

Federal Circuit Patent Bulletin: *Teva Pharms. USA, Inc. v. Sandoz, Inc.*

June 19, 2015

“Regardless of the scientific accuracy of [a prosecution history] statement, a person of ordinary skill in the art would have understood that the applicants defined the term [in a manner] to gain allowance of the claims. This is a legal conclusion unaffected by the scientific error made during prosecution [and does not constitute] a question of fact [given that] the significance of statements made during prosecution to the claim construction is a question of law.”

On June 18, 2015, in *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Moore,* Mayer, Wallach) on remand from the Supreme Court of the United States, affirmed-in-part and reversed-in-part the district court’s judgment that U.S. Patents No. 5,800,808, No. 5,981,589, No. 6,048,898, No. 6,054,430, No. 6,342,476, No. 6,362,161, No. 6,620,847, No. 6,939,539, and No. 7,199,098, which related to glatiramer acetate injection for treating multiple sclerosis, marketed by Teva as Copaxone®, were not invalid for indefiniteness. The Federal Circuit stated:

A patent’s specification must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention” A patent is indefinite “if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” The definiteness requirement must take into account the inherent limitations of language. “Some modicum of uncertainty . . . is the ‘price of ensuring the appropriate incentives for innovation.’” On the other hand, “a patent must be precise enough to afford clear notice of what is claimed, thereby appris[ing] the public of what is still open to them.” . . .

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Claim 1 of the '808 patent recites "molecular weight" without specifying the meaning of that term. The parties agree that "molecular weight" could refer to Mp, Mw, or Mn. And they agree that each of these measures is calculated in a different way and would typically yield a different result for a given polymer sample. But the claim on its face offers no guidance on which measure of "molecular weight" the claims cover. There is no express definition of "molecular weight" in the '808 patent specification. Nowhere in the specification are the terms Mp, Mw, or Mn used. Neither party argues to the contrary. . . .

To the extent that Teva argues that the meaning of "molecular weight" in the context of patents-in-suit is itself a question of fact, it is wrong. A party cannot transform into a factual matter the internal coherence and context assessment of the patent simply by having an expert offer an opinion on it. The internal coherence and context assessment of the patent, and whether it conveys claim meaning with reasonable certainty, are questions of law. The meaning one of skill in the art would attribute to the term molecular weight in light of its use in the claims, the disclosure in the specification, and the discussion of this term in the prosecution history is a question of law. . . . Determining the meaning or significance to ascribe to the legal writings which constitute the intrinsic record is legal analysis. The Supreme Court made clear that the factual components include "the background science or the meaning of a term in the relevant art during the relevant time period." Teva cannot transform legal analysis about the meaning or significance of the intrinsic evidence into a factual question simply by having an expert testify on it. . . .

To determine whether one of skill in the art would be reasonably certain that the claim's use of molecular weight is Mp, we consider as well the prosecution history. Statements made during prosecution history are relevant to claim construction. Applicants can define (lexicography), explain, or disavow claim scope during prosecution. And whether their statements or disclaimers impact the meaning of a claim term in a given patent is a legal question, not a factual one. A statement made during prosecution of related patents may be properly considered in construing a term common to those patents, regardless of whether the statement pre- or post-dates the issuance of the particular patent at issue. The parties do not point to any portion of the '808 patent's prosecution history that is relevant to the construction of "molecular weight." However, they point to, and the district court considered, statements about the meaning of "molecular weight" made during the prosecution of the '847 and '539 patents which are both continuations of the '808 patent. Such statements are legally relevant to the meaning one of skill in the art would attribute to the identical term in the '808 patent. In the prosecution of both patents, the examiner rejected the claims as indefinite because the term average molecular weight was meaningless without specifying whether Mp, Mn, or Mw should be used. . . .

In response to the indefiniteness rejection concerning the meaning of "molecular weight" during the prosecution of the '847 patent, the earlier of the two continuations, the applicants argued that the term "molecular weight" was not indefinite because "[o]ne of ordinary skill in the art could understand that kilodalton units implies a weight average molecular weight," i.e., Mw. To be clear, this was the only basis which the applicant argued in response to the indefiniteness rejection. And the applicant was successful. Defining "molecular weight" as Mw, as the applicant did in response to the rejection, was what overcame the rejection. The district court heard testimony that the statement made during the prosecution of the '847 patent was scientifically erroneous because each type of "molecular weight" can be expressed in kilodaltons. The

fact finding by the district court—that one of skill in the art would understand that each type of “molecular weight” could be expressed in kilodaltons—is not clearly erroneous. However, the fact that Mw, Mn, and Mp can each be expressed in kilodaltons does not erase the confusion created by the patentee about its claim scope. Regardless of the scientific accuracy of the statement, a person of ordinary skill in the art would have understood that the applicants defined the term “molecular weight” as Mw to gain allowance of the claims. This is a legal conclusion unaffected by the scientific error made during prosecution. To the extent that the dissent claims that the significance to be given to the patentee’s express definition of molecular weight as Mw, made to overcome a rejection, is a question of fact, the dissent is wrong. The determination of the significance of statements made during prosecution to the claim construction is a question of law.

The examiner required the applicants to provide a meaning for “molecular weight” and they provided one: Mw. The fact that their explanation contained further elaboration which itself included a scientific error does not undermine the statement’s legal import. “The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent.” We have held patentees to statements containing errors made during prosecution where, for example, nothing in the statement was at odds with the plain language of the claims or the specification. Given the role of the statement in gaining allowance of the claims, a person of ordinary skill in the art would have understood the applicants to have defined “molecular weight” to mean Mw, and the fact that any of the measures (Mw, Mn or Mp) can be expressed in kilodaltons, does not change the significance of the choice made by the patentee, Mw, to overcome the rejection. And importantly, this determination is part of the legal analysis, not as the dissent claims, one of the fact findings to which we owe deference.