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Is a Reference to a Parent Case in a Sequence Appendix Good Enough?



BY CHARLES L. GHOLZ, DANIEL F. PEREIRA AND MARC K. WEINSTEIN

This article is motivated by the decision denying Motion 5 filed by junior party Biogen MA Inc. in *Biogen MA Inc. v. Forward Pharma A/S*, Interference No. 106,023.[1] According to Section I of that motion, the precise relief requested was that the board:

> authorize entry of an Application Data Sheet ("ADS") and/or an Amendment to the specification in Biogen's U.S. Patent Application No. 12/526,296 ("the '296 application"), now abandoned, so that Biogen's priority claim to its U.S. Provisional application that is presented in each of the applications within the chain leading to involved U.S. Patent No. 8,399,514 ("the '514 patent") meets the exact language of 37 C.F.R. § 1.78.[1]

During ex parte prosecution, Biogen had claimed priority to its provisional application, and the PTO had acknowledged the priority claim in each application leading to the '514 patent. Moreover, in the declaration of the interference the administrative patent judge who declared the interference (Judge McKelvey) tentatively accorded Biogen the benefit of the filing date of the provisional application.

However, when Forward Pharma A/S filed its list of intended motions, it included a motion challenging Biogen's entitlement to the benefit of that priority date. At that point, counsel for Biogen woke up to the existence of "a possible procedural technicality that could be the

[1] We do not represent either of the parties to that interference. We do, however, represent an interested third party on whose behalf we are monitoring the record in that on-going interference.

Charles L. Gholz is senior counsel in Oblon, McClelland, Maier & Neustadt LLP in Alexandria, Va. He can be reached at (703) 412-6485 or cgholz@oblon.com. He is also a member of this publication's advisory board.

Daniel F. Pereira is a partner in the firm. He can be reached at (703) 413-6560 or dpereira@oblon.com.

Marc K. Weinstein is special counsel at Oblon. He can be reached at (703) 412-4526 or mweinstein@oblon.com

The views expressed herein are those of the authors and are not necessarily shared by their employer or its clients.

[1] Pre-AIA 37 C.F.R. § 1.78(a)(5)(iii) indicates by use of the word "or" that one of an ADS or an amendment to the specification would be sufficient to meet the exact language. *See also* M.P.E.P. § 211.02(I).[2]

[2] *Biogen* Paper No. 94 at p. 1, available at http://src.bna.com/b9N. Biogen's Motion 5 was initially misidentified as "Biogen's Miscellaneous Motion 1."

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basis of Forward Pharma's generic assertion . . . [that Biogen was not entitled to the benefit of the filing date of its provisional application].''[3] That ''possible procedural technicality'' was that Biogen had not identified the provisional application in either of the two places specified in 37 C.F.R. § 1.78(a)(5)(iii) as it read prior to the enactment of the America Invents Act.

After some initial sparring not relevant here, Biogen filed the miscellaneous motion[4] quoted at the outset of this article. In an opinion authored by APJ McKelvey for a panel that also consisted of APJs Gardner Lane and Katz, the panel denied Biogen's motion on the ground that the relief that Biogen sought was precluded by the applicable statutory law:

> Biogen Motion 5 describes activity in the PTO related to claims for priority made by Biogen and mention of those claim[s] for priority by the PTO. Paper 4, pages 4-6.
>
> We will assume, without deciding, that the described activity would be relevant if we had some discretion in this matter.
>
> However, [35 USC] § 119(e)(1) sets out what is required to provide a ''specific reference [to an alleged priority application].''
>
> We are not free to substitute our judgment by applying equitable principles to a situation explicitly governed by a law enacted by Congress, in this case § 119(e)(1).
>
> Stated in other terms, the law trumps any discretionary decision-making that Biogen believes we can exercise.
>
> To the extent that the applicable law creates an unacceptable hardship, the remedy lies with the Congress. *In re Lukach*, 442 F.2d 967, 970 (CCPA 1971) (to be entitled to § 120 benefit, subject matter claimed in later application must be described in parent in manner required by § 112[,] and[,] ''[i]f the law in these situations really produces inequities, the proper remedy is in Congress.'').[5]

The Issue Discussed Here

We are just kibitzers. We represent neither party to this extremely interesting interference, and we would not publish this article were it not too late to do Biogen any good.[6] There may be a perfectly good reason why counsel for Biogen did not try the gambit we discuss here. However, despite having given the matter a good deal of thought, we are unable to guess what that reason may have been.

At the relevant time, 35 U.S.C. § 119(e)(1) read in relevant part as follows:

> An application for patent filed under section 111(a) . . . for an invention disclosed in the manner provided by section 112(a) . . . in a provisional application filed under section 119(b), by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b), if the application for patent filed under section 111(a) . . . is filed not later than 12 months after the date on which the provisional application was filed *and if it contains* or is amended to contain *a specific reference to the provisional application*.[7]

The only issue pertaining to Biogen's entitlement to the benefit of the filing date of its provisional application discussed in Biogen's Motion 5[8] was whether Biogen could amend its abandoned parent application to ''meet[ ] the exact language of 37 C.F.R. § 1.78.'' Biogen *conceded* that the specification of the abandoned parent application did not ''contain[ ] . . . a specific reference to the provisional application.'' Moreover, Biogen did not seek to revive its abandoned parent application in order to make that amendment in a non-abandoned application.[9]

Our Proposed Gambit

Biogen's concession wasn't accurate. The specification of the abandoned parent application *did* contain a specific reference to the provisional application—just not where it was supposed to be pursuant to 37 C.F.R. § 1.78.

The abandoned parent application included a sequence listing because, as every bio-related patent practitioner knows, that is a requirement when the application contains disclosure pertaining to nucleic acids and proteins.[10] In that sequence listing, there are fields for the title, the inventors, the application number, the application date and the prior application data (if there is or are one or more prior applications the benefit of the earlier filing date or dates of which is or are claimed).

According to the 8th Edition of the MPEP § 608.01 Rev. 6 (dated September 2007 and in effect at the time

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[3] *Biogen* Paper No. 177 at p. 2, available at http://src.bna.com/b7g.

[4] By filing that motion rather than waiting to oppose Forward Pharma's motion to take away from it the benefit that Judge McKelvey had tentatively accorded it in the declaration of the interference, Biogen gained the right to ''have the last word.'' That is, Biogen filed its motion, Forward Pharma opposed, and Biogen then filed its reply to Forward Pharma's opposition.

[5] *Biogen* Paper No. 177 at pp. 10-11.

[6] *See* Gholz and Mandrusiak, *So Long 35 U.S.C. § 146 – It's Been Good To Know You!*, 90 Patent, Trademark & Copyright Journal 2845 (Aug. 7, 2015)(90 PTCJ 2845, 8/7/15), which makes it clear that, barring Supreme Court reversal of the applicable Federal Circuit precedent, the remedy discussed in Gholz and Mandrusiak, *Board Proceedings in Interferences Have Been Reduced to ''Trial Runs'' Which a Dissatisfied Party May ''Do Over'' in District Court*, 21 Intellectual Property Today No. 10 at page 20 (2014), is no longer available to Biogen. That is, Biogen cannot rely on 35 U.S.C. § 146 for a Mulligan.

[7] Emphasis supplied. Amazingly, Judge McKelvey's opinion misquotes the statute (albeit in a non-substantive fashion)!

[8] Another issue which *could* have been discussed in Biogen's Motion 5 (and which *was* discussed in Biogen's request for rehearing of the denial of its Motion 5) was which version of the statute applied to its motion. However, discussing *that* issue in its request for reconsideration was, of course, too late, and the panel that denied the request for reconsideration refused to consider it. *Biogen*, Paper No. 196 p. 4, available at http://src.bna.com/b9O.

[9] In its decision on Biogen's request for rehearing, Paper No. 196, the panel (again in an opinion by Judge McKelvey) pointed out that that would have been the proper way to deal with the issue and, in a stunning display of mercy, sua sponte granted Biogen an opportunity to do it over and to do it right. Assuming that Biogen does do it over and does do it right this time, the issue discussed in this article may well become moot in this specific case. *See generally* Gholz and Cappaert, *Is No-Harm, No-Foul the New Rule?*, 91 Patent, Trademark & Copyright Journal 36 (Nov. 6, 2015) (91 PTCJ 36, 11/6/15), which discusses Judge McKelvey's apparent mellowing. However, we think that this issue has applicability beyond this specific case.

[10] *See* 37 C.F.R. § 1.821(a)(2)(c).

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that Biogen filed its parent application)[11] as well as 37 C.F.R. § 1.71,[12] the sequence listing is part of the patent specification. Indeed, bio-related patent practitioners know that support for claims can exist entirely in that sequence listing and that, unless the sequence listing is unduly large, the sequence listing is published in the pre-grant publication as well as the patent (if one ever issues).

Our point is (1) that the relevant statute only required that the application contain a reference to the provisional application (unlike the earlier version of Section 119 and 37 C.F.R. § 1.78, which required the reference to be in a specific place in the specification), (2) that the sequence listing is part of the application, and (3) that Biogen's sequence listing included that reference.

OK, But What About the Rule?

We submit that Biogen's prosecution counsel did comply with the statute and that that means that the panel's assertion that the motion had to be denied because the board had no authority to waive a statutory requirement is flawed. However, that does not deal with the fact that Biogen's prosecution counsel did *not* comply with the rule. The rule, 37 C.F.R. § 1.78, at the relevant time read in pertinent part as follows:

> (h) *Applications filed before September 16, 2012.* Notwithstanding the requirement in paragraphs (a)(3) and (d)(2) of this section that any specific reference to a prior-filed application be presented *in an application data sheet* (§ *1.76*), this requirement in paragraph (a)(3) and (d)(2) of this section will be satisfied by the presentation of such specific reference *in the first sentence(s) of the specification* following the title in a nonprovisional application filed under *35 U.S.C. 111(a)* before September 16, 2012, or resulting from an international application filed under *35 U.S.C. 363* before September 16, 2012. The provisions of this paragraph do not apply to any specific reference submitted for a petition under paragraph (b) of this section to restore the benefit of a provisional application.

Clearly, the reference to the provisional application in the sequence listing did not comply with the rule because the reference to the provisional application was present neither in the ADS nor at the beginning of the specification.

Since a rule not required by statute can be waived by the PTO Director or the Director's designee under 37 C.F.R. § 1.183 ''[i]n an extraordinary situation, when justice requires . . .,'' that brings us to a brief consideration of the kinds of situations which have in the past been held to meet those exacting standards.

Recent decisions of the PTAB demonstrate an increasing willingness by administrative patent judges to overlook inadvertent mistakes that do not affect the merits of the case or prejudice the other party. Starting in *Volkswagen Group of America, Inc. v. Emerachem Holdings, LLC*, IPR2014-01555 (March 16, 2015),[13] a panel of the board excused the petitioner's failure to comply with 37 C.F.R. § 42.63(b), which requires the petitioner to submit a copy of a foreign language document with a verified translation of the document into English.[14] In its petition for inter partes review, the petitioner had failed to include the proper affidavit verifying the accuracy of the submitted English translation in one of its exhibits. Accordingly it filed motions to submit a corrected exhibit, asserting that the error was merely a clerical mistake or, alternatively, that the board could waive Rule 42.63(b) because the patent owner was not prejudiced.[15] Recognizing that ''[i]nadvertent mistakes generally not affecting the merits of a case happen,'' the panel granted petitioner's motion and waived any technical violation of the rule.[16]

Since the decision in *Volkswagen*, various APJs have continued to show a willingness to waive rules unless real prejudice could be shown due to opposing counsel's failure to follow the rules.[17] In fact, a panel of the board has done so in the Biogen interference, again in an opinion delivered by Judge McKelvey, on a different motion.[18]

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[11] That version of MPEP 608.01 entitled ''Specification'' read as follows:

> The specification is a written description of the invention and of the manner and process of making and using the same. The specification must be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention pertains to make and use the same. See 35 U.S.C. 112 and 37 CFR 1.71. If a newly filed application obviously fails to disclose an invention with the clarity required by 35 U.S.C. 112, revision of the application should be required. See MPEP § 702.01. The written description must not include information that is not related to applicant's invention, e.g., prospective disclaimers regarding comments made by examiners. If such information is included in the written description, the examiner will object to the specification and require applicant to take appropriate action, e.g., cancel the information. The specification must commence on a separate sheet. Each sheet including part of the specification may not include other parts of the application or other information. The claim(s), abstract and sequence listing (if any) should not be included on a sheet including any other part of the application (37 CFR 1.71(f)). That is, the claim(s), abstract and sequence listings (if any) should each begin on a new page since each of these sections (specification, abstract, claims, sequence listings) of the disclosure are separately indexed in the Image File Wrapper (IFW). There should be no overlap on a single page of more than one section of the disclosure.

[12] That version of 37 C.F.R. § 1.71, entitled ''Detailed Description and Specification of the Invention,'' read as follows in relevant part:

> (f) The specification must commence on a separate sheet. Each sheet including part of the specification may not include other parts of the application or other information. The claim(s), abstract and sequence listing (if any) should not be included on a sheet including any other part of the application.

[13] This is the lead opinion discussed in the article cited supra in footnote 9.

[14] Interestingly, the panel's opinion was delivered by APJ McKelvey.

[15] *Volkswagen* paper Nos. 8 and 13.

[16] *Volkswagen* paper No. 20 at 6-7.

[17] *See, e.g., Unified Patents Inc. v. Dragon Intellectual Property, LLC*, IPR2014-01252 (April 14, 2015) (APJ Neil T. Powell for a panel that also consisted of APJs Gregg I. Anderson, and J. John Lee) (allowing Petitioner to file a certified translation as supplemental information under 37 C.F.R. § 42.123(a) because it did ''not change the ground of unpatentability on which trial was instituted'' and because ''Patent Owner would not be prejudiced by the relief requested'').

[18] *Biogen MA Inc. v. Forward Pharma A/S*, Interference No. 106,023 (Aug. 19, 2015) (APJ Fred E. McKelvey for a panel that also consisted of APJs Sally Gardner Lane and Deborah Katz) (stating that ''having one page above the page limit,'' ''the ab-

To determine whether the board would be willing to overlook Biogen's failure to identify the provisional application either in the ADS or in the proper location in the specification, the central issue is whether Forward Pharma would be considered to be prejudiced by the waiver.

Of course, waiving the rule and enabling Biogen to claim priority to the provisional application at least potentially prejudices Forward Pharma by giving Biogen the benefit of an earlier filing date, which may be significant in deciding the winner of the interference.

On the other hand, a panel of the board has already recognized that Biogen has the ability to correct the technical violation of the rule by petitioning to revive the abandoned application. Moreover, Forward Pharma has had notice of Biogen's claim to priority from the beginning of the proceeding, not the least of which on the basis that the priority claim exists on the face of the Biogen patent. Given Biogen's compliance with the statute by identifying the provisional application in the sequence listing and the notice of the priority claim from the face of the patent, it seems more likely than not that the board would have found insufficient prejudice to Forward Pharma to require merciless enforcement of the rule and that it would have been willing to waive the technical violation of Rule 78.

Conclusion

Our proposal here is presumably irrelevant to the parties in the case under discussion. However, we commend to others (particularly to biotech patent practitioners) the notion that they may be able to rely on disclosures in their required sequence listings to overcome problems stemming from their failure to comply with the somewhat confusing language of 37 C.F.R. § 1.78—since the sequence listings are, after all, part of the specifications of their applications.

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sence of a registration number on the signature page,'' ''filing of Biogen Motion 5 at 5:01pm instead of 5:00pm,'' and ''the absence of a letter dated 20 July 2015'' to be insignificant as they had not prejudiced Forward Pharma and had not interfered with reaching the merits of Biogen's arguments).

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