



DOUBLE PATENTING CONSIDERATIONS

by Mark Cohen

The Federal Circuit recently issued an important decision with respect to restriction practice and obviousness double patenting in Pfizer Inc. v. Teva Pharmaceuticals USA, Inc., ____ F.3d ____, 86 USPQ2d. 1001 (Fed. Cir. 2008). Although this decision was in a chemical context, the ramifications of the decision are not so limited and are applicable to any application in any discipline.

The facts of the case are simplified for the purpose of this article. Pfizer, Inc. (“Pfizer”) produces and sells the drug Celebrex, a non-steroidal anti-inflammatory drug (NSAID) for the treatment of osteoarthritis and rheumatoid arthritis. Pfizer owns three patents-in-suit, U.S. Patent Nos. 5,466,823 that is based on application USSN 08/160,594 (“594 application”); 5,563,165; and 5,760,068. These patents encompass a broad genus of NSAIDs, compositions using those compounds and methods of using those compounds, respectively. The claims of each of the patents include celecoxib -- the active ingredient in Celebrex.

During prosecution of the ‘594 application, the United States Patent and Trademark Office (“USPTO”) imposed a restriction requirement, in which the USPTO alleged that the application contained three inventions as follows:

Invention A: Claims directed to the NSAID compounds;

Invention B: Claims directed to compositions using the compounds in Invention A;

and

Invention C: Claims directed to the methods of using these compounds.

In the same Office Action, the USPTO required Pfizer to elect a single disclosed species for prosecution. In response, Pfizer elected to prosecute the generic compounds claimed, that is, Invention A, and the compound species celecoxib. The resulting compound claims remaining in the ‘594 application were ultimately allowed, and the application issued as the ‘823 patent.

Prior to the issuance of the ‘594 application, Pfizer filed a series of applications claiming benefit to the ‘594 application and directed to the non-elected subject matter in the ‘594 application. Specifically, Pfizer filed a divisional application which ultimately issued as the ‘165 patent, that included the restricted-out composition claims (Invention B). In addition, it filed a continuation-in-part application (“CIP”), that included the method claims that were restricted out and non-elected in the ‘594 application. The CIP ultimately issued as the ‘068 patent, and included, as issued, the restricted-out method claims, Invention C.

Pfizer sued Teva Pharmaceutical, USA (“Teva”) for patent infringement.¹

Although the issues in the litigation are complex, this article will focus on one issue and the ramifications thereof. A key issue for the Federal circuit was whether the claims in the CIP application which encompassed method claims (Invention C) which were subject to the restriction requirement in the parent application were invalid for obviousness-type double patenting over the claims of the ‘165 composition patent (Invention B), or whether this restriction requirement issued by the USPTO provided a safe-harbor which prevented the ‘165 patent from serving as prior art with respect to the ‘068 patent pursuant to 35 U.S.C. §121.

35 U.S.C. §121 provides a safe-harbor to patents that issue on applications filed as a result of a restriction requirement when it states:

A patent issuing on an application with respect to which a Requirement for Restriction under this section has been made or 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 or the other applications.

In addition, the courts have construed the statute to require consonance, i.e., the applicant must maintain the line of demarcation between the independent and distinct inventions that caused the restriction requirement. The consonance requirement prevents the applicant from amending claims in a divisional application in a manner that would violate the originally imposed restriction requirement.

The district court held that 35 U.S.C. §121 prevented the ‘165 patent from being prior art to the ‘068 patent, but the Federal Circuit reversed.

Although Pfizer argued that the terms “divisional” and “CIP” are merely labels, the Federal Circuit held that the safe-harbor provisions of 35 U.S.C. §121, by its literal terms only applies to divisional applications (or the original application) and patents issued from these applications.

The Court referred to the legislative history, which included discussions of the safe-harbor protection of §121. It noted that, prior to the 1952 Patent Act, no protection was afforded to patent applications filed as a result of a restriction requirement and that such applications were rejected by the USPTO or held invalid by the courts on double patenting grounds. Prior to the 1952 Patent Act, the PTO and the Courts were thus not precluded from utilizing a parent application to reject the claims of a divisional application directed to non-elected subject matter in the parent application as a result of the restriction requirement

¹ The particular route to the court is technical. Specifically, Teva Pharmaceutical USA, Inc. filed an abbreviated new drug application (“ANDA”) with the FDA for approval to market its generic version of celecoxib capsules. In its ANDA filing, Teva certified that the relevant Pfizer patents were invalid. Suffice it to say, that Teva, in its certification, did not dispute that the filing of its ANDA would infringe the patents, but challenged the validity of the patents. Since the filing of the ANDA was an act of patent infringement, Pfizer sued Teva for infringement in district court.

imposed therein. According to the Court, the purpose of Section 121 was to eliminate this inequity and thereby allow applicants to reasonably rely on restriction requirements imposed by the USPTO. The Court held that there was no suggestion in the legislative history of Section 121 that this safe-harbor provision was or needed to be directed to any other type of application other than a divisional application.

“The need for protection only existed when a divisional application was filed as a result of the restriction. If the section 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.

...[T]he drafters of Section 121 chose to refer specifically and only to divisional (and original) applications. If the drafters wanted to include CIPs within the protection afforded by Section 121, they could have easily done so.

Id., 86 USPQ2d at 1007.

The Court thus held 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. Since the ‘068 patent was a CIP application, the Court held that Section 121 does not preclude the use of the ‘165 patent directed to Invention B against the claims of the ‘068 patent (directed to Invention C).

However, this did not end the inquiry. The next issue decided by the Court was whether the claims directed to Invention C recited in the ‘068 patent were patentably distinct from the claims of the ‘165 patent. Despite the fact that the USPTO had indicated, by virtue of issuing the restriction requirement in the first instance, that the claims to the composition were patentably distinct from claims directed to the method of using the compositions, the Federal Circuit held, to the contrary, that the claims of the ‘068 patent were not patentably distinct from the claims in the ‘165 patent.

Since the ‘068 patent was unable to claim the protection of the ‘165 patent and since the Court adjudged that the claims in the ‘068 patent were not patentably distinct from the claims of the ‘165 patent, the Court held that the claims of the ‘068 patent were accordingly invalid for obviousness-type double patenting.

Thus, the hard lesson learned from the decision is that the filing of a CIP which contains claims to formally restricted out subject matter does not obtain the safe harbor enjoyed by a divisional application for purposes of protection under 35 U.S.C. §121. Further, earlier filed application from the restricted series may be fatal prior art to the CIP. Given the Court’s assessment, if Pfizer had filed a divisional application directed to the method of use claims (Invention C) rather than a CIP application directed to the method of use claims (Invention C), the outcome would have been different. The divisional application containing the method of use claims (Invention C) would be protected by the safe-harbor of 35 U.S.C. §121. Thus, the ‘165 patent directed to the composition (Invention B) would not have been used as a reference against the divisional application.

Thus, the Pfizer case warns that if a parent application is subjected to a restriction requirement, to avoid “invalidity on double patenting grounds”, the non-elected claims should be presented in a divisional application, and not a CIP application, claiming the non-elected subject matter.

Of course, one is left to wonder if Pfizer could have avoided the issue by voluntarily filing a terminal disclaimer even if the issue of obviousness double patenting were not raised during the prosecution of the CIP application or indeed even if it had done so after issuance. The filing of the terminal disclaimer would theoretically obviate any obviousness double patenting rejection raised in a subsequent litigation. Further, inasmuch as the CIP application has benefit of the same effective filing date as the parent or another application in the chain, as long as the ownership of the application remains the same, the patents in the family would expire on the same date. Thus, there would be no loss of term² if a terminal disclaimer were filed.

However, this is an after-the-fact analysis. As a practical matter, what can be done in the future to potentially avoid such an outcome? The applicant who for whatever reason chooses to file a CIP containing restricted of claims in lieu of a pure divisional, needs to determine whether he or she should voluntarily file a terminal disclaimer. The applicant thus needs to assess the strengths and weaknesses of such an action and the ramifications thereof. It seems clear that the applicant needs to be aware of all of the applications/patents in his/her portfolio and to identify those applications/patents that are directed to related subject matter. The applicant, thus, needs to be aware of the related applications/patents. In a company with a large patent portfolio, this may be difficult, but, nevertheless, is necessary. If a company uses outside counsel, it is important that the outside counsel prosecute the related or thematically similar applications, that is, applications not only in the same family, but also dealing with subject matter that is patentably similar. Once the applications/patents are identified, the applicant should then compare the claims in the identified patents and/or applications. More specifically, the applicant should construe the claims in each and determine the difference in each, and determine whether the differences render the claims of one patent/application patentably distinct from the claims of the later filed application/patent. Obviously, the critical inquiry remains whether the later filed claims define an obvious variation of the earlier filed claims. The applicant should assess the patent terms of the patents/applications in question in the absence of any filing of a terminal disclaimer.

After having evaluated the situation, the applicant should make a determination if a voluntary filing of the terminal disclaimer is necessary, weighing this against the potential that such a filing could be used adversely, e.g., as an admission in a later litigation. Nevertheless, each situation is fact-dependent. For example, the considerations would be completely different if the later filed application were a CIP application or an application in a different family claiming related subject than if it were a divisional application. As taught by the Pfizer case, if the later filed application were a CIP application, and if a restriction requirement were imposed in the parent application and the CIP application were directed to claims that were non-elected in the parent application, the applicant cannot rely on the determination that the USPTO considered the claims to be patentably distinct. After making the assessment, the applicant needs to consider the strength of any potential

² Assuming no patent term adjustment occurred as a result of delay by the USPTO during prosecution.

double patenting rejection and the strengths of its arguments to respond to this issue. If the applicant believes that arguments for overcoming a potential double patenting rejection are weak, then he or she may decide to file a voluntary terminal disclaimer, even in the absence of any obviousness-type double patenting rejection in the prosecution of the application.

Nevertheless, failure to make such an assessment, however, may prove fatal, as in the case of Pfizer.