G.D. SEARLE LLC v. LUPIN PHARM., INC., Appeal No. 2014-1476 (Fed. Cir. June 23, 2015). Before Prost, Bryson, and Hughes. Appealed from E.D. Va. (Judge Wright Allen).

Background:

Pfizer filed an application (the "original application") claiming compounds, compositions, and methods of use. The Examiner issued a Restriction Requirement, and Pfizer elected to pursue the compound claims. Pfizer pursued the composition claims in a divisional application, which eventually issued as the '165 Patent.

Before the Restriction Requirement was issued, Pfizer filed another application as a continuation-in-part of the original application. After a series of subsequent filings claiming priority back to the original application and ending with the '113 Application, the Examiner issued a Restriction Requirement. At this time, Pfizer elected the method-of-use claims, and the '113 Application issued as the '068 Patent.

The '068 Patent method-of-use claims were later invalidated during litigation under the doctrine of obviousness-type double patenting in view of the '165 Patent. Pfizer subsequently filed another application seeking reissue of the '068 Patent. Pfizer's preliminary amendment canceled all material in the claims and specification that were not disclosed in the original application, and amended the specification to identify the '113 Application as a divisional of the original application. The preliminary amendment also corrected some technical errors in the claims. The Examiner found that the technical errors provided proper basis for reissue, and the application reissued as the RE '048 Patent.

When Pfizer attempted to enforce the RE '048 Patent, the district court again invalidated the claims under the doctrine of obviousness-type double patenting in view of the '165 Patent.

Issue/Holding:

Did the district court err in holding that the RE '048 Patent was invalid under the doctrine of obviousness-type double patenting? No, affirmed.

Discussion:

At issue was whether the "safe harbor" provision of 35 U.S.C. §121 applied to the RE '048 Patent. This provision prevents a patent that issued on an application in which a restriction requirement had been made, or on an application filed as a result of such a requirement, from being used as a reference in an obviousness-type double-patenting rejection "against a divisional application or against the original application or any patent issued on either of them."

The Federal Circuit held that the RE '048 Patent was not entitled to safe-harbor protection because it did not issue on either the original application or a divisional of that application. The court held that Pfizer could not retroactively alter the nature of the application by deleting the new matter previously added and identifying the '113 Application as a divisional application.

The court also noted that Pfizer had for years enjoyed patent protection for the new matter introduced in the continuation-in-part, and that Pfizer could not later take advantage of the safe-harbor provision after having prevented the public from practicing that new matter.