

# Federal Circuit Confirms That Continuation Patent Type May Not Be Retroactively Altered to Invoke Safe Harbor Provision

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In [\[1\]](#) *In re: Janssen Biotech, Inc.*, the Federal Circuit affirmed the Patent Trial and Appeal Board's ("Board") holding that, for the purposes of the safe harbor provision of 35 U.S.C. § 121, a patent owner of a continuation-in-part ("CIP") may not retroactively relinquish new matter in the CIP to claim divisional patent status in order to invoke the safe-harbor provision of § 121. The safe harbor provision provides that only a *divisional application* is protected from having its parent used as a reference against it. As such, a CIP patent cannot be retroactively converted into a divisional patent to seek protection under § 121. Further, a CIP patent is not immune from having a related patent (including a later-filed CIP patent) used against it under an obviousness-type double patenting rejection.

In this case, Janssen Biotech, Inc. and New York University ("Janssen") appealed from a decision of the Board resulting from an *ex parte* reexamination of U.S. Patent No. 6,284,471 ("the '471 patent"), which covers the Remicade product. The Board affirmed the rejection of claims 1-7 of the '471 patent as unpatentable under the doctrine of obviousness-type double patenting over reference patents U.S. Pat. No. 5,656,272 ("the '272 patent") and U.S. Pat. No. 5,698,195 ("the '195 patent").

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Janssen filed Pat. App. No. 08/013,413 ("the '413 application") to which the USPTO issued a five-way restriction requirement. Rather than responding to the restriction requirement, Janssen abandoned the '413 application and filed CIP applications, Pat. App. No. 08/192,093 ("the '093 application") and Pat. App. No. 08/192,102 ("the '102 application"). The '093 application claimed subject matter not only from the '413 application, but also from Pat. App. No. 08/010,406 ("the '406 application"). Janssen allowed the '406 application to go abandoned shortly after filing the '093 application.

Several months later, Janssen filed a preliminary amendment in the '093 application, which, *inter alia*, canceled claims drawn to a non-elected invention pursuant to the restriction requirement in the '413 application. However, the amendment did not solely limit the claimed subject matter to that of the '413 application. The amended claims of the '093 application still covered subject matter of the '406 application.

Shortly thereafter, the examiner issued an Office action requiring election between claims directed to two different species, species I and species II. The claims directed to species II were originally disclosed and claimed only in the '406 application. Janssen elected species I.

Following Janssen's election, the examiner issued an Office action provisionally rejecting claims of '093 application on obviousness-type double patenting over Pat. App. No. 08/324,799 ("the '799 application"), which was a CIP of the '102 application and '093 application. Janssen filed a preliminary amendment in the '102 application, canceling all pending claims and adding new claims directed to different subject matter. Similarly, Janssen filed a preliminary amendment in the '799 application canceling all pending claims and adding new claims covering subject matter different from the '093 application. The '799 application issued as the '195 patent and the '102 application issued as the '272 patent.

Subsequently, in response to the examiner's obviousness-type double patenting rejection, Janssen canceled and amended claims in the '093 application. However, the examiner issued another Office action maintaining its rejections, and Janssen appealed.

Janssen then filed another amendment in the '093 application and argued that the obviousness-type double patenting rejection over the '799 application should be withdrawn because the claims had been replaced by claims covering different subject matter, and thus, "35 U.S.C. § 121 precludes an obviousness-type double patenting rejection in this case." In light of the amendments made in the '093 and '799 applications, the Examiner withdrew the double patenting rejection in the '093 application. Eventually, the '093 application issued as the '471 patent.

Several years later, prompted by a third-party request, the USPTO instituted reexamination of the '471 patent on double patenting grounds over three reference patents, including the '272 and '195 patents. During reexamination, Janssen canceled claims 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 and that the '093 application be designated as a divisional of that application. The USPTO entered the amendments "for the purpose of reexamination," but did not officially designate the '471 patent as a divisional. Ultimately, because '471 patent was not confirmed a divisional, the examiner maintained the double patenting rejections on the basis that the safe harbor provision did not apply.

In the Board's affirmance, it "[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.

In reviewing this case *de novo*, the Federal Circuit strictly applied the language of 35 U.S.C. § 121, and reasoned that to be entitled to the safe harbor protection "a challenged patent must have 'issue[ed] on' a divisional application." Page 12. Thus, "[t]he '471 patent cannot retroactively become, 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 . . . to receive safe 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."

Put simply, the application of 35 U.S.C. § 121 is limited to divisional applications and patents issued on divisional applications. *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 1362 (Fed. Cir. 2008). A patent that issues from a CIP application cannot later be reassigned divisional status because CIPs include new matter that was not present in the original application. Simply deleting the new matter after issuance cannot change the original nature of the application.

Furthermore, the Federal Circuit found Janssen's arguments unpersuasive. Janssen deliberately and voluntarily filed an application designated as a CIP, and at no time during its pendency did Janssen request changing its status to a divisional application. Significantly, Janssen never indicated that the remaining subject matter was limited to only subject matter claimed and disclosed in the '413 application, nor that the amendment eliminated 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. Also significant, the '471 patent issued on a CIP application, and not a divisional.

As such, the Court held that the safe harbor provision did not apply to the '471 patent, and therefore, it was not protected from invalidation based on the '272 and the '195 reference patents.

The Court also held that Janssen was not entitled to the two-way test for obviousness-type double patenting, as it is pertinent in only very narrow circumstances. Thus, because the one-way test applied, the Court affirmed rejection of claims 1-7 of the '471 patent as unpatentable under the doctrine of obviousness-type double patenting.

**For more information on this topic, please contact a member of the firm's [Intellectual Property/3iP Practice Group](#).**

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[1] See *In Re: Janssen Biotech, Inc.*, No. 17-1257 (Fed. Cir. 2018).