**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| CELGENE CORPORATION, CELGENE INTERNATIONAL SÀRL, AND BRISTOL-MYERS SQUIBB COMPANY,<br><br>Plaintiffs,<br><br>v.<br><br>TEVA PHARMACEUTICALS, INC.,<br><br>Defendant. | Civil Action No. _____ |

**COMPLAINT**

Plaintiffs Celgene Corporation, Celgene International Sàrl, and Bristol-Myers Squibb Company (collectively "Plaintiffs"), by their attorneys, hereby allege as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Teva Pharmaceuticals, Inc. ("Teva"). This action relates to Abbreviated New Drug Application ("ANDA") No. 218751 filed by Teva with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 218751, Teva seeks approval to market 200 mg and 300 mg tablets of azacitidine (the "Teva ANDA Product") prior to the expiration of U.S. Patent Nos. 8,846,628 (the "'628 patent") and 11,571,436 (the "'436 patent") (collectively the "Patents-in-Suit"). The Teva ANDA Product is a generic version of Plaintiffs' Onureg® drug product.

## PARTIES

3. Celgene Corporation is a corporation organized and existing under the laws of Delaware, having a place of business at 86 Morris Avenue, Summit, New Jersey 07901.

4. Celgene International Sàrl is a société à responsabilité limitée organized and existing under the laws of Switzerland, having a place of business at Route de Perreux 1, Boudry CH-2017, Switzerland.

5. Bristol-Myers Squibb Company is a corporation organized and existing under the laws of Delaware, having a place of business at Route 206 and Province Line Road, Princeton, New Jersey 08540.

6. Plaintiffs are engaged in the business of creating, developing, and bringing to market pharmaceutical products to help patients prevail against serious diseases, including treatments for cancer. Plaintiffs sell Onureg® in this judicial district and throughout the United States.

7. Upon information and belief, Teva is a corporation organized and existing under the laws of Delaware, having its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

## JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Venue is proper in this Court as to Teva under 28 U.S.C. § 1400(b).

10. This Court has personal jurisdiction over Teva because, among other things, upon information and belief, Teva is organized and exists under the law of the State of Delaware.

11. This Court also has personal jurisdiction over Teva because, among other things, Teva has engaged in systematic and continuous contacts with Delaware. Upon information and belief, Teva currently manufactures and distributes drug products throughout the United States, including Delaware. Upon information and belief, following approval of ANDA No. 218751, Teva will make, use, import, sell, and/or offer for sale the Teva ANDA Products in the United States, including in Delaware, prior to the expiration of the Patents-in-Suit.

## PATENTS-IN-SUIT

### The '628 Patent

12. On September 30, 2014, the U.S. Patent and Trademark Office duly and legally issued the '628 patent, titled "Oral Formulations of Cytidine Analogs and Methods of Use Thereof." A true and correct copy of the '628 patent is attached hereto as Exhibit A.

13. The claims of the '628 patent are valid, enforceable, and not expired.

14. Celgene Corporation is the owner of the '628 patent. Celgene International Sàrl is the exclusive licensee of the '628 patent. Plaintiffs have the right to enforce the '628 patent.

### The '436 Patent

15. On February 7, 2023, the U.S. Patent and Trademark Office duly and legally issued the '436 patent, titled "Oral Formulations of Cytidine Analogs and Methods of Use Thereof." A true and correct copy of the '436 patent is attached hereto as Exhibit B.

16. The claims of the '436 patent are valid, enforceable, and not expired.

17. Celgene Corporation is the owner of the '436 patent. Celgene International Sàrl is the exclusive licensee of the '436 patent. Plaintiffs have the right to enforce the '436 patent.

## PLAINTIFFS' ONUREG® PRODUCT

18. Bristol-Myers Squibb Company is the current holder of New Drug Application ("NDA") No. 214120, by which the FDA granted approval for the marketing and sale of 200 mg

and 300 mg strength azacitidine tablets. Plaintiffs market azacitidine tablets in the United States under the trade name "Onureg®."

19. Onureg® is a nucleoside metabolic inhibitor indicated for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission ("CR") or complete remission with incomplete blood count recovery ("CRi") following intensive induction chemotherapy and are not able to complete intensive curative therapy. A copy of the complete prescribing information for Onureg® is attached as Exhibit C ("Onrueg® Label").

20. The FDA's Orange Book lists the Patents-in-Suit as covering Onureg® and its use.

**INFRINGEMENT BY TEVA**

21. By letter dated August 8, 2023, Teva notified Plaintiffs that Teva had submitted ANDA No. 218751 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) (the "Notice Letter"). Plaintiffs received the Notice Letter no earlier than August 11, 2023.

22. The Notice Letter states that Teva seeks approval from the FDA to engage in the commercial manufacture, use, sale, offer to sell, and/or importation in the United States of the Teva ANDA Product before the expiration of the Patents-in-Suit. Upon information and belief, Teva intends to, directly or indirectly, engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product promptly upon receiving FDA approval.

23. By filing ANDA No. 218751, Teva has necessarily represented to the FDA that the Teva ANDA Product has the same active ingredient as Onureg®, has the same dosage form, route of administration, and strength as Onureg®, and is bioequivalent to Onureg®.

24. Upon information and belief, Teva is seeking approval to market the Teva ANDA Product for the same approved indications as Onureg®.

25. In the Notice Letter, Teva states that its ANDA contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the claims of the Patents-in-Suit are invalid under 35 U.S.C. § 103. The Notice Letter does not contest that claims 1-2, 6-8, 11-24, 28, 32-35, and 38-43 of the '628 patent and all claims of the '432 patent will be infringed by the commercial manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product to the extent that those claims are valid.

26. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Notice Letter.

**COUNT I**
**(INFRINGEMENT OF THE '628 PATENT)**

27. Plaintiffs incorporate each of the above paragraphs 1 to 26 as though fully set forth herein.

28. Upon information and belief, Teva's submission of ANDA No. 218751 to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product for use in accordance with its proposed label indications prior to the expiration of the '628 patent infringed one or more claims of the '628 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(e)(2)(A). The infringed claims of the '628 patent include at least claims 1-9, 11, 13-26, 28-36, 38, and 40-43. In the Notice Letter, Teva has not contested the infringement of claims 1-2, 6-8, 11-24, 28, 32-35, and 38-43 of the '628 patent to the extent that the patent's claims are valid.

29. Upon information and belief, Teva's commercial manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product for use in accordance with its proposed label indications prior to the expiration of the '628 patent, and/or its inducement or contribution to such conduct, would further infringe one or more claims of the '628 patent, either literally or under the

doctrine of equivalents, under at least 35 U.S.C. §§ 271(a), (b), and/or (c). Those activities would infringe, induce the infringement of, and/or contribute to the infringement of at least claims 1-9, 11, 13-26, 28-36, 38, and 40-43 of the '628 patent.

30. Upon information and belief, upon FDA approval of Teva's ANDA No. 218751, Teva will infringe, either literally or under the doctrine of equivalents, one or more claims of the '628 patent, by making, using, offering to sell, selling, and/or importing the Teva ANDA Product for use in accordance with its proposed label indications, or by actively inducing and contributing to infringement of the '628 patent by others, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless enjoined by the Court. Unless enjoined, those activities would infringe, induce the infringement of, and/or contribute to the infringement of at least claims 1-9, 11, 13-26, 28-36, 38, and 40-43 of the '628 patent.

31. Upon information and belief, the Teva ANDA Product or its use in accordance with its proposed label indications satisfies each and every element of at least claims 1-9, 11, 13-26, 28-36, 38, and 40-43 of the '628 patent.

32. For example, claim 1 of the '628 patent is representative for purposes of Teva's infringement of the patent's composition claims and recites:

> A pharmaceutical composition for oral administration comprising a therapeutically effective amount of 5-azacytidine and at least one pharmaceutically acceptable excipient, wherein the composition is a non-enteric coated tablet.

33. Upon information and belief, the Teva ANDA Product is a pharmaceutical composition for oral administration comprising a therapeutically effective amount of 5-azacytidine and at least one pharmaceutically acceptable excipient, wherein the composition is a non-enteric coated tablet.

34. For example, the Notice Letter states that "the active ingredient of the proposed drug product is Azacitidine; the strength of the proposed drug product is Azacitidine 200mg, and Azacitidine 300 mg," and that "[t]he dosage form of the proposed product is co-packaged tablets for oral use." Notice Letter at 2. "Azacitidine" is another name for "5-azacytidine," and those terms are used interchangeably, as the '628 patent explains. *See, e.g.*, '628 patent, 2:33-35 ("5-[a]zacytidine (National Service Center designation NSC-102816; CAS Registry Number 320-67-2) [is] also known as azacitidine"). The 200 mg and 300 mg dosage strength tablets of Teva's ANDA product include a therapeutically effective amount of 5-azacytidine.

35. Upon information and belief, the Teva ANDA Product is for oral administration, contains at least one pharmaceutically acceptable excipient, and is a non-enteric coated tablet. Onureg® is for oral administration, contains at least one pharmaceutically acceptable excipient, and is a non-enteric coated tablet. Teva asserts that the Teva ANDA Product is bioequivalent to Onureg®, which means that it has the same route of administration (i.e., oral administration) and dosage form (i.e., a non-enteric coated tablet containing at least one pharmaceutically acceptable excipient) as Onureg®.

36. The Notice Letter does not dispute that the commercial manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product would infringe claim 1 of the '628 patent.

37. Claim 28 of the '628 patent is representative for purposes of Teva's infringement of the patent's method of treatment claims and recites:

> A method for treating one or more symptoms of a disease associated with abnormal cell proliferation, comprising orally administering to a subject in need thereof a pharmaceutical composition comprising a therapeutically effective amount of 5-azacytidine and at least one pharmaceutically acceptable excipient, wherein the composition is a non-enteric coated tablet, and wherein the disease associated with abnormal cell proliferation is myelodysplastic syndrome or acute myelogenous leukemia.

38. Upon information and belief, Teva is seeking FDA approval for the Teva ANDA Product for use in a method for treating one or more symptoms of a disease associated with abnormal cell proliferation, comprising orally administering to a subject in need thereof a pharmaceutical composition comprising a therapeutically effective amount of 5-azacytidine and at least one pharmaceutically acceptable excipient, wherein the composition is a non-enteric coated tablet, and wherein the disease associated with abnormal cell proliferation is myelodysplastic syndrome or acute myelogenous leukemia.

39. The Teva ANDA Product is a pharmaceutical composition comprising a therapeutically effective amount of 5-azacytidine and at least one pharmaceutically acceptable excipient, wherein the composition is a non-enteric coated tablet orally administered to a subject in need thereof for all of the reasons described in paragraphs 33-35 above.

40. Onureg® is FDA approved "for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy." Onureg® Label at 1, 2. Acute myeloid leukemia is associated with abnormal cell proliferation and is also referred to as acute myelogenous leukemia. Currently, the only FDA approved indication for Onureg® is for uses covered by the method of treatment claims of the '628 patent, including claim 28. Upon information and belief, Teva is seeking FDA approval to market the Teva ANDA Product for uses covered by the method of treatment claims of the '628 patent, including claim 28.

41. The Notice Letter does not dispute that the commercial manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product would infringe, induce infringement of, or contribute to the infringement of claim 28 of the '628 patent.

42. Upon information and belief, Teva, upon FDA approval, would promote the use of the Teva ANDA Product to infringe one or more claims of the '628 patent, including by encouraging the use of the Teva ANDA Product in accordance with its proposed label indications.

43. Upon information and belief, Teva has knowledge of the '628 patent. For example, the '628 patent is listed in the FDA's Orange Book under the entry for Onureg®. Teva cites both the '628 patent and the Orange Book listing in the Notice Letter. Notice Letter at 1-2.

44. Upon information and belief, Teva is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or medical practitioners will prescribe and/or administer the Teva ANDA Product in accordance with its proposed label indications and therefore will directly infringe one or more claims of the '628 patent.

45. The Teva ANDA Product constitutes a material part of the invention claimed in the '628 patent, is especially adapted for use in infringing the claims of the '628 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Currently, the only FDA approved use of oral azacitidine is for uses covered by the methods claimed in the '628 patent. *See* Onureg® Label at 1, 2.

**COUNT II**
**(INFRINGEMENT OF THE '436 PATENT)**

46. Plaintiffs incorporate each of the above paragraphs 1 to 45 as though fully set forth herein.

47. Upon information and belief, Teva's submission of ANDA No. 218751 to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product for use in accordance with its proposed label indications prior to the expiration of the '436 patent infringed one or more claims of the '436 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(e)(2)(A). The infringed claims of the

'436 patent include claims 1-22. In the Notice Letter, Teva has not contested the infringement of any claim of the '436 patent to the extent that the patent's claims are valid.

48. Upon information and belief, Teva's commercial manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product for use in accordance with its proposed label indications prior to the expiration of the '436 patent, and/or its inducement or contribution to such conduct, would further infringe one or more claims of the '436 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. §§ 271(a), (b), and/or (c). Those activities would infringe, induce the infringement of, and/or contribute to the infringement of claims 1-22 of the '436 patent.

49. Upon information and belief, upon FDA approval of Teva's ANDA No. 218751, Teva will infringe, either literally or under the doctrine of equivalents, one or more claims of the '436 patent, by making, using, offering to sell, selling, and/or importing the Teva ANDA Product for use in accordance with its proposed label indications, or by actively inducing and contributing to infringement of the '436 patent by others, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless enjoined by the Court. Unless enjoined, those activities would infringe, induce the infringement of, and/or contribute to the infringement of claims 1-22 of the '436 patent.

50. Upon information and belief, the Teva ANDA Product or its use in accordance with its proposed label indications satisfies each and every element of claims 1-22 of the '436 patent.

51. For example, claim 1 of the '436 patent, the only independent claim, is representative for purposes of Teva's infringement and recites:

> A pharmaceutical composition for oral administration comprising 180 mg to 360 mg of 5-azacytidine and at least one pharmaceutically acceptable excipient, wherein the composition is a non-enteric coated tablet, and wherein a therapeutically effective amount of 5-azacytidine is not absorbed through oral mucosa upon administration to a human subject.

52. Upon information and belief, the Teva ANDA Product is a pharmaceutical composition for oral administration comprising 180 mg to 360 mg of 5-azacytidine and at least one pharmaceutically acceptable excipient, wherein the composition is a non-enteric coated tablet, and wherein a therapeutically effective amount of 5-azacytidine is not absorbed through oral mucosa upon administration to a human subject.

53. For example, the Notice Letter states that "the active ingredient of the proposed drug product is Azacitidine; the strength of the proposed drug product is Azacitidine 200mg, and Azacitidine 300 mg," and that "[t]he dosage form of the proposed product is co-packaged tablets for oral use." Notice Letter at 2. "Azacitidine" is another name for "5-azacytidine," and those terms are used interchangeably, as the '436 patent explains. *See, e.g.*, '436 patent, 2:52-57 ("5-[a]zacytidine (National Service Center designation NSC-102816; CAS Registry Number 320-67-2) [is] also known as azacitidine"). The 200 mg and 300 mg dosage strength tablets of Teva's ANDA product include a therapeutically effective amount of 5-azacytidine.

54. Upon information and belief, the Teva ANDA Product is for oral administration, contains at least one pharmaceutically acceptable excipient, and is a non-enteric coated tablet. Onureg® is for oral administration, contains at least one pharmaceutically acceptable excipient, and is a non-enteric coated tablet, wherein a therapeutically effective amount of 5-azacytidine is not absorbed through oral mucosa upon administration to a human subject. Teva asserts that the Teva ANDA Product is bioequivalent to Onureg®, which means that it has the same route of administration (i.e., oral administration) and dosage form (i.e., a non-enteric coated tablet containing at least one pharmaceutically acceptable excipient) as Onureg®.

55. The Notice Letter does not dispute that the commercial manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product would infringe claim 1 of the '436 patent.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. A judgment that the claims of the Patents-in-Suit are not invalid, are not unenforceable, and are infringed by Teva's submission of ANDA No. 2168751 under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, and that Teva's making, using, offering to sell, or selling in the United States, or importing into the United States the Teva ANDA Product will infringe, induce the infringement of, and/or contribute to the infringement of the claims of the Patents-in-Suit under 35 U.S.C. §§ 271(a), (b), and/or (c), either literally or under the doctrine of equivalents.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 218751 shall be a date which is not earlier than the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

3. An order permanently enjoining Teva, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States the Teva ANDA Product until after the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

4. An order awarding Plaintiffs their costs in this litigation, including any costs recoverable under 28 U.S.C. § 1920, Federal Rule of Civil Procedure 54(d)(1), and/or Local Rule 54.1.

5. A finding that this is an exceptional case and awarding Plaintiffs their reasonable attorneys' fees, including under 35 U.S.C. § 285.

6. Such further and other relief as this Court deems proper and just.

Dated: September 13, 2023

Respectfully submitted,

FARNAN LLP

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