuance and more than fifteen years after filing to amend inventorship. Defendant further notes plaintiffs only sought the correction after being confronted with its amended pleading. "A delay of more than six years after the omitted inventor knew or should have known of the issuance of the patent will

produce a rebuttable presumption of laches."[38] At this stage of the proceedings, defendant has pled a sufficient affirmative defense under count twelve, and therefore, plaintiffs' motion to strike this affirmative defense should be denied.

E. Recommended Disposition

Consistent with the findings herein, it is recommended that plaintiffs' motion to dismiss defendant's counterclaims five through seven for failure to state a claim upon which relief can be granted under FED. R. CIV. P. 12(b)(6) (D.I. 123) be denied. It is also recommended that plaintiffs' motion to strike defendant's affirmative defenses counts eight through twelve under FED. R. CIV. P. 12 (f) (D.I. 123) be denied.

Pursuant to 28 U.S.C. § 636(b)(1)(B) and (C), FED. R. CIV. P. 72(b) and D.DEL. LR 72.1, any objections to the Report and Recommendation shall be filed within fourteen (14) days limited to ten (10) pages after being served with the same. Any response is limited to ten (10) pages.

The parties are directed to the court's Standing Order in Non Pro Se matters for objections filed under FED. R. CIV. P. 72 dated October 9, 2013, a copy of which is available on the court's website, www.ded.uscourts.gov.

December 7, 2015

/s/ Mary Pat Thynge
CHIEF UNITED STATES MAGISTRATE JUDGE

[38] *A.C. Aukerman Co.*, 960 F.2d 1028-29; *see also Advanced Cardiovascular Sys.*, 988 F. 3d 1163.