2017-1257
(Serial No. 90/012,851)

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

In re: JANSSEN BIOTECH, INC., NEW YORK UNIVERSITY,

Appellants

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in Reexamination Control No. 90/012,851

BRIEF FOR APPELLEE – DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

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35 U.S.C. § 121

Divisional applications

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. 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. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

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STATEMENT OF RELATED CASES

As indicated in Appellant's opening brief, *Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd.*, No. 2017-1120 (Fed. Cir.) will directly affect or be affected by the decision in the instant appeal. The Court has identified this case as a companion case.

I. STATEMENT OF THE ISSUE

In 1994, Janssen filed the '093 application as a continuation-in-part (CIP) of two separate patent applications, the '413 application and the '406 application. The '093 application issued as the '471 patent in 2001.

In 2013, the Board ordered reexamination of the '471 patent on obviousness-type double patenting (ODP) grounds over the claims of two expired Janssen patents, the '195 and '272 patents. ODP is a judicially created doctrine designed to prevent a patentee from obtaining a time-wise extension of patent for the same invention or an obvious variant. In response to the ODP rejection, Janssen attempted to amend the '471 patent to delete the disclosure that had originated from the '406 application, remove the priority claim to the '406 application, and redesignate the '093 application as a divisional application of the '413 application. The Office, upon petition, allowed Janssen to enter the amendments for purposes of examination to enable the Board to address the issue, but stated that the "efficacy of such amendment changing the claim for benefit during reexamination is the issue under appeal."

Janssen concedes that the claims of the '471 patent are not patentably distinct from the claims of the '195 and '272 patents. But Janssen argues that ODP is not applicable because the '093 application is entitled to the safe harbor provision of 35 U.S.C. § 121. Following *Pfizer*, *Amgen*, and *Searle*, the Board

rejected Janssen's argument, finding that the '093 application was not entitled to § 121's safe harbor because it was filed as a CIP, not as a divisional application.

The Board also found that Janssen was not entitled to benefit from § 121's safe harbor for a second reason — the claims of the patents at issue in the ODP rejection did not maintain consonance. And the Board further found that Janssen was not entitled to the two-way ODP test because Janssen was partially responsible for the "delay" that caused the '471 patent to issue after the '272 and '195 reference patents. The first question on appeal is whether the '093 application is entitled to the benefit of the safe harbor of § 121. For Janssen to prevail on this question, Janssen must establish that the Board committed two errors. First, Janssen must establish that the Board erred when it concluded that Janssen's '093 application was not entitled to the safe harbor because it was not filed as a divisional, and cannot be redesignated as such. Second, Janssen must establish that the Board erred when it determined that the patents involved in the ODP rejection did not maintain consonance with the restriction requirement in the '413 application.

If this Court finds that Janssen is not entitled to § 121's safe harbor for either or both reasons, then this Court must also decide whether the Board erred when it found that Janssen is not entitled to the two-way ODP test.

II. STATEMENT OF THE CASE

A. The ’406 and ’413 Applications

1. The ’406 Application: Immunoreceptors specific for TNF alpha or beta or both

On January 29, 1993, Janssen filed application No. 08/010,406 (“the ’406 application”). Appx15471; Appx15512-15515. The field of invention stated that the “present invention relates to immunoreceptor molecules that are specific for tumor necrosis factor-alpha or -beta.” Appx15471. Claim 1 recited an immunoreceptor molecule capable of binding to “TNF alpha or TNF beta or both.” Appx15512. Dependent claims specified that the TNF receptor comprises “at least a portion of p55” (claim 8) or “at least a portion of p75” (claim 9). Appx15512-Appx15513. After Janssen failed to respond to an Office Action, the Office mailed a Notice of Abandonment on September 29, 1994. Appx15521.

2. The ’413 application: Chimeric antibodies specific for TNF alpha

On February 2, 1993, Janssen filed application No. 08/013,413 (“the ’413 application”). Appx13391; Appx13486-13494. The field of invention stated that “the present invention” relates to antibodies “specific for human tumor necrosis factor-alpha.” Appx13391. Its original claims included claims to a chimeric antibody and methods of treatment. Appx13486-13494. All of the chimeric

antibody claims were limited to antibodies that bind to TNF alpha. *Id*. There were no claims to immunoreceptor molecules. *Id.*

On October 27, 1993, the examiner issued a 5-way restriction requirement. As relevant here, Group I was drawn to antibodies, pharmaceutical compositions, and assay methods, and Group IV was drawn to methods for treating an animal by administering a pharmaceutical composition containing an antibody. Appx13496-13526. Janssen did not file a paper in response to the restriction requirement. Instead, on February 4, 1994, Janssen expressly abandoned the '413 application and stated that it was filing a CIP that same day. Appx13529-13530.

B. The '093 Application: A CIP of the '406 and '413 applications

On February 4, 1994, Janssen filed application No. 08/192,093 ("the '093 application"). Appx13918-Appx14086. Janssen designated the '093 application as a CIP of the '406 and '413 applications. The first sentence of the '093 specification states that this "application is a continuation-in-part of each of U.S. Application Serial No. 08/010,406, filed January 29, 1993, and U.S. Application Serial No. 08/013,413, filed February 2, 1993." Appx13918. The transmittal letter accompanying the '093 application repeated that the application was a CIP of the '406 and '413 applications. Appx14111-14112. In addition, Janssen filed a letter in the '413 application stating that it was expressly abandoning the '413 application and filing a continuation-in-part application. Appx13529-13530.

As filed, the '093 application included claims to, *inter alia*, chimeric antibodies and immunoreceptor molecules. Appx14076-14086. Claim 1 was directed to a chimeric antibody capable of binding to TNF, not TNF alpha. Appx14067. The immunoreceptor claims included claims where the TNF receptor was p55 or p75 (claims 60 and 61). Appx14081.

On December 23, 1994, Janssen filed a preliminary amendment which cancelled, amended, and added claims. Appx13852-13856. The preliminary amendment stated that it "cancels subject matter which is drawn to a non-elected invention pursuant to the restriction requirement set forth in parent application Serial No. 08/013,413." Appx13856. The Preliminary Amendment did not limit claim 1 to TNF alpha. Appx13852-13856. It also did not cancel claims 60 and 61 directed to TNF receptors p55 and p75. Appx13854-13855.

On April 7, 1995, the examiner mailed an Office Action requiring applicant to elect between Group I (which included chimeric antibodies and immunoreceptors which comprise the epitope binding region of an antibody) and Group II (which included immunoreceptor molecules comprising TNF receptor fragments p55 or p75). Appx13843-13847. Janssen elected Group I. Appx13841-13842.

On August 23, 1995, the examiner issued an Office Action provisionally rejecting claims on ODP grounds over application No. 08/324,799 ("the '799

application") and the '406 application. Appx13822-13838. Claim 1 was rejected on obviousness, ODP, and ¶112 grounds. *Id.*

On December 22, 1995, Janssen cancelled and amended claims, including limiting claim 1 to TNF alpha. Appx13809-13812. Janssen argued that the provisional ODP rejection over the '406 application was in error because that application had been abandoned. Appx13812. As to the ODP rejection over the '799 application, Janssen stated that "upon resolution of the remaining rejections of record and in the event that these Claims (or other claims drawn to chimeric antibodies) remain pending in the '799 application, a terminal disclaimer will be submitted." *Id.*

On May 1, 1996, the examiner maintained the ODP rejection over the '799 application and other rejections. Appx13789-13796. Janssen filed a Notice of Appeal on October 31, 1996. Appx13787-13788.

On May 5, 1997, Janssen filed an amendment under 37 CFR § 1.129(a), cancelling and amending claims. Appx13758-13783. Janssen stated that

> Claims 1-70 in the '799 application have been cancelled, and new claims drawn to methods of treating rheumatoid arthritis have been added. Thus, the claims now pending in Serial No. 08/324,799 no longer correspond to Claims 1-28, 33-40, 59-61 and 63. 35 U.S.C. § 121 precludes an obviousness-type double patenting rejection in this case. See the restriction requirement mailed in U.S. Serial No. 08/013,413 on October 27, 1993. Withdrawal of the rejection is respectfully requested.

Appx13771.

On August 5, 1997, in an Office Action, the examiner withdrew the ODP rejection over the '799 application "in view of the cancellation" of claims in the '093 and '799 applications, but continued to reject the claims on obviousness grounds. Appx13731-13738. The examiner also stated that claims 136-139 are allowable if rewritten in independent form, and claims 31 and 133 are allowable if "rewritten to be dependent on any one of claims 136-139." Appx13733. After Janssen amended its claims in December 1997, the examiner allowed claims 31, 133, and 136-139 in a March, 1998 final Office Action. Appx13708.

In August, 1998, in an Amendment after Final Rejection, Janssen added new claims directed to polypeptides. Appx13688-13698. Janssen stated that these claims were "the same or similar" to claims pending in application 08/570,674. Janssen stated that it intended to abandon the '674 application and was adding the claims here "to avoid any issue relating to double patenting upon issuance of the instant application." Appx13688-13698 at Appx13692.

The '471 patent[1] issued with 9 claims. Appx176. Claims 1, 3, 5 and 6 are directed to a chimeric antibody specific for TNF alpha. Claims 2 and 4 are

[1] U.S. Patent No. 6,284,471, "Anti-TNFα Antibodies and Assays Employing Anti-TNFα Antibodies," issued to Le, et al., Sept. 4, 2001. Appx90-177.

directed to immunoassay methods for detecting human TNF. Claims 8 and 9 are directed to claims to polypeptides of particular amino acid sequences that bind to hTNF alpha. The Board designated claim 1 of the '471 patent as representative. It reads:

> 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.

Appx5; Appx176.

C. The '272 and '195 Reference Patents

1. The '272 Reference Patent: Method of treating Crohn's Disease

The '272 reference patent[2] issued from application No. 08/192,102 ("the '102 application"), filed on February 4, 1994, which is a CIP of the '406 and '413 applications. Appx271; Appx14510. As filed, the '102 application included claims to compositions capable of binding to at least one of TNF alpha and TNF beta. Appx14667-14673.

[2] U.S. Patent No. 5,656,272, "Methods of Treating TNF-α-Mediated Crohn's Disease Using Chimeric Anti-TNF Antibodies," issued to Le, Aug. 12, 1997. Appx271-357.

On December 5, 1995, Janssen filed a preliminary amendment, cancelling all of the pending claims and replacing them with seven new claims directed to a method of treating Crohn's disease. Appx14398-14400. Janssen stated that the amendment was "made to reduce issues on examination [and] expedite prosecution." Appx14400. Claim 1 recites:

> A method of treating TNFα-mediated Crohn's disease in a human comprising administering to the human an effective TNF-inhibiting amount of an anti-TNF chimeric antibody, wherein said anti-TNF chimeric antibody comprises a non-human variable region or a TNF-binding portion thereof and a human constant region.

Appx357.

Claim 7 recites:

> 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.

Appx357.

2. The '195 Reference Patent: Method of treating rheumatoid arthritis

The '195 patent[3] issued from the '799 application, filed on October 18, 1994, which is a CIP of the '093, '102, and '861 applications. Appx178;

[3] U.S. Patent No. 5,698,195, "Methods of Treating Rheumatoid Arthritis Using Chimeric Anti-TNF Antibodies," issued to Le, Dec. 16, 1997. Appx178-270.

Appx15073. As filed, the '799 application included claims to compositions capable of binding to at least one of TNF alpha and TNF beta. Appx15249-15259.

On January 17, 1996, Janssen filed a preliminary amendment cancelling all of the pending claims and replacing them with seven new claims directed to methods of treatment of rheumatoid arthritis. Appx14964-14966. Janssen stated that the amendment was "made to reduce issues on examination and expedite prosecution." Appx14966.

Claim 1 recites:

> A method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of an anti-TNF chimeric antibody, wherein said anti-TNF chimeric antibody comprises a non-human variable region or a TNF antigen-binding portion thereof and a human constant region.

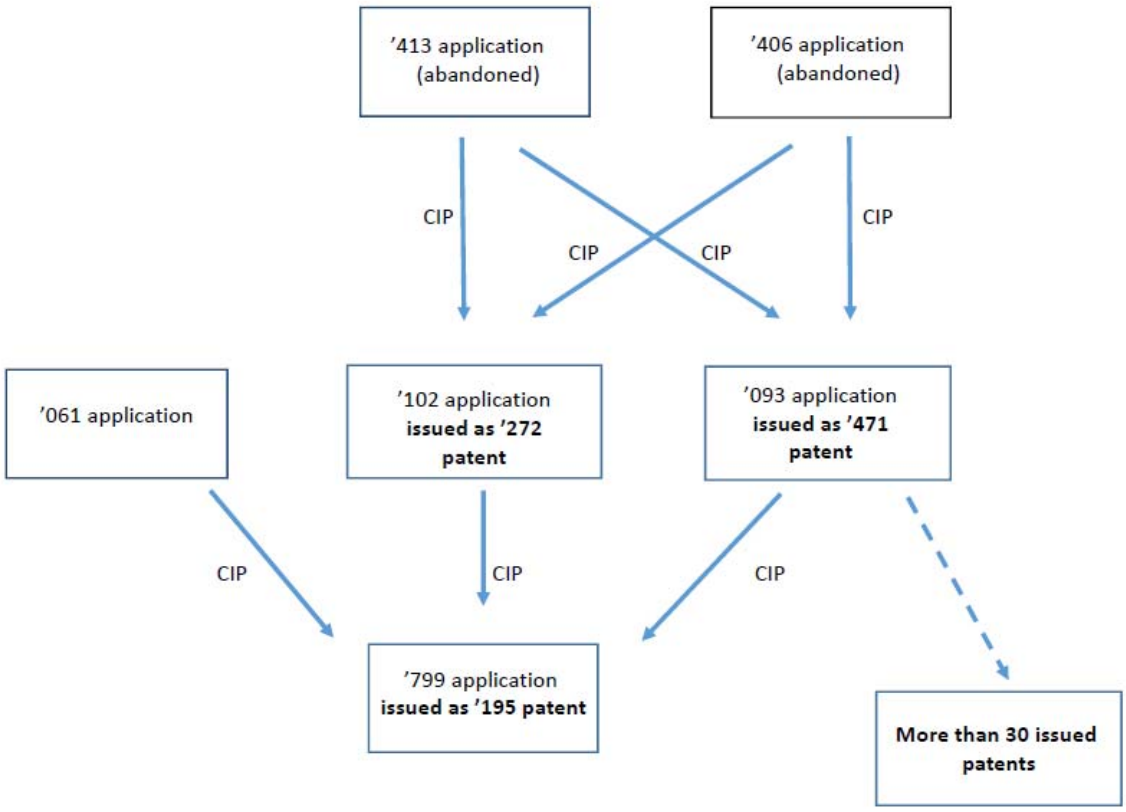
Appx269.

Claim 6 recites:

> A method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF antibody cA2.

Appx269.

Below is a diagram illustrating the relationship between the relevant applications.



D. The Reexamination Proceeding of the '471 Patent

In response to a third-party request, the Office instituted reexamination of the '471 patent on ODP grounds over the '195 and '272 patents.[4] Appx12907-12917.

[4] The Office also instituted reexamination on ODP grounds over U.S. Patent No. 6,277,969. Appx12914.

On December 19, 2013, Janssen cancelled claims 8 and 9, and requested that the '471 patent be amended to delete the claim for benefit to the '406 application. Appx12381-12382. Janssen also requested that the specification, abstract, and drawings of the '471 patent be conformed to the '413 application, and the '471 patent be designated as a divisional of the '413 application. *Id*.

The Office's final rejection did not enter the requested amendments, stating that they were tantamount to a substitute specification, which is not permitted in reexamination. Appx1609-1634, citing 37 C.F.R. § 1.125. On October 26, 2014, Janssen filed a "Petition Under 37 C.F.R. § 1.181 to Direct Entry of Amendments." Appx1117-1134. On November 26, 2014, the Office granted Janssen's petition for purposes of examination and returned the proceeding to the Examiner to issue a new final Office Action. Appx1033-1041.

On April 13, 2015, Janssen filed a "Petition under 37 CFR § 1.181 to Adhere to Prior Restriction Requirement" requesting the Director to order the examiner to withdraw the ODP rejections because the '093 application had been redesignated "as a divisional application." Appx950-963.

In accord with the November, 2014 petition decision, in the April 29, 2015 "Advisory Action Before the Filing of an Appeal Brief" the examiner checked the box that stated "[f]or purposes of appeal, the proposed amendment[s] will be entered and an explanation of how the new or amended claim(s) would be

rejected is provided below or appended." Appx860-863. The examiner then attached a sheet explaining that even if the amendments were entered, Janssen's claims were still unpatentable on ODP grounds. Appx863.

On May 21, 2015, the Office dismissed the April, 2015 petition, stating that the requested relief went to "the merits of a final rejection of claims" and "is not available by petition." Appx854-859 at Appx859.

In its Appeal Brief to the Board, Janssen argued that the "Office ha[d] confirmed the '471 patent's status as a divisional of the parent application." Appx783. In his answer, the Examiner responded that the "Patent Office has not confirmed the status of the '471 patent as a Divisional. The amendment was entered for the purpose of reexamination" and the "*efficacy of such amendment changing the claim for benefit during reexamination is the issue under appeal*." Appx681-697 at Appx689. The Examiner maintained the ODP rejections, citing *Pfizer*, *Amgen*, and *Searle*. The Examiner also noted that the '272 and '195 reference patents, like the '471 patent, were filed as CIPs, not as divisional applications. Appx690.

In its Appeal Brief, Janssen argued that it was unlike *Searle* because Janssen had never received issued claims in the '471 patent on the subject matter originating from the '406 application. Appx798-799. In response, the examiner noted that more than 30 issued patents "reached through the '471 patent for

benefit of a prior filing date" and the "patentability of those claims . . . cannot be determined without reopening examination of those patents in view of the deletion of the subject matter in the '471 patent." Appx691. In addition, the examiner stated that the "mere presence" of the new matter in the '471 specification "acted as a barrier to keep potential competitors out of the area" because a claim to it could have been presented in a continuing application. Appx691-692.

E. The Board's Decision

Before the Board, Janssen did not separately argue the claims of the '471 patent. Appx5. Janssen also did not separately argue the rejections over the '272 and '195 reference patents. *Id*. As a result, the Board focused on claim 1 of the '471 patent and considered the rejections over the '272 and '195 reference patents together. *Id.* When it did so, the Board concluded that claims 1-7 of the '471 patent were properly rejected on ODP grounds over each of the '272 and '195 reference patents. Appx1-41.

Janssen did not dispute that claim 1 of the '471 patent was not patentably distinct over the claims of the '195 and '272 reference patents. Instead, Janssen argued that ODP did not apply because the '093 application was entitled to the safe harbor of § 121. Appx14-15.

The Board explained that § 121 imposes three requirements for a "divisional application" to be shielded from an ODP rejection over a reference patent. Appx15. First, the reference patent must be issued "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." *Id*. Second, the application must be a "divisional application of the original application in which the restriction was made." *Id.* Third, the divisional application must be "filed before the issuance of the patent on the other application." *Id*.

Noting the absence of a statutory definition for a "divisional" application, the Board looked to the MPEP's definition:

> A later application for a distinct or independent invention, carved out of a pending application and *disclosing and claiming* only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division."

Appx16, citing MPEP 201.06 (5th Ed., Rev. 15, Aug. 1993) (emphasis added).

The Board determined that the '093 application, as filed, was not a divisional application because it did not disclose and claim only subject matter disclosed in the earlier or parent application. Appx17. To the contrary, the '093 application disclosed and claimed subject matter not disclosed in the '413 application. *Id.* Specifically, the '093 application claimed chimeric antibodies to the TNF *genus* even though the '413 application had only claimed chimeric

antibodies with specificity to TNF alpha. *Id*. In addition, the '093 application had claims to "immunoreceptor molecules" comprising a TNF receptor portion which is p55 or p75. Appx18. Neither fragment was disclosed in the '413 application. *Id*.

Despite the fact that the '093 application was filed as a CIP and included subject matter not disclosed or claimed in the '413 application, Janssen argued that the '093 application was a divisional when filed. *Id*. Janssen argued that it had "presented claims to the non-elected Group I invention for examination in the '093 Application in response to the restriction and the guidance of the Office to do so" and its Preliminary Amendment stated that it "cancels subject matter which is drawn to a non-elected invention pursuant to the restriction requirement set forth in parent application Serial No. 08/013,413." *Id.*

The Board was not persuaded because Janssen's Preliminary Amendment did not (i) cancel the immunoreceptor claims that were not disclosed or claimed in the '413 application; or (ii) limit claim 1 to TNF alpha. *Id*. And after the examiner issued an election of species, Janssen still did not limit the claims to TNF-alpha, as disclosed and claimed in the '413 application. Appx19. Instead, Janssen presented claims directed to the genus of TNF proteins, which had support only in the '406 application. *Id*. Thus, the Board found that the claims presented for examination in the '093 application were broader than those in the

'413 application and "contained subject matter neither disclosed nor claimed in [the] '413 Application." *Id.*

Thus, "of its own accord," Janssen "chose to describe and claim subject matter not disclosed in the '413 Application and [] forfeited the benefit of the safe harbor of Section 121." *Id*.

The Board then addressed the case law, noting that courts have strictly applied § 121 "[g]iven the potential windfall [a] patent term extension could provide to a patentee." *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1382 (Fed. Cir. 2003). In *Pfizer, Inc. v. Teva Pharms. USA, Inc*., 518 F.3d 1353, 1359 (Fed. Cir. 2008), this Court rejected Pfizer's argument that its CIP application was entitled to § 121's safe harbor. Appx20-21. As the *Pfizer* Court explained, "[i]f the drafters wanted to include CIPs within the protection afforded by section 121, they could have easily done so." *Id*. In *Amgen Inc. v. F. Hoffman-LaRoche Ltd*., 580 F.3d 1340 (Fed. Cir. 2009), this Court held that continuation applications, like CIPs, also did not receive the benefit of § 121. Appx22. And in *G.D. Searle LLC v. Lupin Pharms., Inc*., 790 F.3d 1349 (Fed. Cir. 2015), this Court held that the patentee was not entitled to the safe harbor of § 121 because its application was not a divisional application when it was filed. Appx28.

The Board then addressed the additional requirement of consonance. Appx23-25, citing *Pfizer*, 518 F.3d at 1359. The Board found that Janssen's argument "goes astray of the statutory requirement that the application seeking the safe harbor be designated, when filed, a divisional." Appx24. The Board found that the issued claims in the three patents involved in the ODP rejection are not consonant with the restricted claims in the '413 application. *Id.*

Finally, the Board found that the two-way ODP test was not applicable because Janssen was responsible for significant delays in the prosecution of the '471 patent. Appx29-40. The Board pointed to several instances where Janssen's actions "were not just part of the ordinary processing times between getting an Office Action from the Examiner and then responding . . . but constituted deliberate and unnecessary actions that lengthened the prosecution time of the '093 Application." Appx33.

For all of these reasons, the Board affirmed the ODP rejections of claims 1-7 of the '471 patent. Appx1-41.

III. SUMMARY OF THE ARGUMENT

Three facts matter. The first two are undisputed. Fact one is that the '093 application, which issued as the '471 patent, was filed as a CIP application, not a divisional application. Fact two is that claim 1 of the '471 patent is not patentably distinct from the claims of Janssen's '272 and '195 reference patents.

The third fact, which Janssen *does* dispute, is that Janssen was partially responsible for the "delay" that caused the '471 patent to issue after the '272 and '195 patents. These three facts form the basis of the Board's affirmance of the rejection of the claims of the '471 patent on ODP grounds over the '272 and '195 patents.

The first fact — that Janssen filed the '093 application as a CIP, not a divisional application — extinguishes any claim to § 121's safe harbor. As this Court made clear in *Pfizer*, *Amgen*, and *Searle*, only applications filed as divisionals can claim the benefit of § 121's safe harbor. Janssen, however, argues that these cases are distinguishable because in this reexamination, 20 years after the '093 filing date, Janssen petitioned the Office to permit entry of the amendment which attempted to redesignate the '093 application as a divisional application. But as *Searle* explained, Janssen cannot "retroactively alter the nature" of the original '093 CIP application.

Thus, although Janssen's brief repeatedly (and confusingly) refers to the '093 application as a divisional, it is not.[5] It was not filed as a divisional and was never a divisional during the original prosecution. Nor is it a divisional today

[5] Janssen also repeatedly (and confusingly) refers to the '413 application as "*the* Parent Application." *See, e.g.*, Br. 3, 16, 17. It is not; it is *one* of the Parent Applications. The '406 application is the other.

because the USPTO has entered Janssen's amendment only for the purpose of reexamination to allow the Board to address the issue of whether such a redesignation is effective.

Perhaps recognizing the weakness of its position, Janssen retreats to arguing that the '093 application was somehow a "divisional in form" or a "divisional in substance." Neither is correct. The relevant restriction requirement occurred in the '413 application. Janssen filed the '093 application as a CIP of both the '413 application and the '406 application and included subject matter not disclosed in the '413 application. Thus, there is no way that the '093 application can be considered a divisional of the '413 application in "form" or in "substance."

And even if the '093 application could somehow be considered a divisional application, Janssen cannot fall within § 121's safe harbor for another independent reason — the issued claims in the three patents involved in the ODP rejection did not maintain consonance with the restriction requirement in the '413 application because they rely on subject matter not disclosed in the '413 application.

Finally, the Board correctly found that Janssen was not entitled to the two-way ODP test because Janssen was partially responsible for the "delay" that caused the '471 patent to issue after the '272 and '195 reference patents. The Board pointed to several instances where Janssen delayed. In particular, after

receiving a final rejection in May, 1996, Janssen waited until October, 1996 to file a Notice of Appeal, and then changed its mind in May, 1997 and reopened prosecution. This delay, attributable only to Janssen, establishes that the USPTO was not solely responsible for the "delay" causing the '471 patent to issue after the '272 and '195 reference patents.

IV. ARGUMENT

A. Standard Of Review

Janssen has the burden of showing that the Board committed reversible error. *In re Watts*, 354 F.3d 1362, 1369 (Fed. Cir. 2004). Obviousness type double patenting is a question of law that this Court reviews de novo. *In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997). "De novo review is appropriate because double patenting is a matter of what is claimed, and therefore is treated like claim construction upon appellate review." *In re Metoprolol Succinate Patent Litigation*, 494 F.3d 1011, 1015 (Fed. Cir. 2007) (quoting *Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1326 (Fed. Cir. 1999)). The determination of whether the one-way test or the two-way test applies is a question of law. *In re Fallaux*, 564 F.3d 1313, 1316 (Fed. Cir. 2009).

A court may, however, "evaluate[e] evidentiary submissions to determine whether claims were patentably distinct in obvious-type double patenting challenge." *Metoprolol Succinate*, 494 F.3d at 1015-16. The Board's

determinations as to such evidentiary submissions are reviewed for substantial evidence. *See, e.g., In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000). "Substantial evidence is something less than the weight of the evidence but more than a mere scintilla of evidence," *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000), and "means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. Nat'l Labor Relations Bd.*, 305 U.S. 197, 229 (1938). "If the evidence in record will support several reasonable but contradictory conclusions," this Court "will not find the Board's decision unsupported by substantial evidence simply because the Board chose one conclusion over another plausible alternative." *In re Jolley*, 308 F.3d 1317, 1320 (Fed. Cir. 2002).

B. The Board correctly affirmed the ODP rejections over the '272 and '195 reference patents

1. Janssen concedes that claim 1 of the '471 patent is not patentably distinct from the claims of the '195 and '272 reference patents

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). Here, the '195 and '272 reference patents have both expired, and the '471 patent, with

claims that are not patentably distinct from these patents, has patent term remaining. Appx5.

An obviousness type double patenting analysis requires two steps. First, as a matter of law, a court construes the claims in the earlier patent and the claims in the later patent (or application) and determines the differences. *See, e.g., Eli Lilly and Co. v. Barr Labs, Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001). Second, the court determines whether those differences render the claims patentably distinct. *Id*. A later claim is not patentably distinct from an earlier claim if the later claim is obvious over, or anticipated by, the earlier claim. *Pfizer,* 518 F.3d at 1363.

Janssen concedes that representative claim 1 of the ’471 patent is not patentably distinct from claims 1 and 7 of the ’272 reference patent and claims 1 and 6 of the ’195 reference patent. The ’471 patent has claims to anti-TNF chimeric antibodies. Appx176. The ’272 patent has claims directed to methods of treating Crohn’s disease by administering an anti-TNF chimeric antibody. Appx357. The ’195 patent has claims directed to methods of treating rheumatoid arthritis by administering an anti-TNF chimeric antibody. Appx269. As the Board explained, because anti-TNF antibodies are required to practice the treatment methods, “granting a patent on the antibodies would result in an extension of the patent rights in the [already expired] ’272 and ’195 patents.” Appx30.

2. The safe harbor of § 121 is limited to applications filed as divisionals and the '093 application was not filed as a divisional

The Board correctly determined that the '093 application does not fall within the safe harbor provided by 35 U.S.C. § 121. Section 121 is titled "Divisional applications" and states:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. *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.* The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

(Emphasis added.)

Section 121 provides that the safe harbor is available to "divisional" applications. By its explicit language, section 121 does not protect *any* application from an ODP rejection; it protects a *divisional* application *filed* before issuance of the patent on the other application.

The purpose of the safe harbor is to "protect an applicant from losing rights when an application is *divided*." *Boehringer Ingelheim Int'l GmbH v. Barr Labs,*

Inc., 592 F.3d 1340, 1350 (Fed. Cir. 2010). But here, the '093 application (as well as the applications that led to the '195 and '272 patents) was not a divisional application of the '413 application. Instead, it was a CIP that "add[ed] subject matter not disclosed" in the '413 application. MPEP § 201.06. It also included claims that were not supported by the disclosure of the '413 application.

Janssen, however, argues that "nothing" in § 121 "requires an application at filing be labeled a divisional or to disclose and claim only subject matter of the parent application." Br. 26. Janssen argues that the phrase in § 121 relied upon by the Board "does not identify any requirements of a 'divisional application'" but "simply refers back to the 'divisional application' identified in the previous sentence: the application that is made the subject of a non-elected invention and that is entitled to the parent application's filing date under 35 U.S.C. § 120." *Id*. But the Board, like the *Pfizer* and *Searle* Courts, relied on the MPEP definition of "divisional application." Appx16; *Pfizer*, 518 F.3d at 1359-60; *Searle*, 790 F.3d at 1355. And there is no dispute that Janssen's '093 CIP application, which added new subject matter and new claims based on that new subject matter, does not fall within the MPEP's definition of divisional application. Likewise, the applications that issued as the '195 and '272 reference patents were also filed as CIPs and added new subject matter and claims.

3. This Court's case law confirms that the safe harbor of § 121 is limited to applications filed as divisionals

a) *Pfizer v. Teva*: application filed as a CIP not entitled to § 121's safe harbor

This Court rejected Pfizer's argument that U.S. Patent 5,760,068 ("the '068 patent") was entitled to the benefit of § 121's safe harbor. *Pfizer,* 518 F.3d at 1363.

Pfizer filed U.S. Patent Application No. 08/160,594 ("the '594 application") with claims to compounds, compositions, and methods of using these compounds. *Id*. at 1357. The Office issued a restriction requirement identifying these three groups as patentably distinct subject matter. *Id*. Pfizer elected to prosecute the compound claims and ultimately received U.S. Patent No. 5,466,823. Pfizer filed a divisional application to prosecute the composition claims and ultimately received U.S. Patent No. 5,563,165. *Id*. at 1358. But, as to the method claims, Pfizer filed a CIP application, Serial No. 08/223,629 ("the '629 application"), which ultimately issued as the '068 patent.

Pfizer brought suit against Teva on the '165, '823 and '068 patents. *Id*. at 1356. Teva asserted that the claims of the '068 patent were invalid on ODP grounds over the '165 patent because § 121 applies exclusively to divisional applications and the '068 patent issued from a CIP application, not a divisional application. *Id*. at 1358-59. Pfizer responded that the term "divisional

application" as used in § 121 "refers broadly to any type of continuing application filed as a result of a restriction, regardless of whether it is labeled by the PTO, for administrative purposes, as a divisional, a continuation, or a CIP." *Id.* at 1360.

This Court disagreed with Pfizer. *Id*. Beginning with the words of the statute, this Court found that § 121 "explicitly refers" to divisional applications. *Id*. (the "safe harbor, by its literal terms, protects only 'divisional application[s]'"). The legislative history also "refers specifically" to divisional applications. *Id*. And because the difference between divisional applications and CIPs was well known when § 121 was enacted, this Court found "no suggestion" in the legislative history that "the safe-harbor provision was, or needed to be, directed at anything but divisional applications." *Id*. at 1361-62. All of this led this Court to conclude that "[i]f the drafters wanted to include CIPs within the protection afforded by section 121, they could have easily done so." *Id*. at 1362.

Janssen attempts to distinguish *Pfizer* by arguing that *Pfizer's* "rationale" was based on "denying new matter protection from double patenting rejections." Br. 28. Janssen asserts that this "is not an issue here, as the PTO itself has confirmed that the '471 Patent claims do not depend on new matter but are entitled to the filing date of the Parent Application." *Id*., citing Appx1041. But Janssen ignores that the "rationale" of the *Pfizer* decision was the statutory construction of § 121, not its mention that a "plausible" reason Congress chose

this result was to ensure that CIPs were not accorded an earlier priority date for new matter. *Pfizer*, 518 F.3d at 1362.

Janssen also argues that *Pfizer* "did not consider whether an application must be a divisional at filing for safe harbor protection." Br. 28. But *Pfizer* did rely on the application's status at filing to make its determination. *Pfizer*, 518 F.3d at 1362 ("Here, the '068 patent . . . was filed as a CIP and not a divisional application."). And to the extent that Janssen is merely arguing that *Pfizer* did not present the same fact pattern presented here, where years after issuance a patentee attempts to retroactively designate a CIP application as a divisional application, *Searle* (discussed *infra*) conclusively answers that question.

b) *Amgen v. Hoffman-LaRoche*: application filed as a continuation not entitled to § 121's safe harbor

In *Amgen*, this Court reiterated that the scope of § 121's safe harbor is limited to divisional applications. *Amgen*, 580 F.3d at 1340. Amgen brought a declaratory judgment action alleging that Roche's product would infringe certain Amgen patents if imported into the United States. *Id*. at 1346. Roche asserted a defense of ODP against three Amgen patents, and the district court held that they were entitled to the § 121 safe harbor. *Id*. at 1351. On appeal, Roche contended that the district court erred because the patents "issued from solely continuation applications to which § 121 is inapplicable." *Id*. at 1350-51. Amgen responded

that ODP did not apply because patents that issue from continuation applications are eligible for 121 protection "so long as the other requirements of §121 are met." *Id*. at 1351. Amgen urged this Court to "look to an application's substance — not its designation — to determine whether it qualifies as a divisional application under § 121's safe harbor." *Id*. According to Amgen, the relevant "substance" was that its applications (i) were "carved out of a pending application"; (ii) "contained claims to distinct and independent inventions"; and (iii) "disclosed and claimed only subject matter disclosed in the earlier or parent application." *Id*.

This Court was not persuaded by Amgen's argument. Repeating its analysis from *Pfizer*, this Court found that the language of § 121 refers to divisional applications, and nothing in the legislative history suggests otherwise. *Id*. at 1352. And although continuation applications, unlike CIPs, "are limited to subject matter disclosed in the earlier application," that distinction "does not justify departing from a strict application of the plain language of § 121 which affords its benefits to 'divisional application[s].'" *Id*. at 1353. This Court also rejected Amgen's argument that because Amgen could have filed its continuation applications as divisional applications, this Court should treat them as divisional applications. *Id*. at 1354. Instead, this Court focused on what actually occurred: Amgen "denominated the [] applications continuations," Amgen "checked the

continuation application box on the submitted form," and its applications "met the PTO's definition of a continuation application in MPEP § 201.07." *Id*. For all of these reasons, the *Amgen* Court "decline[d] to construe 'divisional application' in § 121 to encompass Amgen's properly filed, properly designated continuation applications." *Id*.

Janssen argues that *Amgen* can be distinguished because Amgen's patents issued "from applications that were not, and could not possibly have been, divisionals in either form or substance." Br. 27. But Amgen argued the opposite — that it *could* have filed its applications as divisionals — and Janssen does not elaborate as to why it holds a contrary view. *Amgen*, 580 F.3d at 1354.

Janssen also contends that *Amgen* relied on the "*absence of any evidence*" that Amgen intended its applications to be divisionals, whereas Janssen "repeatedly told the PTO that it was prosecuting the '093 Application to pursue examination of a non-elected invention." Br. 28-29, citing Appx13856, Appx13771. Janssen's "evidence" is a sentence in its preliminary amendment that it was cancelling "subject matter which is drawn to a non-elected invention pursuant to the ['413] restriction requirement" and its argument in an amendment that § 121 precludes an ODP rejection over the '799 application. Br. 36. But neither statement can erase Janssen's actions denominating the '093 application

as a CIP and checking the CIP application box on the submitted form. Appx13918; Appx14111-14112.

c) *Searle v. Lupin*: application filed as a CIP and redesignated as a divisional during reissue not entitled to § 121's safe harbor

In *Searle*, this Court again considered the scope of § 121's safe harbor. *Searle*, 790 F.3d 1349. *Searle* concerned reissued U.S. Patent RE 44,048 ("the RE '048 patent") of the '068 patent at issue in *Pfizer*. *Id*. at 1351. The '068 patent issued from CIP application No. 08/648,113 ("the '113 application"), which claimed priority to a previous CIP application, the '629 application.

After the *Pfizer* Court held that Pfizer's '068 patent was not entitled to § 121's safe harbor because it issued from a CIP application, Pfizer filed reissue U.S. Patent Application No. 12/205,319 ("the '319 application") to correct this "error." *Id*. at 1353. Pfizer's preliminary amendment in the '319 application designated the '113 application as a divisional of the '594 application and deleted subject matter not present in the '594 application (by cancelling and amending claims and deleting portions of the specification). *Id*. The preliminary amendment stated that these "actions were taken to conform the '068 patent to a divisional of the '594 application." *Id*. The USPTO allowed Pfizer to correct these "errors" and reissued the patent with these changes. *Id*.

Pfizer sued five generic manufacturers for infringement. *Id*. at 1353-54. The district court held that the "RE '048 patent was not a valid reissue patent, because Pfizer's asserted "error" of prosecuting a prior patent application as a continuation-in-part, rather than as a divisional, "was not correctable by reissue under section 251." *Id*. at 1354. The district court also found that the safe harbor of § 121 did not apply to the RE '048 patent, and, as a result, Pfizer's claims were invalid under ODP. *Id*.

On appeal, this Court held that Pfizer's reissue patent was not entitled to the safe harbor of § 121.[6] *Id*. Noting that *Amgen* requires a "strict application of the plain language of § 121," the Court held that RE '048 is not entitled to safe harbor protection "because it did not issue on either the '594 application or a divisional of the '594 application." *Id.* Relying on the MPEP definition of a divisional application, the Court found that "[t]he '113 application cannot be a divisional of the '594 application, despite being designated as such in the reissue patent, because it contains new matter that was not present in the '594 application." *Id*. at 1354-55. And "[s]imply deleting that new matter from the reissue patent does not retroactively alter the nature of the '113 application." *Id*.

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[6] The *Searle* Court did not address "whether 35 U.S.C. § 251 authorized the PTO to reissue the '068 patent under the circumstances. *Id*.

at 1355. The Court noted that "[m]oreover, when the '113 application issued as the '068 patent in June 1998, Pfizer obtained patent protection for the new matter that was not present in the '594 application" and "[f]or years thereafter, the public was not free to practice that new matter." *Id*. Thus, "[f]airness to the public does not permit Pfizer to convert the '113 application into a division of the original '594 application, and thereby take advantage of the safe harbor provision, simply by designating it as a divisional application years after the fact." *Id*.[7]

Janssen's attempts to distinguish *Searle* fail. Br. 32-35. Janssen argues that *Searle* did not create a "per se rule against applying the safe harbor to applications for which a formal designation as a divisional has later been made." Br. 32. Instead, Janssen advances the argument that the basis for the *Searle* decision was that the patentee had, for years, enjoyed patent protection for claims based on new matter found only in the CIP application. *Id*. In contrast, Janssen stresses that the "public here was in no way prejudiced" by Janssen filing claims in the '093 application "that were never examined" and "did not confer any rights on Janssen at the expense of the public." Br. 33. To the contrary, Janssen declares that its added disclosure "benefitted the public." *Id*. But as the Board

[7] The *Searle* Court also held that § 121 was inapplicable to the RE '048 patent for a second reason: the RE '048 patent and the '165 reference patent were not "derived from the same restriction requirement." *Id*. at 1356.

explained, even if Janssen did not benefit, there is "still . . . no reason to permit [Janssen] now, by amendment, to acquire the benefit of the safe harbor when [it] voluntarily and deliberately filed a [CIP] with claims directed to subject matter absent from the '413 Application and outside the scope of its restriction." Appx28. And the examiner found that Janssen had benefitted because more than 30 patents have issued to Janssen that claim priority to the '471 patent, and the presence of the new matter in the specification was sufficient to keep competitors out of that subject area. Appx691-692. Although Janssen argues that only two patents claim benefit to the '471 patent alone, and none rely on the deleted subject matter for support, that determination is within the Office's purview and cannot be accomplished without reopening examination of each patent. Appx691-692.

4. Longstanding USPTO practice does not support Janssen

Unable to escape the plain language of the statute and this Court's case law, Janssen shifts the focus to USPTO practices to no avail.

Janssen argues that the "Board failed to recognize that the patent statute, as well as the PTO's own rules and examination practices, authorized [Janssen's] amendments." Br. 30-31. But Janssen mischaracterizes the Board's decision. In its Appeal brief to the Board, Janssen stated that the examiner "expressly recognized" the status of the '093 application as a divisional. Appx783. The Board corrected Janssen's overstatement, quoting the examiner: "The Patent

Office has not confirmed the status of the '471 patent as a Divisional. The amendment was entered for the purpose of reexamination" and the "*efficacy of such amendment changing the claim for benefit during reexamination is the issue under appeal*." Appx26, citing Appx681-697 at Appx689. Thus, Janssen's repeated statements throughout its brief that the '093 application is a divisional are incorrect. *See, e.g.*, Br. 1, 15, 31.

Janssen next contends, without supplying specifics, that the PTO permits applications designated as CIPs to be treated as divisionals. Br. 21. Janssen seems to be relying on a PTO practice that permits an applicant to file a divisional application by filing a copy of the parent application (with its original claims) and limiting its claims to one group of the restriction requirement in a preliminary amendment. Br. 27. But that practice has no relevance here because Janssen did not follow it. Janssen did not file a copy of the "parent" application with its original claims; Janssen filed a CIP with claims and subject matter that originated from two applications, the '413 and '406 applications. And Janssen's preliminary amendment did not limit its claims to one group in the '413 restriction requirement; Janssen continued to present claims that relied on subject matter disclosed in both the '413 and '406 applications. Appx13852-13856.

Next, Janssen asserts that the PTO "routinely allowed applicants to designate applications both a 'CIP' and a 'divisional'" and that "belie[s] the

Board's assertion that the PTO enforces a rigid definition that excludes a CIP from ever being considered also a 'divisional.'" Br. 27, citing Appx635, Appx653-662. Janssen is incorrect. A continuation-in-part application is an application "adding subject matter not disclosed" in the earlier application. MPEP §201.06. A divisional is a "later application for an independent or distinct invention, carved out of a [pending] application . . . and disclosing and claiming only subject matter disclosed in the earlier or parent application. *Id*. Thus, the terms divisional and continuation-in-part "are exclusive." U.S. Patent and Trademark Office Official Gazette Notice: 18 March 2003, "Claiming the Benefit of a Prior-Filed Application under 35 U.S.C. §§ 119(e), 120, 121, and 365(c).[8] For that reason, "[a]n application cannot be, for example, both a continuation and a divisional, or a continuation and a continuation-in-part, of the same parent application." *Id*. And Janssen's ability to uncover a handful of patents (out of the more than nine million issued patents) that are nonconforming does not establish a "routine" PTO practice. And even if it did, it does not advance Janssen's argument because, unlike these applications, Janssen never identified the '093 application as *both* a divisional application and a CIP application on the first page

[8] Official Gazette Notice found at: https://www.uspto.gov/web/offices/com/sol/og/2003/week11/patbene.htm.

of the ’093 specification (or anywhere else). Instead, Janssen repeatedly identified the ’093 application as a CIP of both the ’413 and ’406 applications. Appx14111-14112; Appx13529-13530; Appx13918.

Janssen, however, insists that it “informed the Examiner that it was prosecuting the ’093 Application as a divisional” by stating in its preliminary amendment that it was cancelling “subject matter which is drawn to a non-elected invention pursuant to the restriction requirement set forth in parent application Serial No. 08/013,413.” Br. 4, citing Appx13856; Appx13771; Appx13732. But an applicant can file a continuation *or* a CIP *or* a divisional. Janssen chose to file a CIP and told the Office in three separate papers that it was filing a CIP. Appx13918; Appx14111; Appx13529-13530. Thus, Janssen never “informed the Examiner” that it was prosecuting the ’093 application as a divisional of the ’413 application because it was not. As the Board explained, Janssen’s preliminary amendment continued to present claims that encompassed subject matter disclosed in *both* the ’406 and ’413 applications. Appx18-19.

Janssen next contends that “manifest unfairness” would result if Janssen is denied access to the safe harbor. Br. 34. Janssen argues that its added disclosure “has benefitted the public” and “[a]pplicants like Janssen who choose to disclose but not claim new information, while otherwise respecting the requirements of Section 121, should be rewarded — not penalized.” Br. 33. But Janssen has not

"otherwise respect[ed] the requirements of Section 121." Indeed, it is unclear what that could possibly mean since Janssen filed a CIP. Perhaps Janssen could have balanced its needs by filing a divisional application of the '413 application and a CIP to pursue claims to its new disclosure. Janssen chose not to do so.

Janssen also maintains that it relied to its detriment on the examiner's withdrawal of an ODP rejection during the original '093 prosecution. Br. 29, 34, citing Appx13732, Appx13771. Janssen now speculates that if the examiner had maintained the ODP rejection, Janssen could have filed a divisional application. Br. 34. But the timing of Janssen's scenario seems unlikely. To qualify for § 121's safe harbor, a divisional application must be "filed before the issuance of the patent on the other application." 35 U.S.C. § 121. During the two-year period (August 1995-August 1997) the examiner maintained the ODP rejection, Janssen chose not to file a divisional application. Nevertheless, Janssen now argues that if the examiner's final Office Action, mailed on August 5, 1997, had contained an ODP rejection, Janssen would have filed a divisional application before August 12, 1997, the day that the '272 patent issued.

Finally, Janssen's reliance on the *Martek* reexamination No. 90/009,659 is not persuasive. Br. 34-35. The decision by the examiner in *Martek* is not precedential and is not binding on the Board. And importantly, the examiner took

this action in *Martek* in 2011, before the Office had the benefit of this Court's *Searle* decision.

5. Janssen's remaining "divisional in form" and "divisional in substance" arguments carry no weight

Janssen argues that "[e]ven if the '093 Application were denied the effect of Janssen's amendments, it nonetheless should be 'deemed' a divisional for purposes of Section 121" for three reasons: (i) it "was filed before issuance of patents on the elected Group IV invention"; (ii) a "non-elected invention was made its subject"; and (iii) those claims were "supported by the Parent Application and consonant with the restriction applied in the Parent Application." Br. 35-36. But (i) the '093 application was filed as a CIP, not a divisional; (ii) a non-elected invention of the '413 application was not "made its subject" because it also included claims from the '406 application; and (iii) the claims were not "supported" by the '413 application and, as discussed *infra*, were not consonant with the '413 restriction. Moreover, this Court in *Amgen* has already rejected the notion that it should look to an application's "substance," rather than its designation. *Amgen*, 580 F.3d at 1354.

Janssen further contends that before any "substantive" examination, it limited its claims to Group I claims supported by the '413 application. Br. 5-6; Br. 22; Br. 38-43. Janssen says that it accomplished this by amending claims 9

and 42 (to exclude references to TNF beta) and electing the Group I species (thereby removing the Group II immunoreceptor claims from consideration). *Id*. But Janssen did not limit claim 1 to TNF alpha until December 1995, after Janssen received an Office Action on the merits. Br. 6; Appx6-18; Appx13809-13810. Thus, Janssen did not limit its claims to Group I claims before any "substantive" prosecution. Moreover, Janssen's emphasis on the *claims* in the '093 application overlooks that, throughout prosecution, the *specification* of the '093 application contained subject matter not disclosed in the '413 application. And a statement by the examiner as to her understanding of the invention under examination cannot override Janssen's actions. Br. 41, citing Appx13824.

6. Janssen has not established that the claims of the '471 patent and the reference patents maintained consonance with the '413 restriction requirement

If this Court concludes that Janssen is not entitled to § 121's safe harbor because the '093 application was not a divisional application, it need not consider whether Janssen has established consonance. But if the '093 application is a proper divisional application, Janssen must also establish that each of the three patents involved in the ODP rejection maintained "consonance" with the restriction requirement.

"Consonance requires that the line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement be

maintained." *Gerber Garment Tech., Inc. v. Lectra Sys*., *Inc*. 916 F.2d 683, 688 (Fed. Cir. 1990). "Where that line is crossed the prohibition of the third sentence of Section 121 does not apply." *Id*. The "requirement for consonance applies to both the patent challenged for double patenting (the challenged patent) and the patent being used as a reference against the challenged patent (the reference patent)." *St. Jude Medical, Inc. v. Access Closure, Inc*., 729 F.3d 1369, 1377 (Fed. Cir. 2013).

Janssen makes four arguments regarding consonance. First, Janssen says that consonance only requires a comparison of the issued claims with the restriction requirement. Br. 38-39. But under that formulation, Janssen cannot establish consonance. As the Board explained, the issued claims of the '195 reference patent are not limited to the subject matter disclosed in the '413 application because they are not limited to TNF alpha. Appx25. Likewise, Janssen does not establish that the issued claims of the '272 reference patent are limited to TNF alpha.

Second, Janssen asserts that during reexamination the examiners "agreed" that the claims of the '195, '471 and '272 patents "are consonant with the restriction." Br. 47, citing Appx1003, Appx1005. But the pages Janssen cites to do not support its argument. Appx1002-Appx1005. And the Board certainly did

not "agree" that the claims of each patent were consonant with the restriction. Appx23-25.

Third, Janssen insists that the "record demonstrates [that] Janssen's intent from the outset" was "to secure examination of claims that were consonant with the restriction and supported by the Parent Application." Br. 40. But the record demonstrates the opposite. Throughout 1994 and 1995 Janssen presented claims for prosecution that relied on subject matter from the '406 application as well as the '413 application.

Fourth, relying on *Applied Materials*, Janssen argues that the fact that claims 1 and 9 were broader than the original Group I claims did not breach consonance. Br. 44-46; *Applied Materials, Inc. v. Advanced Semiconductor Materials, Inc*., 98 F.3d 1563, 1568 (Fed. Cir. 1996). But here, Janssen's claims are not just broader than the original Group I claims; they are directed to subject matter not disclosed in the '413 application where the restriction was made.

7. Janssen has not established that it is entitled to the two-way ODP test

Janssen has the burden to establish that the two-way test applies. *In re Berg*, 140 F.3d 1428, 1435 (Fed. Cir. 1998). Janssen has not met its burden.

The two-way ODP test is a "narrow exception." *Id*. at 1432. It arose to "prevent rejections for obviousness-type double patenting when the applicants

filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing, rejecting the basic application although it would have been allowed if the applications had been decided in the order of their filing." *Id*. Thus, as *Berg* emphasized, the two-way test is only appropriate in the "unusual circumstance" when the USPTO is "*solely responsible* for the delay in causing the second-filed application to issue prior to the first." *Id.* at 1437 (emphasis added); *accord Eli Lilly*, 251 F.3d at 968, n.7.

Here, because the '093 application and the '102 application (which led to the '272 patent) were both filed on February 4, 1994, Janssen does not contend that there is a "first-filed" or "second-filed" application. Indeed, when applications are filed on the same day, only a one-way test is applicable. MPEP 804 II (B)(2)(b) ("[i]f the application under examination is the later-filed application, *or both applications are filed on the same day, only a one-way determination of distinctness is needed* in resolving the issue of double patenting, i.e., whether the invention claimed in the application would have been anticipated by, or an obvious variation of, the invention claimed in the patent) (emphasis added).

Janssen, however does not acknowledge the MPEP's guidance on this issue. Instead, Janssen argues that the two-way test applies to both the '195 and

'272 reference patents[9] because the "PTO was solely responsible for the delays that caused the '471 Patent to issue after the Reference Patents." Br. 47.

But even if Janssen could set aside the MPEP, it cannot establish that the USPTO is "solely responsible" for any alleged delay associated with the '471 claims. To the contrary, the Board explained that Janssen took, or failed to take, several actions that caused the '471 patent to issue after the '195 and '272 reference patents. Appx29-40; *In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1376 (Fed. Cir. 2008) ("Natta's actions, or inactions, had a direct effect on the prosecution and thus were responsible for any delay in prosecution."); *Emert*, 124 F.3d at 1461 ("Emert had significant control over the rate of prosecution of the application.")

First, Janssen delayed obtaining a first Office Action on the merits in the '093 application by filing a preliminary amendment in December, 1994 which included immunoreceptor claims from the '406 application along with chimeric antibody claims from the '413 application. Appx33-34; Appx13852-13856. Because examination of these two species would require separate and divergent searches, the examiner issued an election of species requirement on April 7, 1995,

[9] The '799 application that led to the '195 reference patent was filed on October 18, 1994. Appx178.

thereby delaying a first Office Action on the merits. Appx33-34; Appx13843-13847.[10]

Janssen argues that the ten months it took to file its preliminary amendment is not relevant because its preliminary amendment did not automatically reset the examination clock, it was filed more than five months before the first Office Action, and "there is no evidence" that it "actually caused any delay." Br. 54-55. But the Board's focus was not only on how long it took Janssen to file its preliminary amendment, but also its substance. By continuing to present claims not supported by the '413 application, Janssen's preliminary amendment led to further delays in the prosecution.

Janssen pursued a different strategy in the applications leading to the '195 and '272 reference patents. In each application, Janssen filed preliminary amendments that were explicitly designed to "reduce issues on examination and expedite prosecution." Appx38-40; Appx 14964-14966 ('195 patent); Appx14398-14440 ('272 patent). Janssen achieved its goal in each reference

[10] Janssen criticizes the Board's statement that Janssen's preliminary amendment "required" the examiner to request an election of species. Br. 54. But Janssen cannot dispute that its preliminary amendment certainly "prompted" the examiner to issue her request.

patent application by limiting the number (seven) and type (methods of treatment) of claims. *Id*.

Janssen dismisses the Board's comparison with the reference patents. Br. 57. But in considering whether the USPTO was "solely responsible" for "delays" that caused the '471 patent to issue after the reference patents, it is certainly relevant that Janssen took active steps in the reference patent applications to "reduce issues on examination and expedite prosecution." Appx14964-14966; Appx14398-14400.

Second, after the examiner sent a final rejection on May 1, 1996, Janssen delayed examination again. Appx34; Appx13789-13796. Janssen waited six months, until October, 1996 to file a Notice of Appeal. Appx13787-13788. Janssen then waited another six months (until May 1997), changed its mind, and then filed a 37 C.F.R. § 1.129(a) amendment, which added new claims and amended claims. Appx13758-13783.

Janssen now asserts that it was the PTO's improper ODP and cA2 rejections that necessitated both of these filings. Br. 58-59. But a Notice of Appeal and a Rule 129 submission are alternatives, and Janssen delayed by waiting six months, choosing to file one, and then waiting another six months to file the other. Nothing that the USPTO did accounts for Janssen's inability to make up its mind as to what course it wanted to follow.

Third, on August 5, 1997, the examiner indicated that claims 136-139 were allowable if written in independent form, and claims 31 and 133 were allowable if rewritten to be dependent on any one of claims 136-139. Appx34; Appx13731-13738 at Appx13733. Yet Janssen chose not to accept allowance of those claims until December 1, 2000. Appx34; Appx13651-13652. *In re Hubbell*, 709 F.3d 1140, 1150 (Fed. Cir. 2013) (two-way test not applicable because, among other reasons, after the examiner allowed claims "very similar" to the issued claims, Hubbell failed to pay the issue fee, let the claims go abandoned, and filed a new application).

Janssen argues that these events "fall outside the critical periods." Br. 60. But it is not clear that they do, at least for the '195 patent which did not issue until December 16, 1997. Janssen also contends that it did not act "improperly" in continuing to seek other claims. Br. 61. But the question is not whether Janssen acted "improperly." The question is whether Janssen contributed to the "delay" causing the '471 patent to issue after the reference patents. Janssen surely did.

Fourth, Janssen waited until August 1998 to add the peptide claims that issued as claims 8 and 9. Appx13688-13698. As this Court has recognized, an admission that claims could have been presented earlier indicates that the delay was not solely caused by the USPTO. *Lilly*, 251 F.3d at 968, fn.7; *Hubbell*, 709 F.3d at 1150.

Janssen asserts that the relevant "delay" was the examiner's "erroneous and inconsistent treatment of cA2 claims." Br. 49-52. But as the Board explained, the question is whether Janssen was also responsible for delays that caused the '471 patent to issue after the '195 and '272 reference patents. Appx37-38. And although Janssen tries to distinguish its actions from applicants who filed a series of applications, Janssen provides no reason why an applicant's delay in a single application should be treated differently than a delay achieved by filing a series of applications. Br. 54, citing *Lilly*, 251 F.3d at 968, n.7; *In re Goodman*, 11 F.3d 1046, 1053 (Fed. Cir. 1993); *Fallaux*, 564 F.3d at 1316-17.

And finally, Janssen's argument that the examiner did not "dispute" that Janssen's claims were patentable under the two-way test is incorrect.[11] Br. 14, Br. 47. The examiner and the Board did not consider the issue because they determined that the two-way test was inapplicable to the facts here. Appx696; Appx29-40.

Thus, because Janssen cannot establish that the USPTO is "solely responsible" for any delay that caused the '471 patent to issue after either of the reference patents, the two-way test is not applicable here.

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[11] Indeed, Janssen's brief repeatedly, and incorrectly, states that certain issues were not "disputed" by the examiners (Br. 11-12) or the Board (Br. 26, 36).

V. CONCLUSION

The Board correctly concluded that Janssen's claims 1-7 were unpatentable on obviousness double patenting grounds. Accordingly, this Court should affirm the Board's decision.

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Respectfully submitted,

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RULE 32(a)(7)(C) CERTIFICATE OF COMPLIANCE

I certify pursuant to Fed. R. App. Proc. 32(a)(7) that the foregoing BRIEF FOR APPELLEE – DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE complies with the type-volume limitation required by the Court's rule. The total number of words in the foregoing brief, excluding the table of contents and the table of authorities, is 10,627 words as calculated using the Word® software program.

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2017, the foregoing BRIEF FOR APPELLEE – DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE was electronically filed using the Court's CM/ECF filing system. Counsel for appellant was electronically served by and through the Court's CM/ECF filing system per Fed. Cir. R. 25(e).

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