

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

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

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

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

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

We affirm.

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## BACKGROUND

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

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

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

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

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

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

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

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

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

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<sup>2</sup> Claims 2 and 4 are rejected over the claims of the ’272 or ’195 Patents in combination with other references.

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

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

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

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

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

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

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

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

#### FINDINGS OF FACT

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

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

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	II. Claims 22 and 23, drawn to methods of treating vertebrates with the immunoreceptors of Group I.
	[FF4] Claims 1, 8, and 9 as originally filed in the '406 Application are reproduced below:  1. An immunoreceptor molecule for binding to TNF, comprising at least a portion of an immunoglobulin heavy chain CH <sub>1</sub> region, at least a portion of a hinge region and at least one immunoglobulin light chain constant region wherein at least one immunoglobulin chain is covalently linked to a non-immunoglobulin molecule capable of binding to TNF $\alpha$ or TNF $\beta$ or both.  8. The immunoreceptor molecule of claim 1 wherein the non-immunoglobulin molecule comprises at least a portion of p55.  9. The immunoreceptor molecule of claim 1 wherein the non-immunoglobulin molecule comprises at least a portion of p75.
09/29/1994	[FF5] A Notice of Abandonment was mailed in the '406 Application because of "Applicant's failure to respond to the Office letter, mailed 3/28/94."
The '413 Application (Appl. No. 08/013,413)	
02/02/1993	[FF6] The '413 Application was filed 2/2/1993.
	[FF7] FIELD OF THE INVENTION The present invention in the field of immunology and medicine relates to antibodies and nucleic acid encoding therefor, which antibodies are specific for human tumor necrosis factor-alpha (hTNF $\alpha$ ) and to pharmaceutical and diagnostic compositions and production, diagnostic and therapeutic methods thereof. '413 Appl. Spec. 1:15–20.
	[FF8] SUMMARY OF THE INVENTION It is an object of the present invention to overcome the deficiencies of the background art. It is also an object of the

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	<p>present invention to provide anti-tissue necrosis factor (TNF) murine antibodies and chimeric antibodies, and fragments and regions thereof, which inhibit or neutralize TNF biological activity in vivo and are specific for human tumor necrosis factor-alpha (hTNF<math>\alpha</math>).</p> <p>'413 Appl. Spec. 6:27–37.</p>
10/27/1993	<p>[FF9] A restriction requirement in the '413 Application was set forth by the Examiner as follows:</p> <p>I. Claims 1–21, 24, 38, 39, and 48, drawn to monoclonal antibodies, detectably labelled monoclonal antibodies, chimeric antibodies, pharmaceutical compositions, and assay methods.</p> <p>II. Claims 22 and 23, drawn to TNF polypeptides.</p> <p>III. Claims 25–31 and 49, drawn to polynucleotides encoding antibodies, transformed hosts, transfected hosts, and processes for preparing antibodies by culturing transformed/transfected hosts;</p> <p>IV. Claims 32, 33, 40–47, 50, 51, and 54–57, drawn to methods for treating an animal by administering a pharmaceutical composition containing an antibody;</p> <p>V. Claims 34–37, 52, and 53, drawn to methods for removing TNF-alpha from a sample and treatment methods involving removal of TNF-alpha from a body fluid and returning said body fluid to an animal.</p>
	<p>[FF10] Claims 1, 3, 24, and 32 as originally filed in the '413 Application are reproduced below:</p> <p>1. A high-affinity mouse monoclonal antibody to human tumor necrosis factor-<math>\alpha</math> (TNF<math>\alpha</math>), wherein said monoclonal antibody (a) competitively inhibits the binding of antibody A2 to TNF and (b) binds to a neutralizing epitope of human TNF<math>\alpha</math>.</p>

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	<p>3. A chimeric immunoglobulin chain comprising at least part of a human immunoglobulin constant region and at least part of a non-human immunoglobulin variable region having specificity to human TNF<math>\alpha</math>.</p> <p>24. A pharmaceutical composition, comprising an antibody according to claim 1, or fragment, region or pharmaceutically acceptable ester, ether, sulfate, carbonate, glucuronide or salt thereof, and a pharmaceutically acceptable carrier.</p> <p>32. A method for treating an animal having a pathology mediated by a TNF comprising administering to said animal a therapeutic amount of a pharmaceutical composition according to claim 24.</p>
	[FF11] All the original chimeric antibody treatment claims in the '413 Application (claims 32, 33, 40–47, 50–57) involved administering an anti-TNF $\alpha$ chimeric antibody).
02/04/1994	[FF12] On 02/04/1994, a paper was filed in the '413 Application expressly abandoning it in view of the filing of a continuation-part application.
	The '093 Application (Appl. No. 08/192,093) (issued as US 6,284,471)
02/04/1994	[FF13] The '093 Application was filed Feb. 4, 1994.
	[FF14] The '093 Application was designated as a “continuation-in-part” of the '413 Application. (“Response in parent case in support of petition and fee for extension of time when filing new application claiming benefit of a prior filing.”)
	[FF15] When it was filed, the '093 Application stated on the first page 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. 08/010,413 filed February 2, 1993.” The '413 Application was also stated to be a progeny of earlier filed applications.
	[FF16] The claims of the '093 Application included chimeric antibody claims and immunoreceptor as represented by claims 1, 9, 35, 36, 60, and 61 reproduced below:



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	<p>1. A chimeric antibody, comprising at least part of a human immunoglobulin constant region and at least part of a non-human immunoglobulin variable region, said antibody capable of binding an epitope specific for human tumor TNF.</p> <p>9. A chimeric antibody according to claim 1, wherein said TNF is selected from TNF<math>\alpha</math> and TNF<math>\beta</math>.</p> <p>35. An isolated immunoreceptor molecule, comprising at least part of an immunoglobulin heavy chain CH<sub>1</sub> or CH<sub>2</sub> region, at least a portion of a immunoglobulin hinge region, and anti-tumor necrosis factor, anti-TNF, peptide capable of binding an epitope specific for a human TNF.</p> <p>36. An immunoreceptor molecule according to claim 35, wherein said anti-TNF peptide is selected from a TNF receptor portion, an epitope binding region of an anti-TNF antibody, and TNF-binding peptide.</p> <p>60. An immunoreceptor molecule of claim 36, wherein said TNF receptor is p55.</p> <p>61. An immunoreceptor molecule of claim 36, wherein said TNF receptor is p75.</p>
12/27/1994	[FF17] A preliminary amendment was filed which canceled and amended claims, and added new claims 115–117. The amendment stated that: “The above Preliminary Amendment 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 (Paper No. 8).”
	[FF18] The preliminary amendment did not cancel claims 60 and 61 directed to TNF receptors p55 and p75
04/07/1995	[FF19] The Examiner mailed a restriction requirement as follows:

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	<p>I. Chimeric antibodies, monoclonal antibodies, an immunoassay using an antibody and immunoreceptors which comprise the epitope binding region of an antibody; and</p> <p>II. Immunoreceptor molecules comprising TNF receptor fragments and anti-TNF peptides which are fragments of TNF receptors.</p>
	<p>[FF20] The Examiner found that Group II contained TNF receptor species p55 and p75, and required an election of species if Group II was elected. Claims 60–64 recite the terms “p55” and “p75.” These terms appear in the ’406 Application and claims, but not in the ’413 Application or its claims.</p>
05/04/1995	<p>[FF21] In response to the Restriction Requirement, Appellants elected Group I, claims 1, 4–20, 31, 35–51, 53, 54, 56–59, 65, 71, 73, 74, 82, and 115–117. Applicant<sup>3</sup> did not amend the claims.</p>
08/23/1995	<p>[FF22] The Examiner mailed an Office Action rejecting the claims, <i>inter alia</i>: 1) under obvious-type double-patenting over claims in the ’799 Application and ’406 Application; 2) as lacking written description, enablement, and best mode of claims 12, 13, 45, 46, 116, and 117; 3) and unpatentable under 35 U.S.C. §§ 102 and 103.</p>
12/26/1995	<p>[FF23] Applicant responded, with a one-month extension of time, by cancelling and amending claims. Claim 1 was limited to TNF<math>\alpha</math>.</p>
	<p>[FF24] In response to the obviousness-type double-patenting rejection, Applicant stated that the ’406 Application was abandoned and, with respect to the ’799 Application, stated: “upon resolution of the remaining rejections of record and in the event that these Claims (or other claims drawn to</p>

<sup>3</sup> We refer to the party prosecuting the applications as “the Applicant.” The Patent Owner in the briefs refers to the “Applicant” as the “Patent Owner.” Thus, while we characterized the party prosecuting the applications as the “Applicant,” it appears that we could have identified such party as the “Patent Owner.”

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	chimeric antibodies) remain pending in the '799 Application, a terminal disclaimer will be submitted.”
	[FF25] With respect to claims 12, 13, 45, 46, 116, and 117, Applicant argued that a deposit was not required, but stated that it “is appreciated” that cancellation of these claims “can also overcome this rejection.”
05/01/1996	[FF26] The Examiner mailed a Final Rejection maintaining the obviousness-type double patenting rejection over the '799 Application and other rejections, including Section 112 (e.g., deposit of the antibody of claim 117) and Section 103 rejections.
11/05/1996	[FF27] Applicant filed a Notice of Appeal.
05/08/1997	[FF28] Applicant filed a submission under 37 C.F.R. § 129(a) which served to have the finality of the Final Rejection automatically withdrawn under the rule.
	[FF29] The submission added new claims 118–139 directed to chimeric antibodies to TNF $\alpha$ and an immunoassay method “for detecting human TNF in a sample.” Applicant also amended claims and responded to the outstanding rejections.
08/05/1997	[FF30] The Examiner mailed a Final Rejection. The Examiner withdrew the obviousness-type double patenting rejection in view of the cancellation of claims in both applications. The Examiner also withdrew the Section 112 rejection of claims 12, 13, 116, and 117. The Examiner indicated that claims 136–139 were allowable if written in independent form. These claims were directed to TNF $\alpha$ chimeric antibodies in which the immunoglobulin variable region had specifically recited sequences. The only outstanding rejection was under 35 U.S.C. § 103.
10/08/1997	[FF31] Applicant requested withdrawal of the finality of the rejection because a new grounds of rejection had been presented and because new claims 118–135 were directed to an antibody isotype that had not been presented before.
11/12/1997	[FF32] The Examiner withdrew finality of the Final Rejection of 05/08/1997.
12/08/1997	[FF33] Applicant responded to the rejection by amending claims 136–139 to make them independent, and presented arguments as to why the remaining pending claims were not

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	obvious. Claim 138 became claim 3 in the '471 Patent and claim 139 became patented claim 7. Claim 134 and 136, amended 8/3/1998, because claims 5 and 1 of the '471 Patent.
03/03/1998	[FF34] The Examiner mailed a Final Rejection maintaining the Section 103 rejection. Claims 31 (immunoassay), 133 (immunoassay), and 136–139 were stated by the Examiner to be allowable.
08/05/1998	[FF35] Applicant responded by adding new claims 140–159 to polypeptides of SEQ ID NO: 3 or 5, including “structural analogs” of these sequences (e.g., claims 150–163). Applicant stated that the claims were added from related Application 08/570,674 to avoid double-patenting issues. Applicant presented arguments as to why rejected the subject matter of the claims would not have been obvious over the cited prior art.
09/28/1998	[FF36] In an Advisory Action, Examiner stated that new claims 140–159 would not be entered upon filing an appeal because they “raise new issues that would require further consideration and/or search”—i.e., “raise all of the new rejections already of record in the Final Rejection of 08/570,674.” The Examiner maintained the Section 103 rejection.
03/04/1999	[FF37] Applicant filed a second submission under 37 C.F.R. § 129(a) which served to have the finality of the Final Rejection automatically withdrawn under the rule and permit entry of the unentered claims.
07/06/1999	[FF38] The Examiner mailed an office action maintaining the Section 103 rejection. The Examiner stated that claims 31 (immunoassay), 133 (immunoassay), and 134–139 were allowable. The Examiner issued new rejections set forth on new claims 140–145 and 150–159. The Examiner stated that new claims 146 and 147 were allowable.
01/10/2000	[FF39] Applicant responded with claims amendments and remarks, cancelling some but not all rejected claims. Applicant responded with arguments as to why the rejected claims were patentable.

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03/28/2000	[FF40] The Examiner mailed a Final Rejection withdrawing rejections, but maintaining others. The Examiner stated claims 31, 133–139, and 146 were “allowed.”
09/27/2000	[FF41] Applicant filed a Notice of Appeal.
09/29/2000	[FF42] Applicant filed remarks pursuant to an interview with Examiners on 08/23/2000.
12/01/2000	[FF43] Applicant canceled all rejected claims.
04/04/2001	[FF44] A Notice of Allowance was mailed. The Notice referred to application amendments authorized by Applicant on 03/15/2001.
7/06/2001	[FF45] Applicant paid the Issue fee.
09/04/2001	[FF46] The '471 Patent issued.

IS THE '093 APPLICATION A DIVISIONAL OF  
 THE PARENT '406 APPLICATION?

Restriction requirements were made by the Examiner in the '406 and '413 Applications. FF3, FF9. Subsequently, the '102 and the '093 Applications, which matured into the '272 and '471 Patents, respectively, were filed on 2/4/1994 as CIPs—not divisionals—of the '406 and '413 Applications. The claims of the '471 Patent are rejected under obviousness-type double-patenting over the claims of the '272 Patent. The '799 Application, which matured into the '195 Patent, was filed as a CIP of the '102 and '093 Applications. The claims of the '471 patent are rejected under obviousness-type double-patenting over the claims of the '195 Patent.

Patent Owner contends that the obviousness-type double-patenting rejections should be withdrawn because the '272 and '195 Patents cannot be used as references against the '471 Patent. Appeal Br. 6–7. Patent Owner contends that the '272 and '195 Patents descended from the '413 Application in which a restriction requirement had been made, or an

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application filed as a result of the restriction requirement, prohibiting the patents from being applied against the '471 Patent under 35 U.S.C. § 121, which itself is a divisional (rather than a continuation-in-part as discussed above) of the '413 Application. *Id.* at 13.

We begin with the statutory language of 35 U.S.C. § 121:

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. . . .

Under Section 121, there are three requirements that must be satisfied for a “divisional application” to be shielded from an obvious-type double patenting rejection over a reference patent. First, the reference patent must be “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.” Second, the application must be a “divisional application” of the original application in which the restriction was made. Third, the divisional application must be “filed before the issuance of the patent on the other application.”

In this case, the '272 and '195 Patents are said by Patent Owner to be patents “issuing on an application with respect to which a requirement for

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restriction under this section has been made,” the first requirement of the statute. Appeal Br. 13–15. Patent Owner contends that the ’093 Application, from which the ’471 Patent issued, is a “divisional” application of the ’093 Application which was filed before the ’272 and ’195 Patents, meeting the second and third requirements of Section 121. Because all the statutory requirements are met, Patent Owner contends that the ’471 Patent is in the “safe harbor” created by Section 121 and cannot be rejected over the ’272 and ’195 Patents.

One of the key issues in this rejection is whether the ’093 Application, from which the ’471 Patent issued, is a “divisional application” of the ’413 Application as that term is used in Section 121 and was filed as a “divisional application” before the issuance of the parent applications. We have not been pointed to a statutory definition of “divisional application.” However, Chapter 200 of the Manual of Patent Examination of Procedure (“MPEP”) defines a divisional application as follows:

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”. It may be filed pursuant to 37 CFR 1.53, >37 CFR< 1.60 or >37 CFR< 1.62. Both must have at least one common applicant. The divisional application should set forth only that portion of the earlier disclosure which is germane to the invention as claimed in the divisional application.

MPEP 201.06 (5th Ed., Rev. 15, Aug. 1993<sup>4</sup>) (emphasis added).

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<sup>4</sup> This is from the edition of the MPEP at the time the restriction requirement was made.

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The '093 Application, as filed, was not “disclosing and claiming only subject matter disclosed in the earlier or parent application.” Rather, when the '093 Application was filed, it was designated as a “continuation-in-part” application of the '406 and '413 Applications. FF13–FF15. A continuation-in-part application, according to MPEP 201.08 (5th Ed., Rev. 15, Aug. 1993) “is an application [ ]filed during the lifetime of an earlier application by the same applicant, repeating some substantial portion or all of the earlier application and *adding matter not disclosed* in the said earlier case.” It was not disputed by Patent Owner that, when the '093 Application was filed, it contained “matter [in its specification] not disclosed” in the '413 Application.

The '093 Application also *claimed* subject matter that was not disclosed in the '413 Application, namely 1) chimeric antibodies to the TNF genus and 2) immunoreceptors. FF16.

Both the '413 and '093 Applications claim chimeric antibodies. FF10, FF16. The '413 Application claimed chimeric antibodies which have “specificity to human TNF $\alpha$ .” FF10. The '093 Application claims, however, were not limited to human TNF $\alpha$ , but rather claimed that the antibody is “capable of binding an epitope specific for human tumor necrosis factor TNF,” a genus of proteins which includes at least TNF $\alpha$  and TNF $\beta$  ('471 Patent, col. 3, ll. 41–43). FF16. Claim 9 of the '093 Application explicitly claimed a “chimeric antibody according to claim 1, wherein said TNF is selected from TNF $\alpha$  and TNF $\beta$ .” FF16. In contrast, in the field of the invention, and in the summary of the invention of the '413 Application, the invention was characterized as antibodies to TNF $\alpha$ . FF7, FF8.



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In addition to chimeric antibody claims, the '093 Application, when filed, had claims to “immunoreceptor molecules” comprising a TNF receptor portion which is p55 or p75. FF16. The '413 Application did not disclose immunoreceptor molecules comprising a TNF receptor portion which is p55 or p75. Instead, this subject matter was disclosed and claimed in the '406 Application. FF3, FF4.

Despite the presence of subject matter not disclosed or claimed in the '406 Application, and the explicit designation of it as a continuation-in-part, Patent Owner argues that the '093 Application was a divisional when it was filed because the “record shows that Patent Owner 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.” Appeal Br. 13. Patent Owner also directed our attention to the Preliminary Amendment of 12/23/1994, stating that the “above Preliminary Amendment 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.* at 58; FF17.

The Preliminary Amendment did not cancel the immunoreceptor claims which were not disclosed or claimed in the '413 Application. FF18. The Preliminary Amendment also did not limit claim 1 to TNF $\alpha$  as they were so limited in the '413 Application. FF10, FF16. While it may be correct that subject matter directed to the non-elected invention of the '413 Application had been cancelled, the statement made by Applicant in the Preliminary Amendment did not state that subject matter from the inventions of the '406 Application, namely, the immunoreceptor claims, had been

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canceled. Indeed, after the Preliminary Amendment was filed, the Examiner restricted the claims into two groups, chimeric antibodies claims and immunoreceptor claims comprising fragments of TNF receptors. FF19. The latter claims were disclosed and claimed only in the '406 Application. FF4. Consequently, we find Patent Owner's statement in the Appeal Brief that "Patent Owner *limited* the claims presented for examination in the '093 Application to the subject matter of Group I of the restriction in the ['413] Parent Application" (Appeal Br. 20) to be incorrect (emphasis added). The claims presented for examination were broader than those in the parent '413 Application and contained subject matter neither disclosed nor claimed in '413 Application. More accurately, the claims presented for examination in the '093 Application encompassed matter subject disclosed in both the '406 and '413 Applications.

Even after Applicant had elected only chimeric antibody claims in response to the Restriction Requirement of April 7, 1995, Applicant did not limit the claims to TNF $\alpha$  as claimed and disclosed in the '413 Application, but voluntarily presented for examination antibodies capable of binding to the genus of TNF proteins. *See* '093 Application, claim 1; FF16. Thus, Applicant filed and maintained a broader scope of claims than in '413 Application. A divisional application must disclose and claim only subject matter disclosed in the earlier or parent application. MPEP 201.06 (5th Ed., Rev. 15, Aug. 1993). Applicant of its own accord chose to describe and claim subject matter not disclosed in the '413 Application and thus forfeited the benefit of the safe harbor of Section 121.

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The courts have strictly applied 35 U.S.C. § 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, 1357 (Fed. Cir. 2008), the validity of U.S. Patent No. 5,760,068 (“the ’068 Patent”) was at issue. A restriction requirement had been made by the Examiner in a patent application having compound, composition, and method claims. Pfizer elected claims for prosecution in the patent application which eventually issued into U.S. Patent No. 5,466,823 (“the ’823 Patent”). *Id.* at 1357–58. Subsequent to the restriction requirement but before the ’823 Patent issued, Pfizer filed “[1] a divisional application, which ultimately issued as the ’165 [P]atent, that included the restricted-out composition claims, and [2] a continuation-in-part application (“CIP”), which ultimately issued as the ’068 [P]atent, that included the restricted-out method claims.” *Id.* at 1358. Teva argued that ’068 Patent was invalid for obviousness-type double-patenting in view of the ’165 Patent. *Id.* at 1356, 1358. Pfizer argued that the ’068 Patent was protected by safe harbor of Section 121. *Id.* at 1359–60. Teva responded that “section 121 applies exclusively to divisional applications, and that because the ’068 [P]atent issued on a CIP rather than on a divisional application, it does not fall within the terms of the statute.” *Id.* at 1359.

The Court of Appeals for the Federal Circuit agreed with Teva. The court found that Section 121 provides a safe harbor to patents that issue on applications filed as a result of a restriction requirement. *Id.* at 1360–61. Section 121 specifically identified divisional applications as falling within

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the safe harbor. *Id.* The court stated that: “If the drafters wanted to include CIPs within the protection afforded by section 121, they could have easily done so.” *Id.* at 1362. The court concluded “that the protection afforded by section 121 to applications (or patents issued therefrom) filed as a result of a restriction requirement is limited to divisional applications.” *Id.* For this reason, the court concluded that the ’068 Patent did not fall within the safe harbor because “though it derived from the application that led to the [’]823 [P]atent, [it] was filed as a CIP and not a divisional application.” *Id.*

Although the ’093 Patent was filed as a continuation-in-part application as was the ’068 Patent in *Pfizer*, Patent Owner attempts to distinguish the present appeal from *Pfizer*, stating that “the [*Pfizer*] court focused on whether claims in a CIP supported only by new matter not found in the parent application should be shielded from double patenting.” Reply Br. 17. To support this position, Patent Owner points to a section in *Pfizer* where the court discussed legislative history of section 121. *Pfizer*, 518 F.3d at 1361. We have reviewed this section and do not see a discussion of the claims in the *Pfizer* patents. Rather, the section describe the legislative history of section 121. Patent Owner specifically pointed to the following sentence:

If the section [121] had included CIPs, which by definition contain new matter, the section might be read as providing the earlier priority date even as to the new matter, contrary to the usual rule that new matter is not entitled to the priority date of the original application. See *Asseff v. Marzall*, 189 F.2d 660, 661 (D.C.Cir.1951). There was no possible reason for protecting the new matter from double patenting rejections.

*Id.* at 1361–62.

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It is not clear to us why this statement, explaining why CIPs were not included in Section 121,

was recognizing that the particular claims at issue failed to satisfy the requirements of the second sentence of § 121, namely that the claims presented in the CIP did not comply “with the requirements of section 120” and thus were not “entitled to the benefit of the filing date of the original application.”

Reply Br. 18. Indeed, the only mention of “the particular claims at issue” in *Pfizer* characterized the ’068 Patent as “includ[ing] the restricted-out method claims.” *Pfizer*, 518 F.3d at 1358.

In *Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340 (Fed. Cir. 2009), the court considered whether continuation applications, filed in response to a restriction requirement, were afforded the safe harbor of Section 121. The court held that the continuation application did not receive the benefit of Section 121 because the applications were designated as continuations, declining “to construe ‘divisional application’ in § 121 to encompass Amgen’s properly filed, properly designated continuation applications.” *Id.* at 1354.

Patent Owner contends that the *Amgen* court reached this conclusion because no “persuasive reason” was provided as to why the continuation applications should be deemed divisionals for the purpose of Section 121. Reply Br. 17 (quoting from *Amgen*, 580 F.3d at 1354). Patent Owner argues:

Unlike *Amgen*, in this case evidence in the prosecution history of the ’093 Application demonstrates that at the time the ’093 Application was filed Patent Owner expressly told the Office it was being filed to prosecute non-elected claims withdrawn from

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examination following the restriction applied in the Parent Application, invoking the protections afforded under § 121.

*Id.*

We have already addressed this issue and found it unpersuasive. The statement referenced by Patent Owner merely states that the “Preliminary Amendment *cancel*s subject matter which is drawn to a non-elected invention pursuant to the restriction requirement set forth in parent application” (emphasis added), but does not state that the remaining subject matter was limited to only subject matter claimed and disclosed in the ’413 Application. As discussed above, the Preliminary Amendment did not eliminate the claimed subject matter derived from the ’406 Application, of which the ’093 Application was also a continuation-in-part. Applicant designated the ’093 Application as a continuation-in-part application when it was filed and, therefore, voluntarily gave up the safe harbor of Section 121.

In sum, we are not persuaded that the ’093 Application as filed was a divisional application.

#### CONSONANCE

Patent Owner contends that the proper inquiry “for eligibility of patent claims for the safe harbor of Section 121 is whether those issued claims, along with those issued in the reference patent, maintained consonance with the restriction requirement that compelled the patent owner to prosecute the claimed inventions in separate applications.” Appeal Br. 17 (citing, in *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990); *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1579 (Fed. Cir. 1991)). Patent Owner defines consonance as “where the subject matter

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claimed in the patent does not cross the line of demarcation set [forth] in the restriction requirement.” *Id.*

In the cited cases, the inquiry was specifically on whether the issued claims had crossed the line of demarcation in a restriction requirement. These cases did not address the statutory requirement of Section 121 that the application must be a “divisional application” of the original application in which the restriction was made. *Pfizer* recognized the “consonance requirement” of Section 121, but held that consonance was in addition, and independent from, the express requirement that an application be a divisional application to obtain the benefit of the statutory safe harbor. *Pfizer*, 518 F.3d at 1359. Because we have determined that the ’093 Application is not a divisional of the ’413 Application, even if the issued claims are consonant with the restriction requirement (which they are not), Section 121 cannot be invoked.

Patent Owner takes the position that Section 121 was enacted to protect an applicant from being penalized for dividing an application in response to a restriction requirement. Appeal Br. 31. For this reason, Patent Owner directs us to only look at the consonance of the ultimately issued claims, and not what actions the Applicant took in prosecuting and securing protection for these claims. This argument, however, goes astray of the statutory requirement that the application seeking the safe harbor be designated, when filed, a divisional, a requirement confirmed in both the *Pfizer* and *Amgen* cases. The terms “continuation”, “divisional”, and “continuation-in-part” are not merely technical terms used for administrative convenience as asserted by Patent Owner, but rather convey to the PTO

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specific characteristics of the application, namely that a divisional is a later application for an independent or distinct invention, carved out of a non-provisional application, and that a CIP is an application that adds new disclosure to an existing application.

Contrary to Patent Owner's statements, the issued claims in the three patents involved in the double-patenting rejection are not consonant with the restricted claims in the '413 Application. All the original antibody treatment claims in the '413 Application (claims 32, 33, 40–47, 50–57) involved administering an anti-TNF $\alpha$  antibody. FF10, FF11.

Indeed not all the treatment claims in the '195 Patent are limited to anti-TNF $\alpha$ . Specifically, Claim 1 of the '195 Patent reads:

1. 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.

Claim 7 of the '195 Patent is also not limited to an anti-TNF $\alpha$  chimeric antibody.

#### AMENDMENTS TO '471 PATENT DURING REEXAMINATION

During the Reexamination of the '471 Patent, Patent Owner requested that the Examiner enter amendments to the '471 Patent which would “properly designate[]” it as “a ‘division’ rather than a ‘continuation-in-part’ application consistent with the evidence establishing the status of the '093 [A]pplication.” Amendment (Oct. 10, 2014), 103. Patent Owner also requested that the text of the specification of the '471 Patent be deleted and



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replaced with the specification disclosure of the '093 Application. *Id. See also* Response (dated Dec. 20, 2013) proposing same amendments. The Examiner refused entry of the amendments for technical and procedural reasons. Final Act. 3 (Aug. 26, 2014). Patent Owner filed a petition under 37 C.F.R. § 1.181 to direct entry of the amendments. Petition (Oct. 26, 2014). The Petition was granted and the Examiner was directed to enter the amendments. Decision on Petition (Nov. 26, 2014).

Patent Owner contends that there is “no dispute that the '471 Patent, which issued from the '093 Application, is a divisional of the Parent Application.” Appeal Br. 13. Patent Owner states that “the Director of the Central Reexamination Unit has confirmed the propriety of the amendments and the designation of the '093 Application as a divisional, and the Examiners have expressly recognized its status as such.” *Id.*

The Examiner did not recognize the '093 Application as a divisional as asserted by Patent Owner. The Examiner made this clear in the Answer:

The Patent Office has not confirmed the status of the [']471 patent as a Divisional. The amendment was entered for the purpose of reexamination. The petition granted (11/25/14) entry of the amendment for purpose of reexamination but did not resolve the substantive issue of whether such amendment would be effective to alter the nature of the patent under reexamination.

Answer 8.

Patent Owner states that the “amendments at issue were ordered to be entered by the Director in response to a petition that was filed by Patent Owner on October 26, 2014, expressly to allow Patent Owner to invoke the protections of § 121.” Reply Br. 11. The Director made no such statement

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that the amendments were entered to allow Patent Owner to invoke the safe harbor of Section 121. Patent Owner has not directed us to statement by the CRU Director that supports Patent Owner's assertion. Rather, as correctly observed by the Examiner, the amendments were entered for procedural reasons. The Director did not, in granting the petition, indicate that the effect of the amendment would be to confirm the '093 Application as a divisional.

The Decision granting the petition explained:

37 CFR 1.530 demands entry of amendments when submitted in compliance with the rules and accompanied by the appropriate fees. Therefore, the amendment filed October 10, 2014 is entered and the proceeding is returned to the Examiner for issuance of a new Final Office action.

Decision on Petition 7.<sup>5</sup>

Patent Owner contends that there is no requirement under the statute that an application be designated as a divisional *as filed*, and thus the subsequent correction by amendment qualifies the application as divisional. Reply Br. 11–12. We have reviewed these arguments, including the *Amgen* and *Pfizer* cases, and find Patent Owner's remarks to be inconsistent with the statutory language of Section 121 that the safe harbor be invoked “if the divisional application is filed before the issuance of the patent on the other application.” We could not identify a clear reason for construing the statute not to require the “Divisional as filed” Rule. *Id.* at 16 (emphasis omitted). Now, Patent Owner after having voluntarily surrendered the safe harbor

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<sup>5</sup> As an analogy, an amendment made to overcome a prior art rejection may be entered if timely filed, but the entry thereof does not necessarily mean the amendment requires allowance.

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provision by filing the '093 Application as a continuation-in-part application, is attempting to go back after ten years to acquire divisional status to obtain additional patent term. In our opinion, such action would violate Section 121 and the inherent notice function of the statutory scheme.

Patent Owner asserts that it did not benefit from the additional disclosure in the CIP application, distinguishing itself from *G.D. Searle LLC v. Lupin Pharms., Inc.*, 790 F.3d 1349 (Fed. Cir. 2015) where the patentee did. Reply Br. 15. Even if Patent Owner did not benefit from the period in which the application was designated as CIP, we still find no reason to permit Patent Owner now, by amendment, to acquire the benefit of the safe harbor when Patent Owner voluntary and deliberately filed a continuation-part application with claims directed to subject matter absent from the '413 Application and outside the scope of its restriction.

Patent Owner cites the *Martek* reexamination, which is an *ex parte* reexamination of U.S. Patent No. 5,698,244 (Control No. 90/009,659), where “the Office determined that an application originally filed with the designation ‘continuation-in-part’ was properly amended to be designated a divisional application and consequently enjoyed safe harbor against earlier issued patents in the same family as the reexamined patent.” Appeal Br. 26. However, a specific action by the Office in one reexamination proceeding does not create a rule binding on appeals before this Board, and certainly not a rule that would be inconsistent with the statutory requirements of Section 121.

Patent Owner also directs our attention to “[m]any examples . . . in which the application issuing as the patent was designated a ‘divisional’

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application of its parent, but which, because it contained added matter, was also designated a continuation-in-part application of that same parent application.” Reply Br. 19. We do not find these “many examples” persuasive because we have not been directed to evidence that such CIP applications were afforded the benefit of the safe harbor, the issue in this case.

### IS THE TWO-WAY TEST APPLICABLE TO THE CLAIMS OF THE '471 PATENT?

There are three groups of patented claims involved in the obviousness-type double-patenting rejection:

1. The '471 Patent: An anti-TNF $\alpha$  chimeric antibody comprising a non-human immunoglobulin variable region which comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5 (claim 1). Patent Owner states that the two recited sequences define the heavy and light chains of the chimeric cA2 antibody. Appeal Br. 22.

2. The '272 Patent: A method of treating TNF $\alpha$ -mediated Crohn's disease comprising administering anti-TNF chimeric antibodies (claim 1); a method of treating Crohn's disease comprising administering the anti-TNF chimeric antibody cA2 (claim 7).

3. The '195 Patent: A method of treating rheumatoid arthritis comprising administering anti-TNF chimeric antibodies (claim 1); a method of treating rheumatoid arthritis comprising administering the anti-TNF chimeric antibody cA2 (claim 6).

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The anti-TNF $\alpha$  antibody claims in the '471 Patent expire later than the claims in the '272 and '195 Patents. Because the anti-TNF $\alpha$  antibodies required to practice the treatment methods, granting a patent on the antibodies would result in an extension of the patent rights in the '272 and '195 Patents. An obviousness-type double-patenting is appropriate in these circumstance to prevent an unjustified extension of the patent term of the '272 and '195 Patents. The obviousness-type double-patenting rejection can be overcome by Patent Owner if it is demonstrated that the '471 Patent claims are patentably distinct from the '272 and '195 Patent claims.

Two different tests have been set forth to determine whether the claims of an application, or patent in this case, are patentably distinct, i.e., obvious, over the claims of a commonly-owned patent. The “one-way” test asks whether the application claims<sup>6</sup> under examination are obvious in view of the patent claims.<sup>7</sup> *Berg*, 140 F.3d at 1432. The one-way test is the test usually applied in obvious-type double patenting rejections. In the “two-way” test, a second question (the second “way”) is asked: whether the patent claims are obvious in view of the application claims. *Id.*

A two-way test is to be applied only when the applicant could not have filed the claims in a single application *and* the Office is solely responsible for any delays. *In re Berg*, 46 USPQ2d 1226 (Fed. Cir. 1998) (“The two-way exception can only apply when the applicant could not avoid separate filings, and even then, only if the PTO controlled the rates of prosecution to cause the later filed species claims to issue before the claims for a genus in an earlier application [.]. . . In *Berg*’s case, the two applications could have been filed as one, so it is irrelevant to

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<sup>6</sup> In this case, the claims of the '471 Patent, currently under reexamination.

<sup>7</sup> In this case, the claims of the '272 and '195 Patents.

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our disposition who actually controlled the respective rates of prosecution.”) . . . .

MPEP § 804.

“The two-way test is only appropriate in the unusual circumstance where, inter alia, the United States Patent and Trademark Office (PTO) is ‘solely responsible for the delay in causing the second-filed application to issue prior to the first.’” *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 n.7 (Fed. Cir. 2001) (quoting *Berg*, 140 F.3d at 1437); see also *Basell*, 547 F.3d at 1376; *Emert*, 124 F.3d at 1461 (applying the one-way test because the applicant “had significant control over the rate of prosecution of the application,” “was responsible for the delays in prosecution,” and “orchestrated the rate of prosecution”); *In re Goodman*, 11 F.3d 1046, 1053 (Fed. Cir. 1993) (applying the one-way test because “PTO actions did not dictate the rate of prosecution”); . . . . In short, the applicant is entitled to the narrow exception of the two-way test when the PTO is at fault for the delay that causes the improvement patent to issue prior to the basic patent.

*In re Fallaux*, 564 F.3d 1313, 1316 (Fed. Cir. 2009).

Applicant could not have filed the antibody claims with the treatment claims because a restriction requirement in the '413 Application had divided the claims into five groups, including group I to antibodies and group IV to treatment methods comprising administering antibodies. FF9. For this reason, we must address the question of whether PTO was solely “responsible for the delay” in causing the antibody claims to issue about four years after the '272 and '195 Patents.

Under *Berg* and *Fallaux*, if the PTO actions are “solely responsible” for the “delay” which led to the broader application issuing first, then the Applicant cannot be held responsible for the order in which the applications

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issued as patents. Neither of these cases explain what kind of activity during patent examination by the PTO constitutes a “delay.” The patent examination process involves an exchange between the Examiner and the Applicant in which the Examiner examines the claims for patentability, informs the Applicant in written “office actions” of his or her determinations, and Applicant subsequently responds to those actions by, for example, making arguments, amending and adding claims, and providing evidence. It is normal that it will take months for the Examiner to take up an Applicant’s response and then to respond to it. Likewise, Applicants are given statutory periods of time in which they have to respond to an Office action. A rejection made by an Examiner will almost always lengthen the time of prosecution because it will entail additional exchange between the Examiner and Applicant.

We know of no reasonable way to determine with certainty whether the time it took an Examiner to address an Applicant’s response was “typical” or “atypical.” For this reason, we understand the “delays” discussed in *Berg* and *Fallaux* to be the periods of time that it takes the PTO to examine claims and respond to Applicant’s attempts to obtain patented claims. When the PTO “controlled the rates of prosecution” because all the “delays” were caused by the PTO’s response times, then the Applicant cannot be held responsible for the broader application issuing as a patent last. Cf. *In re Braat*, 937 F.2d 589, 592 (Fed. Cir. 1991). However, we do not find any language in *Berg* and *Fallaux* that would require a balance sheet be made to determine which delays the PTO are responsible for, and which delays the Applicant are responsible for, and then adding up which

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contribution is greater to make the determination as to who controlled the prosecution rate. Rather, the cases focus on whether the PTO is “solely responsible” for the delay, indicating that when the PTO is not “solely responsible,” and delays were caused by the Applicant, the two-way test inapplicable. Thus, the allegedly “substantial portions” of delay by the PTO in this case (Reply Br. 26–27) are only pertinent if there was no “delay” by the Applicant.

On the other hand, we recognize that it may be difficult to determine whether the Applicant should be held responsible for a delay in patent prosecution because the statute provides for periods of time to respond to Office actions, submissions under Section 129(a), Notices of Appeal, etc., which contribute to lengthening the time it would take for a patent to be granted by the Office. For this reason, we looked for instances where Applicant’s actions were not just part of the ordinary processing times between getting an Office action from the Examiner and then responding to it in accordance with statutory time periods, but constituted deliberate and unnecessary actions that lengthened the prosecution time of the ’093 Application. After reviewing the prosecution history, we find four instances of actions by Applicant that cannot be justified as being ordinary statutory processing times. These are as follows:

1. Applicant delayed obtaining a first Office Action on the merits of the claims by filing a preliminary amendment in the ’093 Application which contained a) immunoreceptor claims from the ’406 Application and b) chimeric antibody claims based on the ’413 Application. FF16. The additional claims from the ’406 Application caused the Examiner to restrict



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the claims and require Applicant to elect a group of claims for examination prior to preparing a first Office Action on the merits. FF19.

2. In response to the Final Rejection (05/01/1996) of the '093 Application (FF26), Applicant delayed examination by Filing a Notice of Appeal and waiting one-year to file a submission under 37 C.F.R. § 129(a) which served to withdraw the finality of the Final Rejection. FF27, FF28. Although Applicant explicitly “appreciated” on 12/22/95 that prosecution could be expedited by canceling rejected claims 12, 13, 45, 46, 116, and 117 (FF25), Applicant did not cancel the claims in the Rule 129 submission five months later.

3. The Examiner stated that claims 136–139 were allowable on 08/05/1997 (FF30), which included application claims that matured into claims 1, 4, 5, and 7 in the '471 Patent. Applicant did not accept allowance of these claims in responding to rejections on 12/08/1997 (FF33), 08/05/1998 (FF35), 03/04/1999 (FF37), 1/10/2010 (FF39), and 09/29/2000 (FF42). Not until 12/01/2000, after more than three years, did Applicant cancel the rejected claims to gain allowance of the claims deemed allowable by the Examiner on 08/05/1997. FF43.

4. On 08/05/1998, Applicant added claims from another application after a Final Rejection. FF35. The claims were not entered by the Examiner because they raised “new rejections.” FF36. Six months later, Applicant filed a second submission which resulted in entry of the new claims. FF37. These claims were subsequently rejected by the Examiner on 07/06/1999. FF38.

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Patent Owner contends that Applicant properly used authorized procedures, such as Section 129(a), and responded “in significantly less time than the maximum time allowed by statute.” Appeal Br. 41.

We do not agree.

Applicant took one year to request withdrawal of the finality of an Office action by filing a first Section 129(a) submission (2 above). Applicant expressly recognized that it could have simplified issues by canceling claims, but did not (*id.*).

The second submission under Section 129(a) was in part necessary to gain entry of claims that had not been heretofore examined by the Examiner (4 above).

Applicant also waited more than three years after the Examiner had indicated that certain claims were allowable to cancel the remaining rejected claims to gain allowance of the allowable claims (3 above).

In view of these deliberate and independent actions which delayed issuance of the '471 Patent, we cannot agree with Patent Owner that “throughout the prosecution of the '093 Application, Applicant diligently pursued its allowance, and took no actions to cause the '471 Patent to issue later than the '272 or '195.” Reply Br. 26. *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.”).

In sum, twice Applicant added claims during prosecution which resulted in delays in examination time because it required the Examiner to request that Applicant elect a group for examination (1 above) and to

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institute new grounds of rejection over the newly added claims (4 above). Thus, while Applicant contends that it was simply availing itself of routine statutory procedures, and points to alleged delays in the PTO responses to Applicant's submissions (Reply Br. 29), Applicant failed to account for the significant time caused by its filing of new sets of claims during the prosecution of the '093 Application and not expediting the patenting of claims that for more than three years the Examiner had repeatedly informed Applicant were allowable.

Patent Owner also argues:

Patent Owner conducted an interview with the Examiner on August 23, 2000, and timely submitted remarks on September 29, 2000. *Id.* ¶¶ F48-F49. No action, however, was taken by the Office until March 15, 2001, when Patent Owner finally resorted to cancelling all rejected claims pending simply "to expedite issuance of the case." *Id.* ¶¶ F51-F53.

Reply Br. 29.

The interview mentioned by Patent Owner took place on 08/23/2000, after the Final Rejection was mailed of 03/28/2000 (FF40). The Applicant stated in the amendment of 12/01/2000, when the rejected claims were finally canceled (FF43), that the Examiner had not returned phone calls subsequent to the interview. However, while the Examiner did not take any action after the remarks of 09/29/2000 were filed by the Applicant, and took three months to respond to the amendment cancelling the claims, as explained above, the Examiner found claims allowable on 08/05/1997 (FF30) and Applicant "finally resorted to cancelling all rejected claims" more than three years later on 12/01/2000 (FF43). Indeed, Applicant did not cancel claims six months after the Final Rejection of 03/28/2000, but

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delayed response time again by filing a Notice of Appeal on 09/27/2000 (FF41), and then two months later on 12/01/2000 finally canceled the claims. Therefore, the Applicant contributed significantly to the “delay” and, consequently, the PTO was not *solely* responsible for the delays—a necessary condition for triggering the two-way test for obviousness.

Patent Owner also contends that the Office’s treatment of dependent claim 117 delayed prosecution because

throughout the period August 1995 to March 1998, the Office rejected the claimed chimeric antibody defined by the term ‘cA2’ in the application leading to the ’471 Patent, while simultaneously deeming the use of the same ‘cA2’ term to define the same chimeric antibody to be appropriate in allowing the method claims of both of the applications issuing as the ’195[] and ’272 Patents.[]”

Reply Br. 31.

We agree that the rejection by the Examiner delayed issuance of a grant of patent, especially in comparison to the ’272 and ’195 Patents in which the same rejection was not made. However, as discussed above, we do not read *Berg* or *Fallaux* as requiring us to create a balance sheet to determine who is responsible for the greater part of the delay in patent examination time. Of course, “delay” in the ordinary course of patent examination is unavoidable because an Examiner cannot be expected to pick up and respond to a patent owner on the day a submission was received. And, likewise, an applicant cannot be held to a one day turn-around, especially when the rules provide specific periods of time to respond. Instead, the question is whether Applicant’s actions contributed to an increase in time in the examination of the later issued patent, in excess of the

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ordinary processing times.<sup>8</sup> As explained above, we found four independent instances where Applicant's actions did.

### PRELIMINARY AMENDMENTS

Further evidence of the control of the rate of prosecution by Applicant is provided by the preliminary amendment filed in the '093 Application. As shown below, there is a striking difference in the preliminary amendments filed in the applications that led to the '272, '195, and '471 Patents.

#### '272 Patent

Applicant's attorney expressed a desire to negotiate allowable claims in an effort to expedite prosecution. Examiner suggested applicants file a supplemental preliminary amendment claiming the specific scope that was desired. Applicants agreed to do so in order to expedite prosecution.

Examiner's Summary of Interview with Applicant's attorneys on 12/1/1995 (emphasis omitted).

Entry of the Preliminary Amendment prior to examination of the application is respectfully requested and pursuant to the telephone conversation between Examiner Nisbet and the undersigned on December 1, 1995. This amendment is made to reduce issues on examination expedite prosecution.

Preliminary Amendment (12/5/1995) 3.

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<sup>8</sup> FN 7 of *In re Hubbell*, 709 F.3d 1140 (Fed. Cir. 2013), the court wrote: "Given that Hubbell has conceded partial responsibility for the delay, his reliance on *Braat* is misplaced." This, again, reinforces *Basell's* holding that the PTO must be SOLELY responsible.

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No restriction requirement was necessary since all the claims were directed to a method of treating Crohn's disease with anti-TNF chimeric antibody. Applicant specifically wrote that the amendment was to expedite prosecution.

#### '195 Patent

Entry of the Preliminary Amendment prior to examination of the application is respectfully requested. This amendment is made to reduce issues on examination and expedite prosecution. Preliminary Amendment (1/22/1996) 3.

On 4/28/1997, the Examiner had interview with Applicant's attorney in which the Examiner wrote that "Applicant agree to Examiner's amendment to bring application into condition for allowance."

No restriction requirement was necessary since all the claims were directed to a method treating rheumatoid arthritis with anti-TNF chimeric antibody.

#### '471 Patent

The above Preliminary Amendment 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 (Paper No. 8)

Preliminary Amendment (12/27/1994).

In addition to the cancellation of subject matter directed to the non-elected invention, Applicant added claims from the '406 application which resulted in a restriction requirement in stark contrast to the '272 and '195 Patents, where Applicant narrowly focused on only the method claims. In

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

### CONCLUSION

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

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

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

### TIME PERIOD FOR RESPONSE

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

AFFIRMED

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