Patent Owner's Parent Application Disclosing Osteoporosis Treatment Methods Did Not Enable the Challenged CIP Claims

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July 11, 2016 — The Patent Trial and Appeal Board recently held that a patent owner's patent claims were unpatentable under 35 U.S.C. § 102(a) over an anticipatory reference because a parent application did not enable the claims and thus did not provide a priority date that predated the reference. The PTAB also held that the patent owner failed to establish conception prior to the critical date of the reference.

IPR2015-00291 – *Daiichi Sankyo Co., Ltd. v. Alethia Biotherapeutics, Inc.* (Paper 75)

A key takeaway from this case is that a petitioner can prevail in an *inter partes* review based on a § 102(a) reference where the challenged claims are not enabled by a parent application filed before the publication date of the reference. Effective use of available evidence by the petitioner that demonstrates lack of enablement of challenged claims is another key takeaway. A third takeaway is that the PTAB will closely scrutinize a patent owner's evidence of alleged conception (including the patent owner's presentation of its clinical studies to the petitioner) before the publication date of a § 102(a) reference. Due to the adversarial nature of an IPR proceeding, a patent owner may have a more difficult time convincing the PTAB on enablement and conception than an applicant has in convincing an examiner on the same issues during an original or *ex parte* examination.

The challenged patent, U.S. 8,168,181 (the '181 patent), discloses methods of modulating osteoclast differentiation, which may be useful in the treatment of bone loss or bone resorption in patients

suffering or susceptible of suffering from certain conditions such as osteoporosis. The patent owner did not dispute that the asserted anticipatory reference discloses the limitations recited in the challenged claims. The PTAB resolved two disputes, both in favor of the petitioner.

The first dispute was whether the challenged claims of the ’181 patent, filed on October 16, 2009, was entitled to its priority claim as a continuation-in-part to WO 2007/093042 (Parent Application), filed on February 13, 2007. The PTAB stated that without the benefit of priority, Hiruma, a PCT Publication published in Japanese on April 16, 2009, becomes available as prior art to the ’181 patent under 35 U.S.C. § 102(a).

On the enablement issue, a question of law, the PTAB considered whether the Parent Application enabled the challenged claims, i.e., did the specification of the Parent Application describe “the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention].” The PTAB stated that the enablement requirement is met when one skilled in the art, having read the specification, could practice the invention without “undue experimentation.” The PTAB went on to consider whether undue experimentation would be required by analyzing the evidence under the *Wands* factors: “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

The PTAB found that the Parent Application discloses a potential target for drug development (i.e., Siglec-15), an assay by which to screen potential inhibitory compounds to osteoclast differentiation, and a general description pertaining to conventional methods of producing antibodies. According to the PTAB, to arrive at the invention of the challenged claims, a person of ordinary skill in the art would have had to choose to pursue anti-Siglec-15 antibodies as a potential inhibitor to test in the disclosed osteoclastogenesis assay, generate anti-Siglec-15 antibodies, and then screen those antibodies until an antibody having the desired biological properties was identified. The PTAB found that while the Parent Application discloses Siglec-15 can potentially impair formation of osteoclasts from precursor cells, it fails to provide sufficient detailed guidance to a person of ordinary skill in the art suggesting more than a mere starting point or direction for further research. The PTAB found that while the Parent Application discloses the protein sequence of Siglec-15, it offers no credible guidance as to unique antigenic regions or epitopes in Siglec-15 that would have been useful for generating antibodies having the required functional properties. The PTAB concluded that the lack of specific guidance would have required a person of ordinary skill in the art to engage in a complicated and lengthy screening process to practice the invention, amounting to undue experimentation.

The PTAB also found that the Parent Application fails to sufficiently describe common structural information to show possession to the genus of antibodies recited in the challenged claims. The PTAB found the patent owner did not prove that the claims of the ’181 patent are entitled to the priority date of February 13, 2007, and concluded that Hiruma thus anticipates the challenged claims under 35 U.S.C. § 102(a).

The second dispute was whether the patent owner could successfully antedate Hiruma, thus removing the reference as prior art under 35 U.S.C. § 102(a). The patent owner contended that the claimed invention was conceived prior to April 16, 2009, and constructively reduced to practice on October 16, 2009, the filing date of the ’181 patent. The patent owner further contended that the inventors were reasonably diligent from April 9, 2009, to the date of the constructive reduction to practice. To demonstrate conception, the patent owner relied on the Parent Application and the declaration testimony of Dr. Mario Filion (named as a co-inventor on the ’181 patent) that the subject matter claimed in the patent was conceived prior to February 13, 2007, the filing date of the Parent Application, or alternatively, prior to June 19, 2007, the date in which he presented the patent owner’s clinical programs to the petitioner. The patent owner also relied upon a copy of the slide deck that accompanied Dr. Filion’s presentation to the petitioner (the Patent Owner Presentation).

The PTAB found that neither the Parent Application nor the Patent Owner Presentation was sufficient to establish that antibodies that could function in the claimed methods had been defined prior to the critical date. The PTAB found that because the patent owner’s records indicated that critical research activity was still necessary before identifying a Siglec-15 antibody capable of performing the functions recited in the challenged claims, the mental embodiment of such antibodies as of the critical date “was a mere hope or expectation, a statement of a problem, but not an inventive conception.” The PTAB held, therefore, that the patent owner failed to antedate Hiruma, which was thus prior art under 35 U.S.C. § 102(a).

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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