

UNITED STATES PATENT AND TRADEMARK
OFFICE

BEFORE THE PATENT TRIAL AND APPEAL
BOARD

APOTEX, INC.,
Petitioner,

v.

CELGENE CORPORATION,
Patent Owner.

Case IPR2023-00512
Patent 8,846,628

PATENT OWNER'S UNOPPOSED MOTION FOR ADMISSION
PRO HAC VICE OF AMY K. WIGMORE

Patent Owner's Unopposed Motion for Admission *Pro Hac Vice* of Amy K. Wigmore

I. Statement of Precise Relief Requested

Pursuant to 37 C.F.R. § 42.10(c), Patent Owner Bristol-Myers Squibb Co. requests that the Patent Trial and Appeal Board (the “Board”) admit Amy K. Wigmore *pro hac vice* in this proceeding, IPR2023-00512. The parties have conferred, and Petitioner does not oppose this motion.

II. Statement of Facts Showing Good Cause for the Board to Recognize Counsel *Pro Hac Vice* During the Proceeding

In accordance with 37 C.F.R. § 42.10(c), the Board may recognize counsel *pro hac vice* during a proceeding upon a showing of good cause, subject to the condition that lead counsel be a registered practitioner and to any other conditions the Board may impose. Section 42.10(c) indicates that, “where the lead counsel is a registered practitioner, a motion to appear *pro hac vice* by counsel who is not a registered practitioner may be granted upon a showing that counsel is an experienced litigating attorney and has an established familiarity with the subject matter at issue in the proceeding.” The facts here establish good cause for the Board to recognize Amy K. Wigmore *pro hac vice* in this proceeding.

1. Lead counsel, Heather M. Petruzzi, is a registered practitioner. Backup counsel Laura Macro and Gabriel Rosanio are also registered practitioners.
2. Amy K. Wigmore is an experienced attorney who has an established familiarity with the subject matter at issue in the proceeding. Accompanying this

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motion as Exhibit 2154 is the Declaration of Amy K. Wigmore in Support of this Motion for Admission *Pro Hac Vice* ("Wigmore Decl."). In her declaration, Ms. Wigmore asserts:

I am a member in good standing of the Bars of the Commonwealth of Massachusetts and District of Columbia. I am admitted to practice before the U.S. District Courts for the District of Columbia, District of Colorado, and District of Massachusetts. I am also admitted to practice before the U.S. Court of Appeals for the Federal Circuit, the D.C. Circuit, and the Sixth Circuit, as well as the Supreme Court of the United States. I am also admitted to practice before the District of Columbia Court of Appeal, the Supreme Judicial Court of Massachusetts, and the United States Court of Appeals for Veterans Claims.

Wigmore Decl. ¶ 3 (Ex.2154). Ms. Wigmore also demonstrates that she has a detailed working knowledge of the relevant subject matter through both prior *inter partes review* experience and her familiarity with pharmaceutical technologies as a result of participation as counsel in related district court litigations on this patent as well as many prior pharmaceutical-related intellectual

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property cases on behalf of both Patent Owners, Bristol-Myers Squibb Co., as well as other pharmaceutical companies. Wigmore Decl. ¶¶ 5–6 (Ex.2154).

3. In her declaration, Ms. Wigmore also attests to each of the listed items required by the Order – Notice of Filing Date Accorded to Petition And Time For Filing Patent Owner Preliminary Response – 37 C.F.R. § 42.10(c) in IPR2023-00512. *See* Wigmore Decl. ¶ 10 (Ex.2154). Ms. Wigmore attests that she has read and will comply with the Patent Office Patent Trial Practice Guide and the Board's Rules of Practice for Trials set forth in 35 C.F.R. § 42. *Id.*, ¶ 11. Ms. Wigmore further attests that she agrees to be subject to the United States Patent and Trademark Office's Rules of Professional Conduct as set forth in 37 C.F.R. §§ 11.101 *et seq.* and disciplinary jurisdiction under 37 C.F.R. § 11.19(a). *Id.*, ¶ 12.

III. Conclusion

For the foregoing reasons, and in view of the Declaration submitted herewith (Ex.2154), Patent Owner respectfully requests that the Board grant this motion and admit Ms. Wigmore *pro hac vice* in this proceeding. The undersigned authorizes the Office to charge \$250 to Deposit Account No. 08-0219 for the fees set forth in 37 C.F.R. § 42.15(e) for this *pro hac vice* motion. Please charge any shortage of fees or credit any overpayments to the above Deposit Account.

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Dated: October 31, 2023

Respectfully submitted,

/Heather M. Petruzzi/

Heather M. Petruzzi (Reg. No. 71,270)

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PATENT OWNER'S EXHIBIT LIST IPR2023-00512

Exhibit No.	Description
2001	Declaration of Dr. Corey Berkland
2002	U.S. Food and Drug Admin., <i>FDA approves Onureg[®] (azacitidine tablets) for acute myeloid leukemia</i> (2020), https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-onureg-azacitidine-tablets-acute-myeloid-leukemia (“FDA Approves Onureg [®] ”)
2003	Aparicio, A. & Weber, J., <i>Review of the clinical experience with 5-azacytidine and 5-aza-2'-deoxycytidine in solid tumors</i> , 3 CURRENT OPINION IN INVESTIGATIONAL DRUGS 627–633 (2002) (“Aparicio”)
2004	Beisler, J., et al., <i>Chemistry of Antitumor Triazine Nucleosides. An Improved Synthesis of Dihydro-5-Azacytidine</i> , 4(5) J. CARBOHYDRATES NUCLEOSIDES NUCLEOTIDES 281–99 (1977) (“Beisler”)
2005	<i>Reserved</i>
2006	Canadian Product 200mg Onureg [®] Product Information
2007	Canadian Product 300mg Onureg [®] Product Information
2008	Canadian Product Monograph Onureg [®]
2009	Chabner, B., et al., <i>Deamination of 5-azacytidine by a human leukemia cell cytidine deaminase</i> , 22 BIOCHEMICAL PHARMACOLOGY 2763–65 (1973) (“Chabner”)
2010	Chen, X., et al., <i>Highly Efficient Regioselective Synthesis of 5'-O-lauroyl-5-azacytidine Catalyzed by Candida antarctica Lipase B</i> , 151 APPL. BIOCHEM. BIOTECHNOL. 21–28 (2008) (“Chen”)
2011	Cheung, Y., et al., <i>Stability of azacitidine in infusion fluids</i> , 41 AM. J. OF HOSP. PHARMACY 1156–59 (1984) (“Cheung”)

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2012	Čihák, A & Šorm, F., <i>Biochemical Effects and Metabolic Transformations of 5-Azacytidine in Escherichia coli</i> , 30 COLLECT. CZECH. CHEM. COMMUN. 2091–2102 (1965) (“Čihák”)
2013	European Commission Decision 17.6.21
2014	CONNORS, K., ET AL., CHEMICAL STABILITY OF PHARMACEUTICALS: A HANDBOOK FOR PHARMACISTS 239 (2nd Ed. 1986) (“Connors”)
2015	Evans, D., et al., <i>Measurement of gastrointestinal pH profiles in normal ambulant human subjects</i> , 29 GUT 1035–41 (1988) (“Evans”)
2016	Perrie, Y. & Rades, T., PHARMACEUTICAL: DRUG DELIVERY AND TARGETING (2010) (“FASTtrack”)
2017	Gaubert, G., et al., <i>Unnatural Enantiomers of 5-azacytidine Analogues: Syntheses and Enzymatic Properties</i> , 20(4–7) NUCLEOSIDES, NUCLEOTIDES & NUCLEIC ACIDS 837–40 (2001) (“Gaubert”)
2018	Kaminskas, E., et al., <i>FDA Drug Approval Summary: Azacitidine (5-azacytidine, Vidaza™) for Injectable Suspension</i> , 10 THE ONCOLOGIST 176–82 (2005) (“Kaminskas”)
2019	Kissinger, L. & Stemm, N., <i>Determination of the Antileukemia Agents Cytarabine and Azacitidine and Their Respective Degradation Products by High-Performance Liquid Chromatography</i> , 353 J. OF CHROMATOGRAPHY 309–18 (1986) (“Kissinger”)
2020	LIEBERMAN, H., ET AL., PHARMACEUTICAL DOSAGE FORMS: TABLETS 3 (2nd Ed. 1990) (“Lieberman”)
2021	Lin, K., et al., <i>High -Performance Liquid Chromatographic Analysis of Chemical Stability of 5-Aza-2'-deoxycytidine</i> , 70 J. OF PHARMACEUTICAL SCI. 1228–32 (1981) (“Lin”)

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2022	Mund, C., <i>Reactivation of Epigenetically Silenced Genes by DNA Methyltransferase Inhibitors: Basic Concepts and Clinical Applications</i> , 1 EPIGENETICS 7–13 (2006) (“Mund”)
2023	National Cancer Institute, <i>Bioassay of 5-azacytidine for Possible Carcinogenicity</i> , U.S. DEP’T OF HEALTH, EDUC., AND WELFARE (1978) (“National Cancer Institute”)
2024	Notari, R. & De Young, J., <i>Kinetics and Mechanisms of Degradation of the Antileukemic Agent 5-Azacytidine in Aqueous Solutions</i> , 64 J. OF PHARMACEUTICAL SCI. 1148–57 (1975) (“Notari”)
2025	Onureg [®] Label
2026	International Pat. Appl. Pub. No. WO2009/139888 (“WO2009/139888”)
2027	Piřhová, P., et al., <i>Nucleic Acids Components and Their Analogues. LXVI. * Hydrolysis of 5-Azacytidine and its Connection with Biological Activity</i> , 30 COLLECT. CZECH. CHEM. COMMUN. 2801–11 (1965) (“Piřhová”)
2028	REMINGTON, THE SCIENCE AND PRACTICE OF PHARMACY 802–938 (21st Ed. 2005) (“Remington 2005”)
2029	Stresemann, C. & Lyko, F., <i>Modes of action of the DNA methyltransferase inhibitors azacytidine and decitabine</i> , 123 INT. J. CANCER 8–13 (2008) (“Stresemann”)
2030	U.S. Pat. Pub. No. US20040186065A1 (“Ionescu-065”)
2031	Weiss, A., et al., <i>Phase I Study of 5-Azacytidine</i> 56 CANCER CHEMOTHERAPY REP. 413–19 (1972) (“Weiss”)
2032	<i>Celgene v. Accord</i> 1:21-cv-01795-RGA Doc 40
2033	U.S. Pat. No. 7,189,740 (“Zeldis”)

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2034	Glover, A., et al., <i>Azacitidine: 10 Years Later</i> , 71 CANCER TREATMENT REP. 737–46 (1987) (“Glover”)
2035	U.S. Pat. No. 6,887,855 (“Ionescu-855”)
2036	U.S. Pat. No. 7,078,518 (“Ionescu-518”)
2037	U.S. Pat. No. 7,772,199 (“Ionescu-199”)
2038	U.S. Pat. Pub. No. US20060247189 (“Ionescu-189”)
2039	U.S. Pat. Pub. No. US20100298253 (“Ionescu-253”)
2040	Ward, M., et al., <i>An oral dosage formulation of azacytidine: A pilot pharmacokinetic study</i> , J. OF CLINICAL ONCOLOGY (2007) (“Ward”)
2041	International Pat. Appl. Pub. No. WO2008/028193 (“WO2008/028193”)
2042	Gibson, M., Pharm. PREFORMULATION AND FORMULATION: A PRACTICAL GUIDE FROM CANDIDATE DRUG SELECTION TO COMMERCIAL DOSAGE FORM 1-11 (2001) (“Gibson Supplemental”)
2043	LIEBERMAN, H., ET AL., PHARMACEUTICAL DOSAGE FORMS 2 (2nd Ed. 1990) (“Lieberman Vol. 2”)
2044	International Pat. Appl. Pub. No. WO2004/082618 (“WO2004/082618”)
2045	<i>Celgene v. Accord</i> 1:21-cv-01795-RGA Doc 35
2046	<i>Reserved</i>
2047	Savage, D., et al., <i>The Gastrointestinal Epithelium and its Autochthonous Bacterial Flora</i> , 127 J. OF EXPERIMENTAL MEDICINE 67–81 (1967) (“Savage”)
2048	Pawar, et al., <i>Integration of Biorelevant Pediatric Dissolution Methodology into PBPK Modeling to Predict In Vivo Performance</i>

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	<i>and Bioequivalence of Generic Drugs in Pediatric Populations: A Carbamazepine Case Study</i> , 25 AAPS J. 67 (2023) (“Pawar”)
2049	Deposition Transcript of Hannah K. Batchelor (“Batchelor Tr.”)
2050	Deposition Transcript of Graham Buckton, Ph.D. (“Buckton Tr.”)
2051	Declaration of Corey Berkland, Ph.D. (“Berkland Decl.”)
2052	Declaration of George M. Grass, Ph.D. (“Grass Decl.”)
2053	Declaration of William G. Blum, M.D. (“Blum Decl.”)
2054	Declaration of Jeffrey B. Etter, Ph.D. (“Etter Decl.”)
2055	U.S. Food and Drug Admin., <i>FDA approves Onureg[®] (azacitidine tablets) for acute myeloid leukemia</i> (2020), https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-onureg-azacitidine-tablets-acute-myeloid-leukemia (“FDA Approves Onureg [®] ”)
2056	Canadian Product 200mg Onureg [®] Product Information
2057	Canadian Product 300mg Onureg [®] Product Information
2058	Canadian Product Monograph Onureg [®]
2059	European Commission Decision 17.6.21
2060	Perrie, Y. & Rades, T., PHARMACEUTICAL: DRUG DELIVERY AND TARGETING (2010) (“FASTtrack”)
2061	<i>Reserved</i>
2062	Onureg [®] Label

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2063	Gibson, M., Pharm. PREFORMULATION AND FORMULATION: A PRACTICAL GUIDE FROM CANDIDATE DRUG SELECTION TO COMMERCIAL DOSAGE FORM 1-11 (2001) (“Gibson Supplemental”)
2064	ALTMAN, R, & SARG, M., CANCER DICTIONARY: REVISED EDITION 16–17, 197 (2000) (“Altman”)
2065	ALLEN, L, ET AL., ANSEL’S PHARM. DOSAGE FORMS AND DRUG DELIVERY SYS. (8th Ed. 2005) (“Ansel”)
2066	Antonsson, B., et al., <i>Effect of 5-Azacytidine and Congeners on DNA Methylation and Expression of Deoxycytidine Kinase in the Human Lymphoid Cell Lines CCRF/CEM/0 and CCRF/CEM/dCk¹</i> , 47 CANCER RESEARCH 3762–78 (1987) (“Antonsson”)
2067	AULTON, M., PHARMACEUTICS: THE SCIENCE OF DOSAGE FORM DESIGN (1988) (“Aulton”)
2068	Bankhead, C., <i>Year in Review: Acute Myeloid Leukemia</i> , MedPage Today (Nov. 29, 2020), https://www.medpagetoday.com/hematologyoncology/leukemia/89909 (“Bankhead”)
2069	<i>Reserved</i>
2070	Ben-Kasus, T., et al., <i>Metabolic activation of zebularine, a novel DNA methylation inhibitor, in human bladder carcinoma cells</i> , 70 BIOCHEM. PHARM. 121–33 (2005) (“Ben-Kasus”)
2071	Carter, J., et al., <i>Targeting multiple signaling pathways: the new approach to acute myeloid leukemia therapy</i> , 5 SIGNAL TRANSDUCTION AND TARGETED THERAPY 288 (2020) (“Carter”)
2072	Choi, Y., et al., <i>Oral Maintenance Chemotherapy with 6-Mercaptopurine and Methotrexate in Patients with Acute Myeloid Leukemia Ineligible for Transplantation</i> , 30 KOREAN ACADEMY OF MED. SCI. 1416–22 (2015) (“Choi”)

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2073	Cogle, C., et al., <i>Oral Azacitidine (CC-486) for the Treatment of Myelodysplastic Syndromes and Acute Myeloid Leukemia</i> , 20 ONCOLOGIST 1404–12 (2015) (“Cogle”)
2074	Covey, J., et al., <i>Differences in DNA Damage Produced by Incorporation of 5-Aza-2'-deoxycytidine or 5,6-Dihydro-5-azacytidine into DNA of Mammalian Cells</i> , 46 CANCER RESEARCH 5511–17 (1986) (“Covey”)
2075	CRAIG, C. & STITZEL, R., MODERN PHARMACOLOGY WITH CLINICAL APP. (6th Ed. 2004) 48–55 (“Craig”)
2076	Curtiss, F., <i>Pharmacy Benefit Spending on Oral Chemotherapy Drugs</i> , 12 J. OF MANAGED CARE PHARMACY 570–77 (2006) (“Curtiss”)
2077	DeSimone, J., et al., <i>Tetrahydrouridine, Cytidine, Analogues, and Hemoglobin F</i> , 18 AM. J. OF HEMATOLOGY 283–88 (1985) (“DeSimone”)
2078	Dressman, J., et al., <i>Dissolution Testing as a Prognostic Tool for Oral Drug Absorption: Immediate Release Dosage Forms</i> , 15 PHARM. RESEARCH 11–22 (1998) (“Dressman”)
2079	Case Reports, 72 BRITISH J. OF HAEMATOLOGY 467–68 (1989) (“Dunbar”)
2080	Ellison, R., et al., <i>Arabinosyl Cytosine: A Useful Agent in the Treatment of Acute Leukemia in Adults</i> , 32 J. OF HEMATOLOGY 507–23 (1968) (“Ellisson”)
2081	The ASCO Post Staff, “FDA Approves Oral Azacitidine as Maintenance Therapy for Adults With AML in First Remission” (Sept. 25, 2020), https://ascopost.com/issues/september-25-2020/fda-approves-oral-azacitidine-as-maintenance-therapy-for-adults-with-aml-in-first-remission/ (“FDA Approves Oral Azacitidine”)

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2082	Frisch, A., et al., <i>How we treat older patients with acute myeloid leukaemia</i> , 191 BRITISH J. OF HAEMATOLOGY 682–91 (2020) (“Frisch”)
2083	Futtermann, B., et al., <i>Studies on the Cytostatic Action Phosphorylation and Deamination of 5-Azacytidine and 5,6-Dihydro-5-Azacytidine in Hela Cells</i> , 27 BIOCHEM. PHARM. 907–9 (1978) (“Futtermann”)
2084	Garcia-Manero, G., et al., <i>Phase I Study of Oral Azacitidine in Myelodysplastic Syndromes, Chronic Myelomonocytic Leukemia, and Acute Myeloid Leukemia</i> , 29 J. OF CLIN. ONCOLOGY 2521–27 (2011) (“Garcia-Manero”)
2085	Goldin, A., et al., <i>Relation of Structure of Purine and Pyrimidine Nucleosides to Antitumor Activity</i> , 1 CANCER CHEMOTHERAPY 1–29, 268 (1968) (“Goldin”)
2086	Griffiths, E., <i>Oral hypomethylating agents: beyond convenience in MDS</i> , 2021 HEMATOLOGY 439–47 (2021) (“Griffiths”)
2087	Grønbaek, K., et al., <i>Epigenetic Changes in Cancer as Potential Targets for Prophylaxis and Maintenance Therapy</i> , 103 BASIC & CLINICAL PHARM. & TOXICOLOGY 389–96 (2008) (“Grønbaek”)
2088	Hrodek, O. & Vesely J., <i>5-Azacytidine in Childhood Leukemia</i> , 18 NEOPLASMA 493–503 (1971) (“Hrodek”)
2089	Kantarjian, H., et al., <i>Acute Myeloid Leukemia: Historical Perspective and Progress in Research and Therapy Over 5 Decades</i> , 21 CLIN. LYMPHOMA, MYELOMA AND LEUKEMIA 580–97 (2021) (“Kantarjian”)
2090	Karon, M., et al., <i>5-Azacytidine: A New Active Agent for the Treatment of Acute Leukemia</i> , 42 BLOOD 359–65 (1973) (“Karon”)
2091	Kipp, D. & Wei, A., <i>The path to approval for oral hypomethylating agents in acute myeloid leukemia and myelodysplastic syndromes</i> , 17(20) FUTURE ONCOL. 2563–71 (2021) (“Kipp”)

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2092	Kornblith, A., et al., <i>Impact of Azacytidine on the Quality of Life of Patients With Myelodysplastic Syndrome Treated in a Randomized Phase III Trial: A Cancer and Leukemia Group B Study</i> , 20 J. OF CLIN. ONCOLOGY 2441–52 (2002) (“Kornblith”)
2093	Lammers, P. & Cashen, A., <i>Azacitidine: A Review of its Use in the Management of Myelodysplastic Syndromes</i> , 1 CLIN. MED. THERAPEUTICS 1189–97 (2009) (“Lammers”)
2094	Lin, R., <i>Allogeneic Transplantation for Older Patients with Acute Myeloid Leukemia: The Dawn of a New Era</i> , 28 TRANSPLANTATION AND CELLULAR THERAPY 793–94 (2022) (“Lin 2022”)
2095	Liu, H., <i>Emerging agents and regimens for AML</i> , 14 J. HEMATOLOGY & ONCOLOGY 19 (2021) (“Liu”)
2096	Lomen, V., et al., “Phase I Study of 5-Azacytidine Using 24 Hrs Continuous Infusion for 5 Days” 16 PROCEEDINGS OF THE AM. ASS. FOR CANCER RESEARCH & AM. SOC. OF CLIN. ONCOLOGY 52 (Mar. 1975) (“Lomen”)
2097	Löwenberg, B., et al., <i>Mitoxantrone Versus Daunorubicin in Induction-Consolidation Chemotherapy</i> , 16 J. OF CLIN. ONCOLOGY 872–81 (1998) (“Löwenberg”)
2098	Ma, X., et al., <i>Myelodysplastic Syndromes: Incidence and Survival in the United States</i> , 109 AM. CANCER SOC. 1536–42 (2007) (“Ma”)
2099	<i>Reserved</i>
2100	McCredie, K., <i>Treatment of Acute Leukemia with 5-Azacytidine (NSC-102816)</i> , 57 CANCER CHEMOTHERAPY REP. 319–23 (1973) (“McCredie”)
2101	Neil, G., et al., <i>Enhancement by Tetrahydrouridine (NSC-112907) of the Oral Activity of 5-Azacytidine (NSC-102816) in L1210 Leukemic Mice</i> , 59 CANCER CHEMOTHERAPY REP. 459–65 (1975) (“Neil”)

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2102	Odenike, O., <i>Incorporating novel approaches in the management of MDS beyond conventional hypomethylating agents</i> , AM. SOC. OF HEMATOLOGY 460–69 (2017) (“Odenike”)
2103	Goodman, A., “Oral CC-486 Maintenance Therapy Extends Survival in Older Patients with AML” THE ASCO POST (Jan. 25, 2020), https://ascopost.com/issues/january-25-2020/oral-cc-486-maintenance-therapy-extends-survival-in-older-patients-with-aml/ (“Oral CC-486”)
2104	Perl, A., <i>The role of targeted therapy in the management of patients with AML</i> , 1 BLOOD ADVANCES AND HEMATOLOGY 2281–94 (2017) (“Perl”)
2105	<i>Reserved</i>
2106	<i>Reserved</i>
2107	PORTA, M., A DICTIONARY OF EPIDEMIOLOGY 226–27 (5th Ed. 2008) (“Porta”)
2108	Preisler, H., et al., <i>Comparison of Three Remission Induction Regimens and Two Postinduction Strategies for the Treatment of Acute Nonlymphocytic Leukemia</i> , 69 BLOOD 1441–49 (1987) (“Preisler”)
2109	<i>Reserved</i>
2110	Récher, C., <i>The beginning of a new therapeutic era in acute myeloid leukemia</i> , 2 J. HAEMATOLOGY 823–33(2021) (“Récher”)
2111	Reville, P., <i>Maintenance Therapy in AML</i> , 10 FRONTIERS IN ONCOLOGY (2021) (“Reville”)
2112	Shnider, B., et al., <i>A Phase I Study of 5-Azacytidine (NSC-102816)</i> , 16(4) J. OF CLIN. PHARMACOLOGY 205–12 (1976) (“Shnider”)
2113	<i>Reserved</i>

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2114	Slater, H., <i>Phase 3 QUAZAR AML-001 Trial Finds Oral Azacitidine Extends Survival in Older Adults with AML</i> , Cancer Network (Jan. 12, 2021) (“Slater”)
2115	Sochacka-Ćwikła, A., et al., <i>FDA-Approved Drugs for Hematological Malignancies—The Last Decade Review</i> , 14 Cancers 87 (2022) (“Sochacka-Ćwikła”)
2116	Sorm, F., et al., <i>5-Azacitidine, a New, Highly Effective Cancerostatic</i> , 20 INSTITUTE OF ORGANIC CHEM. AND BIOCHEM. 202–3 (1964) (“Sorm”)
2117	<i>Reserved</i>
2118	Sorrentino, V., et al., <i>Hypomethylating Chemotherapeutic Agents as Therapy for Myelodysplastic Syndromes and Prevention of Acute Myeloid Leukemia</i> , 14 PHARMACEUTICALS 641 (2021) (“Sorrentino”)
2119	Southall, J., “Oral azacytidine extends survival for patients with AML in remission after chemotherapy” HemOncToday (Jan. 5, 2021) (“Southall”)
2120	Steensma, D., <i>ASH 2010 Meeting Report—Top 10 clinically-oriented abstracts in myelodysplastic syndromes (MDS)</i> , 86 AM. J. OF HEMATOLOGY 385–91 (2011) (“Steensma”)
2121	Surbone, A., et al., <i>Phase I and Pharmacokinetic Study of Arabinofuranosyl-5-azacytosine (Fazarabine, NSC 281272)</i> , 50 CANCER RESEARCH 1220–25 (1990) (“Surbone”)
2122	Toutain, P. & Bousquet-Melou, A., <i>Bioavailability and its assessment</i> , 27 J. VET. PHARMACOLOGY. THERAP. 455–66 (2004) (“Toutain”)
2123	U.S. Provisional 60/824320 File History (“60/824,320”)
2124	U.S. Patent Application US 2008/0057086 (“US2008/0057086”)

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2125	Vigil, C., et al., <i>Safety and efficacy of azacitidine in myelodysplastic syndromes</i> , 4 DRUG DESIGN, DEVELOPMENT AND THERAPY 221–29 (2010) (“Vigil”)
2126	Vogler, W., et al., “Remission Induction in Refractory Myeloblastic Leukemia with Continuous Infusion of 5-Azacitidine” 16 PROCEEDINGS OF THE AM. ASS. FOR CANCER RESEARCH & AM. SOC. OF CLIN. ONCOLOGY 155 (Mar. 1975) (“VoglerI”)
2127	Vogler, W., <i>5-Azacitidine (NSC 102816): A New Drug for the Treatment of Myeloblastic Leukemia</i> , 48 BLOOD 331–37 (1976) (“VoglerII”)
2128	Von Hoff, D., et al., <i>5-Azacitidine A New Anticancer Drug with Effectiveness in Acute Myelogenous Leukemia</i> , 85 ANNALS OF INTERNAL MEDICINE 237–45 (1976) (“VonHoff”)
2129	Wei, A., et al., <i>Long-term survival with oral azacitidine for patients with acute myeloid leukemia in first remission after chemotherapy</i> , 98 AM. J. OF HEMATOLOGY E84–87 (2023) (“Wei”)
2130	Weill Cornell Medicine, “New maintenance treatment for acute myeloid leukemia prolongs the lives of patients” NEW ENGLAND J. OF MED. (Jan. 22, 2021), https://news.weill.cornell.edu/news/2021/01/new-maintenance-treatment-for-acute-myeloid-leukemia-prolongs-the-lives-of-patients , (“Weill Cornell”)
2131	Zielinski, W. & Sprinzl, M., <i>Chemical synthesis of 5-azacytidine nucleotides and preparation of tRNAs containing 5-azacytidine in its 3'-terminus</i> , 12 NUCLEIC ACIDS RESEARCH 5025–36 (1984) (“Zielinski”)
2132	Ziemba, A., et al., <i>Development of an Oral Form of Azacytidine: 2'3'5Triacetyl-5-Azacytidine</i> , 2011 CHEMOTHERAPY RESEARCH AND PRACTICE 1–9 (2011) (“Ziemba”)
2133	Exemestane Label (“Exemestane”)

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2134	Anastrozole Label (“Anastrozole”)
2135	Letrozole Label (“Letrozole”)
2136	Blum W, et al., <i>Maintenance therapy with decitabine in younger adults with acute myeloid leukemia in first remission: a phase 2 Cancer and Leukemia Group B Study (CALGB 10503)</i> , 31 LEUKEMIA 34–39 (2017) (“Blum”)
2137	Cytarabine Label (“Cytarabine”)
2138	Dacogen Label (“Dacogen”)
2139	Mitoxantrone Label (“Mitoxantrone”)
2140	Finkel, M., <i>The Orphan Drug Act and the Federal Government's Orphan Products Development Program</i> , 99 PUBLIC HEALTH REPS. 313–16 (1984) (“Finkel”)
2141	Martinez, M. & Amidon, G., <i>A Mechanistic Approach to Understanding the Factors Affecting Drug Absorption</i> , 42 J. OF CLIN. PHARMACOLOGY 620–43 (2002) (“Martinez”)
2142	European Medicines Agency, Assessment Report of Onureg EMA/308711/2021 (“European Medicines Report”)
2143	Hirayama, H., et al., <i>Distribution and Excretion of Cyclocytidine in Monkeys, Dogs, and Rats</i> , 65 GANN 153–61 (1974) (“Hirayama”)
2144	LIEBERMAN, H., ET AL., PHARMACEUTICAL DOSAGE FORMS: TABLETS 1 (2nd Ed. 1989) (“Lieberman Vol. 1”)
2145	DEAN, D., ET AL., PHARMACEUTICAL PACKAGING TECHNOLOGY (2000) (“Dean”)
2146	GENNARO, A., REMINGTON'S PHARMACEUTICAL SCIENCES 257–309, 1519–44, 1615–32 (18th Ed. 1990) (“Remington 1990”)

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2147	REMINGTON, THE SCIENCE AND PRACTICE OF PHARMACY 319–37, 702–19, 745–75, 1025–36 (21st Ed. 2005) (“Remington 2005 II”)
2148	GIBALDI, M. & PERRIER, D., PHARMACOKINETICS (2nd Ed. 2007) 271–353 (“Gilbaldi”)
2149	First Expert Declaration of James L. Mullins, Ph.D.
2150	Huls, G., et al. <i>Azacitidine maintenance after intensive chemotherapy improves DFS in older AML patients</i> , 133 BLOOD, THE JOURNAL OF THE AMERICAN SOCIETY OF HEMATOLOGY 1457–64 (2019) (“Huls”)
2151	Second Expert Declaration of James L. Mullins, Ph.D.
2152	Declaration of Andrew J. Danford in Support of Unopposed Motion for Admission <i>Pro Hac Vice</i>
2153	Declaration of Nora Q.E. Passamaneck in Support of Unopposed Motion for Admission <i>Pro Hac Vice</i>
2154	Declaration of Amy K. Wigmore in Support of Unopposed Motion for Admission <i>Pro Hac Vice</i>

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CERTIFICATE OF SERVICE

I hereby certify that on November 2, 2023, true and correct copies of the following materials:

- Patent Owner's Unopposed Motion for Admission *Pro Hac Vice* of Amy K. Wigmore
- Exhibit 2154, Declaration of Amy K. Wigmore in Support of Unopposed Motion for *Pro Hac Vice* Admission
- Patent Owner's Exhibit List

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