

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

PHARMACYCLICS LLC,
Patent Owner.

Case IPR2019-00865
U.S. Patent No. 9,795,604

PATENT OWNER'S OBJECTIONS TO PETITIONER'S EVIDENCE

The Federal Rules of Evidence (“FRE”) generally apply to proceedings before the Board. 37 C.F.R. § 42.62(a). Pursuant to 37 C.F.R. § 42.64(b)(1) and the FRE, Patent Owner Pharmacyclics LLC submits the following objections to certain exhibits submitted by Petitioner Sandoz Inc. These objections apply equally to Petitioner’s reliance on these exhibits in any subsequently filed documents. These objections are timely filed and served within ten business days of the Board’s decision to institute trial in these proceedings.

Exhibit 1002

Patent Owner objects to Exhibit 1002 under FRE 401–403 as lacking relevance to the instituted grounds. Exhibit 1002 discloses and claims only *formulations* of ibrutinib, not *methods of treatment* with no *in vitro*, preclinical, or clinical data relevant to treating cGVHD or any other disease. Exhibit 1002 thus does not make any fact more or less probable and is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

Exhibit 1003

To the extent Petitioner relies on the content of Exhibit 1003 for the truth of the matter asserted, Patent Owner objects to Exhibit 1003 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1004

To the extent Petitioner relies on the content of Exhibit 1004 for the truth of the matter asserted, Patent Owner objects to Exhibit 1004 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1005

To the extent Petitioner relies on the content of Exhibit 1005 for the truth of the matter asserted, Patent Owner objects to Exhibit 1005 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

Exhibit 1006

Patent Owner objects to Exhibit 1006, Declaration of James L. Ferrara, M.D. Patent Owner objects to Exhibit 1006 as not being based on sufficient facts or data, the product of reliable principles and methods, and/or a reliable application of the principles and methods to the facts (FRE 702, 703), and/or lacking a disclosed basis of sufficient facts or data (FRE 705). Patent Owner objects to ¶¶ 55–59 and all paragraphs that rely on those paragraphs under FRE 401–403 as lacking relevance to the instituted grounds. Patent Owner further objects to ¶¶ 75, 84, 86, 88, 89, 92, 94, 101, 107–109, 111–113, 115, 118, 123, 131, 132, 134, 135, 137, 139, 140, 144, 149, and all paragraphs that rely on those paragraphs as misleading and/or confusing

(FRE 403). To the extent Petitioner relies on the content of those paragraphs of Exhibit 1006 for the truth of the matter asserted, Patent Owner objects to such content as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exception, including FRE 803, 804, 805, and 807.

Exhibit 1007

To the extent Petitioner relies on the content of Exhibit 1007 for the truth of the matter asserted, Patent Owner objects to Exhibit 1007 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Patent Owner further objects to Exhibit 1007 because it lacks proper foundation and/or authenticity under FRE 901.

Exhibit 1009

Patent Owner objects to Exhibit 1009 as an incomplete document (FRE 106).

Exhibit 1010

To the extent Petitioner relies on the content of Exhibit 1010 for the truth of the matter asserted, Patent Owner objects to Exhibit 1010 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Patent Owner further objects to Exhibit 1010 because it lacks proper foundation and/or authenticity under FRE 901.

Exhibit 1012

To the extent Petitioner relies on the content of Exhibit 1012 for the truth of the matter asserted, Patent Owner objects to Exhibit 1012 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Patent Owner further objects to Exhibit 1012 because it lacks proper foundation and/or authenticity under FRE 901.

Exhibit 1013

Patent Owner objects to Exhibit 1013 as not relevant, confusing, unfairly prejudicial, and wasting time because it is not relevant to any issue in these IPR proceedings (FRE 401–403).

Exhibit 1014

Patent Owner objects to Exhibit 1014 as an incomplete document (FRE 106).

Exhibit 1015

To the extent Petitioner relies on the content of Exhibit 1015 for the truth of the matter asserted, Patent Owner objects to Exhibit 1015 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Patent Owner further objects to Exhibit 1015 because it lacks proper foundation and/or authenticity under FRE 901.

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