

Filed on behalf of Celgene Corporation

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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**

Patent Owner's Objections to Evidence

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,

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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

401 and 402).

Exhibit 1006

Patent Owner objects to Exhibit 1006, what purports to be a copy of Gibson, M., *Ch. 11, Oral Solid Dosage Forms*, PHARMA. PREFORMULATION AND FORMULATION, CRC Press (2001). Patent Owners object to this Exhibit as not properly authenticated under FRE 901 because Petitioner has not presented sufficient evidence that the document is authentic nor that the document is self-authenticating under FRE 902. Patent Owners further object on the basis that this is not an original document under FRE 1002, an authentic duplicate under FRE 1003, nor a document that falls under any exceptions to the original-document requirement, including those of FRE 1004. Petitioner has not established that Gibson is a “printed publication” under 35 U.S.C. §102(b) that was published in 2001 at least because the Exhibit bears no library stamp corresponding to that date, nothing in the Exhibit associates the Gibson chapter to the specific version of the textbook, and inconsistent page sizing within the Exhibit suggests that it is a compilation of multiple documents pieced together by Petitioner.

To the extent Exhibit 1006 is being offered to prove the truth of the matter asserted, Patent Owner also objects to the exhibit as constituting inadmissible

hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807.

Patent Owner further objects to any paragraph of exhibits 1002 and 1003 to the extent they rely on Exhibit 1006 for at least the reasons identified here.

Exhibit 1048

Patent Owner objects to Exhibit 1048 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). Patent Owner further objects to this exhibit under FRE 401, 402, and 403 because the exhibit is not cited in the Petition, or in paragraphs of the Buckton Declaration, or the Batchelor Declaration relied upon in the Petition.

Patent Owner further objects to this document as not properly authenticated under FRE 901 because Petitioner has not presented sufficient evidence that the document is authentic nor that the document is self-authenticating under FRE 902. Patent Owner further objects on the basis that this is not an original document under FRE 1002, an authentic duplicate under FRE 1003, nor a document that falls under any exceptions to the original-document requirement, including those of FRE 1004.

Patent Owner's Objections to Evidence

To the extent exhibit 1048 is being offered to prove the truth of the matter asserted, Patent Owner also objects to the exhibit as constituting inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807.

Patent Owner further objects to any paragraph of exhibits 1002 and 1003 to the extent they rely on Exhibit 1048 for at least the reasons identified here.

Exhibits 1020, 1049, and 1050

Patent Owner objects to Exhibits 1020, 1049, and 1050 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). Patent Owner further objects to these exhibits under FRE 401, 402, and 403 because the exhibits are not cited in the Petition, or in paragraphs of the Buckton Declaration, or the Batchelor Declaration relied upon in the Petition.

To the extent exhibits 1020, 1049, and 1050 are being offered to prove the truth of the matter asserted, Patent Owner also objects to the exhibits as constituting inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807.

Patent Owner further objects to any paragraph of exhibits 1002 and 1003 to the extent they rely on exhibits 1020, 1049, and 1050 for at least the reasons

identified here.

Exhibits 1013, 1027, 1029, 1030, and 1032

Patent Owner objects to Exhibits 1013, 1027, 1029, 1030, and 1032. Patent Owner objects to these documents as not properly authenticated under FRE 901 because Petitioner has not presented sufficient evidence that the documents are authentic nor that the documents are self-authenticating under FRE 902. Patent Owner further objects on the basis that these are not original documents under FRE 1002, authentic duplicates under FRE 1003, nor documents that falls under any exceptions to the original-document requirement, including those of FRE 1004.

To the extent exhibits 1013, 1027, 1029, 1030, and 1032 are being offered to prove the truth of the matter asserted, Patent Owner also objects to the exhibits as constituting inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807.

Patent Owner further objects to any paragraph of exhibits 1002 and 1003 to the extent they rely on exhibits 1013, 1027, 1029, 1030, and 1032 for at least the reasons identified here.

Exhibits 1012, 1034 and 1041

Patent Owner objects to Exhibits 1012, 1034, and 1041. Patent Owner objects to these documents as not properly authenticated under FRE 901 because Petitioner has not presented sufficient evidence that the documents are authentic

nor that the documents are self-authenticating under FRE 902. Patent Owner further objects on the basis that these are not original documents under FRE 1002, authentic duplicates under FRE 1003, nor documents that falls under any exceptions to the original-document requirement, including those of FRE 1004.

To the extent exhibits 1012, 1034, and 1041 are being offered to prove the truth of the matter asserted, Patent Owner also objects to the exhibits as constituting inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807.

Patent Owner further objects to any paragraph of exhibits 1002 and 1003 to the extent they rely on exhibits 1012, 1034, and 1041 for at least the reasons identified here.

Exhibits 1052, 1053, 1054, 1055, 1056, 1057, 1058, and 1059

Patent Owner objects to Exhibits 1052, 1053, 1054, 1055, 1056, 1057, 1058, and 1059. Exhibits 1052, 1053, and 1054 purport to be “The SDF file for the PubChem compound entry for Azacitidine (PubChem CID 9444) (September 16, 2004) (‘Conformer3D_CID_9444 (1).sdf’), printed to PDF,” “ADMET Predictor Output file (‘Azacitidine ADMET.txt’), printed to PDF,” and “CDD file for 200 mg dose (‘Azacitidine 200 mg.cdd’), printed to PDF,” respectively, used for “[i]n *silico* modeling of PK properties” (Exhibit 1003 at ¶ 19; *see also id.* at ¶¶ 33, 42, fn. 3). 1053, 1054, 1055, 1056, 1057, 1058, and 1059 purport to be “ADMET

Predictor Output file ('Azacitidine ADMET.txt'), printed to PDF," "CDD file for 200 mg dose ('Azacitidine 200 mg.cdd'), printed to PDF," "IV plasma concentration-time data file for 200 mg dose ('Azacitidine 200 mg.ipd'), printed to PDF," "Result data file for 200 mg dose ('Azacitidine 200 mg All Data.txt'), printed to PDF," "CDD file for 400 mg dose ('Azacitidine 400 mg.cdd'), printed to PDF," "IV plasma concentration-time data file for 400 mg dose ('Azacitidine 400 mg.ipd'), printed to PDF," "Result data file for 400 mg dose ('Azacitidine 400 mg All Data.txt'), printed to PDF," respectively, generated by the *in silico* modeling (see Exhibit 1003 at ¶¶ 36, 38, 42, 47). These documents contain columns of data without explanation of their meanings, how they were used in the purported *in silico* modeling of PK properties, and/or how they were generated by the purported *in silico* modeling of PK properties. For at least this reason, Patent Owner objects to the above documents as misleading, incomplete, and/or 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/or needlessly presenting cumulative evidence (FRE 106, 401, 402, and 403). Further, Patent Owner objects to these documents under 37 C.F.R. § 42.65. To the extent these documents 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).

Further, Patent Owner objects to these documents as not properly

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authenticated under FRE 901 because Petitioner has not presented sufficient evidence that the documents are authentic or that the documents are self-authenticating under FRE 902. Patent Owner further objects on the basis that these are not original documents under FRE 1002, authentic duplicates under FRE 1003, nor documents that falls under any exceptions to the original-document requirement, including those of FRE 1004.

To the extent exhibits 1052, 1053, 1054, 1055, 1056, 1057, 1058, and 1059 are being offered to prove the truth of the matter asserted, Patent Owner also objects to the exhibits as constituting inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807.

Patent Owner further objects to any paragraph of exhibits 1002 and 1003 to the extent they rely on exhibits 1052, 1053, 1054, 1055, 1056, 1057, 1058, and 1059 for at least the reasons identified here.

Exhibits 1004, 1005, 1007, 1008, 1009, 1010, 1011, 1014, 1015, 1016, 1017, 1018, 1019, 1021, 1022, 1023, 1024, 1025, 1026, 1028, 1031, 1033, 1035, 1036, 1037, 1038, 1039, 1040, 1042, 1043, 1044, 1045, 1046, 1047, and 1051

To the extent exhibits 1004, 1005, 1007, 1008, 1009, 1010, 1011, 1014, 1015, 1016, 1017, 1018, 1019, 1021, 1022, 1023, 1024, 1025, 1026, 1028, 1031, 1033, 1035, 1036, 1037, 1038, 1039, 1040, 1042, 1043, 1044, 1045, 1046, 1047,

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and 1051 are being offered to prove the truth of the matter asserted, Patent Owner objects to the exhibits as constituting inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807.

Patent Owner further objects to any paragraph of exhibits 1002 and 1003 to the extent they rely on exhibits 1004, 1005, 1007, 1008, 1009, 1010, 1011, 1014, 1015, 1016, 1017, 1018, 1019, 1021, 1022, 1023, 1024, 1025, 1026, 1028, 1031, 1033, 1035, 1036, 1037, 1038, 1039, 1040, 1042, 1043, 1044, 1045, 1046, 1047, and 1051 for at least the reasons identified here.

Respectfully submitted,

By: Heather M. Petruzzi
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Laura Macro (Reg. No. 80,908)
Gabriel J. Rosanio (Reg. No. 81,426)

Counsel for Celgene Corporation

CERTIFICATE OF SERVICE

I hereby certify that, on August 3, 2023, I caused a true and correct copy of the following materials:

- Patent Owner's Objections to Evidence Under 37 C.F.R. § 42.64

to be served via email on the attorneys identified in the Petition for Petitioner

Apotex, Inc. (Paper No. 1), who consented to electronic service:

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Petitioner's Appendix of Exhibits

Exhibit No.	Description
1001	U.S. Patent No. 8,846,628 (the “’628 patent”)
1002	Declaration of Dr. Graham Buckton (“Buckton Decl.”)
1003	Declaration of Dr. Hannah K. Batchelor (“Batchelor Decl.”)
1004	WO 2004/082619 (“Ionescu”)
1005	WO 2004/103358 (“Atadja”)
1006	Gibson, M., <i>Ch. 11, Oral Solid Dosage Forms</i> , PHARMA. PREFORMULATION AND FORMULATION, CRC Press (2001) (“Gibson”)
1007	Vidaza Label 2004
1008	Vidaza Label 2007
1009	WO 2004/082822 (“Ionescu ’822”)
1010	Press Release, Pharmion, “Clinical Data Presented on Pilot Pharmacokinetic Study of Oral Azacitidine” (June 2, 2007) (“Pharmion-PR”)
1011	Press Release, Pharmion, “Pharmion’s Oral Azacitidine Granted Fast Track Status for Myelodysplastic Syndromes” (August 29, 2007) (“Pharmion-PR II”)
1012	Pharmion Corporation, Form 10-K (February 29, 2008) (“Pharmion 10-K”)
1013	Excerpts from Rowe, R.C., et al., <i>Handbook of Pharma. Excipients</i> , Pharma. Press, 5th ed. (2006) (“Handbook”)

Exhibit No.	Description
1014	Chan et al., “5-Azacytidine Hydrolysis Kinetics Measured by High-Pressure Liquid Chromatography and ¹³ C-NMR Spectroscopy,” 68 (7) J Pharma. Scis. 807 (1979) (“Chan”)
1015	Kelley et al., “Furanose-Pyranose Isomerization of Reduced Pyrimidine and Cyclic Urea Ribosides,” 29 J. Med. Chem. 2351 (1986) (“Kelley”)
1016	U.S. Patent No. 3,817,980 (“Vorbruggen”)
1017	Marcucci, G., et al., “Bioavailability of Azacitidine Subcutaneous Versus Intravenous in Patients With the Myelodysplastic Syndromes,” 45 J. Clin. Pharmacology 597 (2005) (“Marcucci”)
1018	Thomson, A., “Back to basics: pharmacokinetics,” 272 Pharma. J 769 (2004) (“Thomson”)
1019	U.S. Patent Publication No. 2006/0074046 (“Redkar”)
1020	Dintaman, et al., Pharmaceutical Research, 1999, 16(10), 1550-1556 (“Dintaman”)
1021	U.S. Patent Publication No. 2004/0162263 (“Sands”)
1022	Application File History for the ’628 Patent, U.S. App. No. 12/466,213 (“File History”)
1023	U.S. Patent No. 3,350,388
1024	Piskala, A. and Sorm, F., Collect. Czech. Chem. Commun., 29, 2060-2076 (1964)
1025	Piskala, A. and Sorm, F., GB 1227691 (1971)
1026	U.S. Publication No. 2008/0057086 (“’086 Publication”) (filed as U.S. Application No. 11/849,958 (“’958 application”))

Exhibit No.	Description
1027	GastroPlus version 5.2 Manual (“GP5.2 manual”)
1028	Exhibit number not used
1029	Kotke, M.K. and Rudnic, E.M, Ch. 10, Tablet Dosage Forms, MODERN PHARMACEUTICS, 4th ed. (2002) (“Modern Pharmaceutics”)
1030	Ch. 45, Oral Solid Dosage Forms, and Ch. 46, Coating of Pharmaceutical Dosage Forms, REMINGTON, THE SCIENCE AND PRACTICE OF PHARMACY, 20th ed., Lippincott Williams & Wilkins (2000) (“Remington”)
1031	Dover, G.J., et al., 5-Azacytidine Increases HbF Production and Reduces Anemia in Sickle Cell Disease: Dose-Response Analysis of Subcutaneous and Oral Dosage Regimens, Blood, 66(3): 527-532 (Sep. 1985) (“Dover”)
1032	Hardy et al., Drug Delivery to the Gastrointestinal Tract, 1989 Ch. 7, 83-96 (“Hardy”)
1033	Ewe et al., Digestive Diseases and Science, 1991, 36(2) 146-152 (“Ewe”)
1034	Stoltz et al., Development of an Oral Dosage Form of Azacitidine: Overcoming Challenges in Chemistry, Formulation, and Bioavailability, Blood 108:4850 (2006) (“Stoltz”)
1035	Exhibit number not used
1036	U.S. Provisional Application No. 61/053,609 (“’609 provisional”)
1037	Schwarz et al., Gastrointestinal Transit Times in Mice and Humans Measured With 27Al and 19F Nuclear Magnetic Resonance, Magnetic Resonance in Medicine 48:255-261, 260 (2002) (“Schwarz”)

Exhibit No.	Description
1038	Amidon et al., A theoretical basis for a Biopharmaceutic Drug Classification - The correlation of in vitro drug product dissolution and in vivo bioavailability. Pharm. Res., 12:413-420 (1995) (“Amidon”)
1039	Buck et al., Prediction of Human Pharmacokinetics Using Physiologically Based Modeling: A Retrospective Analysis of 26 Clinically Tested Drugs, Drug Metabolism & Disposition, 35(10):1766-1780 (2007) (“Buck”)
1040	Dannenfelser et al., Development of Clinical Dosage Forms for a Poorly Water Soluble Drug I: Application of Polyethylene Glycol–Polysorbate 80 Solid Dispersion Carrier System, J Pharma. Sci., 93(5):1165-1175 (2004) (“Dannenfelser”)
1041	Press Release, Simulations Plus, Inc., “Simulations Plus Releases GastroPlus™ 5.2” (Nov. 30, 2006) (“GP5.2 PR”)
1042	IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Pharmaceutical Drugs, Vol. 50, 1990 (“IARC”)
1043	Israili et al., The Disposition and Pharmacokinetics in Humans of 5-Azacytidine Administered Intravenously as a Bolus or by Continuous Infusion, Cancer Res. 36:1453-1461 (1976) (“Israili”)
1044	Kuentz et al., A strategy for preclinical formulation development using GastroPlus™ as pharmacokinetic simulation tool and a statistical screening design applied to a dog study, Euro. J. Pharma. Sci., 27:91-99 (2006) (“Kuentz”)
1045	Li et al., IV-IVC Considerations in the Development of Immediate-Release Oral Dosage Form, J Pharma. Sci. 94(7):1396-1417 (2005) (“Li”)
1046	Obach et al., The Prediction of Human Pharmacokinetic Parameters from Preclinical and In Vitro Metabolism Data, J. Pharma. & Exp. Thera., 283(1):46-58 (1997) (“Obach”)

Exhibit No.	Description
1047	Parrott & Lavé, Prediction of intestinal absorption: comparative assessment of gastroplus™ and idea™, Euro. J. Pharma. Sci., 17:51-61 (2002) (“Parrott”)
1048	Simulations Plus, Inc., Form 10-QSB (January 16, 2007) (“SLP 10-QSB”)
1049	FDA Guidance for Industry, Guideline for the Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application, February 1987 (“PK Guideline”)
1050	U.S. Provisional Application No. 61/157,875 (“’875 provisional”)
1051	U.S. Provisional Application No. 61/201,145 (“’145 provisional”)
1052	The SDF file for the PubChem compound entry for Azacitidine (PubChem CID 9444) (September 16, 2004) (“Conformer3D_CID_9444 (1).sdf”), printed to PDF
1053	ADMET Predictor Output file (“Azacitidine ADMET.txt”), printed to PDF
1054	CDD file for 200 mg dose (“Azacitidine 200 mg.cdd”), printed to PDF
1055	IV plasma concentration-time data file for 200 mg dose (“Azacitidine 200 mg.ipd”), printed to PDF
1056	Result data file for 200 mg dose (“Azacitidine 200 mg All Data.txt”), printed to PDF
1057	CDD file for 400 mg dose (“Azacitidine 400 mg.cdd”), printed to PDF
1058	IV plasma concentration-time data file for 400 mg dose (“Azacitidine 400 mg.ipd”), printed to PDF

Exhibit No.	Description
1059	Result data file for 400 mg dose (“Azacitidine 400 mg All Data.txt”), printed to PDF