

BRISTOL-MYERS SQUIBB CO. V. PHARMACHEMIE B. V.

361 F.3d 1343 (Fed. Cir.), rehearing en banc denied, 2004 U.S. App. LEXIS 10300
(Fed. Cir. Apr. 21, 2004)

The Federal Circuit held that under certain circumstances, a restriction requirement placed on a parent application does not apply to a subsequent continuation application for purposes of a double patenting defense under 35 U.S.C. § 121. Specifically, this is the case when a restriction on a parent application is separately imposed and the continuation application record does not support the inference that earlier restrictions carry forward.

Research Corp. Technologies, Inc. is the owner of two patents claiming methods for treating malignant tumors with certain platinum coordination compounds and compositions containing those compounds. Bristol-Myers Squibb Co. ("Bristol-Myers") is the exclusive licensee of the more recently issued patent ("the '927 patent"). Pharmachemie B.V. ("PBV") sought FDA approval to market a cancer treatment drug covered by the '927 patent. Bristol-Meyers brought suit against PBV alleging patent infringement. PBV claimed that the '927 patent was invalid for double patenting over the '707 patent (the '927 patent's parent application). On summary judgment, the district court held that the application that lead to the '927 patent was filed as a result of a restriction requirement placed on the '707 patent application because the restriction was never withdrawn, revoeked or cancelled. Thus, according to the district court, PBV could not cite the '707 patent as a reference against the '927 patent for double patenting purposes under 35 U.S.C. § 121. PBV appealed to the Federal Circuit.

The Federal Circuit reversed the district court's judgment and remanded. The Federal Circuit stated that the success of PBV's double patenting claim turned on whether Bristol-Myers could assert a defense against double patenting under 35 U.S.C. § 121. The court explained that PBV could not use the '707 patent as a reference against the '927 patent if Bristol-Myers could claim that the application that resulted in the '927 patent was filed as a result of a restriction placed on the '707 patent. Therefore, the Federal Circuit focused on the different restrictions that the patent examiners placed on the parent application and continuation applications. The Federal Circuit noted that the examiner for the continuation application did not reinstate or even refer to the parent application restriction requirement, and so the court agreed with PBV that the later restriction requirement was different from and inconsistent with the earlier restriction requirement. Thus, the court held that the restriction requirement was not in effect at the time of the filing of the application that matured into the '927 patent, and the '927 patent could not have been filed as a result of that restriction requirement.