IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY Plaintiffs, v. CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC. Defendants.	**Civil Action No. 1:15-cv-10698** **Civil Action No. 1:16-cv-11117** **CONFIDENTIAL - FILED UNDER SEAL** REQUEST FOR ORAL ARGUMENT

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION *IN LIMINE* NO. 2: TO PRECLUDE EVIDENCE AND ARGUMENT REGARDING REMICADE®

I. INTRODUCTION

Janssen seeks to introduce evidence at trial pertaining to its multi-billion-dollar infliximab drug Remicade®, which now has nothing to do with this case. The Court should thus exclude any evidence and argument regarding Remicade®, including, for example, information about what conditions it treats, how it benefits patients, its sales, and the expense of development.

The '471 patent covering the infliximab antibody is no longer in the case. The only remaining patent, the '083 patent, relates to "a soluble composition, suitable for producing a cell culture media"—food for cells grown in culture. (No. 16-11117, Dkt. 1, Ex. A at Claim 1.) The '083 patent has nothing to do with Remicade®. As the Court has recognized, "[i]n contrast to the '471 patent, the '083 patent does not include any reference to infliximab," and as Janssen admits, ***it "does not use an embodiment of the '083 patent in the production of Remicade®."*** (Dkt. 249 at 4; Ex. 1, Janssen's Reponses to Defendants' First Set of Requests for Admission at 4-5

(emphasis added).) Thus, the issues the jury will be asked to decide—whether the claims of the '083 patent directed to "[a] soluble composition, suitable for producing a final volume of cell culture media" are infringed and whether those claims are invalid—do not require the jury to know anything about Remicade®. (No. 16-11117, Dkt. 1, Ex. A at Claim 1.)

Introducing evidence about Remicade® also risks confusing the issues and leading jurors to draw conclusions that unfairly prejudice Defendants, and will waste time. Evidence about Remicade® thus should be excluded under Federal Rules of Evidence 401-403. Further, evidence or argument suggesting that Defendants made Inflectra® similar to Remicade® or "copied" Remicade® should also be excluded under Rule 404 as improper character evidence that risks a prejudicial inference that Defendants "copied" or were more likely to have "copied" the '083 patent.

II. LEGAL STANDARD

"The essential prerequisite of admissibility is relevance." *U.S. v. Lamberty*, 778 F.2d 59, 60 (1st Cir. 1985); *see also* Fed. R. Evid. 402. "Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. "[A] district court's relevancy determination" is reviewed "for abuse only." *Fernandez v. Leonard*, 963 F.2d 459, 465 (1st Cir. 1992), *modified* (May 29, 1992).

Under Federal Rule of Evidence 403, "[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. "[E]ven where the evidence may shed light on the disputed issues, the district judge can find the 'untoward effects of the proffered evidence' to be so weighty that the evidence should be excluded." *Galarneau v. Merrill Lynch*, 504 F.3d

189, 205 (1st Cir. 2007) (citation omitted). "Rule 403 allows the exclusion of evidence which, though relevant, carries unwanted baggage, such as unfair prejudice or potential juror confusion." *Williams v. Drake*, 146 F.3d 44, 48 (1st Cir. 1998).

Under Rule 404, "prior acts may not be admitted to prove that a person acted in a similar fashion in the case at hand." *Lataille v. Ponte*, 754 F.2d 33, 35 (1st Cir. 1985); *see also* Fed. R. Evid. 404(b) ("Evidence of a crime, wrong, or other act is not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character."); Fed. R. Evid. 404(a). "Character evidence is of slight probative value and may be very prejudicial." Fed. R. Evid. 404 advisory committee's note to 1972 proposed rules. "Evidence offered under [the exceptions to] Rule 404(b) must also be specifically determined to be more probative than it is prejudicial." *Lataille*, 754 F.2d at 36.

III. EVIDENCE ABOUT REMICADE® IS NOT RELEVANT

Janssen initially asserted six patents against the Defendants. (Dkt.[1] 1 at Count 3–Count 8.) One of those patents, the '471 patent, "covers the infliximab…antibody itself." (*Id*. at ¶ 41.) The '471 patent, however, has been found invalid on multiple grounds.[2] (Dkt. 226 at 1-2.) Janssen's lone remaining patent, after a series of dismissals, is the '083 patent, entitled "Chemically Defined Media Compositions." (No. 16-11117, Dkt. 1, Ex. A, '083 Patent at Title.) The '083 patent describes a cell culture media composition "for the culture of eukaryotic cells" of "insect, avian, mammalian, or other origins." (*Id*. at 4:30-33.) It claims "[a] soluble composition" that may be used "in the culture of eukaryotic cells"—in short, cell food. (*Id.* at

[1] Unless otherwise noted, docket citations refer to Civ. No. 15-10698.

[2] On November 14, 2016, the United States Patent Office Patent Trial and Appeal Board affirmed a patent examiner's final rejection of claims 1-7 of the '471 patent in an *ex parte* reexamination proceeding. (Ex. 2, *Ex Parte Janssen Biotech, Inc. et al.*, Appeal 2016-006590, PTAB Order dated 11/14/2016.)

10:49, 4:30-31.) The patent "does not include any reference to infliximab." (Dkt. 249 at 4; *id*. at 12; No. 16-11117, Dkt. 1, Ex. A.)

"Janssen does not use an embodiment of the '083 patent in the production of Remicade®" and "has not used an embodiment of the soluble compositions recited in claims 1 or 2 of the '083 patent in the production of Remicade® for commercial sale in the United States." (Ex. 1, Janssen's Reponses to Defendants' First Set of Requests for Admission at 4-5.) [redacted] (Ex. 3, Epstein Dep. Tr. at 35:22-37:14.) In fact, Remicade® was on the U.S. market for ***six years*** before Janssen's predecessor-in-interest Centocor even filed the provisional application for the '083 patent. (Dkt. 1 at ¶ 35; No. 16-11117, Dkt. 1, Ex. A.) The only issues the jury will be asked to determine at trial relate to Defendants' alleged infringement, and the invalidity, of patent claims covering cell food—cell food that Janssen does not even use for its drug product. Evidence about Remicade® thus does not have "any tendency to make a fact" that is "of consequence" "more or less probable than it would be without the evidence." Fed. R. Evid. 401.[3]

Janssen apparently wants to present evidence that "Remicade® was one of the first drugs of its kind sold in the United States for treatment of a chronic disease," that "Janssen has spent hundreds of millions of dollars in research and development of [Remicade®]," and that the drug "ha[s] been used to treat and improve the lives of more than 2.2 million patients." (No. 16-11117 Dkt. 1 at ¶¶ 32, 40, 41.) But "evidence of 'good corporate character,' such as a comment about how many lives are saved per minute by [plaintiff's] products, is irrelevant to any issue

[3] Janssen seems to agree that the Court should exclude at least ***some*** evidence about infliximab, because it has proposed its own motion *in limine* seeking to preclude evidence and argument about the "economic benefits, consequences, or implications" of Defendants' infliximab drug. (Ex. 4, Email from A. Fischer to E. Cutri dated 12/29/16.)

that the jury will be asked to decide and, hence, not admissible under Rules 401 and 402." *Medtronic, Inc. v. Boston Sci. Corp.*, No. 99-1035, 2002 WL 34447587, at *45 (D. Minn. Aug. 8, 2002); *see also Beane v. Util. Trailer Mfg. Co.*, No. 10-0781, 2013 WL 869380, at *4 (W.D. La. Mar. 7, 2013) (evidence of defendant's "corporate character" was "not relevant"); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & PMF Prod. Liab. Litig.*, No. 09-10012, 2011 WL 6740391, at *16 (S.D. Ill. Dec. 22, 2011) (precluding party from arguing that its drugs "greatly benefited society").

Janssen also should not be permitted to introduce evidence or argument, like it has done once already in these proceedings, about Celltrion's efforts to make Inflectra® similar (or more properly, biosimilar) to Remicade®. (*See* Dkt. 282 at ¶ 8.) Even in a case in which a drug product is at issue, evidence about making a "generic" or follow-on drug similar or bioequivalent to the reference drug is "irrelevant to patent law." *See, e.g.*, *Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1348 n.3 (Fed. Cir. 2008) ("FDA equivalence is irrelevant to patent law because it involves fundamentally different inquiries"). Here, there is ***no allegation that Inflectra® infringes***, making any arguments or evidence about Inflectra® compared to Remicade® even further afield of the issues.

Evidence and argument about Remicade® should be excluded under Rules 401 and 402.

IV. ANY MINIMAL PROBATIVE VALUE OF REMICADE® EVIDENCE IS SUBSTANTIALLY OUTWEIGHED BY RISK OF CONFUSION, UNFAIR PREJUDICE, AND WASTE OF TIME

The evidence also should be excluded under Rule 403. If the jury is permitted to hear evidence and argument regarding Remicade®—for example, information about what conditions it treats, how it benefits patients, the efforts and expense to develop the drug, *etc*.—they are likely to become confused and believe that there is a relationship between Remicade® and the '083 patent. Jurors are likely to believe, for example, that the '083 patent media compositions

form some part of Remicade®, or are required for Remicade® to be made. Any such belief would be the result of juror confusion, and would be factually incorrect.

Janssen has already injected such confusion into these proceedings. As part of summary judgment briefing, Janssen pointed to testimony from Celltrion witness Soo Young Lee, and told the Court that [redacted] (Dkt. 282 at ¶ 8.) In doing so, Janssen led the Court to believe that Celltrion "instructed HyClone to make at least some changes to improve the similarity of the infliximab drug made with Celltrion's media to ***Janssen's drug made with the patented media***." (Ex. 5, 12/22/16 Hearing Tr. at 12:18-21 (emphasis added).)

This is not correct. Janssen's drug is ***not*** made with the patented media. The risk of jurors being confused and coming to the same mistaken conclusion as the Court is high. Such confusion would be unfairly prejudicial to Defendants because it would link the '083 patent and infliximab even though no such link exists, and would risk jurors attributing perceived value or benefits of Remicade® to the '083 patent.

Evidence or argument regarding Celltrion's attempt to make Inflectra® similar to Remicade® is especially prejudicial. Allowing Janssen to argue that Celltrion sought to mimic or "copy" Remicade® may wrongly and unfairly mislead the jury into thinking Celltrion did something wrong by creating a biosimilar version of Remicade®. There is no such claim in the case, of course. If Janssen were to try to make such an argument, Defendants would need to explain to the jurors the complex statutory process designed to ***encourage*** exactly what Celltrion did—that is, apply to market a less expensive biosimilar product.

Moreover, the '471 "antibody patent" has been invalidated by this Court and the Patent Office. Evidence and argument regarding Celltrion's attempt to make Inflectra® similar to Remicade® risks the jury believing that Celltrion unlawfully "took" Janssen's infliximab antibody and rendering a verdict based on that non-existent "infringement" of Remicade®. *See Cooper Indus., Inc. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 441 (2001) ("But, as the Court of Appeals correctly held, such copying of the functional features of an unpatented product is lawful.").

Janssen contends that evidence about Remicade® is relevant for the background and history of this case. But information about Janssen's and the Defendants' roles within the biosimilars regime is entirely unnecessary for the jurors to pass on the questions of infringement and invalidity of the '083 patent. "[P]urported character or 'background' evidence" presents "a considerable degree of potential undue prejudice" and an "effort to pander" to the jury. *M-Edge Accessories LLC v. Amazon.com Inc.*, No. 11-3332, 2015 WL 403164, at *17 (D. Md. Jan. 29, 2015), *appeal dismissed* (June 11, 2015).

Lastly, evidence related to Remicade® would unnecessarily take up the Court's and jurors' time. *Cf. Stathos v. Bowden*, 728 F.2d 15, 19 (1st Cir. 1984) (affirming exclusion of evidence in an employment action concerning defendants' actions at other plants, as "[e]vidence of what happened at other plants, if relevant at all, is so tangential to the case as tried as to be excludable as a 'waste of time'. . ."). And even if all the various forms of confusion about the non-existent relationship between the '083 patent and Remicade® could be successfully dispelled by the Defendants, to do so would waste more time.

The dangers of unfair prejudice, confusion of the issues, and wasting time require exclusion under Rule 403. *Williams*, 146 F.3d at 48.

V. EVIDENCE ABOUT DEFENDANTS' EFFORTS TO MAKE INFLECTRA® "SIMILAR" TO REMICADE® IS INADMISSIBLE CHARACTER EVIDENCE

Evidence or argument that Celltrion developed a drug product that was similar to Remicade®, or that it engaged in any efforts to make its Inflectra® product more similar to Remicade®, is independently inadmissible as improper propensity evidence under Federal Rule of Evidence 404. "Evidence of a[n]…act is not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character." Fed. R. Evid. 404(b)(1); *see also* Fed. R. Evid. 404(a)(1). Although there is no claim in this case that creating a biosimilar version of Remicade® was in and of itself wrong or illegal (it was not), Janssen should not be permitted to allege that Celltrion "copied" Remicade®, thereby creating an inference that Celltrion was more likely to have "copied" Janssen in some other respect—*i.e.*, by infringing its '083 patent. "It is well settled that prior acts may not be admitted to prove that a person acted in a similar fashion in the case at hand." *Lataille*, 754 F.2d at 35.

Any whiff of purported "copying" would be seriously prejudicial to Defendants. It is well recognized that "there is significant prejudice associated with [copying] evidence, as a jury may use evidence of copying to unfairly conclude that Defendant's products *infringe* the patents-in-suit . . . even though the two analyses must necessarily be distinct." *Finjan, Inc. v. Blue Coat Sys., Inc.*, No. 13-03999, 2015 WL 4129193, at *6 (N.D. Cal. June 8, 2015) (emphasis in original). The term "copying" also carries a connotation of unsavory practices and is often used by patentees to "portray an accused infringer in the most negative light." Kenneth R. Adamo, *et al., The Curse of "Copying,"* 7 J. Marshall Law Rev. Intell. Prop. L. 296, 297 (2008). "In jury cases, the term is doubly damning, in that a juror's everyday experience, stemming from earliest school days, generates the lay biases and pejorative flavor the word 'copy' carries." *Id.*

Evidence and argument about efforts to make Inflectra® "similar" to Remicade® should be excluded under Rule 404.

VI. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant Defendants' motion *in limine* regarding Remicade®.

Dated: January 12, 2017

Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc.

By: */s/*Andrea L. Martin

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CERTIFICATE OF SERVICE

I, Andrea L. Martin, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on January 12, 2017.

/s/Andrea L. Martin, Esq.
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Defendants' Motion *in Limine* No. 2 Exhibit 1

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**
	)	
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC.	)	
Defendants.	)	
	)	

PLAINTIFFS JANSSEN BIOTECH, INC. AND NEW YORK UNIVERSITY'S OBJECTIONS AND RESPONSES TO DEFENDANTS' FIRST SET OF REQUESTS FOR ADMISSION

Pursuant to Rule 36 of the Federal Rules of Civil Procedure and Rule 36.1 of the Local Rules of the United States District Court for the District of Massachusetts, Plaintiffs Janssen Biotech, Inc. and New York University (collectively, "Janssen") hereby submit these objections and responses to the First Set of Requests for Admission (the "Requests") served by Defendants Celltrion Healthcare Co. Ltd., Celltrion, Inc., and Hospira, Inc. (collectively, "Defendants").

GENERAL OBJECTIONS

Janssen makes the following General Objections, whether or not separately set forth in response to each request, to each and every instruction, definition, and question posted in the Requests for Admission:

1. Janssen objects to each Request to the extent that it seeks information protected by the attorney-client privilege, work-product immunity, common interest or joint defense privilege or any other applicable privilege or protection as provided by any applicable law.

Request No. 2

Admit that the ingredient "Insulin-Human Recombinant, Zn (ADCF) (USP/EP)" contained in HyClone's Cell Media is a protein.

Response to Request No. 2

Admitted.

Request No. 3

Admit that the ingredient "Insulin-Human Recombinant, Zn (ADCF) (USP/EP)" contained in HyClone's Cell Media is a recombinant protein.

Response to Request No. 3

Admitted.

Request No. 4

Admit that the ingredient "IGF1 W/O BSA (ADCF)" contained in HyClone's Cell Media is a protein.

Response to Request No. 4

Admitted.

Request No. 5

Admit that the ingredient "IGF1 W/O BSA (ADCF)" contained in HyClone's Cell Media is a recombinant protein.

Response to Request No. 5

Admitted.

Request No. 6

Admit that "Janssen does not use an embodiment of the '083 patent in the production of Remicade." *See* Jan 14, 2016 Ltr. from A. Cohen.

Response to Request No. 6

Admitted.

Request No. 7

Admit that Janssen has not used an embodiment of the soluble compositions recited in claims 1 or 2 of the '083 patent in the production of Remicade® for commercial sale in the United States.

Response to Request No. 7

Admitted.

Request No. 8

Admit that Janssen has not received approval from the FDA to use an embodiment of the soluble compositions recited in claims 1 or 2 of the '083 patent in the production of Remicade® for commercial sale in the United States.

Response to Request No. 8

Admitted.

Dated: May 31, 2016

Respectfully Submitted,

/s/ Aron Fischer

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Defendants' Motion *in Limine* No. 2 Exhibit 2

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY
Patent Owner and Appellant

Appeal 2016-006590
Reexamination Control 90/012,851
Patent 6,284,471 B1
Technology Center 3900

Before ROMULO H. DELMENDO, RICHARD M. LEBOVITZ, and JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on an appeal by Patent Owner from the Examiner's final rejection of claims 1–7 in the above-identified *ex parte* reexamination of U.S. Patent No. 6,284,471 B1. The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134(b), and 306.

We affirm.

BACKGROUND

This appeal involves U.S. Patent No. 6,284,471 B1 ("the '471 Patent") which issued September 4, 2001. A Request for Reexamination was filed by Phillip M. Pippenger of Miller, Matthias & Hull LLP purporting to represent a Third-Party Requester on April 29, 2013 pursuant to 35 U.S.C. §§ 302–307 and 37 C.F.R. § 1.510.

The real parties-in-interest are identified in the Appeal Brief ("Appeal Br.") as the patent owners, namely Janssen Biotech, Inc. and New York University (collectively referred to as "Patent Owner"). Appeal Br. 1. The '471 Patent is the subject of litigation in district court,[1] which is summarized in the Appeal Brief. *Id.* at 2–3.

The claims in the '471 Patent subject to reexamination are directed to a chimeric antibody capable of binding to human tumor necrotic factor TNFα. TNFα is a polypeptide produced in humans which has pro-inflammatory activity. '471 Patent, col. 1, ll. 45–53. The claimed chimeric antibody to TNFα is a chimera, or mixture, of human and non-human regions of immunoglobulin. The non-human immunoglobulin variable region in the chimeric antibody has specific amino acid sequences of SEQ ID NO: 3 and 5 which are encoded by the nucleic acid sequences of SEQ ID NO: 2 and 4, respectively. '471 Patent, col. 7, ll. 19–24, col. 87–92. The anti-TNFα antibody having the sequences recited in the claims is present in

[1] A Motion for Summary Judgement of Invalidity of the '471 Patent was decided in favor of defendants, the court holding that the '471 Patent is invalid. Memorandum and Order of Aug. 19, 2016 in the U.S. District Court of Massachusetts (D.J. Wolf). *Janssen Biotech, Inc. et al. v. Celltrion Healthcare Co., Inc.*, Case No. 1:15-cv-10698-MLW (D. Mass.) (Doc. 226).

Remicade®, an FDA-approved drug to treat Crohn's disease and rheumatoid arthritis. Declaration of John Ghrayeb, Ph.D. ¶¶ 5, 9, 14. According to Dr. Ghrayeb, as of 2013, Remicade® "generate[d] annual sales in excess of $6 billion across all of its indications." *Id.* ¶ 15.

This appeal involves obviousness-type double-patenting rejections. The anti-TNF chimeric antibody of claims 1–7 in the '471 Patent stand rejected by the Examiner under the doctrine of obviousness-type double-patenting as obvious in view of the claims of the commonly-owned U.S. Patent Nos. 5,656,272 ("the '272 Patent") (patented Aug. 12, 1997) and 5,698,195 ("the '195 Patent") (patented Dec. 16, 1997).[2] Ans. 2–5. Patent Owner appeals from the Examiner's final rejection of the '471 Patent claims.

The '471 Patent issued from U.S. Patent Application No. 08/192,093 ("the '093 Application"). The '093 Application states that it is a continuation-in-part ("CIP") application of U.S. Patent Application Nos. 08/010,406 (filed 01/29/1993) ("the '406 Application") and 08/013,413 (filed 02/02/1993) ("the '413 Application"). The '413 Application is, itself, a CIP of three additionally listed applications.

The '272 Patent issued from U.S. Patent Application No. 08/192,102 ("the 102 Application"), filed 02/04/1994, which (like the '471 Patent) is a CIP of the '406 and '413 Applications.

The '195 Patent issued from U.S. Patent Application No. 08/324,799 ("the '799 Application"), filed 10/18/1994, which is a CIP of the '093 (the '471 Patent) and the '102 (the '272 Patent) Applications.

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[2] Claims 2 and 4 are rejected over the claims of the '272 or '195 Patents in combination with other references.

An oral hearing before the PTAB panel was held September 28, 2016. A transcript will be entered into the record in due course.

Claim 1 of the '471 Patent is representative and is reproduced below:

> 1. A chimeric antibody comprising at least part of a human immunoglobulin constant region and at least part of a non-human immunoglobulin variable region, said antibody capable of binding an epitope specific for human tumor necrosis factor TNFα, wherein the non-human immunoglobulin variable region comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5.

The two recited sequences define the heavy and light chains, respectively, of the chimeric cA2 antibody. Appeal Br. 4.

Patent Owner did not argue the claims separately. Patent Owner also did not argue the obviousness-type double-patenting rejections over the '272 and '195 Patents separately (*see* App. Br., generally; Final Act. 6–8 (Rejections 2, 3, 4)). Consequently, we have considered all three rejections together and have focused entirely on claim 1. Claims 2–7 fall with claim 1.

The '195 Patent has claims to treating rheumatoid arthritis comprising administering an anti-TNF chimeric antibody. The '272 Patent has claims to treating Crohn's disease comprising administering an anti-TNF chimeric antibody. Both the '272 and '195 Patents have expired. The '471 Patent, with claims to the chimeric antibody, itself, was patented about four years later, and still has patent term remaining. All three patents are commonly-owned and descended from common parent applications.

"The doctrine of double patenting is intended to prevent a patentee from obtaining a time-wise extension of patent for the same invention or an

obvious modification thereof." *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997). "It requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent." *In re Berg*, 140 F.3d 1428, 1431 (Fed. Cir. 1998). "Obviousness-type double patenting . . . is judicially created and prohibits an inventor from obtaining a second patent for claims that are not patentably distinct from the claims of the first patent." *Lonardo*, at 965.

FINDINGS OF FACT

The following findings of fact (""FF") are pertinent to the obviousness-type double patenting issue. Application No. 08/010,406 ("the '406 Application") and Application No. 08/013,413 ("the '413 Application") are the parent applications from which the '471, '272, and '195 Patents descended.

The '406 Application (Appl. No. 08/010,406)	
01/29/1993	[FF1] The '406 Application was filed 01/29/1993.
	[FF2] FIELD OF THE INVENTION The present invention in the field of immunology and medicine relates to immunoreceptor molecules that are specific tumor necrosis factor-alpha or -beta (TNFα or β); fragments, regions and derivatives thereof; '406 Appl. Spec. 1:4–9.
01/11/1994	[FF3] A restriction requirement was set forth by the Examiner during the prosecution of the '406 Application as follows: I. Claims 1–21 and 24–26, drawn to immunoreceptor conjugates fusing antibody constant regions to TNF receptor binding domains, and

both the '272 and '195 Patents, Applicant stated that the amendment was to "expedite prosecution" and took action consistent with this. In the '471 Patent, no statement was made that the amendment was intended to expedite prosecution.

CONCLUSION

We conclude that the '471 Application is not a divisional of the '406 Application and, therefore, cannot avail itself of the safe harbor of 35 U.S.C § 121.

Because Applicant was responsible for significant delays in the prosecution of the '471 Patent, the two-way test for determining whether the '471 Patent claims are obvious in view of the claims of the '272 and '195 Patents is not applicable.

Patent Owner did not present arguments as to why the claims of the '471 Patent would have been obvious in view of the claims of '272 and '195 Patents (the one-way test). Consequently, the obviousness-type double-patenting rejections of claims 1–7 are affirmed.

TIME PERIOD FOR RESPONSE

Requests for extensions of time in this *ex parte* reexamination proceeding are governed by 37 C.F.R. § 1.550(c). *See* 37 C.F.R. § 41.50(f).

AFFIRMED

Appeal 2016-006590
Reexamination Control 90/012,851
Patent 6,284,471 B1

PATENT OWNER:

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA RD.
CONCORD, MA 01742

FOR THIRD-PARTY REQUESTER:

MILLER, MATTHIAS & HULL, LLP
ONE NORTH FRANKLIN STREET
SUITE 2350
CHICAGO, IL 60606

Defendants' Motion *in Limine* No. 2
Exhibit 3
(Filed Under Seal)

Defendants' Motion *in Limine* No. 2 Exhibit 4

Parrado, Alvaro

From: Fischer, Aron (x2363) <afischer@pbwt.com>
Sent: Thursday, December 29, 2016 3:01 PM
To: Cutri, Elizabeth A.
Cc: #Hospira-Infliximab; inflixWS; Diskant, Gregory L. (x2710); Royzman, Irena (x2081); Cohen, Andrew (x2605); Kleban, David S. (x2641); Alison Casey (ACasey@nutter.com) (ACasey@nutter.com); hrepicky@nutter.com; Dennis Kelly; Andrea L. Martin
Subject: RE: Janssen v. Celltrion: MIL list exchange

Thank you, Liz. Our list so far:

1. Motion to exclude the testimony of Dr. Glacken premised on erroneous legal instructions
2. Motion to preclude evidence or argument regarding the alleged economic benefits, consequences, or implications of defendants' biosimilar product

I am generally available tomorrow afternoon before 5 pm.

Yours
Aron

Aron Fischer
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afischer@pbwt.com

From: Cutri, Elizabeth A. [mailto:elizabeth.cutri@kirkland.com]
Sent: Thursday, December 29, 2016 3:00 PM
To: Fischer, Aron (x2363)
Cc: #Hospira-Infliximab; inflixWS; Diskant, Gregory L. (x2710); Royzman, Irena (x2081); Cohen, Andrew (x2605); Kleban, David S. (x2641); Alison Casey (ACasey@nutter.com) (ACasey@nutter.com); hrepicky@nutter.com; Dennis Kelly; Andrea L. Martin
Subject: RE: Janssen v. Celltrion: MIL list exchange

Aron,

Below is a list of motions in limine, provided in no particular order and without prejudice to Defendants' ability to change or add to it. This list does not include motions Defendants may file in connection with any hearing on Janssen's request for injunctive relief. Let us know a time on Friday when you propose meeting and conferring.

Regards,
Liz

1. Exclude evidence related to Janssen's relationship or dealings with Thermo Fisher/HyClone with respect to MET 1.5 or any subject matter of the '083 patent, or related to any alleged copying of the subject matter of the '083 patent

2. Preclude evidence regarding Celltrion's purchase of media products from Singapore to show or suggest culpability/knowledge of culpability
3. Exclude evidence allegedly showing that Celltrion "hid" or "concealed" information about the accused media products, including testimony regarding the same and any discussion of attorney correspondence
4. Exclude evidence regarding Remicade, including without limitation evidence regarding any efforts by Celltrion to make biosimilar infliximab similar to Remicade
5. Preclude references to Celltrion as, *e.g.*, foreign, Korean, or Asian, in any way that incites bias or is suggestive with respect to liability, wrongdoing, disregard for U.S. patents or laws, or similar
6. Exclude evidence related to alleged acts of inducement that took place prior to April 13, 2016
7. Preclude use of deposition testimony or eliciting of testimony from Beverly Ingram aimed at showing that Hospira allegedly knew or knows the formulas of the accused media products
8. Preclude Plaintiffs from calling more than one expert witness on any given issue
9. Exclude evidence regarding Celltrion importing media samples or spent media samples into the United States for purposes related to regulatory approval under the safe harbor of 35 U.S.C. 271(e)(1)

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From: Fischer, Aron (x2363) [mailto:afischer@pbwt.com]
Sent: Thursday, December 29, 2016 12:38 PM
To: Cutri, Elizabeth A.
Cc: Royzman, Irena (x2081); Cohen, Andrew (x2605); Kleban, David S. (x2641); Hales, Bryan S.; Silverman, Peter B.; Kane, Ryan; McConnell, James; *cklein@winston.com; *dhoang@winston.com; Alison Casey (ACasey@nutter.com) (ACasey@nutter.com); hrepicky@nutter.com; Andrea L. Martin (amartin@burnslev.com)
Subject: RE: Janssen v. Celltrion: MIL list exchange

Yes, we agree to exchange a non-binding list of MILs at 3.

Thanks
Aron

From: Cutri, Elizabeth A. [mailto:elizabeth.cutri@kirkland.com]
Sent: Thursday, December 29, 2016 1:37 PM
To: Fischer, Aron (x2363)
Cc: Royzman, Irena (x2081); Cohen, Andrew (x2605); Kleban, David S. (x2641); Hales, Bryan S.; Silverman, Peter B.; Kane, Ryan; McConnell, James; *cklein@winston.com; *dhoang@winston.com; Alison Casey (ACasey@nutter.com) (ACasey@nutter.com); hrepicky@nutter.com; Andrea L. Martin (amartin@burnslev.com)
Subject: RE: Janssen v. Celltrion: MIL list exchange

Aron,

Thanks. We will file today.

Does Janssen agree to exchange lists of motions in limine by 3:00 ET today?

Liz

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From: Fischer, Aron (x2363) [mailto:afischer@pbwt.com]
Sent: Thursday, December 29, 2016 12:35 PM
To: Cutri, Elizabeth A.
Cc: Royzman, Irena (x2081); Cohen, Andrew (x2605); Kleban, David S. (x2641); Hales, Bryan S.; Silverman, Peter B.; Kane, Ryan; McConnell, James; *cklein@winston.com; *dhoang@winston.com; Alison Casey (ACasey@nutter.com) (ACasey@nutter.com); hrepicky@nutter.com; Andrea L. Martin (amartin@burnslev.com)
Subject: RE: Janssen v. Celltrion: MIL list exchange

Liz, this is fine to file.

Thanks

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From: Cutri, Elizabeth A. [mailto:elizabeth.cutri@kirkland.com]
Sent: Thursday, December 29, 2016 1:00 PM
To: Fischer, Aron (x2363)
Cc: Royzman, Irena (x2081); Cohen, Andrew (x2605); Kleban, David S. (x2641); Hales, Bryan S.; Silverman, Peter B.; Kane, Ryan; McConnell, James; *cklein@winston.com; *dhoang@winston.com; Alison Casey (ACasey@nutter.com) (ACasey@nutter.com); hrepicky@nutter.com; Andrea L. Martin (amartin@burnslev.com)
Subject: RE: Janssen v. Celltrion: MIL list exchange

Aron,

Following up on our discussion from earlier today, please see the attached draft motion regarding page limits. As discussed, we restyled it as a joint motion, in addition to broadening it to apply to the memoranda in support of and in opposition to our Daubert motion and your motion in limine due on January 3. We included a request with respect to reply briefs as well.

We would like to file as soon as possible today. Can you please let me know if we may proceed?

Thank you.

Regards,
Liz

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elizabeth.cutri@kirkland.com

From: Fischer, Aron (x2363) [mailto:afischer@pbwt.com]
Sent: Thursday, December 29, 2016 10:35 AM
To: Cutri, Elizabeth A.
Cc: Royzman, Irena (x2081); Cohen, Andrew (x2605); Kleban, David S. (x2641); Hales, Bryan S.; Silverman, Peter B.; Kane, Ryan; McConnell, James; *cklein@winston.com; *dhoang@winston.com; Alison Casey (ACasey@nutter.com) (ACasey@nutter.com); hrepicky@nutter.com; Andrea L. Martin (amartin@burnslev.com)
Subject: RE: Janssen v. Celltrion: MIL list exchange

Thanks, Liz.

Following up on your request for 30 pages for your Daubert motion, we assent on the condition that we have 30 pages for our motion (and of course that both parties get 30 pages for their opposition briefs).

Yours
Aron

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afischer@pbwt.com

From: Cutri, Elizabeth A. [mailto:elizabeth.cutri@kirkland.com]
Sent: Wednesday, December 28, 2016 11:25 PM
To: Fischer, Aron (x2363)
Cc: Royzman, Irena (x2081); Cohen, Andrew (x2605); Kleban, David S. (x2641); Hales, Bryan S.; Silverman, Peter B.; Kane, Ryan; McConnell, James; *cklein@winston.com; *dhoang@winston.com
Subject: Janssen v. Celltrion: MIL list exchange

Aron,

We agree to exchange lists of motions in limine on Thursday, without prejudice to the ability to modify or add to the lists thereafter. We propose exchanging by 3:00 pm Eastern.

We are available to meet and confer on Friday regarding the MILs. Friday afternoon would be preferable.

Regards,
Liz

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Defendants' Motion *in Limine* No. 2
Exhibit 5
(Filed Under Seal)