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See Fed. Rule of Appellate Procedure 32.1 generally governing citation of judicial decisions issued on or after Jan. 1, 2007. See also U.S.Ct. of App. Fed. Cir. Rule 32.1.

United States Court of Appeals,
Federal Circuit.

CLASSEN IMMUNOTHERAPIES, INC., a Maryland
Corporation, Plaintiff-Appellant

John Barthelow Classen, Counterclaim Defendant

v.

ELAN PHARMACEUTICALS, INC., a Delaware
Corporation, Defendant/Counterclaimant-Appellee

2017-1033

October 17, 2017

Appeal from the United States District Court for the
District of Maryland in No. 1:04-cv-03521-RDB, Judge
Richard D. Bennett.

Attorneys and Law Firms

Joseph J. Zito, DNL ZITO, Washington, DC, argued for
plaintiff-appellant. Also represented by Luiz Felipe V S
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Garrett & Dunner, LLP, Washington, DC, argued for
defendant/counterclaimant-appellee. Also represented
by Paul William Browning.

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(Prost, Chief Judge, Lourie and Taranto, Circuit Judges).

JUDGMENT

Per Curiam

This Cause having been heard and considered, it is

Ordered and Adjudged:

AFFIRMED. *See* Fed. Cir. R. 36.

3a
United States District Court,
D. Maryland.

CLASSEN IMMUNOTHERAPIES, INC., Plaintiff,
v.
ELAN PHARMACEUTICALS, INC., Defendants.

Civ. No.: RDB-04-3521
Signed September 27, 2016

Attorneys and Law Firms

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MEMORANDUM OPINION

Richard D. Bennett, United States District Judge

This case is again before this court on remand from the United States Court of Appeals for the Federal Circuit. (ECF No. 231.)¹ Currently pending is defendant Elan Pharmaceuticals, Inc.'s (“Elan” or “Defendant”) Motion for Summary Judgment of Non-Infringement (“Elan's Motion”) (ECF No. 249). Plaintiff Classen Immunotherapies, Inc. (“Classen” or “Plaintiff”) has filed an Opposition to Elan's Motion (“Classen's Opposition”) (ECF No. 250), and Elan has filed a Reply to Classen's Opposition (“Elan's Reply”) (ECF No. 251). The Court conducted a hearing on the parties' submissions on September 22, 2016. (ECF No. 252.) For

the reasons set forth below, Elan's Motion is GRANTED.

FACTUAL AND PROCEDURAL BACKGROUND

The pertinent factual and procedural history of this case was set forth by the Federal Circuit in its decision remanding this case to this Court. *Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 894–95 (Fed. Cir. 2015).

“Classen owns the '472 patent, which is directed to a method for accessing and analyzing data on a commercially available drug to identify a new use of that drug, and then commercializing that new use. Classen sued Elan in 2004, alleging that Elan infringed the '472 patent when it studied the effect of food on the bioavailability of Skelaxin, used the clinical data to identify a new use of the drug, and commercialized the new use. *Classen*, 466 F.Supp.2d at 624. Elan moved for summary judgment of noninfringement. The district court granted the motion in 2006, finding Elan protected by the safe harbor provision of § 271(e)(1)² because Elan submitted its clinical data to the FDA with its citizen petition and sNDA, and thus its activities were “reasonably related to the submission of information” under the Federal Food, Drug, and Cosmetic Act (“FDCA”). *Id.* at 625.

“The lawsuit was then stayed pending an *ex parte* reexamination of the '472 patent, during which the PTO cancelled 107 of the 137 originally issued claims. Of the remaining claims, only

claims 36, 42, 48–50, 59, 73–76, 84, 131, and 135 were asserted against Elan. Prior to issuing the reexamination certificate, the PTO Examiner stated, as reasons for patentability, that the “prior art of record fails to teach or fairly suggest the limitation of ‘a manufacturer or distributor of the product must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product.’ ”

...

“After the reexamination certificate issued in 2010, Classen filed a motion in the district court seeking to lift the stay and to vacate the 2006 summary judgment. Classen argued that our decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) warranted reconsideration of the summary judgment because we held in *Biogen* that certain post-approval routine submissions to the FDA are outside the safe harbor of § 271(e)(1). In response, the district court lifted the stay but denied reconsideration of its 2006 decision. The court concluded that Elan was protected by the safe harbor under both *Biogen* and our subsequent decision in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (Fed. Cir. 2012). The court reasoned that unlike *Biogen*, where the post-approval submissions were routine, Elan's submissions to the FDA were “not routine” because they were necessary to update the Skelaxin product label and to change

the FDA-approval process for generic versions of Skelaxin. *Classen*, 981 F.Supp.2d at 421–22.

“On the parties' joint motion, the district court entered final judgment of noninfringement under Rule 54(b) of the Federal Rules of Civil Procedure.”

Classen, 786 F.3d at 895–96.

On May 13, 2015, the Federal Circuit vacated and remanded Judge Quarles' 2012 judgment of non-infringement in favor of Elan. (ECF No. 232.) In its opinion remanding this case to this Court, the Federal Circuit concluded that “the district court correctly decided that § 271(e)(1) exempts Elan's activities reasonably relating to developing clinical data on its approved drug Skelaxin® (“Skelaxin”) and submitting that information to the Food and Drug Administration (“FDA”) in a citizen petition and a supplemental new drug application (“sNDA”).” *Classen*, 786 F.3d at 894. However, the court also found that because Judge Quarles' opinion did not address Plaintiff's “assert[ion] that certain activities that occurred after the FDA submissions infringed the '472 patent and that those activities are not exempt under the safe harbor of § 271(e)(1),” remand was appropriate. *Id.* Accordingly, the sole question now before this court is whether Elan's “post-submission activities constituted infringement of the '472 patent or whether they were exempt under the safe harbor.” *Id.* at 898–99.

This case was transferred to the undersigned on January 22, 2016 following Judge Quarles' retirement from the bench. A new Scheduling Order (ECF No.

248) was issued, and, consistent with that Order, Elan filed its now-pending Motion on March 31, 2016. (ECF No. 249.) The Court conducted a hearing on September 22, 2016, and the matter is fully ripe for the Court's resolution. (ECF No. 252.)

STANDARD OF REVIEW

Rule 56 of the Federal Rules of Civil Procedure provides that a court “shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). A material fact is one that “might affect the outcome of the suit under the governing law.” *Libertarian Party of Va. v. Judd*, 718 F.3d 308, 313 (4th Cir. 2013) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986)). Thus, summary judgment is proper “only when no ‘reasonable jury could return a verdict for the nonmoving party.’ ” *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1257 (Fed. Cir. 2001) (quoting *Anderson*, 477 U.S. at 255, 106 S.Ct. 2505)). When considering a motion for summary judgment, a judge's function is limited to determining whether sufficient evidence exists on a claimed factual dispute to warrant submission of the matter to a jury for resolution at trial. *Anderson*, 477 U.S. at 249, 106 S.Ct. 2505.

In undertaking this inquiry, this Court must consider the facts and all reasonable inferences in the light most favorable to the nonmoving party. *Libertarian Party of Va.*, 718 F.3d at 312; *see also Scott v. Harris*, 550 U.S. 372, 378, 127 S.Ct. 1769, 167 L.Ed.2d 686 (2007). However, this Court must also abide by its affirmative

obligation to prevent factually unsupported claims and defenses from going to trial. *Drewitt v. Pratt*, 999 F.2d 774, 778–79 (4th Cir. 1993). If the evidence presented by the nonmoving party is merely colorable, or is not significantly probative, summary judgment must be granted. *Anderson*, 477 U.S. at 249–50, 106 S.Ct. 2505. On the other hand, a party opposing summary judgment must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986); *see also In re Apex Express Corp.*, 190 F.3d 624, 633 (4th Cir. 1999). As this Court has previously explained, a “party cannot create a genuine dispute of material fact through mere speculation or compilation of inferences.” *Shin v. Shalala*, 166 F.Supp.2d 373, 375 (D. Md. 2001) (citations omitted).

DISCUSSION

I. No Additional Discovery Is Required

At oral argument, the parties conceded that no additional factual discovery is required in order for the Court to rule on Elan's Motion. Specifically, counsel for Plaintiff indicated that now is the time to apply the law to the facts of this case. Counsel for Defendant agreed that no further discovery was needed and that the court could rule on the pending motion for summary judgment.

Although Classen argues that “the complex facts in this matter are not fully presentable to the Court in a comprehensive and understandable manner” and that “[t]he fact that the issues were remanded to the *trial*

court clearly indicates that they are not ripe for summary determination but require a full, fair and comprehensive factual hearing, i.e., a trial on the merits” these arguments do not indicate what purpose additional discovery would serve. (ECF No. 250 at 7-8)(emphasis in original.)

II. The Federal Circuit's Guidance

In its decision remanding this case to this Court, the Federal Circuit offered the following guidance with respect to Plaintiff's claims:

“To assist the district court in its analysis of infringement, if the court reaches that issue on remand, we make the following observations of the record. **Filing a patent application is generally not an infringement of a patent. It is not the making, using, offering to sell, selling, or importing of an invention.** It is the act of approaching an agency of the government in order to obtain a limited privilege and to fulfill a public goal of making knowledge of an invention available to the public. It is not commercializing an invention, which requires introducing an invention into commerce, or making preparations to do so. Moreover, infringing a multi-step method claim requires carrying out all the steps of the claim. As filing a patent application is not commercializing an invention, a method claim requiring commercialization, as claim 36 does, is likely not infringed by Elan's actions here.

“In addition, placing the information submitted to the FDA on the product label after sNDA approval generally cannot be an infringement. Information obtained from exempt activities does not cease to be exempt once the sNDA is approved. It is a requirement of law that a drug product contains the labeling approved by the FDA. This is not to say that a pharmaceutical patent claiming a method of treatment, a method of preparation, or a composition of matter cannot be infringed by the subsequent actions of making, using, offering to sell, selling, or importing of a drug covered by that patent based on information derived from exempt activities. But that is not the case here.”

Classen, 786 F.3d at 898–99 (emphasis added).

While Plaintiff interprets the Federal Circuit's use of the term “generally” to indicate that exceptions may apply to these general rules, this argument—unsupported by authority—is unpersuasive. (ECF No. 250 at 8.) Moreover, when this issue was raised during the hearing, counsel for Plaintiff was unable to indicate why the Federal Circuit's guidance should not govern this Court's analysis.³ Accordingly, this Court is bound to follow the Federal Circuit's statement of the applicable law in its analysis of the pending Motion.

III. Plaintiff's Claims Fail as a Matter of Law

Elan argues that summary judgment is appropriate because its allegedly infringing activities are protected by 35 U.S.C. § 271(e)(1)'s safe harbor provision.⁴ In addition, as set forth in its Reply and at the hearing

held on its Motion, Elan argues that summary judgment is warranted because Classen “has failed to provide any evidence supporting” its allegations of infringement. (ECF No. 251 at 5, 8.)

In its Opposition, Classen argues that Elan's post-submission activities—that is, submission of clinical data to the FDA—are aimed at commercialization and thus, in Classen's view, fall outside of the safe harbor of § 271(e)(1). (ECF No. 250 at 2-4, 14-17.) The allegedly infringing activities are: (1) “reanalyzing the clinical data to identify patentable information and filing patent applications;” and (2) “making and selling Skelaxin with the revised label that contained the information derived from the clinical study.” *Classen*, 786 F.3d at 897–98.

1Following the Federal Circuit's guidance, it is clear that Elan's alleged “reanalyzing the clinical data to identify patentable information and filing patent applications,” and “making and selling Skelaxin with the revised label that contained the information derived from the clinical study” fall squarely within the safe harbor of § 271(e)(1). This conclusion is also consistent with the decision of this Court in *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F.Supp.2d 569, 578 (D. Md. 2014), *aff'd*, 586 Fed.Appx. 585 (Fed. Cir. 2014). In *Shionogi*, Judge Titus of this Court rejected Classen's nearly identical argument to that raised here, stating:

“Classen's attempts to avoid the safe harbor run aground under *Momenta*. Classen argues that its patent infringement allegations are not barred by § 271(e)(1) because its patents include claims that are “commercialization steps which are not used to develop or submit

information to the FDA.” Classen admits that “[c]linical trials generate information, such as the proper manufacturing method or the proper dosage requirements or methods of treatment,” and that “[t]his information is submitted to the FDA,” and “thus the generation and use of this information during the clinical trials...is protected.” Nevertheless, Classen asserts that “[t]he subsequent generation and/or use of this same information during commercial sales is not protected.” Classen's argument rests on its theory that “the safe harbor expires after FDA approval is obtained. If it did not, no pharmaceutical patents would ever be enforceable.” Classen relies on *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011), for the proposition that the safe harbor “ ‘does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained.’ ” **However, the later decision in Momenta⁵ clarified that there is no pre/post FDA approval dichotomy under the safe harbor provision. To the extent that there is any tension between Biogen and Momenta, Momenta controls, as it is the more recent Federal Circuit decision. Thus, § 271(e)(1) precludes Classen's infringement claims from proceeding.”**

Shionogi, 993 F.Supp.2d at 578 (internal citations omitted) (emphasis added). Notably, *Shionogi* involved the same Plaintiff alleging a nearly identical legal theory.⁶ And there, the Court dismissed Classen's complaint for failing to state a legally plausible claim.

So, too, does this Court conclude that Classen's claims fail as a matter of law.

This Court's conclusion that Elan's post-submission activities fit within the scope of § 271(e)(1)'s safe harbor is further supported by *Telectronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1523–24 (Fed. Cir. 1992). As the Federal Circuit explained, *Telectronics* stands for the proposition that “the subsequent disclosure or use of *information* obtained from an exempt clinical study, even for purposes other than regulatory approval, does not repeal that exemption of the clinical study, provided that the subsequent disclosure or use is itself not an *act of infringement* of the asserted claims.” *Classen*, 786 F.3d at 898 (emphasis in original) (citing *Telectronics*, 982 F.2d at 1523–24). On this basis, the defendant in *Telectronics* remained within the safe harbor when it “present[ed] clinical trial data at a cardiology conference, report[ed] clinical trial progress to investors, analysts and journalists, and describe[ed] clinical trial results in a private fund-raising memorandum.” *Id.* The alleged acts of commercialization by Elan—the filing of patent applications based on the reanalyzed clinical data and the sale of Skelaxin with the revised label containing information derived from the clinical trial—appear, contrary to Classen's argument, far less “commercial” in nature than those activities deemed protected in *Telectronics*. Accordingly, these activities remain within the scope of § 271(e)(1)'s safe harbor, and Elan is entitled to summary judgment.

IV. Plaintiff Fails to Raise a Genuine Issue of Material Fact

Even if Classen's claims were not barred as a matter of law, Classen still fails to raise a genuine issue of material fact sufficient to preclude summary judgment. To be sure, while the burden remains on the movant to show that there is no genuine dispute of material fact and that it is entitled to judgment as a matter of law, the party opposing summary judgment must "make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

2Here, with discovery long complete and this case having worn on for nearly twelve years, Classen has produced no evidence of Elan's alleged reanalysis of the data for commercial purposes so as to raise a genuine issue of material fact regarding Elan's infringement. Attached to Classen's Opposition brief are copies of Classen's and Elan's patents at issue in this case (ECF Nos. 250-1, 250-5), materials related to Dr. Classen's November 2001 presentation (ECF No. 250-2), Elan's 2001 Clinical Study Report (ECF No. 250-6), Elan's 2001 Citizen's Petition to the FDA (ECF No. 250-7), and portions of the deposition transcripts of Nancy Santilli (ECF No. 250-3) and Steve Cartt (ECF No. 250-4). While the deposition excerpts may support the inference that Ms. Santilli, Mr. Cartt, and other Elan employees attended Dr. Classen's presentation, met with Dr. Classen, and even explored the possibility of entering into a business relationship with him, these materials say nothing of Elan's alleged reanalysis of clinical study data and commercialization of that data. *See* ECF Nos. 250-3, 250-4. Thus, even if Classen's allegations were not barred as a matter of law on

account of § 271(e)(1)'s safe harbor, Classen has failed to show that there exists a genuine issue of material fact with respect to a key element of its allegations.⁷ Summary judgment is therefore appropriate.

CONCLUSION

For the foregoing reasons, this 27th day of September, 2016, Elan Pharmaceuticals, Inc.'s Motion for Summary Judgment as to Non-Infringement (ECF No. 249) is GRANTED.

A separate Order follows.

Footnotes

1 This case was transferred to the undersigned on January 22, 2016 following Judge Quarles' retirement from the bench.

2 35 U.S.C. § 271(e)(1). Footnote added.

3 Unsurprisingly, Elan expressly relies upon the Federal Circuit's guidance in support of its Motion. (ECF No. 249-1 at 13, 15.)

4 “This provision shields drug manufacturers from patent infringement liability for using patented inventions in activities that are ‘reasonably related to the development and submission of’ information pursuant to the federal regulatory process of pharmaceuticals.” *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F.Supp.2d 569, 576 (D. Md. 2014), *aff'd*, 586 Fed.Appx. 585 (Fed. Cir. 2014) (quoting *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 195, 125 S.Ct. 2372, 162 L.Ed.2d 160 (2005)). “Congress enacted this provision of the Hatch–Waxman Act in 1984 to ‘balance the need to stimulate innovation against the goal of furthering the public interest.’ ” *Id.*

(internal citation omitted). *See also* H.R. Rep. 98–857, pt. 2, at 2714 (1984), 1984 U.S.C.C.A.N. 2686, 2714).

5 *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012).

6 Indeed, the *Shionogi* court cites Judge Quarles' 2006 summary judgment opinion in this case in analyzing the applicability of the § 271(e)(1) safe harbor to Classen's allegations that Shionogi infringed its now-cancelled '639 Patent by taking “commercialization steps which are not used to develop or submit information to the FDA.” *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F.Supp.2d 569, 577–78 (D. Md. 2014), *aff'd*, 586 Fed.Appx. 585 (Fed. Cir. 2014) (citing *Classen Immunotherapies, Inc. v. King Pharm., Inc.*, 466 F.Supp.2d 621, 623 (D. Md. 2006)).

7 There does not appear to be any dispute as to whether Elan sold Skelaxin with the updated label derived from the clinical study test results. However, as set forth above, “placing the information submitted to the FDA on the product label after sNDA approval generally cannot be an infringement. Information obtained from exempt activities does not cease to be exempt once the sNDA is approved.” *Classen*, 786 F.3d at 898–99.

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United States Court of Appeals,
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Corporation, Plaintiff–Appellant
John Barthelow Classen, Counterclaim Defendant
v.
ELAN PHARMACEUTICALS, INC., a Delaware
Corporation, Defendant/Counterclaimant–Appellee.

No. 2014–1671.
May 13, 2015.

Joseph J. Zito, DNL Zito, Washington, DC, argued for
plaintiff-appellant.

James B. Monroe, Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP, Washington, DC, argued for
defendant/counterclaimant-appellee. Also represented
by Paul William Browning.

Before PROST, Chief Judge, LOURIE, Circuit Judge,
and GILSTRAP, District Judge.*

Opinion

LOURIE, Circuit Judge.

Classen Immunotherapies, Inc. (“Classen”) appeals from the decision of the United States District Court for the District of Maryland granting summary judgment that Elan Pharmaceuticals, Inc. (“Elan”) did not infringe U.S. Patent 6,584,472 (“the ‘472 patent”) based on the safe harbor provision of 35 U.S.C. § 271(e)(1). *See Classen Immunotherapies, Inc. v. King*

Pharm., Inc., 466 F.Supp.2d 621 (D.Md.2006) (granting summary judgment); *Classen Immunotherapies, Inc. v. King Pharm., Inc.*, 981 F.Supp.2d 415 (D.Md.2013) (denying reconsideration). We conclude that the district court correctly decided that § 271(e)(1) exempts Elan's activities reasonably relating to developing clinical data on its approved drug Skelaxin® (“Skelaxin”) and submitting that information to the Food and Drug Administration (“FDA”) in a citizen petition and a supplemental new drug application (“sNDA”).

Classen also asserts that certain activities that occurred after the FDA submissions infringed the '472 patent and that those activities are not exempt under the safe harbor of § 271(e)(1). Because the district court did not determine whether those activities constituted infringement or whether they were exempt from liability under the safe harbor, we *vacate* the judgment of noninfringement and *remand*.

Background

Elan has marketed and sold metaxalone, a muscle relaxant, under the brand-name Skelaxin, and was the owner of an approved new drug application (“NDA”). In early 2001, years after the initial approval of Skelaxin, Elan learned that another company conducted *in vivo* bioequivalence fasting studies and *in vitro* dissolution tests on metaxalone and that, based on the results of those studies, the FDA proposed to change the designation of metaxalone tablets from “non bioproblem” to “bioproblem.” J.A. 1531–32.

In July 2001, Elan initiated its own clinical study on Skelaxin administered with and without food in humans

and observed a significant effect of food on the drug's bioavailability. In October 2001, Elan submitted a citizen petition to the FDA, requesting that the FDA require both fed and fasting bioavailability data from an applicant of an abbreviated new drug application ("ANDA") for a generic version of Skelaxin. Concurrently, Elan also submitted an sNDA, *viz.*, a labeling supplement to the Skelaxin NDA, to revise its product label. *See* 21 C.F.R. § 314.70. Elan included its clinical study report with those FDA submissions and explained to the FDA that the results of its clinical study showed that "the bioavailability [of Skelaxin] was significantly increased when Skelaxin was administered with food in that both the rate ... and extent of absorption ... were increased." J.A. 1532. The FDA subsequently granted Elan's citizen petition and approved its sNDA.

In December 2001 and March 2002, Elan filed two patent applications in the United States Patent and Trademark Office ("PTO") based on its clinical bioavailability data. The second application is a continuation of the first and shares the same specification. Those applications issued as U.S. Patents 6,407,128 and 6,683,102 ("the Elan patents"). However, all claims of the Elan patents were later invalidated in light of prior art. *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1283 (Fed.Cir.2010).

Classen owns the '472 patent, which is directed to a method for accessing and analyzing data on a commercially available drug to identify a new use of that drug, and then commercializing that new use. Classen sued Elan in 2004, alleging that Elan infringed the '472 patent when it studied the effect of food on the

bioavailability of Skelaxin, used the clinical data to identify a new use of the drug, and commercialized the new use. *Classen*, 466 F.Supp.2d at 624. Elan moved for summary judgment of noninfringement. The district court granted the motion in 2006, finding Elan protected by the safe harbor provision of § 271(e)(1) because Elan submitted its clinical data to the FDA with its citizen petition and sNDA, and thus its activities were “reasonably related to the submission of information” under the Federal Food, Drug, and Cosmetic Act (“FDCA”). *Id.* at 625.

The lawsuit was then stayed pending an *ex parte* reexamination of the '472 patent, during which the PTO cancelled 107 of the 137 originally issued claims. Of the remaining claims, only claims 36, 42, 48–50, 59, 73–76, 84, 131, and 135 were asserted against Elan. Prior to issuing the reexamination certificate, the PTO Examiner stated, as reasons for patentability, that the “prior art of record fails to teach or fairly suggest the limitation of ‘a manufacturer or distributor of the product must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product.’ ” J.A. 1484.

Claim 36 is representative of the asserted method claims and depends from cancelled claim 33; both are reproduced below:

33. [(cancelled during reexamination)] A method for creating and using data associated with a commercially available product, wherein the method comprises the steps of:

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accessing at least one data source, comprising together or separately, adverse event data associated with exposure to or use of the product and commercial data regarding marketing, sales, profitability or related information pertaining to the product;

analyzing the accessed data to *identify* (i) at least *one new adverse event* associated with exposure to or use of the product, (ii) at least *one new use* for the product responsive to identification of the at least one new adverse event, and (iii) the potential commercial value of the at least one new use for the product; and

commercializing the newly identified product information based upon the analyzed data.

36. The method of claim 33, wherein the *commercializing* step comprises formatting the data relating to at least one new adverse event associated with exposure to, or use of the product, or documenting same, such that *a manufacturer or distributor of the product must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product.*

'472 patent col. 26 ll. 38–53, 60–67 (emphases added). The asserted kit claims depend from the method claims. Claim 59 is representative and reads as follows:

59. A proprietary kit comprising (i) product and (ii) *documentation notifying a user* of the

product of at least *one new adverse event* relating to the product, wherein determination of the new adverse event is based upon the data provided by the method of claim 36.

'472 patent reexamination certificate col. 2 ll. 5–9 (emphases added).

After the reexamination certificate issued in 2010, Classen filed a motion in the district court seeking to lift the stay and to vacate the 2006 summary judgment. Classen argued that our decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed.Cir.2011) warranted reconsideration of the summary judgment because we held in *Biogen* that certain post-approval routine submissions to the FDA are outside the safe harbor of § 271(e)(1). In response, the district court lifted the stay but denied reconsideration of its 2006 decision. The court concluded that Elan was protected by the safe harbor under both *Biogen* and our subsequent decision in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (Fed.Cir.2012). The court reasoned that unlike *Biogen*, where the post-approval submissions were routine, Elan's submissions to the FDA were “not routine” because they were necessary to update the Skelaxin product label and to change the FDA-approval process for generic versions of Skelaxin. *Classen*, 981 F.Supp.2d at 421–22.

On the parties' joint motion, the district court entered final judgment of noninfringement under Rule 54(b) of the Federal Rules of Civil Procedure. Elan's invalidity counterclaim is still pending at the district court. Classen appealed from the judgment of

noninfringement, and we have jurisdiction under 28 U.S.C. § 1295(a)(1).¹

Discussion

We review the grant of summary judgment under the law of the regional circuit in which the district court sits, here, the Fourth Circuit. *Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP*, 661 F.3d 1378, 1381 (Fed.Cir.2011). Applying the law of the Fourth Circuit, we review the district court's grant of summary judgment *de novo*. *Gallagher v. Reliance Standard Life Ins. Co.*, 305 F.3d 264, 268 (4th Cir.2002). Summary judgment is appropriate when, drawing all justifiable inferences in the non-movant's favor, “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed.R.Civ.P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

Section 271(a) of the patent statute provides that “[e]xcept as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a). In 1984, as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch–Waxman Act), Congress created an exemption from the general rule of infringement for certain uses of a patented invention in the federal regulatory process. Pub.L. No. 98–417, § 202, 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271(e)(1)). The safe harbor provision of § 271(e)(1) provides in relevant part that:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... *solely for uses reasonably related to the development and submission of information* under a Federal law which regulates the manufacture, use, or sale of drugs....

35 U.S.C. § 271(e)(1) (emphasis added).

In the district court, Classen alleged that Elan infringed the '472 patent by conducting a clinical study on the bioavailability of Skelaxin and submitting the results to the FDA to revise the Skelaxin product label, among other accused activities. *Classen*, 466 F.Supp.2d at 624; *see also Classen Immunotherapies, Inc. v. King Pharm., Inc.*, No. 04-3521, ECF No. 123-8, 2005 WL 6702932 (D.Md. Dec. 23, 2005). On appeal, Classen no longer asserts that Elan's clinical study and FDA submissions are infringing, Appellant's Br. 7, 20-27, 29, 40, 43, 45, 46-47, 50, but it nevertheless argues that the district court erred in finding those activities exempt under the safe harbor because, according to Classen, those activities are merely routine post-approval reporting to the FDA, *id.* at 4 & n. 2, 29.

Under § 271(e)(1), the exemption from infringement “extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA.” *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202, 125 S.Ct. 2372, 162 L.Ed.2d 160 (2005) (emphasis in original). The statute does not exclude “certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in

which it could be included.” *Id.* Nor does the statute limit the safe harbor only to those activities necessary for seeking approval of a generic version of a brand-name drug product. *Id.* at 206, 125 S.Ct. 2372.

Although in the post-approval context it may be less straightforward to determine whether an accused infringer's use of a patented invention was “*solely* for uses reasonably related to the development and submission of information” under the FDCA, 35 U.S.C. § 271(e)(1) (emphasis added), the statutory language does not categorically exclude post-approval activities from the ambit of the safe harbor, *Momenta*, 686 F.3d at 1359. Indeed, under the FDCA, drug manufacturers may voluntarily, or sometimes may be required to, conduct post-approval studies on their products for purposes of developing and submitting information to the FDA. *See* 21 U.S.C. § 355(e), (o); *id.* § 356(c)(2)(A); 21 C.F.R. § 314.70.

In some circumstances, drug manufacturers voluntarily conduct post-approval scientific studies and clinical trials to support “supplemental” new drug applications, seeking the FDA's approval to revise the label of their products. *See* 21 C.F.R. § 314.70. Just like NDA or ANDA applicants, sNDA applicants must submit relevant data to the FDA to support their applications. *Id.* § 314.70(b)(3). Thus, after the initial approval of a drug, its manufacturer may perform additional research to further characterize the drug and submit that information to the FDA for a labeling change. Such post-approval studies serve similar purposes as pre-approval studies in ensuring the safety and efficacy of approved drugs. As an integral part of the regulatory approval process, those activities are “reasonably

related to the development and submission of information” under the FDCA, 35 U.S.C. § 271(e)(1), and are therefore exempt from infringement liability.

Here, Elan's clinical study and its FDA submissions clearly fall within the scope of the safe harbor. After learning that the FDA proposed to change the designation of metaxalone tablets, Elan initiated its own clinical trial to characterize the effect of food on the absorption of Skelaxin and observed a significant increase in bioavailability when Skelaxin was administered with food. Elan submitted that information to the FDA to revise the Skelaxin product label and to propose changes to the approval requirements for generic versions of Skelaxin. Those activities were anything but “routine” post-approval reporting, *Biogen*, 659 F.3d at 1070; rather, they were “necessary” to the approval of both the brand-name and generic versions of Skelaxin, *Momenta*, 686 F.3d at 1358. The district court therefore did not err in holding that Elan's clinical activities and FDA submissions are exempt from infringement under the safe harbor provision.

Classen also argues that after Elan generated and submitted the clinical data to the FDA, its subsequent actions of reanalyzing the clinical data to identify patentable information and filing patent applications are commercial activities outside the scope of the safe harbor. Classen also argues that Elan infringed the kit claims by making and selling Skelaxin with the revised label that contained the information derived from the clinical study. Classen contends that the safe harbor does not protect those post-submission commercial uses of information derived from the clinical study.

Elan responds that it generated the clinical data on Skelaxin mainly for submission to the FDA and that it did not reanalyze the data when filing the patent applications. Elan contends that subsequent uses of clinical data generated for the FDA in other contexts do not result in the removal of the safe harbor protection. Elan also responds that because each of the kit claims depends from a method claim that Elan did not infringe, Elan's making and selling of Skelaxin with the revised label is likewise not infringing.

As indicated, we have concluded that Elan's clinical study and its FDA submissions are exempt under the safe harbor provision. We have also held that the subsequent disclosure or use of *information* obtained from an exempt clinical study, even for purposes other than regulatory approval, does not repeal that exemption of the clinical study, provided that the subsequent disclosure or use is itself not an *act of infringement* of the asserted claims. *Telectronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1523–24 (Fed.Cir.1992).

In *Telectronics*, the patentee conceded that the dissemination of *information* derived from an exempt clinical study, including the activities of “presenting clinical trial data at a cardiology conference, reporting clinical trial progress to investors, analysts and journalists, and describing clinical trial results in a private fund-raising memorandum,” did not, in and of itself, constitute an act of infringement in that case. *Id.* We held that the patent statute does not identify the mere dissemination of data as a potentially infringing activity and that, when enacting § 271(e)(1), Congress did not intend to prevent competitors “from using, in an

admittedly non-infringing manner, the derived test data for fund raising and other business purposes.” *Id.* at 1524–25.

Here, unlike in *Telectronics*, Classen alleges that Elan's post-submission *activities* using the clinical data for non-regulatory purposes *infringed* the claims of Classen's '472 patent. Specifically, Classen asserts that Elan's filing of patent applications based on the clinical data infringed the method claims and that Elan's sale of Skelaxin with the revised label containing information derived from the clinical trial infringed the kit claims. As indicated, when granting summary judgment of noninfringement, the district court did not determine whether those post-submission activities constituted infringement of the '472 patent or whether they were exempt under the safe harbor. Rather than deciding those issues in the first instance on appeal, we vacate the judgment of noninfringement and remand the case to the district court for further proceedings on the parties' pending claims and counterclaims, including issues of validity, enforceability, and infringement of the asserted patent.

To assist the district court in its analysis of infringement, if the court reaches that issue on remand, we make the following observations of the record. Filing a patent application is generally not an infringement of a patent. It is not the making, using, offering to sell, selling, or importing of an invention. It is the act of approaching an agency of the government in order to obtain a limited privilege and to fulfill a public goal of making knowledge of an invention available to the public. It is not commercializing an invention, which requires introducing an invention into

commerce, or making preparations to do so. Moreover, infringing a multi-step method claim requires carrying out all the steps of the claim. As filing a patent application is not commercializing an invention, a method claim requiring commercialization, as claim 36 does, is likely not infringed by Elan's actions here.

In addition, placing the *information* submitted to the FDA on the product label after sNDA approval generally cannot be an infringement. Information obtained from exempt activities does not cease to be exempt once the sNDA is approved. It is a requirement of law that a drug product contains the labeling approved by the FDA. This is not to say that a pharmaceutical patent claiming a method of treatment, a method of preparation, or a composition of matter cannot be infringed by the subsequent *actions* of making, using, offering to sell, selling, or importing of a drug covered by that patent based on information derived from exempt activities. But that is not the case here.

Having stated the above, we leave it to the district court to deal with any infringement or other issues as it deems appropriate.

Conclusion

We have considered Classen's remaining arguments but find them unpersuasive. For the foregoing reasons, we vacate the district court's judgment of noninfringement and remand.

VACATED AND REMANDED

Costs
Costs to Elan.

Footnotes

*Honorable Rodney Gilstrap, District Judge, United States District Court for the Eastern District of Texas, sitting by designation.

1Because issues of validity are not before us in this appeal, we express no opinion as to whether the asserted claims cover patent ineligible subject matter in light of the Supreme Court's decision in *Alice Corp. v. CLS Bank International*, 573 U.S. —, 134 S.Ct. 2347, 189 L.Ed.2d 296 (2014).

31a
10/31/13
IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND, NORTHERN
DIVISION

CLASSEN	*	
IMMUNOTHERAPIES,	*	
INC.	*	
	*	
Plaintiff,	*	
	*	CIVIL NO.: WDQ-
	*	04-3521
v.	*	
	*	
KING	*	
PHARMACEUTICALS,	*	
INC. et al.,	*	
	*	
Defendants.	*	

MEMORANDUM OPINION

Classen Immunotherapies, Inc. (“Classen”) sued Elan Pharmaceuticals, Inc. (“Elan”) for infringement of two patents. ECF No. 1 at 1-2. The litigation was stayed while the United States Patent and Trademark Office (“PTO”) completed a reexamination of the patents. ECF Nos. 179 at 1, 204 at 1. Pending is

Classen's motion to lift the stay on this litigation, dismiss claims based on an invalidated patent, and vacate the Court's prior grant of summary judgment to Elan. ECF No. 204 at 2-3. No hearing is necessary. Local Rule 105.6 (D. Md. 2012). For the following reasons, Classen's motion will be granted in part and denied in part.

I. Background¹

Classen is a Maryland corporation that developed and patented methods for identifying and commercializing new uses of existing drugs. ECF No. 1 at 1. Classen is the holder of Patent 6,584,472 B2, "Method, System and Article for Creating and Managing Proprietary Product Data" (the "472 patent"). *Id.* It was also previously the holder of Patent 6,219,674 B1, "System for Creating and Managing Proprietary Product Data" (the "674 patent"). *See id.* However, upon reexamination, the PTO determined that the 674 patent is invalid. ECF Nos. 179 at 1, 204 at 1.

Elan is an Irish pharmaceutical company. ECF No. 1 at 2. Until 2003, Elan produced Skelaxin, a muscle relaxant. ECF Nos. 1 at 3, 123-3 at 2. In 2001, Elan learned of a study, conducted by a generic drug manufacturer, which indicated that Skelaxin's rate of absorption differed inside and outside the body. *See*

¹ The facts are taken from the complaint, ECF No. 1; the amended answer, ECF No. 119; Elan's motion for summary judgment, ECF No. 123, and supporting exhibits; Classen's opposition to Elan's motion, ECF No. 138 (sealed), and supporting exhibits; Classen's motion to vacate, ECF No. 204, and supporting exhibits; and Elan's opposition to Classen's motion to vacate, ECF No. 205, and supporting exhibits.

ECF No. 123-5 at 1-2. Elan conducted its own study in July 2001, and found that food had a significant effect on Skelaxin's bioavailability. *See id.* Based on these findings, Elan submitted a Citizen Petition to the Food and Drug Administration ("FDA") requesting that the FDA require drug manufacturers seeking approval of generic forms of Skelaxin to submit fed and fasted studies in Abbreviated New Drug Applications ("ANDA"). *See id.*; ECF No. 123-1 at 3. Elan also submitted a labeling supplement to its New Drug Application ("NDA") for Skelaxin that included the results of the study. ECF No. 123-7.

The FDA granted Elan's request for a requirement of fed and fasted studies for all generic Skelaxin ANDAs and approved Elan's amendments to the Skelaxin product label. ECF No. 123-6. Elan was also ultimately granted patent numbers 6,407,128 and 6,683,102 on the relabeled Skelaxin. ECF No. 123-3 at 2.

Classen alleged that Elan infringed the 472 and 674 patents when it: 1) studied the effect of food on the bioavailability of Skelaxin; 2) used the study data to identify a new use of the drug; and 3) commercialized the new use. ECF No. 123-8 at 5-6. Elan counterclaimed, arguing that Elan did not infringe Classen's patents, the patents are unenforceable and invalid, and that Classen defamed Elan, invaded its privacy and damaged its business by issuing a false press statement and by claiming that Elan and Classen had an ongoing business relationship. ECF No. 119 at 7-12.

On August 17, 2006, the Court granted Elan summary judgment on Classen's infringement claims. ECF No. 167. The Court held that Elan's use of Classen's patent process was "reasonably related to the

submission of information under the FDCA,”² and was accordingly protected by a statutory safe harbor, 35 U.S.C. § 271(e)(1). ECF No. 166 at 5. The Court also denied Classen’s motion for partial summary judgment on Elan’s counterclaims. *Id.* at 6-9.

On December 14, 2006, the Court administratively closed the case pending the PTO’s reexamination of the 674 and 472 patents. ECF Nos. 179 at 1, 204 at 1. Following the completion of the examination, on December 19, 2012, Classen moved to reopen the case, lift the stay,³ vacate the Court’s grant of summary judgment to Elan,⁴ and dismiss all claims and counterclaims based on the now invalid 674 patent. ECF No. 204 at 2. On January 7, 2013, Elan opposed the motion. ECF No. 205. On January 26, 2013, Classen replied. ECF No. 207.

II. Analysis

A. Motion to Dismiss Claims

Classen requests dismissal of all patent infringement claims, affirmative defenses, and counterclaims based on the 674 patent. ECF No. 204 at 2. Elan does not oppose this motion, except as to its 674

² “FDCA” refers to the Food, Drug, and Cosmetic Act. Elan submitted its supplemental NDA (“sNDA”) pursuant to § 505(b) of the Act (35 U.S.C. § 355(b)). ECF No. 123-7 at 1. The Citizen Petition was submitted under FDA Rule 21 C.F.R. § 10.30. ECF No. 123-5 at 1.

³ Because this case was stayed pending the PTO’s reexamination of the patents, *see* ECF No. 179, and this review is now complete, ECF No. 204 at 1-2, the motion to lift the stay will be granted.

⁴ Classen asserts that the Federal Circuit’s recent decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, warrants reconsideration of the Court’s decision. ECF No. 204 at 2-3.

patent unenforceability counterclaim. ECF No. 205 at 15-16.

Elan's amended answer's requested relief for its counterclaims includes an award of costs and attorneys' fees under 35 U.S.C. § 285. This provision authorizes an award of attorney fees in "exceptional cases." § 285. Exceptional cases may include those in which the patent holder has engaged in inequitable conduct in obtaining the patent. *See Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001). Elan asserts that the unenforceability counterclaim "is a component of Elan's motion for exceptional case and attorneys' fees," if "Elan is determined to be the prevailing party." ECF No. 205 at 15. Elan also contends that "a finding of unenforceability of the '674 patent may be used to render the '472 patent unenforceable based on infectious unenforceability principles." *Id.* at 16.

In *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1242-43 (Fed. Cir. 2008), the Federal Circuit held that a district court retains jurisdiction over a patent unenforceability claim after the patent is no longer in suit in order to determine whether a patent holder engaged in "inequitable conduct" and thus may be liable to the prevailing party for attorneys' fees. *Cf. Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340, 1348 (Fed. Cir. 2005) ("[A] counterclaim questioning the validity or enforceability of a patent raises issues beyond the initial claim for infringement that are not disposed of by a decision of non-infringement.").

The *Monsanto* court also noted that it had previously held that "because inequitable conduct with respect to one or more patents in a family can infect related applications," there is "no abuse of discretion" when a district court retains jurisdiction over

unenforceability claims as to withdrawn patents. See 514 F.3d at 1243 (*quoting Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1230 (Fed. Cir. 2007)); *cf. Fox Indus., Inc. v. Structural Pres. Sys., Inc.*, 922 F.2d 801, 804 (Fed. Cir. 1990) (“[A] breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application.”). Accordingly, this Court retains jurisdiction over Elan’s 674 patent unenforceability counterclaim, despite the patent’s invalidity.

The Court has already granted Elan summary judgment on all of Classen’s infringement claims, *see* ECF Nos. 123, 166-67, 173-1 at 9, and will not reconsider that holding, *see infra* Section II.B. Accordingly, the Court will deny Classen’s motion to dismiss its infringement claims related to the 674 patent as moot. The Court will grant Classen’s motion to dismiss all defenses and counterclaims related to the 674 patent, except Elan’s unenforceability counterclaim.

B. Motion to Vacate

Although Classen does not caption its motion as a motion to reconsider, or identify the Federal Rule of Civil Procedure it brings this motion under, Classen asserts that the Federal Circuit’s decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, “warrants the reconsideration” of the Court’s grant of summary judgment to Elan. ECF No. 204 at 2.

A party may move to alter or amend a judgment under Rule 59(e), or for relief from a judgment or order under Rule 60(b). *See* Fed. R. Civ. P. 59(e) & 60(b). A motion to alter or amend filed within 28 days of the judgment is analyzed under Rule 59(e); if the motion is filed later, Rule 60(b) controls. *See* Rule 59(e); *MLC*

Auto., LLC v. Town of S. Pines, 532 F.3d 269, 280 (4th Cir. 2008); *In re Burnley*, 988 F.2d 1, 2-3 (4th Cir. 1992). Because the Plaintiff's motion was filed more than 28 days following the summary judgment order,⁵ it will be analyzed under Rule 60(b).

Rule 60(b) permits the Court to amend a final judgment, order, or proceeding because of: (1) mistake, inadvertence, surprise, or excusable neglect; (2) newly discovered evidence; (3) fraud, misrepresentation, or misconduct by an opposing party; (4) a void judgment; (5) satisfaction, release, or discharge of a judgment; or (6) any other reason justifying relief. Rule 60(b). Relief on the first three grounds must be requested "no more than a year after the entry of the judgment." Rule 60(b)(c)(1).

A Rule 60(b) motion is appropriate to raise a significant change in the law or facts, or when "the Court has patently misunderstood a party, or has made a decision outside the adversarial issues presented to the Court by the parties, or has made an error not of reasoning but of apprehension." *See Above the Belt, Inc. v. Mel Bohannon Roofing, Inc.*, 99 F.R.D. 99, 101 (E.D. Va. 1983). "A motion to reconsider is inappropriate where it merely seeks to re-debate the merits of a particular motion," *Remediation Products, Inc. v. Adventus Americas, Inc.*, 3:07CV153-RJC-DCK, 2010 WL 2572555, at *1 (W.D.N.C. June 22, 2010), or merely requests that the district court change its mind, *United*

⁵ Classen's motion to reconsider the Court's August 17, 2006 order granting summary judgment was filed on December 19, 2012. ECF Nos. 166-67, 204. Although the case has been stayed for almost seven years, more than 28 days passed between the disputed order of August 17, 2006 and the implementation of the stay on December 14, 2006. *See* ECF No. 179.

States v. Williams, 674 F.2d 310, 313 (4th Cir. 1982).⁶

1. Safe Harbor Applicability

Classen contends that the Court's holding that Elan was protected by the § 271(e)(1) safe harbor is no longer valid in light of the Federal Circuit's decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) cert. denied, 133 S. Ct. 973, 184 L. Ed. 2d 751 (2013). See ECF No. 204-1 at 13-14, 16. Elan asserts that Classen relies on a distorted interpretation of *Classen*, and that the Federal Circuit's decision in *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012) cert. denied, 133 S. Ct. 2854 (2013), confirms that Elan was protected by the safe harbor. See ECF No. 205 at 8-9.

Section 271(e)(1) provides that it is not patent infringement "to make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." This Court previously held that Elan had not infringed Classen's patents, because it was covered by this safe harbor:

Even assuming that Elan employed Classen's patented process when it studied Skelaxin's bioavailability problem and used the results to repatent the drug, the results of the 2001 study

⁶ See also *Pritchard v. Wal Mart Stores, Inc.*, 3 F. App'x 52, 53 (4th Cir. 2001); *Medlock v. Rumsfeld*, 336 F. Supp. 2d 452, 470 (D. Md. 2002); *Erskine v. Bd. of Educ.*, 207 F. Supp. 2d 407, 408 (D. Md. 2002).

were submitted to the FDA in Elan's Citizen Petition and labeling supplement to its NDA. Therefore, Elan's use of the patented process was reasonably related to the submission of information under the FDCA and so is protected under § 271(e)(1).

ECF No. 166 at 5.

In 2011, the Federal Circuit considered the scope of § 271(e)(1) in a suit brought by Classen against Biogen IDEC ("Biogen") and GlaxoSmithKline ("GSK") claiming infringement of three of Classen's other patents. *See Classen*, 659 F.3d at 1060, 1070. Biogen and GSK participated in studies "to evaluate suggested associations between childhood vaccinations, particularly against hepatitis B and Haemophilus influenza and risk of developing type 1 diabetes; and to determine whether timing of vaccination influences risk." *See id.* at 1070. (internal quotation marks and punctuation omitted). They submitted the results of these studies to the FDA, because the FDA requires annual progress reports of any post-approval studies that produce "adverse information." *See id.* at 1084 (Moore, dissenting) (*citing* 21 C.F.R. §§ 600.80, 601.70). The Court held that the safe harbor "does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained." *Id.* at 1071. The Court also emphasized that the purpose of the safe harbor is "to expedite development of information for regulatory approval of generic counterparts of patented products." *Id.*

In 2012, the Federal Circuit again considered the scope of § 271(e)(1) in *Momenta*. Momenta, already a manufacturer of a generic version of enoxaparin, sued another drug manufacturer, Amphastar, which sought to bring its own generic version of enoxaparin to

market. See *Momenta*, 686 F.3d at 1351. Momenta claimed that Amphastar used one of Momenta's patented methods to test its drug for the presence of a particular non-naturally occurring sugar. *Id.* at 1352. Amphastar asserted that its testing was covered by § 271(e)(1), because it was required by the FDA "as a condition for the post-FDA approval sale of enoxaparin." *Id.* at 1352-53. The Court emphasized that the statutory language of the safe harbor mandated a broad interpretation of its coverage, noting that the Supreme Court "explicitly rejected the notion that § 271(e)(1) was limited 'to the activities necessary to seek approval of a generic drug.'" See *id.* at 1356 (quoting *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206, 125 S. Ct. 2372, 2383, 162 L. Ed. 2d 160 (2005)). If the alleged infringer "has a reasonable basis for believing' that use of the patented invention might yield information that 'would be appropriate to include in a submission to the FDA, that use is reasonably related to the development and submission of information under ... Federal law.'" *Id.* (quoting *Merck KGaA*, 545 U.S. at 207) (internal quotation marks omitted). Consistent with this broad view, the Court rejected any "artificial" distinction in the safe harbor's coverage between pre-FDA approval and post-approval activities. *Id.* at 1358-59.

The Court held that Amphastar's post-approval studies were covered by the safe harbor, because they were "reasonably related to the development and submission of information" under the FDCA. *Id.* at 1358-59. The Court distinguished *Classen*, which involved "routine[]" studies that "did not facilitate marketing a generic drug by 'expedit[ing] development of information for regulatory approval,'" from *Momenta* which involved information "necessary both to the

continued approval of the ANDA and to the ability to market the generic drug.” *See id.* at 1358. Amphastar’s studies were far from “routine,” because they were required to maintain FDA approval. *Id.*

Here, the results of Elan’s study were submitted to the FDA, pursuant to 21 C.F.R. § 10.30, in a Citizen’s Petition which requested that “the Commissioner of Food and Drugs [] require an acceptable *in vivo* bioequivalence study conducted under fasting and fed conditions as a requirement for approval of an abbreviated new drug application (ANDA) for a generic version of Skelaxin.” ECF No. 123-5 at 1. In addition, Elan included the results of the study in its sNDA to update Skelaxin’s label to account for the study’s findings. *See* ECF No. 123-7 at 1. As this Court held previously, these activities are “reasonably related to the submission of information under the FDCA.” ECF No. 166 at 5. That these activities occurred after Skelaxin’s FDA approval does not automatically remove them from the safe harbor. *See Momenta*, 686 F.3d at 1358-59.

Although, unlike the defendants in *Momenta*, Elan was not required to submit the study results to the FDA, *Momenta* did not hold that only information that the FDA “required” could be considered not “routine” under *Classen*. *See, e.g., id.* at 1356 (safe harbor not limited to activities required to obtain approval of a generic drug). Instead, *Momenta* emphasized that the safe harbor should be interpreted expansively. *See, e.g., id.* at 1356 (“‘Under a federal law’ extends beyond just the ‘most barebones information’ required by the FDA, and instead encompasses all ‘materials the FDA demands in the regulatory process.’” (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1683-84, 182 L. Ed. 2d 678

(2012)). Unlike the activities of the *Classen* defendants, which involved simply reporting their studies' results to the FDA,⁷ Elan's allegedly infringing study prompted its request for changes to the FDA approval process for generic versions of Skelaxin. See ECF No. 123-5 at 2. In other words, Elan's study "expedit[ed] development of information for regulatory approval" of a generic version of Skelaxin, an activity that the *Classen* court suggested was directly related to the purpose of the safe harbor, and, thus, presumably not "routine."⁸ See *Classen*, 659 F.3d at 1070; see also *Momenta*, 686 F.3d at 1358 (*Classen* holding based in part on fact that defendants did not "facilitate marketing a generic drug"). In addition, submission of the study results to the FDA was necessary to update the label to include the findings of that study,⁹ and thus according to *Momenta*, was not routine. See *Momenta*, 686 F.3d at 1358. Accordingly, because Elan's study resulted in submissions to the FDA that were not routine and were "reasonably related to the submission

⁷ See *Classen Immunotherapies, Inc. v. Biogen IDEC*, 381 F. Supp. 2d 452, 455 (D. Md. 2005) (GSK and Biogen argue that their study falls under the safe harbor, because the FDA "collects vaccine data from vaccine manufacturers after their vaccines have been approved").

⁸ Elan did not market a generic version of the drug, but the study altered the approval process for generic versions of Skelaxin produced by other manufacturers. See ECF Nos. 57-2 at 6, 123-6 at 1. *Classen* does not hold that the safe harbor is limited to actual generic manufacturers, see, e.g., *Classen*, 659 F.3d at 1070, and *Momenta* suggests that the only limits on the safe harbor is the requirement that the submission not be routine under *Classen* and that it be "pursuant to a federal law regulating the 'manufacture, use, or sale of drugs or veterinary biological products,'" see *Momenta*, 686 F.3d at 1357-59.

⁹ See ECF Nos. 123-1 at 4, 7 n. 3; 123-7 at 1-2.

of information under the FDCA,” *see* ECF No. 166 at 5, it was within the safe harbor after *Classen* and *Momenta*. Classen’s motion to reconsider the Court’s grant of summary- judgment to Elan will be denied.

2. Other Arguments

Other than Classen’s arguments that the *Classen* and *Momenta* decisions require this Court to vacate its previous grant of summary judgment to Elan, Classen makes no new arguments in its motion to reconsider. Instead, Classen simply resubmits the arguments it made in opposition to Elan’s motion for summary judgment. *Compare* ECF No. 138 at 5-28, *with* ECF No. 204-1 at 17-29. The Court will not grant a motion to reconsider based on arguments it has considered and rejected.¹⁰ Accordingly, the motion to reconsider will be denied.

III. Conclusion

For the reasons stated above, Classen’s motion will be granted in part and denied in part--the stay on this case will be lifted.

Date

William D. Quarles Jr.
USDJ

¹⁰ *See Pritchard*, 3 F. App’x at 53 (“When the motion raises no new arguments, but merely requests the district court to reconsider a legal issue or to ‘change its mind,’ relief is not authorized.”).

44a
United States District Court,
D. Maryland,
Northern Division.

CLASSEN IMMUNOTHERAPIES, INC., Plaintiff,
v.
KING PHARMACEUTICALS, INC., et al.,
Defendants.

No. CIV. WDQ-04-3521.
Aug. 16, 2006.

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Memorandum Opinion

QUARLES, District Judge.

Classen Immunotherapies, Inc. (“Classen”) has sued Elan Corporation, PLC, and Elan Pharmaceuticals, Inc. (“Elan”) for patent infringement. Elan has counterclaimed alleging noninfringement, unenforceability of Classen's patents, defamation, false light invasion of privacy and unfair competition. Pending are Elan's motions for summary judgment, for clarification, to seal, and for discovery. Also pending is

Classen's motion for partial summary judgment. For the following reasons, Elan's motion for summary judgment, for clarification, and to seal will be granted. Elan's motion for discovery and Classen's motion for partial summary judgment will be denied.

I. Background

Classen Immunotherapies, Inc. ("Classen") is a Maryland corporation that has developed and patented methods for identifying and commercializing new uses of existing drugs. Complaint, p. 1. Classen is the holder of Patents 6,219,674 B1, "System for Creating and Managing Proprietary Product Data" (the "674 patent"), and 6,584,472 B2, "Method, System and Article for Creating and Managing Proprietary Product Data" (the "472 patent"). *Id.*

Elan is an Irish pharmaceutical company. Until 2003, Elan produced Skelaxin, a muscle relaxant.

In 2001, Elan learned of a study, conducted by a generic drug manufacturer, that indicated that Skelaxin's rate of absorption differed inside and outside the body. Elan conducted its own study in July 2001, and found that food had a significant impact on Skelaxin's bioavailability. Browning Decl., Ex. 1. Based on these findings, Elan submitted a Citizen Petition to the FDA requesting that the FDA require drug manufacturers seeking approval of generic forms of Skelaxin to submit fed and fasted studies in Abbreviated New Drug Applications ("ANDA"). Elan also submitted a labeling supplement to its own New Drug Application ("NDA")¹ for Skelaxin that included the results of the study. *Id.* at Ex. 3.

The FDA granted Elan's request for a requirement of fed and fasted studies for all generic Skelaxin ANDAs and approved Elan's amendments to the Skelaxin product label. Browning Decl., Ex. 2,3. Elan was also ultimately granted patent numbers 6,407,128 and 6,683,102 on the relabeled Skelaxin. Goldman Decl, ¶ 4.

Classen alleges that Elan infringed the 472 and 674 patents when it: 1) studied the effect of food on the bioavailability of Skelaxin; 2) used the study data to identify a new use of the drug; and 3) commercialized the new use. Plaintiff's First Supplemental Response to Defendant Elan Pharmaceuticals Interrogatory No. 3. Elan has moved for summary judgment on Classen's claims.

Elan has counterclaimed, arguing that Elan did not infringe Classen's patents, the patents are unenforceable, and that Classen defamed Elan, invaded its privacy and damaged its business by issuing a false press statement and by claiming that Elan and Classen had an ongoing business relationship. Classen has moved for summary judgment on Elan's defamation, invasion of privacy and damage to business claims.

II. Elan's Motion for Summary Judgment

Under Rule 56(c), summary judgment is appropriate when there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). A dispute about a material fact is genuine “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106

S.Ct. 2505, 91 L.Ed.2d 202 (1986). In considering a motion for summary judgment, “the judge's function is not ... to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.” *Id.* at 249, 106 S.Ct. 2505. Thus, “the judge must ask ... whether a fair-minded jury could return a verdict for the [nonmoving party] on the evidence presented.” *Id.* at 252, 106 S.Ct. 2505.

The court must view the facts and reasonable inferences drawn therefrom “in the light most favorable to the party opposing the motion.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). However, the opposing party must produce evidence upon which a reasonable fact finder could rely. *Celotex Corp. v. Catrett*, 477 U.S. 317, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). The mere existence of a “scintilla” of evidence is insufficient to preclude summary judgment. *Anderson*, 477 U.S. at 252, 106 S.Ct. 2505.

Elan has moved for summary judgment arguing that even if its conduct fell within the scope of the 674 and 472 patents (which it does not concede), it is immune from patent enforcement under the “safe harbor” provision of the Patent Act, 35 U.S.C. § 271(e)(1), because the results of its research were submitted to the Food and Drug Administration (“FDA”). Classen argues in response that § 271(e)(1) is inapplicable to the patents and the conduct in question.

Under § 271, “whoever without authority makes, uses, offers to sell, or sells any patented invention...infringes the patent.” 35 U.S.C. § 271(a). Section 271(e)(1), however, provides that:

[i]t shall not be an act of infringement to make, use, offer to sell or sell...a patented invention...solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs....

35 U.S.C. § 271(e)(1).

The Supreme Court has interpreted § 271(e)(1) broadly, holding that the provision “extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA.” *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 125 S.Ct. 2372, 2380, 162 L.Ed.2d 160 (2005)(emphasis in the original). According to the Court, “there is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.” *Id.*

Even assuming that Elan employed Classen's patented process when it studied Skelaxin's bioavailability problem and used the results to repatent the drug, the results of the 2001 study were submitted to the FDA in Elan's Citizen Petition and labeling supplement to its NDA. Therefore, Elan's use of the patented process was reasonably related to the submission of information under the FDCA and so is protected under § 271(e)(1). Accordingly, Elan's motion for summary judgment will be granted.²

III. Classen's Motion for Partial Summary Judgment

In its December 12, 2005 order, the Court granted Elan's motion to amend its answer to add counterclaims for defamation, false light invasion of privacy and unfair competition. Classen has moved for partial summary judgment, arguing that Elan has failed to offer sufficient evidence in support of the new claims.

A. Defamation

Elan has alleged that Classen defamed Elan when it accused Elan of patent infringement in a November 29, 2004 press release; that the allegations are false; that Classen made the statement with malice or at least negligence; and that Elan's business reputation was harmed as a result. Elan has further alleged that Elan's business reputation was harmed when Classen claimed to have a business relationship with Elan in promotional materials sent to other pharmaceutical companies.

To recover for defamation under Maryland law, a plaintiff must establish that: 1) the defendant made a defamatory statement regarding the plaintiff to a third person; 2) the statement was false; 3) the defendant was legally at fault; and 4) the plaintiff was harmed as a result. *Holt v. Camus*, 128 F.Supp.2d 812 (D.Md.1999). A defamatory statement is one that tends to expose a person to public scorn, hatred, contempt or ridicule, thereby discouraging others in the community from having a good opinion of, or from associating or dealing with, that person. *Batson v. Shiflett*, 325 Md. 684, 722–723, 602 A.2d 1191 (Md.1992).

Classen has moved for summary judgment arguing that Elan has failed to prove that the press release was

false, that the statement was defamatory, that Classen was at fault and that Elan was harmed as a result.

As the Court has found that Elan did not infringe the Classen patent, Classen's accusation in the 2004 press release was false. Because Classen accused Elan of patent infringement, the accusation was a potentially defamatory statement. As Classen impugned Elan's business reputation, it has potentially defamed Elan *per se* and, therefore, harm is assumed. Whether Classen was legally at fault for making the statement (whether he made the statement with knowledge of its falsity or with reckless disregard of its falsity), remains a genuine issue in dispute. Accordingly, Classen's motion for summary judgment on Elan's defamation claim will be denied.

B. False Light Invasion of Privacy

To make a claim for false light invasion of privacy Elan must establish: (1) it was exposed to publicity that portrayed it in a false light; (2) a reasonable person would find the publicity highly offensive; and (3) Classen had knowledge of the falsity of the publicity or acted in reckless disregard of its truth or falsity. *Holt*, 128 F.Supp.2d 812.

In moving for summary judgment Classen again argues that the statements made in the press release were true. However, as noted above, the Court has found that Elan did not infringe the Classen patents and, therefore, the statements are false. As the release accuses Elan of patent infringement, a reasonable person might find the statements highly offensive. Additionally, as noted above, Classen's legal fault

remains in dispute. Accordingly, Classen's motion for summary judgment on the false light invasion of privacy counterclaim will be denied.

C. Unfair Competition

Unfair competition is generally defined as “damaging or jeopardizing another's business by fraud, deceit, trickery or unfair methods.” *Cavalier Mobile Homes, Inc. v. Liberty Homes, Inc.* 53 Md.App. 379, 454 A.2d 367 (1983); *Baltimore Bedding Corp. v. Moses*, 182 Md. 229, 34 A.2d 338 (1943).

Classen argues for summary judgment of Elan's claim of unfair competition on the grounds that its allegations of patent infringement are true. However, as the Court has found that Elan did not infringe the Classen patents, Classen's argument is without merit. Accordingly, Classen's motion for summary judgment of Elan's unfair competition claim will be denied.

D. Conclusion

For the reasons stated above, Classen's motion for partial summary judgment will be denied.

IV. Elan's Motions for Discovery

Elan's motion to add its counterclaims was granted on December 6, 2005. Discovery closed on December 16, 2005. Elan has now moved to reopen discovery for 45 days to answer Classen's motion for partial summary judgment pursuant to Rule 56(f), and in order to gather additional evidence for presentation at trial. Elan argues that it needs further discovery to substantiate

its counterclaims and because Classen has persistently refused to comply with discovery requests.

As the Court has denied Classen's motion for partial summary judgment, Elan's motion for additional discovery to answer Classen's motion pursuant to Rule 56(f) will be denied as moot.

As Elan failed to move for a continuation of discovery or to compel discovery between the time its motion to amend its answer was granted and the time discovery closed, the Court will not reopen the discovery process. Accordingly, Elan's motion for additional discovery to gather evidence to present at trial will be denied.

V. Elan's Motions to Seal

On May 11, 2005 the parties entered into a stipulated protective order regarding the confidentiality of discovery material. Under the protective order a party can designate material confidential if the person providing the material believes in good faith that it contains sensitive information, trade secrets or commercial information. Protective Order, ¶ 1(a). Motions filed with the Court that refer to or include information designated confidential are to be filed under seal. *Id* at ¶ 2. A designation of confidentiality may be challenged through a subsequent motion to the Court. *Id* at ¶ 5.

Elan has moved to seal: 1) its Opposition to Classen's Motion for Partial Summary Judgment; 2) its Reply in Support of its Motion for Summary Motion; 3) Classen's Motion for Partial Summary Judgment; and 4) Classen's Opposition to Elan's Motion for Summary Judgment.

Elan argues for sealing the motions in question on the grounds that they contain reference to and in some cases include, the deposition testimony of Perry Goldman, Nancy Santilli and Steve Cartt; testimony which Elan classified as confidential on November 16, 2005 and December 19, 2005. Elan has also moved to sanction Classen for its failure to abide by the terms of the protective order. Classen opposes the motions to seal arguing that Elan has failed to show that sealing is necessary.

As Classen failed to oppose the designation of Goldman's, Santilli's and Cartt's testimony as confidential, it cannot now oppose Elan's motion to seal or refuse to abide by the terms of the protective order. Accordingly, Elan's motion to seal: 1) its Opposition to Classen's Motion for Partial Summary Judgment; 2) its Reply in Support of its Motion for Summary Motion; 3) Classen's Motion for Partial Summary Judgment; and 4) Classen's Opposition to Elan's Motion for Summary Judgment will be granted.

VI. Motion for Clarification

On December 6, 2005, the Court granted summary judgment to defendant King Pharmaceutical ("King"). On December 20, 2005, the Court granted judgment to King. Elan has moved for clarification of the Court's December 20, 2005, order and requests that the Court: 1) declare that it was not granting King final judgment under Federal Rule of Civil Procedure Rule 54(b); and 2) strike Classen's improper notice of appeal.

As claims against Elan and Classen remained before the Court at the time, the Court's December 20, 2005,

order did not grant judgment for King under Rule 54(b). As the Federal Circuit has already dismissed Classen's appeal, Elan's request to strike Classen's notice of appeal is moot.

VII. Conclusion

For the reasons stated above, Elan's motion for summary judgment will be granted; its motions for additional discovery will be denied; its motions to seal will be granted; and its motion for clarification will be granted. Classen's motion for partial summary judgment will be denied.

Footnotes

¹Submitted pursuant to § 505(b) of the Federal Food, Drug and Cosmetic Act (“FDCA”).

²The Supreme Court in *Merck* specifically declined to rule on whether the use of “research tools” was protected under § 271(e)(1). *Merck*, 125 S.Ct. at 205, n. 7. Although the Classen process could be considered a “research tool” the Court finds extension of the safe harbor to cover the use of these tools warranted by the language of *Merck* and a plain reading of the statute.