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Think Twice Before Filing That CIP Application

It is best practice to consider alternative measures

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During the pendency of a patent application, U.S. Patent Law allows for the filing of “continuation” applications which are entitled to the benefit of the filing date of an earlier filed case (the “parent” application), provided that the specification of the parent presents adequate written description for the continuation’s claims in order to satisfy the statutory conditions of 35 U.S.C. Section 112. This section of the code requires that “[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.” Unlike continuation practice in other countries, U.S. Patent Law also allows the addition of new subject matter not previously presented in the parent application, while still maintaining at least partial benefit of the earlier filing date. Such continuation applications

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containing new matter are called continuation-in-part applications, or “CIPs.” With a CIP application, the subject matter carried over from the parent application will be entitled to the earlier priority date of the parent, while the newly added disclosure will be entitled to the later filing date of the CIP.

CIP applications are often filed when there are further developments to a technology that is already the subject of a pending patent application, a common occurrence in the life sciences field. For example, new data may be generated; a new species encompassed by an earlier disclosed genus may be identified; or previously unknown properties (e.g., those relating to new methods of treatment) may be uncovered, all of which may be of value to the applicant and thus desirable to be included in a patent application. However, there are potential caveats associated with the filing of a CIP application and alternative measures to protect the new developments should be explored.

A major negative impact associated with a CIP application is the reduction of patent term for the newly added subject matter. Prior to the U.S. being a party to the Trade-Related Aspects of Intellectual Property Rights (TRIPS), the term of a U.S. patent was 17 years from the issue date of the patent, regardless of the earliest claimed priority date. Therefore, making a priority claim to an earlier filed applica-

tion in a continuation or continuation-in-part application did not have any effect on the expiration date of the later filed patent. However, under TRIPS, the term for a U.S. patent, filed on or after June 8, 1995, is now 20 years from the earliest effective U.S. filing date to which the application claims priority (not including provisional applications). Therefore, in the case of a CIP application, this results in a loss of a portion of the patent term based on the difference between the filing date of the earlier filed parent application and the filing date of the CIP. For example, if a parent application is filed on January 1, 2000, and a CIP application claiming priority to that parent application is filed on January 1, 2005, the patent term will be calculated as 20 years from the filing date of the parent application, i.e. calculated from January 1, 2000, not January 1, 2005. Effectually, five years of patent term is lost in this scenario. Such a loss of patent term can potentially mean a loss of significant revenue from products or methods that are encompassed by patent claims which are supported by new disclosure in a CIP application.

In the situation described above, an alternative approach is to make the newly added subject matter the basis of a new patent application which does not claim priority to the earlier filed application. This strategy will result in any resultant patent having an extended term, as compared to the term of a patent filed as a CIP application.

Another problem associated with CIP applications is that issues of validity may be raised with respect to the parent. For example, if new data is added to a CIP application, it may spark questions of enablement in the parent, as it can be asserted that the new data was information necessary to make and use the invention and thus critical for enablement. Therefore, the parent patent, which is void of the new data, may have an open door for a patent challenger to come in and assert an invalidity claim due to nonenablement under 35 U.S.C. Section 112, based on the filing of the CIP application.

It is a common misconception that a CIP application should be filed to obtain the benefit of the earlier filing date of a parent application in order to overcome prior art that may have published after the filing date of the parent but before the filing of the CIP. However, as discussed previously, the new subject matter will not be entitled to the earlier priority date if it does not meet the written description requirement of 35 U.S.C. Section 112. It is also noted that entitlement of priority must be proven by the patentee during patent litigation. "When neither the PTO nor the Board has previously considered priority, there is simply no reason to presume that claims in a CIP application are entitled to the effective filing date of an earlier filed application." *PowerOasis v. T-Mobile* 522 F.3d 1299, 1305 (Fed. Cir. 2008). Thus simply claiming priority to an earlier application upon filing may not absolve the patentee from having to expressly show support for the claims in question later on down the road.

The examiner may also reject a CIP's claims based on "obvious-type" double patenting over the claims of the parent. The rationale for this is to prevent a patent owner from having an unexpired patent that is an obvious modification of an expired patent, thereby avoiding an unfair monopoly of unexpired patents. A cure for obvious-type double patenting rejections is the filing of a terminal disclaimer, whereby the portion of the term of the later filed patent that extends beyond the expiration date of the earlier filed patent is disclaimed. It is important to note that if the claims of the CIP application are obvious variants of the parent application, not only will they be prime for an obvious-type double patenting rejection, they also will not satisfy the requirements of 35 U.S.C. Section 112 and not be entitled to an earlier filing date. In *Tronzo v. Biomet*, 156 F.3d 1154, 1159 (Fed. Cir. 1998), the court stated that in order to be entitled to priority, the subject matter of the claims "must necessarily be present in the parent application's specification such that one skilled in the art would recognize such a disclosure." The court also stated that "[a] disclosure in a parent application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations." Therefore, claiming priority to a previous application will not cure the unpatentability of obvious subject matter.

CIP applications are not the only avenue to obtain patent protection on new subject matter of a previously filed,

currently pending application. In situations where support for the new matter is not clearly set forth in the parent, it may be advantageous to file a separate, unrelated application instead of a CIP application, and take a stand as to the patentably distinctiveness of the new claims to avoid the necessity of a terminal disclaimer and obtain the benefit of a full patent term.

If prior art is a concern and there is an argument that the newly filed information is entitled to the filing date of the earlier application based on the existence of adequate written description in the parent, sufficient to satisfy the requirements of 35 U.S.C. Section 112, the issue should not be clouded by filing a CIP application. In such instances, a continuation application should be filed with new claims that capture the intended subject matter. It is also recommended that the new claims in a continuation application be introduced by preliminary amendment, rather than by simply adding a new claim set at the end of a patent application. If the examiner enters the amendment without making a new matter rejection, it appears that this would be some evidence that the claims of a continuation application are entitled to their priority date, based on the *PowerOasis* decision.

The filing of a CIP application may result in significant loss of patent term for newly added material and can potentially raise issues of validity for related patents. Therefore, it is best practice to consider alternative measures and think twice before filing that CIP. ■