Keywords: **divisional application; double patenting; 35 U.S.C. 121**

General: **Section 121 shields later filed applications stemming from a parent against rejections for double patenting only if the file reflects that the later filed application was necessitated by a restriction requirement by the examiner.**

Geneva Pharmaceuticals v. GlaxoSmithKline PLC
68 U.S.P.Q.2d 1865 (Fed. Cir. 2003)
Decided November 21, 2003

I. Facts

GlaxoSmithKline (GSK) owns a series of patents relating to antibiotics administered in combination with other substances, such as potassium clavulanate. The latter substance prevents products produced by some bacteria from deactivating the antibiotic ingredients, making the combination more effective in treatment. Most of the GSK patents at issue stem from a single filing made in 1975. Three patents issued in 1985, with 4 additional patents issuing in 2000 and 2001. The patents are all related to pharmaceutical compositions and methods of interaction of the ingredients. GSK filed the 2000/2001 patent applications following discussions with the examiner of the 1985 patents, but the later patents were examined by a different examiner. An interview summary did appear to show that the discussion involved filing of different claims in divisional applications, but the file did not include a specific reference to a restriction requirement by the examiner, and no such requirement was ever issued by the PTO.

Geneva is one of several generic drug manufactures wishing to file for FDA approval, which itself would constitute infringement of the GSK patents. They filed for declaratory judgment of invalidity of the 1985 patents based on double patenting. The district court ruled in favor of Geneva, and held the patents invalid. GSK appealed.

II. Issues

A. Does 35 U.S.C. 121 shield divisional and continuation applications from a double patenting rejection absent a clear showing of a restriction requirement by the examiner?

III. Discussion

A. No.

The doctrine of double patenting has two prongs: (1) statutory double patenting; and (2) non-statutory (obviousness-type) double patenting. For former precludes the patenting of the same thing twice, and cannot be overcome without amendment of the claims of a second application. The latter, developed by the predecessor court of the CAFC, holds that, although two related (e.g. parent/child) applications do not claim exactly the same thing, obvious variants of what is claimed in the first application cannot be claimed in the second. This rejection can be overcome by a terminal disclaimer that limits the life of the second resulting patent to that of the first, and ties the two resulting patents together to prevent their separate assignment.

Section 121 of the patent statute, however, precludes a double patenting rejection against a subsequent related patent application where the second application resulted from a restriction requirement by an examiner. The reasoning behind Section 121 is that, once an examiner has

expressed that an application claims two separate and distinct inventions, it is then inconsistent to hold that the second application directed to a separate and distinct invention not elected in the first application claims a mere obvious variant of the first.

Section 121 reads:

> 35 U.S.C. 121 Divisional applications.
>
> 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 of this title 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. If a divisional application is directed solely to subject matter described and claimed in the original application as filed, the Director may dispense with signing and execution by the inventor. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention. (Emphasis added.)

Thus, the statute only shields the subsequent application where it resulted from a restriction requirement. Otherwise, the double patenting rejection should be made.

GSK counsel presented an interview summary that stated simply that:

> [I]t was agreed that 'simple B-lactamase inhibition' composition claims, i.e., new claims 97 through 112, are proper in the present case but that the method of use claims, that is a method of effecting B-lactamase inhibition in humans and animals would not be proper in the present case and therefore an appropriate set of method of use claims corresponding to new claims 97 through 112 will be presented in Divisional Application, Serial no. 964,035.

Because, however, no actual restriction requirement was issued, the court held that there was no evidence of record that such a restriction was made, and that Section 121 did not shield the later applications from a non-statutory double patenting rejection.

Interestingly, the court observed that an amendment presenting the method claims at issue was not entered, which may have been the reason no restriction requirement was made. However, if the applicants wanted the shielding effect of Section 121, they should have requested entry of the amendment, followed by restriction. Without entry of the amendments, no such restriction was made, and the later applications were subject to the double patenting rejection. Invalidity was confirmed by the CAFC.

The case also contains interesting discussions (on somewhat separate issues) of the terms "effective amount," "synergistically effective amount," and on the distinction by reference to purity, common in chemical and, particularly, pharmaceutical patents.

It should be noted that in this case, due to the filing date of the parent application, the progeny would have received the alternative duration treatment (17 years from the issue date or 20 years from the earliest filing date). In more recently filed applications, this treatment would not, of

course, be accorded. The reasoning of this line of cases, and caselaw cited by this court regarding the danger of mischief in extending the life of further patent applications absent a double patenting rejection is, therefore, now somewhat less relevant. However, the doctrine of non-statutory double patenting and the shielding accorded by Section 121 is still in place, and the holding of this case is still relevant to all progeny applications not resulting from a restriction requirement of record.