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Paper 109
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LABORATOIRE FRANCAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES S.A.,
Petitioner,

v.

NOVO NORDISK HEALTHCARE AG,
Patent Owner.

IPR2017-00028
Patent 9,102,762 B2

Before ERICA A. FRANKLIN, SUSAN L. C. MITCHELL, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* MITCHELL.

Opinion concurring-in-part and dissenting-in-part filed by *Administrative Patent Judge* FRANKLIN.

MITCHELL, *Administrative Patent Judge*.

JUDGMENT
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)
Granting-in-Part Patent Owner's Motion to Exclude
37 C.F.R. § 42.64

I. INTRODUCTION

Laboratoire Francais du Fractionnement et des Biotechnologies S.A. ("LFB" or "Petitioner") filed a Petition (Paper 1, "Pet."), requesting institution of an *inter partes* review of claims 1–15 of U.S. Patent No. 9,102,762 B2 (Ex. 1001, "the '762 patent") based on the following ten grounds:

Reference(s)[1]	Basis	Challenged Claims
Tomokiyo,[2] Hill,[3] and Burnouf[4]	§ 103(a)[5]	1, 2, 4–6, and 10–15
Tomokiyo, Hill, Burnouf, and Pedersen[6]	§ 103(a)	3 and 7–9
Tolo[7]	§§ 102(b) or 103(a)	1, 2, 4–7, and 12–15
Tolo and Pedersen	§ 103(a)	3, 8, and 9

[1] All citations to the references in this Decision refer to the page numbers added by Petitioner.
[2] K. Tomokiyo et al., Large-scale production and properties of human plasma-derived activated Factor VII concentrate, 84 VOX SANGUINIS 54–64 (2003) (Ex. 1002, "Tomokiyo").
[3] Frank G. H. Hill, Guidelines on the selection and use of therapeutic products to treat haemophilia and other hereditary bleeding disorders, 9:1 HAEMOPHILIA 1–23 (2003) (Ex. 1003, "Hill").
[4] T. Burnouf & M. Radosevich, Nanofiltration of plasma-derived biopharmaceutical products, 9:1 HAEMOPHILIA 24–37 (2003) (Ex. 1004, "Burnouf").
[5] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), included revisions to 35 U.S.C. §§ 102 and 103 that became effective after the filing of the application that led to the '762 patent. Therefore, we apply the pre-AIA versions of 35 U.S.C. §§ 102 and 103.
[6] Anders H. Pedersen et al., Autoactivation of Human Recombinant Coagulation Factor VII, 28:24 BIOCHEMISTRY 9331–36 (1989) (Ex. 1005, "Pedersen").
[7] Tolo et al., WO 99/64441; Dec. 16, 1999 (Ex. 1006, "Tolo").

Reference(s)[1]	Basis	Challenged Claims
Tolo and Hill	§ 103(a)	10
Tolo and Mollerup[8]	§ 103(a)	11
Eibl '023[9] and Mollerup	§ 103(a)	1, 2, 4, 6, and 11–15
Eibl '023, Mollerup, and Pedersen	§ 103(a)	3 and 7–9
Eibl '023, Mollerup, and Burnouf	§ 103(a)	5
Eibl '023, Mollerup, and Hill	§ 103(a)	10

Novo Nordisk Healthcare AG ("Patent Owner") filed a Preliminary Response (Paper 6). We determined, based on the information presented in the Petition and Preliminary Response, that there was a reasonable likelihood that Petitioner would prevail in challenging claims 1–15 as unpatentable under 35 U.S.C. § 103(a). Pursuant to 35 U.S.C. § 314, we instituted trial on April 11, 2017, as to those claims of the '762 patent on only the Tomokiyo and the Tolo obviousness grounds. Paper 7, 23 ("Institution Decision" or Paper 9 (Erratum correcting claim listings)).

We did not originally include the Tolo anticipation ground within the scope of this *inter partes* review. For this ground, we stated:

> We determine that Petitioner has not demonstrated a reasonable likelihood of prevailing with respect to its anticipation challenge based on Tolo. In particular, Petitioner relies upon Tolo's Example 3, in which a solution of 0.04 mg/mL IFN-α was nanofiltered, and we do not find any express

[8] Inger Mollerup et al., *The Use of RP-HPLC for Measuring Activation and Cleavage of rFVIIa During Purification*, 48 BIOTECHNOLOGY & BIOENGINEERING 501–05 (1995) (Ex. 1007, "Mollerup").
[9] Eibl, WO 2004/011023 A1; Feb. 5, 2004 (Ex. 1008, "Eibl '023"); Ex. 1009 (English Translation).

> or inherent teaching in Tolo that the same concentration could be used for rFVIIa. In assessing whether a reference anticipates, the Board is not permitted to "fill in missing limitations simply because a skilled artisan would immediately envision them." *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd*, No. 2016-1900, 2017 WL 977034, at *3 (Fed. Cir. Mar. 14, 2017).

Inst. Dec. 18.

We also did not include the obviousness grounds based on combinations including Eibl '023 and Mollerup within the scope of this *inter partes* review. *Id*. at 20–22. For these grounds, we found that Petitioner had not demonstrated a reasonable likelihood of prevailing with respect to its obviousness challenges based on combinations including Eibl '023 and Mollerup. *Id*. at 22. We stated that:

> In particular, Petitioner has not explained sufficiently why a skilled artisan would have looked to Mollerup's teachings in order to increase the concentration of Factor VIIa to be nanofiltered to within the claimed range when Eibl '023 only discloses the limited use of Factor VIIa as part of the prothrombin complex or as a separate "activator substance" at a much lower concentration. *See* Ex. 1009, 40–41.

Id.

Following our institution, Petitioner filed a Motion to Submit Supplemental Information under 37 C.F.R. § 42.123(a), to which Patent Owner filed an Opposition. Paper 17; Paper 19. We denied Petitioner's Motion to Submit Supplemental Information. Paper 22.

Patent Owner filed a Response to the Petition (Paper 27, "PO Resp.") and Petitioner filed a Reply to Patent Owner's Response (Paper 40, "Reply"). An oral hearing was held on December 12, 2017. The transcript of the hearing has been entered into the record. Paper 52 ("Tr."). We issued

a Final Written Decision in which we determined that Petitioner had not shown by a preponderance of the evidence that any challenged claim of the '762 patent was unpatentable under the instituted obviousness grounds. Paper 53 at 41.

After our Final Written Decision was entered, but during the time in which Petitioner could file a Request for Rehearing, the United States Supreme Court issued its opinion in *SAS Institute, Inc. v. Iancu* requiring that all claims challenged in a petition must be included in any trial. *See SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1354–60 (2018) ("*SAS*") (holding that 35 U.S.C. § 318(a) requires a final written decision addressing all of the claims challenged in a petition). Shortly thereafter, the Office issued guidance stating that "[i]f the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." *Guidance on the Impact of SAS on AIA Trial Proceedings* (April 26, 2018) ("Office Guidance") (available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial).

At the request of Petitioner, we held a conference call with the parties and granted Petitioner a three-week extension and more pages for its Request for Rehearing "to address all issues, including matters discussed in the Final Written Decision, *SAS*, and the previously non-instituted grounds." Paper 54, 4. In deciding the Request for Rehearing, we stated "we find no reason to modify our analysis or conclusions in the FWD [Final Written Decision] with respect to the Tomokiyo Grounds," Paper 60, 6, and "we find no reason to modify our analysis or conclusions in the FWD with respect to the Tolo Grounds" based on obviousness. Paper 60, 8. In view of *SAS* and the Office Guidance, however, we also stated that "it is appropriate to grant

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