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POSITA Motivated to Pursue Clinical Development of Therapy Disclosed in Prior Art Despite Potential Safety and Efficacy Hurdles

By Robert H. Resis

March 6, 2015 – The PTAB recently held that the challenged claims in two patents assigned to Genzyme and one patent assigned to Duke University on methods for treating Pompe disease are invalid.

IPR2013-00534 – BioMarin Pharmaceutical Inc. v. Genzyme Therapeutic Products Limited Partnership (review of U.S. 7,351,410)
IPR2013-00537 – BioMarin Pharmaceutical Inc. v. Genzyme Therapeutic Products Limited Partnership (review of U.S. 7,655,226)
IPR2013-00535 – BioMarin Pharmaceutical Inc. v. Duke University (review of U.S. 7,056,712)

In the Genzyme decisions, the PTAB noted that Genzyme did not contend that the combination of references failed to address each element of claim 1. Rather, Genzyme contended that a person of ordinary skill in the art (POSITA) would not have had a reasonable expectation of success for a method of treating a human patient with Pompe disease using the claimed enzyme (GAA) biweekly to reduce and/or arrest further accumulation of glycogen in the skeletal muscle of a human patient. Notwithstanding the Board's recognition that such a combination of references could introduce safety and efficacy hurdles, the Board disagreed with Genzyme and held that a POSITA would have been motivated to combine the references.

Specifically, in IPR2013-00534, the PTAB found that the record did not contain any evidence that human clinical trials were initiated before the priority date of the '410 patent. The PTAB stated that a POSITA could not have predicted with absolute certainty that a safe and effective dosing regimen for using GAA in a method of treating Pompe disease could have been achieved.

The PTAB found that a POSITA would have understood that to treat Pompe disease effectively using GAA, sufficient quantities of enzyme would have to reach the patient's muscle cells, which could potentially require high doses that could introduce safety and efficacy hurdles resolvable only with human clinical trials. Despite this recognized difficulty, however, the PTAB held that a POSITA would have been motivated to pursue the clinical development of the therapy disclosed in one reference (Reuser et al., WO/97/05771), which disclosed all of the claim limitations except for a biweekly dosing schedule for the disclosed therapeutic containing GAA. The PTAB held that the evidence established that the selection of the dose and dosing schedule would have been a routine optimization of the therapy outlined in Reuser, which would have been achievable through the use of standard clinical procedures. The PTAB held that the motivation to optimize the therapy disclosed in Reuser "flows from the 'normal desire of scientists or artisans to improve upon what is already generally known.'"

Similarly, in IPR2013-00537 the PTAB held that a POSITA would have had a reasonable expectation of success at the time the invention was made; all that remained was the execution of human clinical trials (arguably "routine" to a POSITA, to verify the expectation that a specific dosage – within a previously suggested dosage range – and corresponding dosage regimen would have been safe and effective).

In IPR2013-00535, the PTAB held that a prior art patent (van Bree et al., U.S. 7,351,410) anticipated the challenged claims of the '712 patent. Separately, the PTAB held that the challenged claims would have been obvious over Reuser in view of other prior art. The PTAB held that a showing of obviousness in this case did not require *in vivo* data as "proof" that an otherwise clear statement in Reuser was correct, when it was reasonably based on *in vitro* studies and other information discussed in the reference.

The Leahy-Smith America Invents Act established new patent post-issuance proceedings, including the inter partes review, post grant review and transitional program for covered business method patents, that offer a less costly, streamlined alternative to district court litigation. With the U.S. Patent and Trademark Office's Patent Trial and Appeal Board conducting a large and increasing number of these proceedings, and with the law developing rapidly, Banner & Witcoff will offer weekly summaries of the board's significant decisions and subsequent appeals at the U.S. Court of Appeals for the Federal Circuit.

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