

In Fight Over Recombinant Blood Clotting Factor, PTAB Denies Motion to Submit Supplemental Information

Jun 16, 2017

Reading Time : **2 min**

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Patent owner Novo Nordisk Healthcare AG owns U.S. Patent No. 9,102,762 B2, entitled “Virus filtration of liquid factor VII compositions.” Factor VII (“FVII”) is a polypeptide involved in blood clotting. It is dissolved in blood plasma and circulates freely until it is attracted to a site of injury and converted to its active form, Factor VIIa (“FVIIa”). Novo Nordisk markets synthetic, recombinant FVIIa under the name NovoSeven. The claims of the patent relate to methods of removing viruses from a composition of recombinant FVII, using a nanofilter with a pore size of 80 nm or less and “where 50-100% of the Factor VII polypeptides . . . are in an activated form (FVIIa) prior to nanofiltration.”

Pursuant to 37 CFR § 42.123(a), once a trial has been instituted, a party *may* file a motion to submit supplemental information, provided that the party does so within one month of the date trial is instituted and the information is relevant to a claim for which trial was instituted. Petitioner Laboratoire Francais sought to submit several items as supplemental information: a chapter of a French book, a supplemental declaration from its expert, and two journal articles that cite the book as a reference in order to show that the chapter was publicly accessible before the December 2003 filing date.

While Laboratoire Francais’ submission was within the one-month deadline, the PTAB denied the motion. Citing to prior PTAB decisions, the panel noted that “the provision for submitting supplemental information is not intended to offer a petitioner a routine avenue for bolstering deficiencies in a petition raised by a patent owner in a preliminary response.” In other words, a

petitioner cannot wait and see what facts and arguments the patent owner comes back with in its response to then introduce new prior art in the proceeding.

Although Laboratoire Francais tried to argue that the book chapter was only recently uncovered in a search of prior art, the PTAB was not convinced. The book chapter was authored by Thierry Burnouf, who was an employee of Laboratoire Francais, a colleague of Laboratoire Francais's expert, Dr. Chtourou, and the author of another reference that was submitted with the IPR petition. Unfortunately for petitioner, the two journal articles submitted as proof that the book was available as of the filing date cut against the motion; the PTAB cited them as proof that the book was not an obscure reference, but was widely disseminated and available to persons skilled in the art.

Laboratoire Francais du Fractionnement et des Biotechnologies S.A. v. Novo Nordisk Healthcare AG, IPR2017-00028, Paper 22 (June 13, 2017).

Categories

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Inter Partes Review

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