Pfizer v. Lee: Defective Restriction Requirement Stops Patent Term Adjustment

Peter A. Jackman and Lori M. Brandes

On January 22, 2016, the Court of Appeals for the Federal Circuit decided *Pfizer v. Lee*, holding that a "defective" restriction requirement was sufficient to stop the period of patent term adjustment granted when the U.S. Patent and Trademark Office fails to issue a first action within 14 months from the date an application is filed. *Pfizer v. Lee*, No. 2015-1265 (Fed. Cir., January 22, 2016).

The Defective Restriction Requirement

Under U.S. patent law, applicants are entitled to additional patent term when the U.S. Patent and Trademark Office (USPTO) has delayed issuance of a patent. For example, 35 U.S.C. § 154(b)(1)(A)(i) provides an applicant with a patent term adjustment (PTA) if the USPTO fails "to provide at least one of the notifications under section 132 or a notice of allowance" no later than 14 months from the application filing date (also known as "A delay"). A notification under 35 U.S.C. § 132 includes rejections, objections and restriction requirements.

If multiple inventions are claimed in an application, the USPTO examiner will issue a restriction requirement that specifies which claims correspond to each invention and requires the applicant to elect one of the inventions for examination. In *Pfizer,* the examiner issued an initial restriction requirement but failed to assign six dependent claims into the groups of separate inventions identified. Pfizer contacted the examiner and informed him of the error. The examiner acknowledged that the initial restriction requirement was defective and agreed to withdraw it and issue a corrected restriction requirement. The question at issue in *Pfizer* was whether issuance of the defective restriction requirement was sufficient to meet the requirement of a notification under section 132 that would end the period of A delay.

The Court's Decision

Pfizer argued that the defective restriction requirement was not sufficient notification under section 132 to end the period of A delay because it omitted six claims. Pfizer also argued that the defective restriction requirement should be considered a "non-event" because it was withdrawn by the examiner. However, the Court of Appeals disagreed.

Relying on its decision in *Chester v. Miller* (906 F.2d 1574 (Fed. Cir. 1990))("*Chester*"), the Court found the defective restriction requirement in *Pfizer* satisfied the notification requirement under section 132 because it provided detailed descriptions of the invention groups and sufficient information to which the applicant could have responded. In particular, the Court said Pfizer could have taken direction from the defective restriction requirement because the dependent claims the examiner failed to assign would naturally fall within a group assigned to their respective independent claims. The Court also indicated that Section 814 of the USPTO's Manual of Patent Examining Procedure provides that a restriction requirement is not automatically invalid because it fails to account for a particular claim.

The Court noted that other courts had reached similar conclusions based on similar facts. For example, the District Court for the District of Columbia held that an examiner's reissuance of a restriction requirement in response to an applicant's arguments that it was erroneous does not automatically mean that an application has been "delayed" for the purposes of patent term adjustment. *Univ. of Mass. v. Kappos*, 903 F. Supp. 2d 77 (D.D.C. 2012)("*UMass*").

In addition, the Court distinguished *Pfizer* from two cases in which applicants successfully obtained additional PTA for defective restriction requirements, because in both cases the examiner *sua sponte* rescinded and replaced the issued restriction requirements without explanation and without prompting from the applicant. *In re: Patent No. 7,803,385, Matthew C. Coffee, Decision on Application For Patent Term Adjustment*, May 24, 2012 ("*Oncolytics*") and *Janssen Pharmaceutica v. Rea*, 928 F. Supp. 2d 103 (D.D.C. 2013)("*Janssen*"). According to the Court, the applicant's and examiner's exchanges in *Pfizer* were part of the typical "back and forth" process of patent prosecution, and therefore not the type of error for which the PTA statue was intended to compensate.

Judge Newman dissented in *Pfizer*, arguing that the majority's holding was in conflict with the intent of the PTA statute to compensate applicants for delay caused by the USPTO. In particular, she explained that the majority's holding did not compensate Pfizer for the delay caused by the defective restriction requirement and in effect required Pfizer to file a speculative response to the restriction requirement despite acknowledgment by the USPTO that the restriction requirement was defective.

The PTA Landscape After Pfizer

Pfizer will make it even more difficult for applicants to obtain additional PTA based on a defective initial restriction requirement or office action. But, the *Pfizer* majority distinguished *Oncolytics* and *Janssen*, two cases in which applicants successfully obtained additional PTA for a defective restriction requirement, on the basis that the examiner in those cases voluntarily withdrew the defective restriction requirement without prompting from the applicants.

In *Oncolytics*, the USPTO granted additional PTA where the examiner had agreed to a specific grouping of inventions that the applicant proposed, but then later changed his mind and issued an office action on the merits based on a different grouping of inventions. When granting the additional PTA, the USPTO indicated that the facts of *Oncolytics* were a "rare occurrence" for which it was appropriate for them to treat as a "non-event" for the purposes of calculating PTA.

In *Janssen*, the first action issued by the examiner was a 185-way restriction requirement. Before the applicant had an opportunity to respond, the examiner issued another action that "rescinded and replaced" the prior action and imposed a three-way restriction requirement on the claims.

When an examiner issues a defective action, applicants should consider whether correction of the PTA is warranted in view of the facts of cases like *Oncolytics* and *Janssen*. Correction of the PTA can be petitioned by filing a request at the USPTO within two months of the issuance of a patent (extendible for up to five additional months upon payment of a fee).

In addition, the majority in *Pfizer* expressly declined to hold that the section 132 notification requirement can never be satisfied where the classification of an *independent* claim is omitted. A restriction requirement that is defective for failure to assign an independent claim to an invention group could be more compelling evidence that the restriction requirement fails to meet the section 132 notification requirement, particularly if the disposition of the omitted claim is not clear.