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Federal Circuit Patent Bulletin: *G.D. Searle LLC v. Lupin Pharms., Inc.*

June 25, 2015

"The safe harbor provision of section 121 protects a patent issuing on an application with respect to which a restriction requirement has been made, or on an application filed as a result of such a restriction requirement."

On June 23, 2015, in *G.D. Searle LLC v. Lupin Pharms., Inc.*, the U.S. Court of Appeals for the Federal Circuit (Prost, Bryson,* Hughes) affirmed the district court's judgment that U.S. Patent No. RE44,048 (a reissue of U.S. Patent No. 5,760,068), which related to the treatment of pain and inflammation without the harmful side effects associated with certain traditional anti-inflammatory drugs, was invalid for obviousness-type double patenting. The Federal Circuit stated:

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. . . . The parties present two principal issues on appeal: (1) whether 35 U.S.C. § 251 authorized the PTO to reissue the '068 patent under the circumstances; and (2) assuming reissue was authorized, whether the safe harbor provision of 35 U.S.C. § 121 applies to the RE '048 patent and protects it from invalidation based on the '165 patent. Because we find that the safe harbor provision of section 121 does not apply to the RE '048 patent, even assuming it was proper to grant the reissue patent under section 251, we affirm the district court's judgment. . . .

The safe harbor provision of section 121 protects a patent issuing on an application with respect to which a restriction requirement has been made, or on an application filed as a result of such a restriction requirement. It is undisputed that the reference '165 patent issued on a divisional of the original '594 application, which was filed as a result of the July 1994 restriction requirement. The challenged RE '048 patent, however, is not entitled to safe harbor protection, because it did not issue on either the '594 application or a divisional of the '594 application.

The RE '048 patent issued from the '319 application, a reissue of the '068 patent, which in turn issued from the '113 application. The '113 application cannot be a divisional of the '594 application, despite being designated as such in the reissue patent, because it contains new matter that was not present in the '594 application. Simply deleting that new matter from the reissue patent does not retroactively alter the nature of

the '113 application. Moreover, when the '113 application issued as the '068 patent in June 1998, Pfizer obtained patent protection for the new matter that was not present in the '594 application. For years thereafter, the public was not free to practice that new matter (e.g., the now cancelled claims 2-12 and 18 of the '068 patent) because of that patent protection. Pfizer cannot now identify the '113 application as a divisional of the '594 application (for purposes of section 121) and retroactively relinquish the new matter in the '113 application, after having enjoyed years of patent protection for it. Fairness to the public does not permit Pfizer to convert the '113 application into a division of the original '594 application, and thereby take advantage of the safe harbor provision, simply by designating it as a divisional application years after the fact. . . .

Section 121 is inapplicable to the RE '048 patent for a second reason as well: The RE '048 patent (the challenged patent) and the '165 patent (the reference patent) are not "derived from the same restriction requirement." When separate restriction requirements are imposed on separate applications and the record does not show that any of the various restriction requirements carried forward from one application to the next, the earlier restriction requirement cannot be viewed as having continued in effect with respect to the later-filed application.

In 1994, the examiner imposed a three-way restriction requirement on the original '594 application (the "1994 restriction requirement"), prohibiting Pfizer from prosecuting all three classes of claims—compounds, compositions, and methods of use—in the same application. Pfizer elected to prosecute the compound claims in the'594 application and separately prosecuted the composition claims in the '059 application, a division of the '594 application.

The '059 application matured into the '165 patent. It is undisputed that the '165 patent is derived from the1994 restriction requirement. The RE '048 patent, on the other hand, identifies itself as being descended from the '113 application and the PCT '720 application. Both of those applications, as filed, contained three classes of claims: compounds, compositions, and methods of use. During the national stage prosecution of the '113 application, and in an April 8, 1997, supplemental amendment, Pfizer noted that the examiner had issued "[a] lack of unity rejection/restriction requirement" during a telephone conference (the "1997 restriction requirement"). The 1997 restriction requirement again limited Pfizer to an election among the claimed compounds, compositions, and methods of use. Pfizer elected to prosecute only method-of-use claims in the '113 application, which matured into the '068 patent. . . .

Pfizer admits that the '113 application contains claims directed at "subject matter that was newly added. . . and had not been disclosed in the . . . '549 application[]." Thus, while the 1994 restriction requirement and the 1997 restriction requirement both limited Pfizer to an election among compounds, compositions, and methods of use, they did not apply to the same compounds, compositions, and methods of use. They are therefore not the same restriction requirement.

Furthermore, the record is devoid of any evidence showing that the examiner "reinstate[d] or even advert[ed] to" the 1994 restriction requirement when issuing the 1997 restriction requirement. There is no evidence that the examiner made any reference to the 1994 restriction requirement at all during prosecution of the '113

application. Without such evidence, the 1994 and the 1997 restriction requirements, although appearing similar, must be deemed to have been "separately imposed with respect to" the '594 and the '113 applications. Because the '165 patent and the RE '048 patent are derived from two separately imposed restriction requirements, section 121 does not apply as between those two patents.