

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BIOGEN MA INC,
Patent Owner.

Case IPR2018-01403
Patent No. 8,399,514 B2

Before SHERIDAN K. SNEDDEN, JENNIFER MEYER CHAGNON, and
JAMIE T. WISZ, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

ORDER

Denying In Part and Dismissing In Part Patent Owner's Motion to Exclude
37 C.F.R. § 42.64(c)

I. INTRODUCTION

Patent Owner filed a motion to exclude evidence. Paper 75. Petitioner opposed (Paper 77) and Patent Owner submitted a reply in support of its motion (Paper 82). Patent Owner moves to exclude Exhibits 1010, 1012, 1036, 1037, 1054, 1055, 1066, and 1122 as inadmissible under the Federal Rules of Evidence (“FRE”). We consider each of Patent Owner’s contentions below.

A. Exhibits 1036, 1037, and 1066

Patent Owner moves to exclude Exhibits 1036, 1037, and 1066 because these documents were published after Biogen’s Phase III results with the claimed 480 mg/day dose were known and long after the February 2007 priority date of U.S. Patent No. 8,399,514 B2. Paper 75, 1. Patent Owner contends that the exhibits “should be excluded because they have no relevance to Mylan’s obviousness challenge and any probative value is substantially outweighed by the danger of unfair prejudice from hindsight bias.” *Id.* at 3 (citing FRE 401–403); Paper 82, 1–2.

Petitioner contends that it does not rely on these documents as “obviousness references,” but as evidence “to corroborate Drs. Corboy’s, Benet’s, and Greenberg’s testimony on a POSA’s interpretation of prior-art clinical trials results, which refutes the basis for Biogen’s claim of unexpected results.” Paper 77, 2–3.

Evidence is relevant if “it has any *tendency* to make a fact more or less probable than it would be without the evidence” and “the fact is of consequence in determining the action.” FRE 401 (emphasis added). Given that Petitioner relies on the documents to show how skilled artisans would

interpret the prior art and to refute Patent Owner's claim of unexpected results, we agree with Petitioner that these exhibits cross the very low threshold for relevance. Paper 77, 4.

As for Patent Owner's arguments that the evidence should be excluded under FRE 403, we do not discern any prejudice to Patent Owner under that rule in allowing these exhibits into evidence. Rather, we determine that the premise of Patent Owner's argument goes to the weight that should be afforded to the evidence. Such argument is not proper in a motion to exclude, which is for challenging the admissibility of evidence, not for challenging its sufficiency. *See* Office Patent Trial Practice Guide August 2018 Update, at 16 (available at <https://go.usa.gov/xU7GP>) (stating that a motion to exclude may not be used to challenge the sufficiency of the evidence to prove a particular fact); *see also* November 2019 Consolidated Trial Practice Guide, at 79 (available at <https://go.usa.gov/xdj8z>) (stating the same).

In view of the above, Exhibits 1036, 1037, and 1066 will not be excluded.

B. Exhibit 1012

Patent Owner moves to exclude the Butler Declaration (Ex. 1012, 1), which is relied on by Petitioner to establish the public availability date of the Schimrigk 2004 Poster (Ex. 1012, 4). Paper 75, 3–4. Patent Owner moves to exclude Exhibit 1012 for lack of foundation, personal knowledge, and authentication. *Id.* at 4 (citing FRE 602, 901). In particular, Patent Owner contends that “[t]he Butler declaration does not provide any testimony

demonstrating personal knowledge of whether the poster was actually archived or publicly available before the critical date.” *Id.*

We are not persuaded. Rather, we agree with Petitioner that “[Patent Owner’s] attacks on the Butler Decl. and Schimrigk 2004 Poster go directly to the sufficiency of the evidence to establish the Schimrigk 2004 Poster as prior art,” which is improper. Paper 77, 5 (footnote omitted). Mr. Butler’s testimony does not aver that he has personal knowledge as to whether the printouts attached to his affidavit were actually posted at an accessible location on the Internet. Mr. Butler’s testimony instead is directed to the general workings of the Internet Archive’s Wayback Machine. *See* Ex. 1012, 1. Exhibit 1012 will not be excluded.

C. Exhibit 1054

Patent Owner moves to exclude an attorney declaration from Robert Mihail Esq. (Ex. 1054) as inadmissible hearsay and as lacking foundation and personal knowledge. Paper 75, 7–11. We do not rely on Exhibit 1054 in our final written decision. Thus, Patent Owner’s motion to exclude Exhibit 1054 is dismissed as moot.

D. Exhibit 1010

Patent Owner moves to exclude Clinical Trials (Ex. 1010) as lacking authentication and as inadmissible hearsay. Paper 75, 7–11. Patent Owner contends that “the date on the face of Clinical Trials that Mylan relies on to prove the date of alleged public availability is inadmissible hearsay.” *Id.* at 10. Patent Owner further contends that “[Petitioner] has not proffered any

testimony or evidence establishing the publication date of Clinical Trials, aside from inadmissible testimony from Mr. Mihail.” *Id.*

Petitioner contends that it reproduced Clinical Trials (Ex. 1057) and provided Patent Owner, as supplemental evidence, this reproduction and an attorney declaration explaining how the reproduction was obtained. Paper 77, 14 (citing Paper 35, 2). Petitioner also contends that Clinical Trials is subject to hearsay exceptions under FRE 803(8) because “Clinical Trials is a public record of NIH, a federal agency, setting out its legally-mandated duty to maintain a clinical trial registry, and there is no lack of trustworthiness.” Paper 77, 13.

We agree with Petitioner that these Exhibits 1010 and 1057 fall within the “public records” exception to the hearsay rules under FRE 803(8) because they are public records that set out the office’s activities under FRE 803(8)(A)(i) and because Patent Owner has not shown that the source of information or other circumstances indicate a lack of trustworthiness under FRE 803(8)(B). Exhibit 1010 will not be excluded.

E. Exhibits 1055 and 1122

Patent Owner moves to exclude a declaration from Ms. Jennifer Rock (Exs. 1055 and 1122¹), which it contends is relied on by Petitioner to establish the prior art date of three press releases available on Westlaw, namely Exhibits 1005, 1016, and 1026. Paper 75, 11–13. Patent Owner

¹ Patent Owner contends that it “objected to Exhibit 1055 and Mylan failed to remedy the objections with its supplemental Exhibit 1122.” Paper 75, 11.

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