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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.

Case IPR2017-00028
Patent 9,102,762 B2

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

PAULRAJ, *Administrative Patent Judge.*

DECISION
On Request for Rehearing
37 C.F.R. § 42.71

I. INTRODUCTION

Laboratoire Francais du Fractionnement et des Biotechnologies S.A. ("LFB" or "Petitioner") filed a Request for Rehearing (Paper 56, "Req. Reh'g") of our Final Written Decision dated April 5, 2018, which held that claims 1–15 of U.S. Patent 9,102,762 B2 ("the '762 patent") have not been shown to be unpatentable under 35 U.S.C. § 103 based on the patentability challenges instituted in this proceeding. Pursuant to our authorization, Novo Nordisk Healthcare AG ("Patent Owner") filed a Response to Petitioner's Request for Rehearing (Paper 57).

In its Request, Petitioner argues, with respect to the "Tomokiyo Grounds," that the FWD misapprehends or overlooks key points with respect to 1) a reasonable expectation of success; 2) a motivation to nanofilter after activation; and 3) the claimed concentration. Req. Reh'g 1–17. With respect to the "Tolo Grounds," Petitioner argues that the FWD erred in its findings with respect to degradation concerns and the required concentration of FVIIa. *Id.* at 17–20. Additionally, Petitioner contends that the non-instituted grounds set forth in the Petition should now be instituted in light of the Supreme Court's decision in *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018) ("*SAS*"). Req. Reh'g 20.

For the reasons set forth herein, we deny Petitioner's Request for Rehearing with respect to the grounds previously instituted and addressed in our FWD. However, in view of *SAS*, the Office's Guidance on the impact of *SAS*, and subsequent Federal Circuit decisions, we grant Petitioner's Request with respect to modifying our institution decision to include the grounds that were previously denied institution in this proceeding.

II. STANDARD OF REVIEW

37 C.F.R. § 42.71(d) states the following:

> A party dissatisfied with a decision may file a single request for rehearing without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

III. DISCUSSION

A. Tomokiyo Grounds

We determined in the FWD that Petitioner did not establish by a preponderance of the evidence that the challenged claims were obvious based on prior art combinations including Tomokiyo[1] (the "Tomokiyo Grounds"). FWD 18–35. In particular, we found that Petitioner did not establish: 1) that the concentration requirement of the claims (0.01 to 5 mg/mL) is taught or suggested by Tomokiyo; 2) that the skilled artisan would have had a reason to modify Tomokiyo's process by conducting nanofiltration after activation; or 3) that the skilled artisan would have had a reasonable expectation of success in nanofiltering FVIIa. *Id.*

Petitioner contends that our conclusions regarding reasonable expectation of success are erroneous because "[t]he claims contain no limitations relating to degradation, nor does the '762 patent even teach a maximum level of acceptable degradation." Req. Reh'g. 1. We are

[1] 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").

unpersuaded that we erred on this basis. Although the claims do not specify a particular degradation limit, the invention claimed and described in the '762 patent is directed to a method of removing viruses from Factor VII so that it may be used for therapeutic purposes. The'762 patent itself indicates that unwanted degradation would have been a concern to the skilled artisan seeking to practice the claimed invention. *See, e.g.*, Ex. 1001, 45–54 (discussing degradation concerns). In fact, Petitioner identified degradation as a relevant issue from the very beginning, asserting in its Petition that the skilled artisan "would have had a reasonable expectation of success . . . because Mollerup taught that . . . 'the autolytic reaction rate of rFVIIa [i.e., the degradation rate] in this system is low.'" Petition (Paper No. 1), 22. As such, we appropriately took degradation concerns into account in our reasonable expectation of success analysis.

Petitioner also contends that we improperly relied upon Example 5 of the '762 patent specification in the FWD because Patent Owner failed to substantiate the data with a witness. Req. Reh'g. 4 (citing 37 C.F.R. § 42.61(c)). Our limited reliance on Example 5 of the '762 patent is consistent with 37 C.F.R. § 42.61(c), as we merely cited to that Example to show what the specification describes rather than as evidence of the truth of the underlying data. *See* FWD 31 (noting that Example 5 "shows subjecting FVIIa (>90% activation) to nanofiltration only resulted in a 0.4% increase in degradation (i.e., 11.9% degradation prior to nanofiltration and 12.3% degradation afterwards)"); *see also* 37 C.F.R. § 42.61(c) ("A specification or drawing of a United States patent application or patent is admissible as evidence only to prove what the specification or drawing describes."); *Noven Pharms., Inc. v. Novartis AG*, IPR2014–00550, Paper 69 at 41 (PTAB Sept.

28, 2015) (denying exclusion under 37 C.F.R § 42.61(c) because statement only offered to prove what the specification describes); 77 Fed. Reg. 48612, 48624 (Aug. 14, 2012) (explaining that 37 C.F.R. § 42.61(c) addresses the "problem in which a party mistakenly relies on a specification to prove a fact other than what the specification says").

We have considered Petitioner's other arguments in its Request for Rehearing concerning the Tomokiyo Grounds. Req. Reh'g 8–17. In these arguments, Petitioner merely expresses disagreement over how we weighed the competing evidence in this proceeding. For instance, Petitioner contends that we misapprehended or overlooked certain teachings in the prior art. *See* Req. Reh'g 3 (discussing Tomokiyo's teaching that degradation can be controlled "by suppressing FVII activation ≈ 50%"); *id.* at 6–7 (discussing teachings of Mollerup and Burnouf); *id.* at 8–13 (discussing prior art teachings concerning placing nanofiltration towards the end of the production process and contamination concerns). Petitioner also cites testimony of Dr. Chtourou to assert that the concentration of FVII before nanofiltration is essentially the same as the concentration of FVII after nanofiltration. *Id.* at 13 (citing Ex. 1010 ¶ 61). We fully considered the cited evidence and arguments to the extent they were previously raised by Petitioner,[2] but did not find them persuasive for the reasons set forth in our

[2] As noted by Patent Owner, Petitioner attempts to raise some arguments for the first time in its Request for Rehearing, which is improper. *See* Paper 57, 7–8 (identifying new arguments by Petitioner concerning how the concentration requirement is satisfied based on Tomokiyo's teachings with respect to Figure 4); *Telit Wireless Solutions Inc. v. M2M Solutions LLC*, IPR2016-00055, Paper 13 at 3, 5 (PTAB May 24, 2016) (rejecting petitioner's "belated[]" attempt to use rehearing "to provide explanation we

FWD. A Request for Rehearing is not an opportunity to express mere disagreement with how we considered arguments and weighed the evidence in the FWD.

As such, we find no reason to modify our analysis or conclusions in the FWD with respect to the Tomokiyo Grounds.

B. Tolo Grounds

We also determined in the FWD that Petitioner did not establish by a preponderance of the evidence that the challenged claims were obvious based on prior art combinations including Tolo[3] (the "Tolo Grounds"). FWD 35–38. As with the Tomokiyo Grounds, we found that Petitioner did not established sufficiently that the skilled artisan would have reasonably expected success with respect to nanofiltering the activated form of FVII. FWD 37. We further found that the record in this proceeding does not show persuasively that the skilled artisan would have reasonably expected that the same concentration disclosed in Example 3 of Tolo for IFN-α (0.04 mg/mL) could be successfully used for the nanofiltration of activated FVII. *Id.* at 37–38.

Petitioner's arguments that we erred in our conclusions regarding reasonable expectation of success are unpersuasive for the same reasons as discussed with respect to the Tomokiyo Grounds. Req. Reh'g. 17. Petitioner further argues that "Tolo is presumptively enabled (*In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012)), and therefore its disclosure of nanofiltering rFVIIa carries with it an expectation of success."

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found lacking in the original Petition"). We decline to consider those new arguments at this point.

[3] Tolo et al., WO 99/64441; Dec. 16, 1999 (Ex. 1006, "Tolo").

Id. at 18. We are unpersuaded by this argument as Petitioner has identified nothing in *Antor Media* suggesting a prior art printed publication is presumptively entitled to a reasonable expectation of success for any general disclosure contained therein.

Petitioner also contends that we erred in the FWD's conclusion that the concentration requirement is not satisfied because "0.04 mg/ml is the only concentration taught by Tolo," and a skilled artisan "reading Tolo would logically start with 0.04 mg/ml because Tolo provides no other suggestions." Req. Reh'g 18. We are unpersuaded by this argument as the 0.04 mg/ml concentration disclosure identified in Tolo was only made with respect to a specific example concerning IFN-α. Ex. 1006, 12:12–14, 13:22–23. As noted in the FWD, the evidence of record established that FVIIa and IFN-α are different proteins with different properties (including molecular weight, size, and structure), such that the skilled artisan would not have necessarily considered them interchangeable in a nanofiltration process. FWD 38. Petitioner criticizes our reliance on Dr. Krishnaswamy's testimony to support this finding on the grounds that he is not an expert on nanofiltration, and that he did not attest that differences in the size and shape would be expected to impact nanofiltratrion. Req. Reh'g 19. But Petitioner's own expert acknowledged such differences. *See* Ex. 2010, 145:3–25 (Dr. Chtourou acknowledging differences in molecular weight and size between IFN-α and FVII). Furthermore, Patent Owner's nanofiltration expert, Dr. Belfort, attested that "a person of ordinary skill would not draw conclusions about nanofiltration of FVII/FVIIa based on nanofiltration of an entirely different protein. . . . Interferon-α differs from FVIIa in many regards, none of which Dr. Chtourou has addressed in his declaration"

(Ex. 2012 ¶ 37), and Dr. Belfort's testimony remained unchallenged in this proceeding. Thus, Petitioner has not demonstrated that we did not appropriately weigh all the relevant and submitted testimony of the parties' experts in reaching our conclusions. As noted above, a Request for Rehearing is not an opportunity to express mere disagreement about how we weighed such evidence in our FWD.

As such, we find no reason to modify our analysis or conclusions in the FWD with respect to the Tolo Grounds.

C. Non-Instituted Grounds

In our Institution Decision, we declined to proceed based on the following grounds ("non-instituted grounds"):

References	**Basis**	**Claims challenged**
Tolo	§ 102(b)	1, 2, 4–7, and 12–15
Eibl '023[4] and Mollerup[5]	§ 103(a)	1, 2, 4, 6, and 11–15
Eibl '023, Mollerup, and Pedersen[6]	§ 103(a)	3 and 7–9
Eibl '023, Mollerup, and Burnouf[7]	§ 103(a)	5

[4] Eibl, WO 2004/011023 A1; Feb. 5, 2004 (Ex. 1008, "Eibl '023"); Ex. 1009 (English Translation).
[5] 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").
[6] Anders H. Pedersen et al., *Autoactivation of Human Recombinant Coagulation Factor VII*, 28:24 BIOCHEMISTRY 9331–36 (1989) (Ex. 1005, "Pedersen").
[7] T. Burnouf & M. Radosevich, Nanofiltration of plasma-derived biopharmaceutical products, 9:1 HAEMOPHILIA 24–37 (2003) (Ex. 1004, "Burnouf").

References	Basis	Claims challenged
Eibl '023, Mollerup, and Hill[8]	§ 103(a)	10

Paper 7 (Inst. Dec.), 5, 18, 20–23.

In view of the Supreme Court's Decision in *SAS*, Petitioner contends that these non-instituted grounds should now be instituted. Req. Reh'g. 20. Patent Owner argues that *SAS* did not hold that the Board must institute as to every legal theory raised in a Petition. Paper 57, 16.

We determine that it is appropriate to grant rehearing to now institute on the previously non-instituted grounds. Our decision is based not only on *SAS*, but also on Office policy concerning the implementation of *SAS*, as reflected in the April 26, 2018 "Guidance on the Impact of *SAS* on AIA Trial Proceedings" ("Guidance"). The Federal Circuit has recently embraced the approach set forth in the Guidance, explaining:

> Equal treatment of claims and grounds for institution purposes has pervasive support in *SAS*. Although 35 U.S.C. § 318(a), the primary statutory ground of decision, speaks only of deciding all challenged and added "claim[s]," the Supreme Court spoke more broadly when considering other aspects of the statutory regime, and it did so repeatedly. The Court wrote that "the petitioner is master of its complaint and normally entitled to judgment on all of the claims it raises." *SAS*, 138 S. Ct. at 1355. It said that § 312 contemplates a review "guided by a petition describing 'each claim challenged' and 'the grounds on which the challenge to each claim is based,'" and it added that the Director does not "get[ ] to define the contours of the proceeding." *Id.* The Court also said that § 314's language "indicates a binary choice—either institute review or don't."

[8] 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").

> *Id.* It further reasoned that "[n]othing suggests the Director enjoys a license to depart from the petition and institute a *different* inter partes review of his own design" and that "Congress didn't choose to pursue" a statute that "allows the Director to institute proceedings on a claim-by-claim and ground-by-ground basis" as in ex parte reexamination. *Id.* at 1356 (emphasis in original). And the Court concluded that "the petitioner's petition, not the Director's discretion, is supposed to guide the life of the litigation," *id.*, and the "petitioner's contentions . . . define the scope of the litigation all the way from institution through to conclusion," *id.* at 1357.
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> We read those and other similar portions of the *SAS* opinion as interpreting the statute to require a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition, and we have seen no basis for a contrary understanding of the statute in light of *SAS*.

PGS Geophysical AS v. Iancu, 891 F.3d 1354, 1360 (Fed. Cir. 2018). Accordingly, we are not persuaded otherwise by Patent Owner's argument that *SAS* does not require institution of all the grounds set forth in the Petition.

Petitioner argues that a supplemental Patent Owner Response and Reply should be allowed for the previously non-instituted grounds, with each party having an opportunity for cross-examination regarding any new declaration testimony, and an oral hearing should be held on the newly instituted grounds. Req. Reh'g 16. Patent Owner contends that the existing record is sufficient to rule on the non-instituted grounds. Paper 57, 17–19. We note that we previously addressed the merits of the non-instituted grounds in our Institution Decision. Paper 7, 20–22. However, we determine that it is appropriate to allow the parties the opportunity for additional briefing and evidence to address the newly instituted grounds.

The parties shall meet and confer to discuss the schedule going forward, and thereafter contact the Board within 5 business days of the entry of this Decision to schedule a conference call.

IV. ORDER

Accordingly, it is:

ORDERED that Petitioner's Request for Rehearing is denied as to the previously instituted Tomokiyo Grounds and Tolo Grounds;

FURTHER ORDERED that Petitioner's Request for Rehearing is granted as to the previously non-instituted grounds;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(a), the *inter partes* review in this proceeding is modified to include the following grounds of unpatentability as to claims 1–15 of U.S. Patent No. 9,102,762 B2:

A. Claims 1, 2, 4–7, and 12–15 under 35 U.S.C. § 102(b) as anticipated by Tolo;

B. Claims 1, 2, 4, 6, and 11–15 under 35 U.S.C. § 103(a) as obvious over the combination of Eibl '023 and Mollerup;

C. Claims 3 and 7–9 under 35 U.S.C. § 103(a) as obvious over the combination of Eibl '023, Mollerup, and Pedersen;

D. Claim 5 under 35 U.S.C. § 103(a) as obvious over the combination of Eibl '023, Mollerup, and Burnouf; and

E. Claim 10 under 35 U.S.C. § 103(a) as obvious over the combination of Eibl '023, Mollerup, and Hill;

FURTHER ORDERED that the parties shall meet and confer to discuss the schedule going forward, and thereafter contact the Board within 5 business days of the entry of this Decision to schedule a conference call.

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