

Filed on behalf of Celgene Corporation

By: Heather M. Petruzzi  
Laura Macro, Ph.D.,  
Gabriel J. Rosanio, Ph.D.  
Wilmer Cutler Pickering Hale and Dorr LLP  
2100 Pennsylvania Avenue N.W.  
Washington, DC 20037

**UNITED STATES PATENT AND TRADEMARK OFFICE**

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

APOTEX INC.  
Petitioner

v.

CELGENE CORPORATION  
Patent Owner of  
U.S. Patent No. 8,846,628 B2 to Etter et al.

---

IPR Trial No. IPR2023-00512

---

**PATENT OWNER'S OBJECTIONS TO EVIDENCE  
UNDER 37 C.F.R. § 42.64**

Pursuant to 37 C.F.R. § 42.64, Patent Owner hereby objects under the Federal Rules of Evidence ("FRE") and 37 C.F.R. § 42.62 to the admissibility of evidence that Petitioner filed in support of its Petition. Patent Owner's objections apply equally to Petitioner's reliance on these exhibits in any subsequently filed documents. These objections are timely, having been filed within ten business days of the Institution Decision (July 20, 2023).

### **Exhibits 1002**

Patent Owner objects to Exhibits 1002, the Declaration of Dr. Buckton. Patent Owner objects to ¶¶ 39, 48, 50, 66, 79, 93, 104, 112, 119, 121, 122, 125, 126, 136-138, 140, 143, 144, 149, 152-154, 156, 157, 163, 166-168, 171, 173-175, 178, 179, 181, 182, 184, and 187 of Exhibit 1002, and all paragraphs that rely on those paragraphs. These paragraphs lack a disclosed basis of sufficient facts or data (FRE 705; 37 C.F.R. § 42.65), are not based on sufficient facts or data, and/or are not the product of reliable principles and methods (FRE 702). Additionally, Patent Owner objects to the above referenced paragraphs of Exhibit 1002, and all paragraphs that rely on those paragraphs as misleading, incomplete, and lacking relevance and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and needlessly presenting cumulative evidence (FRE 106,

401, 402, and 403). In particular, Patent Owner objects to:

- ¶¶ 39, 48, 50, 66, 79, 93, 104, 112, 119, 121, 122, 125, 126, 136-138, 140, 143, 144, 149, 152-154, 156, 157, 163, 166-168, 171, 173-175, 178, 179, 181, 182, 184, and 187 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited;
- ¶¶ 40-42 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and improperly characterize the teachings of Atadja (Exhibit 1005);
- ¶ 49 as misleading, incomplete, and irrelevant because it lacks support for the contentions for which it is cited and improperly characterize the teachings of Gibson (Exhibit 1006).

Additionally, Patent Owner further objects to ¶¶ 1-42, 44-91, 93-107, 113-118, 123-125, 129-137, 139, 144-151, 154, 155, 157-166, 168-171, 177-186, and 191-193 of Exhibit 1002, and all paragraphs that rely on those paragraphs. These paragraphs are irrelevant (FRE 401 and 402), and any probative value is substantially outweighed by the risk of undue prejudice and/or confusion (FRE 403). These paragraphs are not directly cited in the Petition and the relevance of

these paragraphs is not apparent (FRE 401, 402 and 403).

Patent Owner further objects to ¶¶ 35, 43, 51, 55, 61, 69, and 163 which contain citations to Exhibits that are not cited in the Petition and/or that form no part of the grounds on which *inter partes* review was instituted, as irrelevant (FRE 401 and 402).

### **Exhibits 1003**

Patent Owner objects to Exhibit 1003, the Declaration of Dr. Batchelor. Patent Owner objects to ¶¶ 19, 20, 22, 25, 27, 28, 30, 32, 34, 35, and 43 of Exhibit 1003, and all paragraphs that rely on those paragraphs. These paragraphs lack a disclosed basis of sufficient facts or data (FRE 705; 37 C.F.R. § 42.65). Further, the above paragraphs purport to be related to “[i]n silico modeling of PK properties” (Exhibit 1003 at ¶ 19) but fail to provide sufficient description of the program used for this modeling. For at least this reason, Patent Owner also objects to the above paragraphs, and all paragraphs that rely on those paragraphs, on the basis that they are not based on sufficient facts or data, not the product of reliable principles and methods, and/or not a reliable application of the principles and methods to the facts (FRE 702 and 703). Additionally, Patent Owner objects to the above referenced paragraphs of Exhibit 1003, and all paragraphs that rely on those paragraphs, as lacking relevance, incomplete, and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues,

misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence because they lack support for the contentions for which they are cited (FRE 106, 401, 402, and 403).

Additionally, Patent Owner objects to ¶¶ 1-19, 21, 22, 24, 27, 28, and 48 as well as appendices III.A, III.A.1, III.B, III.C, III.D, and III.E of Exhibit 1003, and all paragraphs that rely on those paragraphs and appendices, as lacking relevance, incomplete, and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence (FRE 106, 401, 402, and 403). These paragraphs are not directly cited in the Petition and the relevance of these paragraphs is not apparent (FRE 401 and 402).

Further, Patent Owner objects to ¶¶ 19-47 as well as Appendices I-III including Appendices I.A.1, I.A.2, I.B, I.C, I.D.1, I.D.2, I.D.3, I.D.4, I.D.5, II.A, II.A.1, II.B, II.C, II.D, II.E, III.A, III.A.1, III.B, III.C, III.D, and III.E under 37 C.F.R. § 42.65. To the extent these paragraphs and appendices are, or contain, technical test or data from such a test, they lack support and explanation in a sufficient affidavit (37 C.F.R. § 42.65).

Patent Owner further objects to ¶¶ 18, 22, 27, 34, 35, 38, 41, and 45 which contain citations to Exhibits that are not cited in the Petition and/or that form no part of the grounds on which *inter partes* review was instituted, as irrelevant (FRE

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.