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**

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. 6,284,471 FOR OBVIOUSNESS-TYPE DOUBLE-PATENTING

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Other Authorities

Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. (together, "Celltrion") and Hospira, Inc., respectfully submit this memorandum in support of their Motion for Summary Judgment of Invalidity of asserted claims 1, 3 and 5–7 of U.S. Patent No. 6,284,471 ("the '471 patent") for obviousness-type double-patenting over any one of U.S. Patent Nos. 6,790,444 ("the '444 patent"), 5,656,272 ("the '272 patent"), or 5,698,195 ("the '195 patent").

INTRODUCTION

Straightforward application of a "bedrock principle of our patent system" compels this Court to find the asserted claims of the '471 patent invalid as a matter of law. This "bedrock principle" holds that "when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention." *Gilead Sci., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1214 (Fed. Cir. 2014). That "principle is violated when a patent expires and the public is nevertheless barred from practicing obvious modifications of the invention . . . because the inventor holds another later-expiring patent" on those "obvious modifications." *Id.* The doctrine of double patenting thus forbids a patent owner from obtaining more than one patent on the same or obvious variants of the same invention if those patents have different expiration dates. But Janssen has done just that—asserting a later-expiring patent that claims the same invention as its already-expired patents—which mandates a finding of invalidity of the later-expiring patent for double patenting.

Janssen's expired '444 patent claims the same antibodies covered by the claims of Janssen's presently-asserted '471 patent. The pertinent claims in those two patents are nearly word-for-word identical. And whatever trivial textual differences exist, there is no possible dispute that the later-expiring '471 patent claims either the same or an obvious variant of the inventions claimed in the '444 patent. Indeed, when faced with Celltrion's obviousness-type

double patenting defense as part of the pre-litigation exchange of positions under the Biologics Price Competition and Innovation Act (BPCIA) statute, Janssen did not argue otherwise.

Instead, Janssen argued that the '444 patent could not qualify as an invalidating "reference patent" because it happened to *issue* after—even though it *expired* before—the '471 patent. But the Federal Circuit already rejected that very argument in its 2014 *Gilead* decision, holding that courts should "look[] to the expiration date instead of issuance date" to assess double patenting. *Id.* at 1216. Under *Gilead,* Janssen's patent monopoly on this invention should have ended with the expiration of the '444 patent in 2011. The Court should thus find the '471 patent invalid for double patenting.

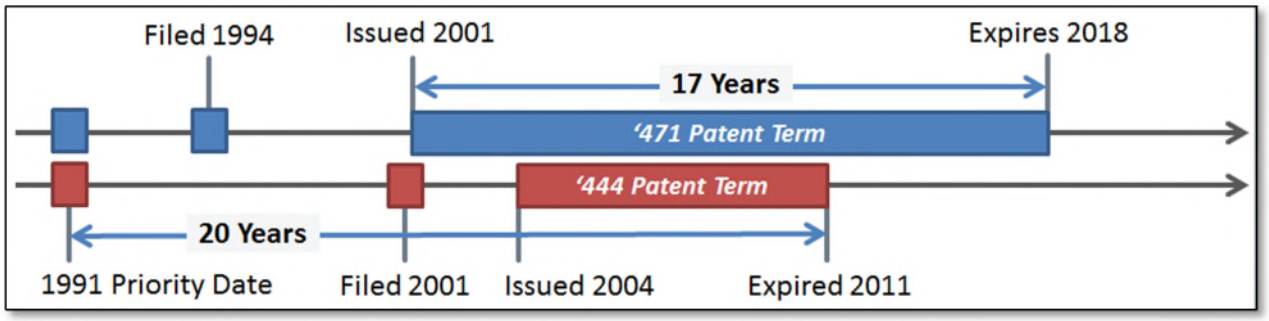
In fact, the Patent Office has *already* held the '471 patent invalid during reexamination for double patenting over *other* expired patents that Janssen owns: the '195 and '272 patents. In a pending Patent Office proceeding—which could take years to resolve—Janssen is relying on various inapplicable technicalities to attempt to overturn the Patent Office's decision. But none of those arguments have any merit, and the same grounds on which the Patent Office has rightfully relied provide further independent bases for finding that the '471 patent is invalid for double patenting. The asserted claims of the '471 patent should be declared invalid.

I. The Court Should Grant Summary Judgment Of Invalidity Of The '471 Patent For Double Patenting Using Either The '444, '195 Or '272 Reference Patents

Janssen is asserting its '471 patent against Defendants in this litigation. Facts 1, 2. Janssen is also the owner of the expired '444 patent. Fact 3. Both patents list the same set of inventors, relate back to several of the same priority patent applications, and share the same earliest effective filing date of March 18, 1991. Fact 4. The '471 patent resulted from U.S. Patent Application No. 08/192,093, filed on February 4, 1994, whereas the '444 patent resulted from U.S. Patent Application No. 09/756,301, filed on January 8, 2001. Facts 5, 6.

The two patents' different filing dates result in different expiration dates. Facts 5, 6. Patents resulting from applications filed before 1995, such as the '471 patent, have a term of seventeen years from the patent issue date or twenty years from the earliest effective filing date, whichever is longer. *See* 35 U.S.C. § 154(a)(2), (c)(1); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1547–1548 (Fed. Cir. 1996). In 1995 the law changed, such that patents resulting from applications filed after 1995, such as the '444 patent, have a term of twenty years from the patent's earliest effective filing date regardless of issue date. *Id.*

The Patent Office issued the '471 patent on September 4, 2001. Fact 5. It issued the '444 patent on September 14, 2004. Fact 6. Because of their filing dates, the '444 and '471 patents are governed by different means for calculating patent terms, resulting in the later-issued '444 patent having expired twenty years after its 1991 effective filing date in 2011, while the earlier-issued '471 patent does not expire until seventeen years after its 2001 issue date in 2018. Facts 5, 6. The timeline below shows the different patent terms:



Both the '444 reference patent and the '471 patent-in-suit claim the same "chimeric antibody," i.e., infliximab. Facts 18–20. An antibody is a large, Y-shaped protein (i.e., a polypeptide) used by the immune system that recognizes unique molecules; a chimeric antibody is an antibody designed by man to contain non-naturally occurring protein sequences. Facts 21, 22. The chimeric antibody of the '471 and '444 patents is known as infliximab or "cA2," and it

recognizes a protein involved in inflammation known as tumor necrosis factor alpha (TNF-α). Fact 23. By binding to this protein, infliximab is used to treat autoimmune disorders. Fact 24.

Both the ’471 and the ’444 patents claim infliximab—in some claims by reciting the corresponding nucleic acid sequences, and in other claims, by reciting the corresponding amino acid sequences (i.e., the chains of amino acids forming the polypeptide), but they are two ways of saying the same thing. Fact 25. The ’444 patent includes claims that are nearly verbatim to those of the ’471 patent. *See* Appendix 1 (claim chart); Facts 13, 14. The only difference is that the ’444 patent claims recite a single antibody, infliximab, rather than the group of antibodies claimed by the ’471 patent. The group of antibodies claimed by the ’471 patent includes infliximab. Fact 20. In other words, the ’471 patent recites a genus of antibodies, and the ’444 patent recites a single species (infliximab) contained within that genus.

The ’195 and ’272 patents, which share the same effective filing date of March 18, 1991 as the ’471 patent, claim methods of treatment using infliximab. Facts 4, 16, 17. Both the ’195 and ’272 patents expired in 2014. Facts 7, 8. During reexamination of the ’471 patent, the examiner at the Patent Office rejected the claims of the ’471 patent under the doctrine of obviousness-type double patenting in view of both the ’195 and ’272 patents. Fact 27. Janssen has appealed that determination. Fact 27.

II. Legal Standards

A. Summary Judgment

Summary judgment should be granted when “there is no genuine dispute as to any material fact” and “the movant party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). An issue is “genuine” when a reasonable fact-finder could find for the non-moving party; a fact is “material” when it might affect the outcome of the suit under the applicable law. *Morris v. Gov’t Dev. Bank,* 27 F.3d 746, 748 (1st Cir. 1994). The non-moving party bears the burden of

placing at least one material fact into dispute after the moving party shows the absence of any disputed material fact. *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 15 (1st Cir. 1994) (discussing *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)).

B. Obviousness-Type Double Patenting

Double patenting is a question of law. *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008); *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1352 (Fed. Cir. 2009). It is "intended to prevent a patentee from obtaining a timewise extension of [a] patent for the same invention or an obvious modification thereof." *Sun Pharma. Indus. v. Eli Lilly & Co.*, 611 F.3d 1381, 1384 (Fed. Cir. 2010) (quoting *In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1375 (Fed. Cir. 2008)). "It is based on the core principle that, in exchange for a patent, an inventor must fully disclose his invention and promise to permit free use of it [to the public] at the end of his patent term." *Gilead Sci.*, 753 F.3d at 1212. By "limiting a patentee to one patent term per invention or improvement," the doctrine of double patenting "preserve[s] the public's right to use not only the exact invention claimed by an inventor when his patent expires, but also obvious modifications of that invention that are not patentably distinct improvements." *Id.* The doctrine applies so long as the earlier and later expiring patents have at least one common inventor, subject to a narrowly-construed safe harbor in 35 U.S.C. § 121 (discussed below). *In re Hubbell*, 709 F.3d 1140, 1145–46 (Fed. Cir. 2013).

III. The '471 Patent Is Invalid In View Of The '444 Patent Under The Doctrine Of Obviousness-Type Double-Patenting

In response to Defendants' pre-suit explanation that the '471 patent is invalid for double patenting over the '444 patent, Janssen failed to assert that the '471 patent was patentably distinct from the '444 patent. Fact 40. That leaves the only issue that Janssen has ever raised—whether the later-issuing, earlier-expiring '444 patent can serve as an invalidating double-

patenting reference against the earlier-issuing, later-expiring '471 patent. Because as a legal matter the answer to that question is clearly yes under the Federal Circuit's decision in *Gilead*, this Court should enter summary judgment of invalidity.

A. The Claims Of The '471 Patent Are Not Patentably Distinct From The Claims Of The '444 Patent

Under the doctrine of obviousness-type double patenting, a claim in a second patent is invalid if it is "not patentably distinct from the claims of [a] first patent," *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985), such that "the later patent claim is obvious over, or anticipated by, the earlier claim." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001) (citations omitted). The analysis may "tak[e] into account the skill of the art and prior art other than the invention claimed in the [earlier] patent." *Longi*, 759 F.2d at 892.

Here, it is beyond dispute that at least claims 1 and 2 of the '444 patent anticipate all of the asserted claims of the '471 patent. It is black letter law that "a generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." *In re Slayter*, 276 F.2d 408, 411 (C.C.P.A. 1960); *In re Gosteli*, 872 F.2d 1008, 1010 (Fed. Cir. 1989). That is precisely the case here. Claim 1 of the '444 patent claims infliximab, also known as cA2: "The chimeric antibody cA2." Fact 19. Each of the asserted claims of the '471 patent-in-suit (claims 1, 3 and 5–7) covers a genus that includes cA2—otherwise, there could be no allegation of infringement. Fact 20. Because the species of '444 patent claim 1 anticipates the asserted claims of the '471 patent, those genus claims are not patentably distinct.

Claim 2 of the '444 patent provides an independent basis for finding no patentable distinction, because it likewise anticipates the asserted claims of the '471 patent. Indeed, the asserted claims of the '471 patent are recited nearly *verbatim* in claim 2 of the '444 patent. *See*

Appendix 1 (claim chart); Facts 13, 14. There are only three textual differences, none of which makes any possible *patentable* difference. The first is highlighted below:

'444 Patent (Expired 2011)	**'471 Patent (Expires 2018)**
Claim 2	**Claim 1**
A chimeric antibody comprising at least part of a human IgG1 constant region and	A chimeric antibody comprising at least part of a human immunoglobulin constant region and
at least part of a non-human immunoglobulin variable region,	at least part of a non-human immunoglobulin variable region,
said antibody capable of binding an epitope specific for human [tumor necrosis factor] TNFα,	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.	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 "human immunoglobulin constant region" is a genus as shown by dependent claim 6 of the '471 patent, which further recites that the "IgGl" is one of the species within the "the human immunoglobulin constant region." Fact 13. Thus, the '444 patent recites a species of the genus recited by the '471 patent, which is not a patentable distinction as a matter of law. *Slayter*, 276 F.2d at 411; *Gosteli*, 872 F.2d at 1010.

The second textual difference is found in claims 5 and 6 of the '471 patent:

'444 Patent (Expired 2011)	**'471 Patent (Expires 2018)**
Claim 2	**Claim 5**
A chimeric antibody	A chimeric antibody
comprising at least part of a human IgG1 constant region and	comprising two light chains and two heavy chains, each of said chains comprising at least part of a human immunoglobulin constant region
at least part of a non-human immunoglobulin variable 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,	said variable region capable of binding an epitope of human tumor necrosis factor hTNFα,

’444 Patent (Expired 2011)	’471 Patent (Expires 2018)
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.	wherein said light chains comprise variable regions comprising SEQ ID NO: 3 and said heavy chains comprise variable regions comprising SEQ ID NO: 5.
	Claim 6
	A chimeric antibody according to claim 5, wherein the human immunoglobulin constant region is an IgG1.

Claim 2 of the ’444 patent states that the chimeric antibody comprises “at least part of a human IgGl constant region,” particularly identifying the immunoglobulin as an IgG1. Fact 14. Claim 5 of the ’471 patent more broadly recites that the chimeric antibody contains a human immunoglobulin constant region. Fact 13. Thus, the subject matter of claim 5 of the ’471 patent is broader than claim 2 of the ’444 patent, but the subject matter of claim 2 falls squarely within the scope of claim 5.[1] Claim 2 of the ’444 patent thus anticipates claim 5 of the ’471 patent (and by extension claim 6). Indeed, claim 6 of the ’471 patent more particularly specifies that the “human immunoglobulin constant region” of claim 5 “is an IgG1,” and claim 2 of the ’444 patent specifically recites “a human IgG1 constant region.” Facts 13, 14. There is thus no patentable distinction here either.

The third and final insignificant textual difference is found in claims 3 and 7 of the ’471 patent. *See* Appendix 1; Fact 13. Both claims 3 and 7 refer to a “polypeptide *encoded by* a nucleic acid sequence selected from the group consisting of SEQ ID NO: 2 and SEQ ID NO: 4,” while claim 1 of the ’471 patent refers to “an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5.” Fact 13. Those are just different ways of saying the same thing. Fact 25. SEQ ID NOS: 2 and 4 are nucleic acids (DNA) that serve as a

[1] Moreover, the “non-human immunoglobulin variable region” is defined as comprising the same amino acid sequences (SEQ ID NOS: 3 and 5) as the “light” and “heavy chains” of the ’471 patent. Fact 15.

template for a corresponding polypeptide (amino acid sequence).[2] And the polypeptide encoded by SEQ ID NO: 2 is the same as the polypeptide of SEQ ID NO: 3; the polypeptide encoded by SEQ ID NO: 4 is the same as the polypeptide of SEQ ID NO: 5. Fact 26. Claims 3 and 7 of the '471 patent thus recite *exactly* the same chimeric antibody as claims 1 and 2 of the '444 patent, just using different words. Fact 25.

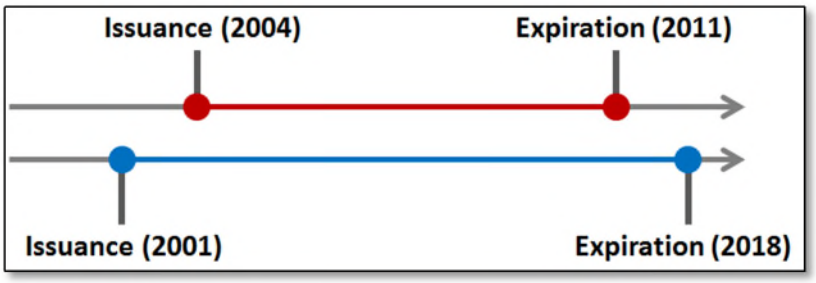
Accordingly, at least claims 1 and 2 of the '444 patent anticipate each of the asserted claims of the '471 patent, which is presumably why Janssen has never before made any attempt to argue any patentable distinctions between the '444 and '471 patent claims. *See* Fact 40.

B. Under *Gilead*, The Earlier-Expiring '444 Patent Can Be Used As A Double-Patenting Reference To Invalidate The Later-Expiring '471 Patent

Janssen cannot escape double patenting based on the relative *issue* dates of the '444 and '471 patents, because only *expiration* dates matter. In a typical double-patenting scenario, an earlier-issuing and earlier-expiring patent (the red line below) invalidates a later-issuing and later-expiring patent (blue line):

Here, however, an intervening change in the law governing patent terms resulted in the earlier-expiring '444 patent (the red line below) issuing *after* the later-expiring '471 patent (blue line):

[2] A polypeptide can be specified either by its amino acid sequence or by the nucleic acid sequence that results in the same polypeptide. *See In re Wallach*, 378 F.3d 1330, 1334 (Fed. Cir. 2004) (stating it is "a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it.").



After the change in the law governing patent term, there was some uncertainty whether an earlier expiring patent could serve as a reference patent for double patenting if it was later-issuing. The Federal Circuit's 2014 *Gilead* decision put any uncertainty to rest. 753 F.3d at 1217.

Under *Gilead*, what matters for a double-patenting reference is whether it *expires* before the second patent, not whether it *issued* before the second patent. The Federal Circuit addressed the precise issue before this Court—that is, "whether a later-issued patent can serve as a double patenting reference for an earlier-issued patent if the later [issued] one expires first." *Id.* at 1214. To answer that question, the court relied heavily on the "bedrock principle of our patent system that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention." *Id.* It observed: "that principle is violated when a patent *expires* and the public is nevertheless barred from practicing obvious modifications of the invention." *Id.* (emphasis added). From there, the Court looked solely to the relative *expiration* dates of the two patents to conclude that the "bedrock" principle was being violated:

> The '375 patent expires on February 27, 2015. Thus, come February 28, 2015, the public should have the right to use the invention claimed in the patent and all obvious variants of that invention. That was the condition upon which the '375 patent was issued to the inventors. But the public will not be free to do so. The '483 patent does not expire until December 27, 2016, and it … covers obvious modifications of the invention claimed in the '375 patent. The '483 patent, therefore, extends the inventors' term of exclusivity on obvious variants of the invention claimed in the '375 patent for an additional twenty-two months past the expiration of the '375 patent. That plainly violates the public's right to use the

> invention claimed in the '375 patent and all obvious variants of it after the '375 patent expires.

Id. (internal citations omitted). That is enough to resolve the key issue before the Court here.

Gilead went further, however, specifically refusing the argument that the *issue* date has any bearing on the analysis. The Court saw "little import . . . in the fact that the '483 patent issued first." *Id.* It reviewed earlier case law referring to the *issue* date, and noted that in those cases the issue date merely served "as a reliable stand-in for the date *that really mattered*—patent expiration." *Id.* at 1215 (emphasis added). In cases, such as this one, "in which a patent that issues first does not expire first," the *Gilead* Court made clear "it is the comparison of [the] patent expiration dates that should control."[3] *Id.* The Court also discussed why reliance "on issuance date" would "have several shortcomings," including that patent terms could be subject to gamesmanship, and that patents with filing dates only days apart could have widely-varying expiration dates. *Id.* Thus, "[l]ooking instead to the earliest expiration date of all the patents an inventor has on his invention and its obvious variants best fits and serves the purpose of the doctrine of double patenting." *Id.* at 1216. Such a rule "guarantees a stable benchmark that preserves the public's right to use the invention (and its obvious variants) that are claimed in a patent when that patent expires." *Id.*

In view of the reasoning and holding of *Gilead*, summary judgment is unavoidable here. Although the patents at issue in *Gilead*, unlike here, were not technically part of the same patent family, the Federal Circuit placed no significance on that fact, which was irrelevant to its reasoning. *Id.* at 1214–17. Nor did the court make any finding that the manner in which the

[3] Because patent term was typically determined by issue date prior to the changes effecting patent term enacted in 1994, issue date once served as a stand-in for a patent's expiration date. *Gilead*, 753 F.3d at 1215; *see also id.* at 1211 (discussing changes to patent term that became effective June 8, 1995). Because the '444 patent was filed after those changes to patent term became effective, its issue date cannot serve as a stand-in for its expiration date, which controls.

Gilead patentee had obtained its patents was improper, or that it had engaged in any "gamesmanship" in crafting a separate chain of applications. *Id.* Put simply, under *Gilead* it makes no difference *why* the patents have different expiration dates—so long as one patent survives the expiration of the other. Ultimately, the court concluded that "[i]n cases where such obviousness-type double patenting is present, a terminal disclaimer"—which officially abandons the extra patent term otherwise provided by the later-expiring patent—"can preserve the validity of the later-expiring patent by aligning its expiration date with that of the earlier-expiring patent. That disclaimer will most effectively enforce the fundamental right of the public to use the invention claimed in the earlier-expiring patent and all obvious modifications of it after that patent's term expires." *Id.* at 1217. So too here. To hold otherwise in this case would "violate[] the public's right to use the invention claimed in the ['444] patent and all obvious variants of it after the ['444] patent expire[d]." *Id.* at 1214.

Gilead is indistinguishable. The '444 patent expired in 2011, but the '471 patent expires in 2018. Facts 5, 6. Thus, the '444 patent is a proper double-patenting reference against, and serves to render invalid, the '471 patent as a matter of law.

C. Janssen Cannot Claim Refuge In The Safe Harbor Of § 121

There is a limited safe harbor when double-patenting occurs as a result of the Patent Office's requirements, but that safe harbor is inapplicable here and cannot save the '471 patent. The third sentence of 35 U.S.C. § 121 provides:

> A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. § 121; *see also Amgen*, 580 F.3d at 1353. "In effect, the third sentence of § 121 shields patents that issue on applications filed as a result of a restriction requirement from double patenting invalidation." *Id.* at 1350. The courts apply "a strict test" for application of section 121, "[g]iven the potential windfall [a] patent term extension could provide to a patentee." *G.D. Searle LLC v. Lupin Pharms., Inc.*, 790 F.3d 1349, 1354 (Fed. Cir. 2015) (citing *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1382 (Fed. Cir. 2003)). Janssen is not entitled to the protection of § 121's safe harbor provision as a matter of law.

As a threshold matter, Janssen's '471 patent simply fails to meet the express requirement to invoke § 121. In Patent Office practice, there are different types of continuing applications, including "divisional," "continuation," and "continuation-in-part" applications, each having different legal requirements and effects. By its express terms, § 121 is available only to applications filed as "divisional" applications, and is unavailable for applications filed as "continuation" or "continuation-in-part" applications. *G.D. Searle*, 790 F.3d at 1355; *Amgen*, 580 F.3d at 1352–53; *Pfizer*, 518 F.3d at 1362. Janssen filed the '471 patent application as a "continuation-in-part" application on February 4, 1994, and filed the '444 patent application as a "divisional" application on January 8, 2001. Facts 5, 6. As discussed further below, that fact alone prohibits Janssen from now seeking protection under the safe harbor.

Even if Janssen could satisfy the statutory threshold, the safe harbor cannot apply for a second substantive reason—Janssen cannot establish the requisite "consonance" to the restriction requirement that resulted in the issuance of separate patents. *Gerber Garment Tech, Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990); *St. Jude Med., Inc. v. Access Closure, Inc.*, 729 F.3d 1369, 1377 (Fed. Cir. 2013). If the Patent Office believes that an application contains claims to independent, distinct inventions, it will issue what is known as a "restriction"

requirement requiring the patent applicant to elect one group of claims to one of the inventions, leaving the other group or groups of claims to the other inventions to be further prosecuted in separate applications. "Consonance requires that the line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement be maintained." *Gerber Garment*, 916 F.2d at 688. As such, the divisional "may not contain claims drawn to the invention set forth in the claims elected and prosecuted to patent in the parent application." *Id.*; *see also St. Jude Medical*, 729 F.3d at 1377.

In 1993, during the prosecution of one of Janssen's early parent applications to the '471 and '444 patents, the Patent Office issued a restriction requirement, forcing Janssen to elect to prosecute in that particular application only one group of claims out of several groups. Fact 10. The first group identified by the examiner, so-called "Group I," was drawn to claims reciting "chimeric antibodies." Janssen could (and did) prosecute the non-elected groups of claims in separate, continuing patent applications. Facts 10, 11. In particular, the '471 patent claims "chimeric antibodies," the subject of Group I of the restriction requirement of the parent application; but, the '444 patent *also* claims "chimeric antibodies" and is therefore directed to the same subject matter of Group I. Facts 10–12. Because Janssen has claims to the same restricted invention in the two patents, it has not maintained the line of demarcation of the restriction requirement and thus fails the "consonance" test. Thus, for this additional reason, the safe harbor of § 121 is unavailable to Janssen.

IV. The '471 Patent Is Also Invalid In View Of The '195 And '272 Patents Under The Doctrine Of Obviousness-Type Double Patenting

As an independent ground for summary judgment, the '471 patent is also invalid under the doctrine of obviousness-type double patenting in view of two other already-expired patents that Janssen owns. The '195 patent expired on December 16, 2014, and the '272 patent expired

on August 12, 2014. Facts 7, 8. Both recite claims that are not patentably distinct from the '471 claims as a matter of law. Summary judgment of invalidity could be granted on either of these alternative grounds as well.

Claim 6 of the '195 patent recites a "method for treating rheumatoid arthritis" by administering infliximab, i.e., the "chimeric anti-TNF anti[b]ody cA2." Fact 16. Claim 7 of the '272 patent recites a "method for treating TNFα-mediated Crohn's disease," an autoimmune disorder, by administering infliximab: "chimeric anti-TNF antibody cA2." Fact 17. Because the earlier-expiring '272 and '195 patents' method claims disclose the use of the infliximab composition, they anticipate (or at the very least render obvious) the '471 patent's later-expiring claims to the infliximab antibody itself.

In the Patent Office, Janssen is attempting to avoid invalidity through the rarely-applied "two-way" test for obviousness-type double patenting. But there is a strong presumption in favor of the "one-way" test, in which the validity of *only* the *asserted claims* are evaluated against the reference patent claims. *In re Fallaux*, 564 F.3d 1313, 1316 (Fed. Cir. 2009). Under the two-way test, by contrast, the validity of the *reference patent claims* are *also* evaluated against the asserted claims—that is, the obviousness of *both* sets of claims are evaluated against each other. But a two-way test applies "*only* in the 'unusual circumstance' where 'the PTO is *solely responsible* for the delay in causing the second-filed application to issue prior to the first.'" *Hubbell*, 709 F.3d at 1149 (emphasis added, internal citation omitted). "The determination of whether a one-way or two-way analysis applies is . . . a question of law . . . ." *Bassell Poliolefine*, 547 F.3d at 1375–76.

Janssen cannot overcome the presumption favoring the one-way test—as the PTO examiner found—because the Patent Office plainly was not "solely" responsible for the timing

producing the double-patenting problems. Fact 30. Janssen was at least *partially* responsible for the massive delay in the issuance of the '471 patent. *See id.* For example, Janssen requested and received at least *six* extensions of time. Fact 38. Moreover, although the Patent Office repeatedly indicated that there was allowable subject matter—which could have resulted in immediate issuance—Janssen further delayed prosecution by submitting amendments and even new claims drawn to non-elected subject matter, resulting in years and years of delay. Facts 31–37; *see also* Fact 30.

In any event, even if the two-way test applies, Janssen cannot avoid double patenting. A "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use." *Sun Pharm.*, 611 F.3d at 1387 (citation omitted). That is the case here. The '471 patent claims recite the composition infliximab, and the specification of the '471, '195 and '272 patents all disclose the utility of infliximab to treat various conditions including rheumatoid arthritis and Crohn's disease. Fact 29. Thus, the claims of the '195 and '272 patents (methods of using infliximab) are not patentably distinct over the claims of the '471 patent (infliximab antibody) and the express disclosure of the utility of infliximab to treat rheumatoid arthritis and Crohn's disease.

Finally, Janssen cannot rely on the safe harbor, because (as discussed above) it filed its '471 application as a "continuation-in-part" application on February 4, 1994, rather than a "divisional" application filed as a result of a restriction requirement as required to invoke the safe harbor. Recognizing this problem, Janssen is attempting to convert its "continuation-in-part" application into a "divisional" through maneuverings before the Patent Office. But as of now, the application remains a "continuation-in-part." Even Janssen in its papers filed with this

Court acknowledges that the amendments to the specification of the '471 patent "will not take effect outside of the PTO until the reexamination proceedings are complete." Fact 39.

In any event, even if that amendment were to take effect in the *future*, it would not save the '471 patent. The safe harbor statute not only requires a divisional (as opposed to a continuation-in-part) application to be filed as a result of a restriction requirement, it further requires that this "divisional application [be] filed *before* the issuance of the patent on the other application." 35 U.S.C. § 121 (emphasis added). As an historical fact, the '471 application was not filed as a "divisional" as a result of a restriction requirement, not did Janssen amend its continuation-in-part to a divisional "*before*" the issuance of the '195 and '272 patents.[4] Facts 5, 7, 8. *See id.*; Manual of Patent Examining Procedure § 804.01 (noting § 121 requires that "the *divisional application* is filed before the issuance of the patent." (emphasis added)); Federico, P. J., *Commentary on the New Patent Act* in 75 *J. Pat. & Trademark Off. Soc'y* 161, 196 (1993) (commenting that "if two or more *divisional applications* are filed as a result of a multiple requirement for restriction, they each must be filed before the original application is patented in order to obtain the benefit of this provision [35 U.S.C. § 121]."). Accordingly, the safe harbor protection of § 121 does not apply.

CONCLUSION

For the reasons above, the asserted claims of the '471 patent are invalid under the doctrine of obviousness-type double patenting in view of any one of the '444, '195 and '272 patents, and the Court should grant summary judgment to the Defendants.

* * *

[4] The '471 patent application was filed as a "continuation-in-part" and remained a continuation-in-part when it issued, years after the '195 and '272 patents issued. Fact 5, 7, 8. Therefore, even if the '471 patent is called a divisional sometime in the future, it would still not have been filed as a divisional prior to the issuance of the reference patents.

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Respectfully submitted,

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By their attorneys,

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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 February 19, 2016.

/s/Andrea L. Martin, Esq.
Andrea L. Martin, Esq.

APPENDIX 1: CLAIM CHARTS

’444 Patent (Expired 2011)	**’471 Patent (Expires 2018)**
Claim 2	**Claim 1**
A chimeric antibody comprising at least part of a human IgG1 constant region and	A chimeric antibody comprising at least part of a human immunoglobulin constant region and
at least part of a non-human immunoglobulin variable region,	at least part of a non-human immunoglobulin variable region,
said antibody capable of binding an epitope specific for human [tumor necrosis factor] TNFα,	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.	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.
Claim 2	**Claim 3**
A chimeric antibody comprising at least part of a human IgG1 constant region and	A chimeric antibody comprising at least part of a human immunoglobulin constant region and
at least part of a non-human immunoglobulin variable region,	at least part of a non-human immunoglobulin variable region,
said antibody capable of binding an epitope specific for human [tumor necrosis factor] TNFα,	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.	wherein the non-human immunoglobulin variable region comprises a polypeptide encoded by a nucleic acid sequence selected from the group consisting of SEQ ID NO: 2 and SEQ ID NO: 4.

’444 Patent (Expired 2011)	**’471 Patent (Expires 2018)**
Claim 2	**Claim 5**
A chimeric antibody	A chimeric antibody
comprising at least part of a human IgG1 constant region and	comprising two light chains and two heavy chains, each of said chains comprising at least part of a human immunoglobulin constant region
at least part of a non-human immunoglobulin variable 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,	said variable region capable of binding an epitope of human tumor necrosis factor hTNFα,
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.	wherein said light chains comprise variable regions comprising SEQ ID NO: 3 and said heavy chains comprise variable regions comprising SEQ ID NO: 5.
Claim 2	**Claim 6**
…comprising at least part of a human IgG1 constant region and…	A chimeric antibody according to claim 5, wherein the human immunoglobulin constant region is an IgG1.
Claim 2	**Claim 7**
A chimeric antibody comprising at least part of a human IgG1 constant region and	A chimeric antibody comprising at least part of a human IgG1 constant region
at least part of a non-human immunoglobulin variable region,	and at least part of a non-human immunoglobulin variable region,
said antibody capable of binding an epitope specific for human TNFα,	said antibody capable of binding an epitope specific for human 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.	wherein the non-human immunoglobulin variable region comprises a polypeptide encoded by a nucleic acid sequence selected from the group consisting of SEQ ID NO: 2 and SEQ ID NO: 4.

’195 Patent (Expired 2014)	’272 Patent (Expired 2014)	’471 Patent (Expires 2018)
Claim 6	**Claim 7**	**Claim 1**
A method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF anti[b]ody cA2.	A method of treating TNFα-mediated Crohn's disease in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF antibody cA2.	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.
Claim 6	**Claim 7**	**Claim 3**
A method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF anti[b]ody cA2.	A method of treating TNFα-mediated Crohn's disease in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF antibody cA2.	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 a polypeptide encoded by a nucleic acid sequence selected from the group consisting of SEQ ID NO: 2 and SEQ ID NO: 4.

’195 Patent (Expired 2014)	’272 Patent (Expired 2014)	’471 Patent (Expires 2018)
Claim 6	**Claim 7**	**Claim 5**
A method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF anti[b]ody cA2.	A method of treating TNFα-mediated Crohn's disease in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF antibody cA2.	A chimeric antibody
		comprising two light chains and two heavy chains, each of said chains comprising at least part of a human immunoglobulin constant region
		and at least part of a non-human immunoglobulin variable region,
		said variable region capable of binding an epitope of human tumor necrosis factor hTNFα,
		wherein said light chains comprise variable regions comprising SEQ ID NO: 3 and said heavy chains comprise variable regions comprising SEQ ID NO: 5.
Claim 6	**Claim 7**	**Claim 6**
A method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF anti[b]ody cA2.	A method of treating TNFα-mediated Crohn's disease in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF antibody cA2.	A chimeric antibody according to claim 5, wherein the human immunoglobulin constant region is an IgG1.
Claim 6	**Claim 7**	**Claim 7**
A method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF anti[b]ody cA2.	A method of treating TNFα-mediated Crohn's disease in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF antibody cA2.	A chimeric antibody comprising at least part of a human IgG1 constant region
		and at least part of a non-human immunoglobulin variable region,
		said antibody capable of binding an epitope specific for human TNFα,
		wherein the non-human immunoglobulin variable region comprises a polypeptide encoded by a nucleic acid sequence selected from the group consisting of SEQ ID NO: 2 and SEQ ID NO: 4.