

United States Court of Appeals for the Federal Circuit

IN RE: JANSSEN BIOTECH, INC., NEW YORK
UNIVERSITY,
Appellants

2017-1257

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

Decided: January 23, 2018

WILLIAM C. ROOKLIDGE, Gibson, Dunn & Crutcher
LLP, Irvine, CA, argued for appellants. Also represented
by JEFFREY PAUL KUSHAN, Sidley Austin LLP, Washing-
ton, DC.

FRANCES LYNCH, Office of the Solicitor, United States
Patent and Trademark Office, Alexandria, VA, argued for
appellee Joseph Matal. Also represented by NATHAN K.
KELLEY, KAKOLI CAPRIHAN.

Before PROST, *Chief Judge*, REYNA and WALLACH,
Circuit Judges.

PROST, *Chief Judge*.

Janssen Biotech, Inc., and New York University (col-
lectively, “Janssen”) appeal from a decision of the United

States Patent and Trademark Office (“PTO”), Patent Trial and Appeal Board (“Board”) resulting from an ex parte reexamination of U.S. Patent No. 6,284,471 (“’471 patent”). The Board affirmed the rejection of claims 1–7 of the ’471 patent as unpatentable under the doctrine of obviousness-type double patenting. Because the claims are barred under that doctrine, we affirm.

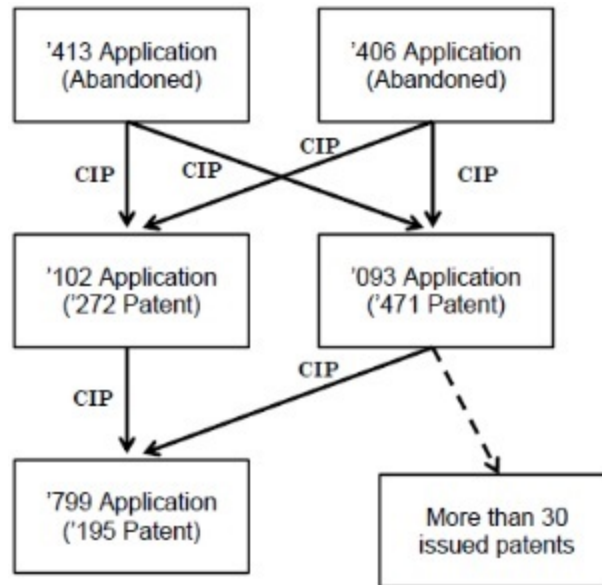
I

“The doctrine of obviousness-type double patenting is intended to prevent the extension of the term of a patent by prohibiting the issuance of the claims of a second patent that are not patentably distinct from the claims of the first patent.” *G.D. Searle LLC v. Lupin Pharm., Inc.*, 790 F.3d 1349, 1351 (Fed. Cir. 2015) (citing *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1376 (Fed. Cir. 2012)). In this case, Janssen’s principal argument is that obviousness-type double patenting is not applicable because the safe-harbor provision of 35 U.S.C. § 121 protects the ’471 patent claims. Thus, as in *Searle*, the double-patenting issue in this case turns on whether Janssen is entitled to invoke § 121 as a defense against a double patenting rejection. That issue depends, in turn, on an interpretation of the prosecution history of the ’471 patent and that patent’s relationship to application No. 08/013,413 (“’413 application”).

IN RE: JANSSEN BIOTECH, INC.

3

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



See Appellee's Br. 11.

On October 27, 1993, an examiner issued a 5-way restriction requirement in the '413 application.¹ 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. On February 4, 1994, rather than filing a

¹ "If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a *requirement for restriction* (also known as a requirement for division)." 37 C.F.R. § 1.142(a) (emphasis added).

response to the restriction in the '413 application, Janssen expressly abandoned that application and stated that it was filing a continuation-in-part ("CIP") application.² That same day, Janssen filed application No. 08/192,093 ("093 application") and application No. 08/192,102 ("102 application"). The challenged patent, the '471 patent, issued on the '093 application. A reference patent, U.S. Patent No. 5,656,272 ("272 patent"), issued on the '102 application.

When Janssen filed the '093 application, it disclosed and claimed subject matter not only from the '413 application, but also from application No. 08/010,406 ("406 application"). Accordingly, Janssen designated the '093 application as a CIP of the '413 application and as a CIP of the '406 application. The '413 application relates to antibodies specific to human tumor necrosis factor ("TNF") alpha. Its original claims included claims to a chimeric antibody and methods of treatment. All of the chimeric antibody claims were limited to antibodies that bind to TNF alpha. The '406 application relates to immunoreceptor molecules that are specific for TNF alpha or beta. Claim 1 recited an immunoreceptor molecule capable of binding to TNF alpha or TNF beta or both. Dependent claims specified that the TNF receptor comprises at least a portion of p55 or at least a portion of p75. Janssen allowed the '406 application to go abandoned about six months after it filed the '093 application.

² "A continuation-in-part 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." Manual of Patent Examining Procedure ("MPEP") § 201.08 (5th ed., Rev.15, 1993) (emphasis added); *see also* MPEP § 201.08 (2015).

IN RE: JANSSEN BIOTECH, INC.

5

A little over ten months after the filing date, Janssen filed a preliminary amendment in the '093 application, which cancelled, amended, and added claims. The amendment cancelled claims drawn to the non-elected treatment-method invention (Group IV) pursuant to the restriction requirement set forth in the '413 application. The amendment did not, however, limit the claimed subject matter to only subject matter claimed and disclosed in the '413 application. After the amendment, the '093 application still included claims directed to chimeric antibodies (based on the '413 application) and immunoreceptor molecules comprising TNF receptors p55 or p75 (based on the '406 application). The amendment also did not limit claim 1 to the *species* TNF alpha but rather retained language regarding binding to the TNF *genus* generally.

About three months after Janssen filed the preliminary amendment, the examiner mailed an office action requiring Janssen to elect between species I (which included chimeric antibodies and immunoreceptors which comprise the epitope binding region of an antibody) and species II (which included immunoreceptor molecules comprising TNF receptors p55 or p75). The claims directed to species II were originally disclosed and claimed only in the '406 application and not in the '413 application. Janssen elected species I.

The examiner next issued an office action in the '093 application provisionally rejecting claims on obviousness-type double patenting grounds over yet another application, No. 08/324,799 ("799 application"). The '799 application is a CIP of the '102 application. As noted, the '102 application has the same filing date as the '093 application, and it is similarly a CIP of both the '406 and '413 applications. After receiving the double patenting rejection in the '093 application, Janssen filed a preliminary amendment in the '102 application, cancelling all of the pending claims and replacing them with seven new claims

directed to a method of treating Crohn's disease. Janssen similarly filed a preliminary amendment in the '799 application, replacing all of the pending claims with seven new claims directed to methods of treatment of rheumatoid arthritis. The '799 application issued as U.S. Patent No. 5,698,195 ("195 patent") and, as noted, the '102 application issued as the '272 patent. Both the '272 and the '195 patents are reference patents in this appeal.

Following the examiner's double patenting rejection in the '093 application, Janssen cancelled and amended claims in that application, including limiting claim 1 to TNF alpha. The examiner issued another office action maintaining these rejections and Janssen appealed.

Janssen then filed another amendment cancelling and amending claims. Janssen argued that the double patenting rejection over the '799 application should be withdrawn because all of the claims in that application had been cancelled and replaced by seven new claims directed to methods of treatment of rheumatoid arthritis. Accordingly, Janssen argued, pointing to the October 1993 restriction requirement received in the '413 application, that "35 U.S.C. § 121 precludes an obviousness-type double patenting rejection in this case." J.A. 13771. In view of the cancellation of claims in the '093 and '799 applications, the examiner withdrew the double patenting rejection in the '093 application but continued to reject the claims on other grounds.

The '093 application eventually issued as the '471 patent on September 4, 2001, with 9 claims. Claims 1, 3, and 5-6 are directed to a chimeric antibody specific for TNF alpha. Claims 2 and 4 are directed to immunoassay methods for detecting human TNF. Claims 8 and 9 are directed to polypeptides of particular amino acid sequences that bind to hTNF alpha.

Several years later, in 2013, in response to a third-party request, the PTO instituted reexamination of the

IN RE: JANSSEN BIOTECH, INC.

7

'471 patent on double patenting grounds over three patents including the '272 and '195 patents (the reference patents). During the reexamination, Janssen cancelled claims 8 and 9 and requested that the '471 patent be amended to delete the benefit claim to the '406 application. Janssen also requested that the specification, abstract, and drawings of the '471 patent be conformed to the '413 application (i.e., by deleting portions that were not present in the '413 application) and that the '093 application be designated as a divisional of that application.

The PTO entered the amendments for the “purpose of reexamination” but did not confirm the status of the '471 patent as a divisional. Whether the amendment would be effective to alter the nature of the '471 patent remained a live issue. The examiner ultimately maintained the double patenting rejections on the basis that the safe harbor did not apply. The examiner noted that, although Janssen had never received issued claims in the '471 patent on the subject matter originating from the '406 application, more than thirty-two 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.” J.A. 691. The examiner further concluded that only the one-way test for double patenting applied because the PTO was not “solely responsible” for the '471 patent’s later issuance and that the claims of the '471 patent are unpatentable under that test.

The Board affirmed the double patenting rejections. The Board confirmed that Janssen’s amendments during the reexamination proceeding were only entered for “procedural reasons” and that “[t]he Director did not, in granting the petition, indicate that the effect of the amendment would be to confirm the '093 [a]pplication as a divisional.” J.A. 27. The Board “f[ou]nd no reason to

permit [Janssen] now, by amendment, to acquire the benefit of the safe harbor when [Janssen] voluntar[il]y and deliberately filed a continuation[-in]-part application with claims directed to subject matter absent from the '413 [a]pplication and outside the scope of its restriction.” J.A. 28. The Board then applied the one-way test for double patenting because it found that there were at least four instances where Janssen’s actions “constituted deliberate and unnecessary actions that lengthened the prosecution time of the '093 [a]pplication.” J.A. 33.

Janssen appeals the Board’s decision. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

II

The main issue on appeal is whether the safe-harbor provision of 35 U.S.C. § 121 applies to the '471 patent and protects it from invalidation based on the '272 and '195 reference patents. If the safe harbor applies, then the reference patents cannot be used as references against the '471 patent in a double-patenting rejection. Conversely, the reference patents are available as references against the '471 patent if the safe harbor does not apply. Whether the requirements of § 121 have been satisfied is a question of law that we address de novo. *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1348 n.1 (Fed. Cir. 2004).

The safe-harbor provision of § 121 provides as follows:

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

IN RE: JANSSEN BIOTECH, INC.

9

divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. § 121.

This court follows “a strict application of the plain language of § 121.” *Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1353 (Fed. Cir. 2009); *see also Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1382 (Fed. Cir. 2003) (“Given the potential windfall [a] patent term extension could provide to a patentee, this court applies a strict test for application of § 121.” (footnote omitted)).

The § 121 safe harbor, “by its literal terms, protects only divisional applications (or the original application) and patents issued on such applications.” *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 1360 (Fed. Cir. 2008) (internal quotation marks omitted). Accordingly, patents issued on CIP applications are not within the scope of § 121. *Id.* at 1362. Nor are patents issued on continuation applications. *Amgen*, 580 F.3d at 1354. Our precedent is clear: aside from the original application and the original patent, the protection afforded by § 121 is limited to divisional applications and patents issued on divisional applications.³ *Pfizer*, 518 F.3d at 1362.

³ We recognize that this court has held that a patent need not have *directly* issued on a divisional application to receive § 121 protection. Any intervening continuing applications, however, must descend from a divisional application filed as a result of a restriction requirement. *See, e.g., Boehringer Ingelheim Int’l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1352 (Fed. Cir. 2010) (intervening divisional application); *Amgen*, 580 F.3d at 1354 (citing *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991)) (intervening continuation

A

This case presents the question of whether, several years after a challenged patent issues on a CIP application, a patent owner can retroactively bring the challenged patent within the scope of the § 121 safe harbor by amending the CIP application during a reexamination proceeding to redesignate it as a divisional application. In *Searle* we answered this question in the reissue context, holding that the patent owner could not take advantage of the safe-harbor provision simply by designating the CIP as a divisional application in a reissue application years after the fact. 790 F.3d at 1354–55.

Leading up to the *Searle* case, this court in *Pfizer* concluded that the statutory safe-harbor provision did not shield a challenged patent when it issued on a CIP and not a divisional application. *Searle*, 790 F.3d at 1352 (citing *Pfizer*, 518 F.3d at 1362). Following the disposition in *Pfizer*, the patent owner filed an application with the PTO seeking reissue of the patent challenged in *Pfizer*. *Searle*, 790 F.3d at 1353. Just as Janssen's reexamination amendments do here, the patent owner's preliminary amendments accompanying the reissue application deleted portions of the challenged patent's specification that were not present in the original application and changed the designation of the application on which the challenged patent had issued from a CIP to a divisional application. *Id.* The preliminary amendments also cancelled claims that were not present in the original application. *Id.* The PTO eventually allowed the claims of the reissue application, which issued as a reissue patent. *Id.*

application). The effect of intervening applications is not at issue here because the '471 patent issued on the '093 application, which descends directly from the original application.

IN RE: JANSSEN BIOTECH, INC.

11

The patent owner filed suit, alleging infringement of the reissue patent. *Id.* at 1353–54. The district court found that the safe-harbor provision did not apply to the reissue patent and that the relevant claims were invalid for obviousness-type double patenting in light of the same reference patent at issue in *Pfizer*. *Id.* at 1354. The patent owner appealed. *Id.*

Applying “a strict test” to determine whether the reissue patent was entitled to § 121 protections, the court in *Searle* concluded that, even assuming it was proper to grant the reissue patent under 35 U.S.C. § 251, the reissue patent was not entitled to safe-harbor protection. *Id.* The application on which the challenged patent had issued was not a divisional because it contained new matter that was not present in the original application. *Id.* at 1354–55. Nor could the nature of that application be retroactively altered by simply deleting that new matter. *Id.* at 1355. Moreover, the court concluded that the patent owner could not (for purposes of § 121) retroactively relinquish the new matter in the CIP application after having enjoyed years of patent protection for it. *Id.*

We are persuaded by the reasoning in *Searle* that a patent owner cannot retroactively bring its challenged patent within the scope of the safe-harbor provision by amendment in a reexamination proceeding.⁴ In *Searle*, the court assumed the reissue patent was properly granted and still concluded the safe harbor did not apply. *Id.* at 1354. Thus, here too, even assuming Janssen’s

⁴ Although *Searle* involved amendments made under the Patent Act’s reissue provisions rather than the reexamination provisions, the analysis in *Searle* is applicable to the effect, if any, of amendments made during reexamination on the applicability of § 121 to a challenged patent.

amendments made during reexamination were to become effective by way of a reexamination certificate, we conclude that the '471 patent is not entitled to safe-harbor protection.

The reissue patent in *Searle* “[wa]s not entitled to safe harbor protection, because *it did not issue on* either the [original] application or a divisional of the [original] application.” *Id.* (emphasis added). The reissue patent issued on a CIP application, and that CIP application could not retroactively become, for the purposes of § 121, a divisional application. We explained that, “despite being designated as such in the reissue patent,” the CIP application could not be a divisional of the original application because it contained new matter that was not present in the original application. *Id.* at 1354–55. “Simply deleting that new matter from the reissue patent d[id] not retroactively alter the nature of the [CIP] application.” *Id.* at 1355. Here, following the reasoning in *Searle*, once the '471 patent issued on the '093 application—which, like the application in *Searle*, at the time of issuance included new matter not disclosed in the original application and so was a properly designated CIP—the '471 patent was barred from safe-harbor protections.

A strict application of the plain language of § 121 also supports this holding. Under the language of the statute, in order to fall within the scope of the safe harbor, a challenged patent must have “issue[ed] on” a divisional application. 35 U.S.C. § 121 (stating that a reference patent “shall not be used as a reference . . . against a divisional application or against the original application or any patent *issued on* either of them” (emphasis added)). The '471 patent cannot retroactively become, for the purposes of § 121, a “patent issued on” a divisional application after it already issued on a CIP application; not even if that CIP application is effectively redesignated as a divisional application during reexamination. *See Searle*, 790 F.3d at 1355. For a challenged patent to receive safe-

IN RE: JANSSEN BIOTECH, INC.

13

harbor protections, the application must be properly designated as a divisional application, at the very latest, by the time the challenged patent issues on that application.

Janssen argues that *Searle* is distinguishable because, unlike the patent in *Searle*, no *issued* claims in the '471 patent relied upon any of the new matter in the '093 application. Janssen, therefore, maintains that it never enjoyed, at the public's expense, any benefit from having filed the '093 application as a CIP of both the '406 and '413 applications rather than as a divisional of the '413 application. We disagree. For example, the examiner found that Janssen *had* benefitted because more than thirty patents issued to Janssen claiming priority to the '471 patent and/or the '093 application as a CIP of both the '406 and '413 applications. Determining whether any of those patents rely on the deleted subject matter for support cannot be accomplished without reopening examination of each patent. *Cf. Searle*, 790 F.3d at 1355 (observing that where a patent owner had obtained foreign patent protection based on a PCT application, altering the scope of the PCT application could call into question the proper scope of those foreign patents).

Even if Janssen did not benefit from the period in which the application was designated as a CIP, we nonetheless find no reason, under the plain language of § 121 or under our precedent, to permit Janssen now, by amendment, to acquire the benefit of the safe harbor.

Janssen voluntary and deliberately filed an application properly designated as a CIP, having subject matter not disclosed in the original '413 application. At no time during the pendency of the '093 application did Janssen request, by submitting amendments or otherwise, that the relationship of the '093 application to the '413 application be changed to anything other than a CIP. Janssen contends that it informed the PTO that the '093 applica-

tion was a divisional of the '413 application because it "repeatedly" told the PTO that it was prosecuting the '093 application to pursue examination of a non-elected invention. As the Board correctly recognized, however, the statement Janssen references merely states that the "Preliminary Amendment cancels subject matter which is drawn to a non-elected invention pursuant to the restriction requirement set forth in parent application." J.A. 23 (citing J.A. 13856). Importantly, Janssen never indicated that the remaining subject matter was limited to only subject matter claimed and disclosed in the '413 application, nor did the amendment eliminate the claimed subject matter derived from the '406 application. Not until the reexamination amendments did Janssen ever attempt to delete the subject matter disclosed in the '406 application from its '093 application. These statements, therefore, cannot undo Janssen's filing the '093 application as a CIP and properly designating it as such. See *Amgen*, 580 F.3d at 1354 (declining "to construe 'divisional application' in § 121 to encompass . . . properly filed, properly designated continuation applications"). And once the '471 patent issued on a CIP application, it was not entitled to safe-harbor protections.⁵

B

Janssen argues that our holding today creates a rigid "divisional as filed" test. Such a test, Janssen argues, lacks any statutory basis and ignores longstanding PTO rules and practices that permit applicants to amend the disclosure and claims of an application after it is filed.

⁵ Given our conclusion, we do not consider the PTO's alternative argument that § 121 does not apply because the '471 patent and the reference patents did not maintain consonance with the restriction requirement made in the '413 application. *Pfizer*, 518 F.3d at 1362.

Amending an application to change its relationship to a prior-filed application—for example, from a CIP to a divisional—is expressly permitted. *See* 37 C.F.R. § 1.78(d)(2) (2015) (providing that the specification must “contain *or be amended to contain* a reference to each such prior-filed application” and that “reference also must identify the relationship of the applications”) (emphasis added); *see also* MPEP § 211.03 (permitting the correction of “a timely submitted benefit claim” by “[c]hanging the relationship of the applications (e.g., changing . . . from ‘continuation-in-part’ to ‘continuation’ or ‘divisional’)”).

Janssen points us to a “widely followed practice,” where an applicant files a copy of the original application with the same claims as those that were subjected to a restriction and then files a preliminary amendment limiting the claims to one or more of the non-elected inventions prior to the commencement of examination. This practice is permitted, Janssen argues, by MPEP § 714.01(e), which specifically allows references to prior applications for priority claims to be made after filing. Janssen also asserts that the PTO does not enforce a rigid definition that excludes a CIP from ever being considered also a divisional because it “routinely” allowed applicants to designate applications as both a CIP and a divisional.⁶

These practices, whether or not they are widely practiced or even permitted under PTO rules, have no relevance here because Janssen did not follow them. When filing its ’093 application, Janssen did not file a copy of

⁶ Any applications designated as both a CIP and divisional application, at the very least under the current revision of the MPEP, were most likely improperly designated as such. *See* MPEP § 201.06 (2015) (“A continuation-in-part application should not be designated as a divisional application.”).

the '413 application with its original claims. Janssen filed a CIP with claims and subject matter that originated from both the '413 and '406 applications. Although Janssen's preliminary amendment may have limited 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. Janssen also never identified the '093 application as both a divisional application and a CIP application. Instead, Janssen repeatedly identified the '093 application only as a CIP of both the '413 and '406 applications. When the '471 patent issued, it issued on a CIP application.

Because the practices Janssen points to are not presented in this case, we do not decide whether such filing practices or amendments made prior to issuance—wherein an application is designated as a divisional application by the time the challenged patent issues on that application—would be sufficient to bring the challenged patent within the scope of the safe-harbor protections.

III

Because we find that Janssen's '471 patent is not entitled to § 121 safe-harbor protections, we must also decide whether the Board erred when it found that Janssen is not entitled to the two-way test for obviousness-type double patenting. The question of whether the one-way test or the two-way test applies is one of law and is therefore reviewed by this court without deference. *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998).

When determining whether claims are invalid for obviousness-type double patenting, a one-way test is applied, in which “the examiner asks whether the application claims are obvious over the patent claims.” *In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1376 (Fed. Cir. 2008) (quoting *Berg*, 140 F.3d at 1432). In “unusual circumstances,” however, a two-way test may

IN RE: JANSSEN BIOTECH, INC.

17

apply, in which “the examiner also asks whether the patent claims are obvious over the application claims.” *Id.* (quoting *Berg*, 140 F.3d at 1432). Those unusual circumstances occur only “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.” *Berg*, 140 F.3d at 1432.

Accordingly, the two-way test is a “narrow exception to the general rule of the one-way test,” and is only appropriate where (1) a second-filed application issues prior to a first-filed application, and (2) “the PTO is solely responsible for the delay” in the issuance of the first-filed application. *Basell*, 547 F.3d at 1376–77 (quoting *Berg*, 140 F.3d at 1437). Because neither of these circumstances is present here, we are unpersuaded by Janssen’s assertion that the Board erred by failing to apply a two-way test for double patenting.

First, because the ’471 patent and the ’272 patent were both filed on February 4, 1994, at least for the ’272 patent, the second-filed application issuing prior to a first-filed application circumstance is not present here. Nor does Janssen contend that either the ’272 patent or the ’195 patent is directed to “a basic invention” or that the ’471 patent is directed to “an improvement” over an earlier filed basic invention. Thus, the “essential concern” that the two-way test is intended to alleviate is not present here. *Berg*, 140 F.3d at 1432.

Second, the Board found that Janssen took, or failed to take, several actions that caused the ’471 patent to issue after the ’272 and ’195 reference patents. The Board identified four specific instances where Janssen’s “actions were not just part of the ordinary processing times.” J.A. 33. These instances were: (1) Janssen’s filing a

preliminary amendment in the '093 application, which contained claims from both the '406 application and the '413 application; (2) Janssen's filing a Notice of Appeal and waiting one year to file a submission under 37 C.F.R. § 1.129(a); (3) Janssen's waiting more than three years after the examiner deemed certain claims allowable to cancel the rejected claims in order to gain allowance; and (4) Janssen's adding claims from another application after a final rejection in this application. We find no error with regard to the Board's findings and conclude that Janssen cannot establish that the PTO is "solely responsible" for any alleged delay associated with the '471 claims. For this reason alone, the two-way test for double patenting does not apply. We have considered Janssen's arguments and find them unpersuasive.

Because the safe-harbor provision of 35 U.S.C. § 121 does not apply to the '471 patent to protect it from invalidation based on the '272 and '195 reference patents, and because Janssen is not entitled to the two-way test for obviousness-type double patenting, we affirm the Board's rejection of claims 1–7 of the '471 patent as unpatentable under the doctrine of obviousness-type double patenting.

AFFIRMED