UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner

v.

CELGENE CORPORATION,
Patent Owner

—

Case IPR2023-00512
U.S. Patent No. 8,846,628
Issued: September 30, 2014

Title:
ORAL FORMULATIONS OF CYTIDINE ANALOGS AND METHODS OF USE THEREOF

PETITIONER'S OBJECTIONS TO PATENT OWNER'S EVIDENCE PURSUANT TO 37 C.F.R. § 42.64

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Apotex Inc. ("Petitioner") submits the following objections to evidence served by Celgene Corporation ("Patent Owner") with Patent Owner's Preliminary Response ("POPR") (Paper No. 7), in the above-captioned proceeding. These objections are timely under 37 C.F.R. § 42.64(b)(1) because they are being filed within ten (10) business days of institution of trial. Petitioner's objections provide notice to Patent Owner that Petitioner may move to exclude these exhibits under 37 C.F.R. § 42.64(c). Petitioner's objections apply equally to Patent Owner's reliance on the exhibit in any subsequently-filed documents.

In this paper, a reference to "FRE" means the Federal Rules of Evidence and "'628 patent" means U.S. Patent No. 8,846,628. Exhibit descriptions provided in Table 1 are from Patent Owner's exhibit list and are used for identification purposes only. The use of an exhibit description does not indicate that Petitioner agrees with that description or characterization of the document.

Notwithstanding these objections, Petitioner expressly reserves the right to rely on any evidence submitted by Patent Owner, including on the ground that such evidence constitutes a party admission.

Petitioner objects to Exhibit 2001 as incomplete, lacking relevance, and because any probative value is substantially outweighed by the danger of undue prejudice (due to confusing the issues, misleading the fact finder, undue delay,

wasting time, and/or needlessly presenting cumulative evidence). *See* Fed. R. Evid. 106, 401, 402, and 403. Petitioner also objects to Exhibit 2001 for lacking relevance to the extent it relies on or cites to a document with a purported date that is after the priority date of the '628 patent. *See* Fed. R. Evid. 401, 402, and 403. Petitioner also objects to Exhibit 2001 to the extent it relies on out of court statements for their truth, thus constituting impermissible hearsay. *See* Fed. R. Evid. 801-804. Petitioner also objects to Exhibit 2001 to the extent it relies on a document lacking proper authentication. *See* Fed. R. Evid. 901-902.

Petitioner further objects to the following paragraphs of Exhibit 2001:

- ¶ 41 for the same reasons as those presented below for Exhibit 2042 in Table 1, due to its reliance on Exhibit 2042. Petitioner further objects to all paragraphs that rely on this paragraph for the same reasons;
- ¶ 47 for the same reasons as those presented below for Exhibit 2025 in Table 1, due to its reliance on Exhibit 2025. Petitioner further objects to all paragraphs that rely on this paragraph for the same reasons;
- ¶ 64 for the same reasons as those presented below for Exhibit 2016 in Table 1, due to its reliance on Exhibit 2016. Petitioner further objects to all paragraphs that rely on this paragraph for the same reasons;

- ¶ 70 for the same reasons as those presented below for Exhibit 2023 in Table 1, due to its reliance on Exhibit 2023. Petitioner further objects to all paragraphs that rely on this paragraph for the same reasons.

Petitioner further objects to Patent Owner's exhibits and Patent Owner's reliance on them for the reasons set forth below in Table 1 and the Objection Key.

Table 1.

Exhibit	Patent Owner's Description	Objections
2002	FDA approves Onureg® (azacitidine tablets) for acute myeloid leukemia ("FDA Approves Onureg®")	B, C, D, E, F, G, H
2006	Canadian Product 200mg Onureg® Product Information	B, C, D, E, F, G, H
2007	Canadian Product 300mg Onureg® Product Information	B, C, D, E, F, G, H
2008	Canadian Product Monograph Onureg®	B, C, D, E, F, G, H
2013	European Commission Decision 17.6.21	B, C, D, E, F, G, H
2016	FASTtrack 2010 ("FASTtrack")	B, C, D, E, F, G
2023	National Cancer Institute 1978 ("National Cancer Institute")	A, C, D, E
2025	Onureg® Label	B, C, D, E, F, G
2026	International Pat. Appl. Pub. No. WO2009/139888 ("WO2009/139888")	B, C, D, E, H
2030	U.S. Pat. Pub. No. US20040186065A1 ("Ionescu-065")	C, D, E, H
2035	U.S. Pat. No. 6,887,855 ("Ionescu-855")	C, D, E, H
2036	U.S. Pat. No. 7,078,518 ("Ionescu-518")	C, D, E, H
2037	U.S. Pat. No. 7,772,199 ("Ionescu-199")	C, D, E, H
2038	U.S. Pat. Pub. No. US20060247189 ("Ionescu-189")	C, D, E, H
2039	U.S. Pat. Pub. No. US20100298253 ("Ionescu-253")	C, D, E, H
2040	Ward 2007 ("Ward")	C, D, E, H
2042	Gibson Supplemental	A, C, D, E

Petitioner further objects to Patent Owner's reliance on Exhibit 1022, in particular the Declaration of Dr. Charles L. Beach under 37 C.F.R. § 1.132 ("Beach Decl."), as relying on out of court statements for their truth, thus constituting impermissible hearsay.

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