IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY, Plaintiffs,	)	
v.	)	Civil Action No. 1:15-cv-10698-MLW Civil Action No. 1:16-cv-11117-MLW
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC., Defendants.	)	

JANSSEN'S MEMORANDUM IN SUPPORT OF ITS MOTIONS *IN LIMINE*

Plaintiff Janssen Biotech, Inc. moves *in limine* to: (1) exclude evidence or argument about the alleged price benefits to the public from Defendants' biosimilar product, describing Inflectra as a generic drug, or concerning Janssen's prices, revenues, and profits (MIL No. 1); (2) exclude evidence or argument regarding prior unrelated proceedings in this case and other patents relating to infliximab or methods for using infliximab (MIL No. 2); and (3) to exclude evidence or argument of non-infringement based on the presence of unclaimed ingredients as contrary to the Court's claim construction ruling (MIL No. 3).

I. JANSSEN'S MIL NO. 1: TO EXCLUDE EVIDENCE OR ARGUMENT ABOUT THE ALLEGED PRICE BENEFITS TO THE PUBLIC FROM DEFENDANTS' BIOSIMILAR PRODUCT, DESCRIBING INFLECTRA AS A GENERIC DRUG, OR CONCERNING JANSSEN'S PRICES, REVENUES, AND PROFITS

At trial, Defendants should not be able to offer evidence or argument: (a) that their biosimilar drug would benefit the public by being available at a lower price than Remicade or competing with Remicade; (b) referring to Inflectra as a generic drug; or (c) concerning Janssen's prices, revenues, or profits on Remicade. Such evidence and argument would not be relevant to any issue in this case and would only serve to prejudice the jury. It should be excluded under Federal Rules of Evidence 402 and 403.

In the liability phase of this case, there are only two issues for the jury to resolve: (1) "whether all of the claim limitations [of claim 1 of the '083 patent] are present [in the accused cell media], either literally or by a substantial equivalent," *Innovation Toys, LLC v. MGA Entertainment, Inc.*, 637 F.3d 1314, 1318-19 (Fed. Cir. 2011); and (2) Defendants' liability for that infringement, either as direct infringers under 35 U.S.C. § 271(a), as inducers under 35 U.S.C. § 271(b), or vicariously by reason of their participation in a joint enterprise. The evidence in issue on this motion has no relevance to either issue.

The concern addressed by this motion often arises in patent cases when a defendant wants to present evidence that its product would benefit the public by increasing competition and being available at a lower price than the plaintiff's patented product. Such evidence has no relevance to the issues of patent infringement or validity, and thus is inadmissible under Rules 401 and 402. *See, e.g.*, *PDL Biopharma, Inc. v. Sun Pharm. Indus.*, No. 07-CV-1788, 2008 U.S. Dist. LEXIS 105464, at *10-11 (D.N.J. Dec. 11, 2008) (excluding such evidence as "not relevant to any claim or defense asserted by [the parties]"); *Abbott Labs. v. Sandoz, Inc.*, 743 F. Supp. 2d 762, 778 (N.D. Ill. 2010) (granting motion *in limine* to "exclude as irrelevant and prejudicial any evidence or argument regarding the general benefits of generic drugs over branded drugs" and precluding defendants "from extolling the benefits of generic drug pricing"); *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., USA*, No. 07-CV-5855, 2011 U.S. Dist. LEXIS 10512, at *7-8 (D.N.J. Feb. 3, 2011) (excluding evidence of the benefits of generic drug pricing).

For the same reason, Defendants and their witnesses should not be permitted to refer to Inflectra as a generic drug, or to refer to Janssen's prices, revenues, or profits on Remicade. Members of the public are aware that generic drugs are sold at much lower prices than brand-name drugs. But Inflectra is not a generic drug; it is a biosimilar. There is no point in referring to it as a generic drug other than to imply what should not be stated: that Inflectra should be on the market in order to provide lower cost drugs to the public. In the liability phase of this case, the pricing and profits for the parties' products have no bearing on any issue.

In addition to its lack of probative value, evidence or argument about pricing for the parties' products also should be excluded under Fed. R. Evid. 403 because of its prejudicial nature. Testimony or argument about the pricing of brand name pharmaceutical product and alleged benefits to the public of generic drugs and biosimilars is an "emotionally-charged and

potentially politically-divisive topic[]" whose relevance, even in the damages context, "is substantially outweighed by the danger of unfair prejudice under [Fed. R. Evid.] 403." *PDL Biopharma*, 2008 U.S. Dist. LEXIS 105464, at *10-11; *see also Abbott Labs*, 743 F. Supp. 2d at 778 (such evidence "conjure[s] negative stereotypes of branded pharmaceutical companies and appeal[s] to the popular concern about the perceived role of such companies in contributing to the rising cost of healthcare.").

Referring to Inflectra as a form of generic competition to Remicade would be especially prejudicial because it would likely lead jurors to overestimate the actual cost benefits of Inflectra (which as noted above are irrelevant in any event). Inflectra is being introduced at a 15% list-price discount to Remicade and the difference in true price after rebates may be smaller.[1] Because there are very few biosimilars on the market, however, jurors would be likely to assume incorrectly that Inflectra's price differential is analogous to those of small-molecule generic drugs, which are typically sold at much larger discounts to name-brand drugs, often on the order of 80% or more.[2] This misimpression would amplify the prejudice of allowing irrelevant information and argument about the pricing or "generic" nature of Inflectra.

Defendants should accordingly be barred from offering evidence or argument about the alleged benefits to the public from Defendants' biosimilar drug, describing Inflectra as a generic drug, or concerning Janssen's prices, revenues, or profits.

[1] *See* National Public Radio, "Small Savings For Drugs Made To Mimic Biotech Blockbusters," *available at* http://www.npr.org/sections/health-shots/2016/10/19/498559386/small-savings-for-drugs-made-to-mimic-biotech-blockbusters.

[2] *See id.*

II. JANSSEN'S MIL NO. 2: TO EXCLUDE EVIDENCE OR ARGUMENT REGARDING PRIOR UNRELATED PROCEEDINGS IN THIS CASE AND PATENTS COVERING INFLIXIMAB OR METHODS OF USING INFLIXIMAB

Defendants should be barred from offering evidence or argument regarding: (a) prior unrelated proceedings in this case, including this Court's decisions granting summary judgment that the asserted claims of the '471 patent are invalid for obviousness-type double patenting; and (b) patents covering infliximab or methods of using infliximab.

This Court's ruling on obviousness-type double patenting for the asserted claims of the '471 patent has no bearing whatsoever on any issue here. The '471 patent covers a different invention than the '083 patent, and it is not the subject of the upcoming trial. The Court's earlier ruling on the validity of the '471 patent has no bearing on "whether all of the claim limitations [of claim 1 of the '083 patent] are present [in the accused cell media], either literally or by a substantial equivalent," *Innovation Toys, LLC v. MGA Entertainment, Inc.*, 637 F.3d 1314, 1318-19 (Fed. Cir. 2001), or on Defendants' liability for that infringement. Evidence or argument concerning that ruling and other pre-trial rulings has no probative value and does not meet the standards for relevant evidence under Rule 402. *See FujiFilm Corp. v. Motorola Mobility LLC,* No. 12-cv-03587-WHO, 2015 U.S. Dist. LEXIS 35236, at *18-19 (N.D. Cal. Mar. 19, 2015) (granting motion *in limine* to "[p]reclude parties from making reference to any prior rulings by the Court").

Evidence concerning the '471 patent generally, or Janssen's other patents covering infliximab or methods of using infliximab, are similarly irrelevant and should also be excluded. *See Read Corp. v. Portec, Inc.*, 748 F. Supp. 1089, 1101-02 (D. Del. 1990), *aff'd in relevant part, rev'd in part on other grounds*, 970 F.2d 816 (Fed. Cir. 1992) (finding "no error" in the

court's *in limine* ruling "exclud[ing] evidence from the trial concerning two other patents owned by the plaintiffs . . . [where] the plaintiffs were not asserting any claims concerning these patents" and "such evidence therefore was irrelevant to the disputes concerning the '194 and '836 patents.").

Even if there were some relevance to evidence about other patents, or about the Court's prior rulings, *e.g.*, on obviousness-type double patenting for the '471 patent, such evidence would create a "sideshow," "caus[ing] undue prejudice, jury confusion, and waste of time," and therefore be inadmissible under Rule 403. *Advanced Tech. Incubator, Inc. v. Sharp Corp.*, No. 5:09-CV-135, 2010 U.S. Dist. LEXIS 145630, at *7 (E.D. Tex. Mar. 31, 2010). Indeed, Defendants have repeatedly introduced arguments to the Court regarding the '083 patent by referring to the invalidation of the '471 patent and suggesting that the '083 patent is not as important as the '471 patent. *See, e.g.*, Dkt. No. 265, at 1; Dkt. No. 340, at 1. Such arguments would do nothing but prejudice the jury and are improper. Under Rules 402 and 403, the Court should exclude evidence and argument on these topics.

III. JANSSEN'S MIL NO. 3: TO EXCLUDE EVIDENCE OR ARGUMENT OF NON-INFRINGEMENT BASED ON THE PRESENCE OF UNCLAIMED INGREDIENTS AS CONTRARY TO THE COURT'S CLAIM CONSTRUCTION RULING

Last year, Defendants contended that the term "cell culture media" in claim 1 of the '083 patent should be construed as limited to "chemically defined" or "protein-free" media and therefore not to cover cell culture media like the Defendants' that include unclaimed ingredients that are not chemically defined or are proteins. Dkt. No. 145, at 2-3. The Court ruled in Janssen's favor, construing the term "cell culture media" in claim 1 as meaning "nutritive media for culturing cells." Dkt. No. 226, at 5-6. Based on the Court's construction, Defendants should

not be permitted to make arguments or introduce evidence implying that the presence of unclaimed ingredients is indicative of non-infringement. Such evidence and arguments are inadmissible under Fed. R. Evid. 402 or 403, as they are both irrelevant and likely to confuse a jury.

During claim construction proceedings, the parties agreed that the accused Celltrion Media were not chemically defined and were not protein-free, and that as a result, Defendants' proposed claim construction would have excluded its media because of the presence unclaimed ingredients. Dkt. No. 145, at 2-3. Janssen, by contrast, argued that the term "cell culture media" should be construed to include any "nutritive media for culturing cells," and that because the claim is a "comprising" claim, the presence of unclaimed ingredients on top of the claimed formula was irrelevant to infringement. Dkt. No. 149, at 7-9, 11; Dkt. No. 162-1, at 7-8.

Following briefing and oral argument, the Court adopted Plaintiffs' proposed construction, expressly rejecting Defendants' argument that the claim should be construed to exclude their media merely because they include unclaimed proteins and chemically undefined ingredients. Dkt. No. 233 (8/17 Hearing Tr.), at 105, 115. In so doing, the Court affirmed that claim 1 is an open-ended claim that covers products that meet the claim elements regardless of the presence of extra unclaimed ingredients. *See id.*

In view of this ruling, Defendants should not be permitted to present any evidence or make any argument that would suggest or imply to the jury that the presence of unclaimed ingredients in its media is relevant to infringement of the patent claims. Such evidence or argument would directly contradict the Court's claim construction and be contrary to the language of claim 1.

Courts in this district and elsewhere routinely exclude evidence and argument that are contrary to, or inconsistent with, the court's claim construction ruling. *See, e.g.*, *Smith & Nephew, Inc. v. Interlace Med., Inc.*, No. 10-10951-RWZ, 2012 U.S. Dist. LEXIS 115791, at *4 (D. Mass. Aug. 17, 2012) (granting motion *in limine* to "exclude argument or evidence that is inconsistent with the court's claim construction"); *Colassi v. Cybex Int'l, Inc.*, No. 02-11909-RWZ, 2005 U.S. Dis. LEXIS 17045, at *4-5 (D. Mass. Aug. 16, 2005) ("Plaintiff shall not offer evidence or argue in a manner inconsistent with the court's claim construction . . . ."); *see also, e.g.*, *Multimedia Patent Trust v. Apple Inc.*, No. 10-CV-2618-H (KSC), 2012 U.S. Dist. LEXIS 191199, at *17 (S.D. Cal. Nov. 20, 2012) (same); *Hypertherm, Inc. v. Am. Torch Tip Co.*, No. 05-cv-373-JD, 2009 U.S. Dist. LEXIS 17821, at *6-7 (D.N.H. Feb. 19, 2009) (same).

Similarly, it is black-letter law that "comprising" in patent law means "including but not limited to." *See, e.g.*, *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009) ("comprising" is "well understood in patent law to mean 'including but not limited to'"). Claim 1, a "comprising" claim, therefore reads on cell culture media that include all of the claim's required ingredients, regardless of the presence of additional ingredients. Any suggestion that the presence of unclaimed ingredients is relevant to infringement would be contrary to the law in addition to being contrary to the Court's claim construction ruling. Furthermore, any marginal relevance of such evidence or argument would be far outweighed by its potential to confuse the jury. *See, e.g.*, *United States v. Pierre*, 599 F.3d 19, 23 (1st Cir. 2010) (excluding expert testimony offered to establish legally impermissible defense under Rule 403 due to its potential to confuse and mislead).

The Court should therefore preclude Defendants from introducing evidence and making arguments of non-infringement based on the presence of unclaimed ingredients in the accused products.

CONCLUSION

For the reasons set forth above, this Court should grant Janssen's motions *in limine* Nos. 1, 2, and 3.

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/s/ Alison C. Casey

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CERTIFICATE OF SERVICE

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/s/Alison C. Casey
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