

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHIGENIX, INC.
Petitioner

v.

IMMUNOGEN, INC.
Patent Owner

Case IPR2014-00676
Patent 8,337,856 B2

**PHIGENIX, INC.'S MOTION TO EXCLUDE
UNDER 37 C.F.R. § 42.64(c)**

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U.S. Patent and Trademark Office
P.O. Box 1450
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Pursuant to 37 C.F.R. 42.64(c) and 37 C.F.R. § 42.62(a) (applying the Federal Rules of Evidence to *Inter Partes* Review proceedings), Petitioner Phigenix, Inc. (“Phigenix”) moves to exclude the new evidence designated PO Materials (“Belated Materials”)¹, served by Patent Owner ImmunoGen, Inc. (“ImmunoGen”) on February 12, 2015, as improperly produced under 37 C.F.R. § 42.63; as lacking foundation under F.R.E. 901; and as inadmissible hearsay under F.R.E. 802.

Accordingly, Phigenix further moves to exclude Exhibits 2240, 2241, 2242, 2243, 2244, 2256, 2319 and 2320, which rely on the Belated Materials, as improper hearsay under F.R.E. 802. Phigenix also moves to exclude those portions of Exhibit 2131 (“Jarosz Declaration”) (paragraphs 12, 14, 44, 45, 46, 55, 56, 57, 58, 107 of the Jarosz Declaration) that rely on Exhibits 2240, 2241, 2242, 2243, 2244, 2256, 2319 and 2320 as improper hearsay under F.R.E. 802 and not qualified to be the basis for an expert opinion under F.R.E. 703.

Phigenix additionally moves to exclude all those elements of ImmunoGen’s Expert Reports improperly incorporated by reference under 37 C.F.R § 42.6(a).

¹ The Belated Materials pertain to alleged sales information of KADCYLA™. Thus, these are only relevant should the Board rely on such sales as evidence of commercial success.

I. Statement of Facts

ImmunoGen submitted its Patent Owner's Response to the Petition with accompanying Exhibits 2240, 2241, 2242, 2243, 2244, 2256, 2319 and 2320 and the Jarosz Declaration on January 22, 2015. Pursuant to 37 C.F.R. § 42.64(c), on January 29, 2015, Phigenix timely served its Objections to Evidence ("Objections"), including specific objections to Exhibits 2240, 2241, 2242, 2243, 2244, 2256, 2319 and 2320 and the Vahdat, O'Shaughnessy and Jarosz Declarations. *See* Exhibit A. Pursuant to 37 C.F.R. § 42.64(b)(2), on February 12, 2015, ImmunoGen responded to the Objections by serving its Supplemental Evidence. *See* Exhibit B. ImmunoGen's Supplemental Evidence included a Supplemental Declaration of John C. Jarosz, dated February 10, 2015. *See* Exhibit C. ImmunoGen's Supplemental Evidence also included "[s]ervice of confidential supplemental evidence ("PO Materials [designated herein as "Belated Materials"]") related to Exhibits 2240-2244, 2256, 2319, and 2320 [] made subject to the Patent Trial and Appeal Board's Default Protective Order provided in Appendix B of the Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,771 (Aug. 14, 2012)." *See* Exhibit C.

The Belated Materials served by ImmunoGen consist of two pdf files: one file entitled "PROTECTIVE ORDER MATERIAL - Supp. Evidence - IMS pt. 1" is a chart of data that is 72 pages long; another file entitled "PROTECTIVE

ORDER MATERIAL - Supp. Evidence - IMS pt. 2” is a chart of data that is 18 pages long. ImmunoGen did not previously produce or file either chart of data in any format.

Pursuant to 37 C.F.R. § 42.64(c), on February 20, 2015, Phigenix timely served its Objections to New Evidence Produced by ImmunoGen, Inc. on February 12, 2015, in which Phigenix objected to the Belated Materials. *See* Exhibit D. ImmunoGen did not produce any further supplemental evidence in response to Phigenix’s objections to the Belated Materials. The Belated Materials have not yet been filed as evidentiary Exhibits by ImmunoGen.

II. Argument

i. The Belated Materials Are Improper Under 37 C.F.R. § 42.63

37 C.F.R. § 42.63(a) states the following:

Exhibits required. Evidence consists of affidavits, transcripts of depositions, documents, and things. **All evidence must be filed in the form of an exhibit.**

37 C.F.R. § 42.63(a) (bold added).

Neither of the charts produced as supplemental evidence in the Belated Materials by ImmunoGen has been filed as an exhibit. Indeed, the Belated Materials have never been filed in any format and, as such, constituted new documents produced to Phigenix on February 12, 2015.

Under 37 C.F.R. § 42.64(b)(1), “[o]nce a trial has been instituted, any objection must be served within five business days of service of evidence to which the objection is directed.” This rule does not exclude objections to evidence when that evidence is first produced as supplemental evidence. Accordingly, on February 20, 2015, Phigenix objected to the Belated Materials within five business days of service of the newly produced documents, including raising an objection under 37 C.F.R. § 42.63. ImmunoGen took no action to address this objection.

Accordingly, Phigenix requests that the Board exclude the Belated Materials as evidence that may be relied upon by ImmunoGen because the Belated Materials are improper as evidence under 37 C.F.R. § 42.63.

ii. The Belated Materials Lack Foundation Under F.R.E. 901

As discussed above, the Belated Materials cannot be relied upon as evidence under 37 C.F.R. § 42.63. Even if, *arguendo*, the Belated Materials may be considered proper under 37 C.F.R. § 42.63, the Belated Materials lack foundation and have not been authenticated under F.R.E. 901. ImmunoGen produced a Supplemental Declaration of John C. Jarosz on February 10, 2015, which states as follows: “Exhibits 2240-224, 2256, 2319, and 2320 are compilations of data provided by IMS Institute for Healthcare Informatics (“IMS”).” *See* para. 6 of Exhibit C. The Supplemental Declaration does not make any reference to the actual Belated Materials themselves nor does it explain their provenance. As such,

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