IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ANDRULIS PHARMACEUTICALS CORP., Plaintiff, v. CELGENE CORP., Defendant.	)	Civil Action No. **JURY TRIAL DEMANDED**

COMPLAINT

For its Complaint, Andrulis Pharmaceuticals Corp., by and through its attorneys, alleges as follows:

Nature of the Action

1. This action alleges patent infringement under the patent laws of the United States, Title 35, United States Code, e.g., 35 U.S.C. §§ 271-287.

The Parties

2. Plaintiff Andrulis Pharmaceuticals Corp. ("Andrulis") is a Maryland corporation with its principal place of business at 179 Rehoboth Avenue, Unit 1378, Rehoboth, Delaware 19971.

3. Defendant Celgene Corp. ("Celgene") is a Delaware corporation with its principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

4. Upon information and belief, Celgene is global biopharmaceutical company with operations in more than fifty countries worldwide. Upon information and belief, Celgene regularly conducts business in Delaware, and it maintains continuous and systematic contacts

with Delaware, including offering to sell and selling substantial quantities of drug products in Delaware.

5. Celgene has appointed The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, as its agent for service of process.

Jurisdiction and Venue

6. This action arises under the patent laws of the United States, Title 35, United States Code (35 U.S.C. § 1 *et seq*.). The Court has subject-matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

8. The Court has personal jurisdiction over Celgene because, among other things, Celgene is a Delaware corporation and it maintains continuous and systematic contacts with Delaware.

The Patent in Suit

9. U.S. Patent No. 6,140,346 ("the '346 patent"), entitled "Treatment of Cancer with Thalidomide Alone or in Combination with Other Anti-Cancer Agents," was duly and legally issued on October 31, 2000. The '346 patent concerns cancer treatment with thalidomide in combination with an alkylating agent, such as mechlorethamine, cyclophosphamide, ifosamide, melphalan, chlorambucil, busulfan, thiotepa, carmustine, lomustin, cisplatin, or carboplatin. A true and correct copy of the '346 patent is attached as Exhibit A.

10. Andrulis has been the only owner of the '346 patent since its issuance. Andrulis has the right to bring suit and recover damages for infringement of the '346 patent.

Celgene's Knowledge of the Patent in Suit

11. Upon information and belief, Celgene knew about '346 patent at least as early as 2005.

12. The following 22 United States patents identify Celgene as the assignee:

7,230,012
7,323,479
7,354,948
7,393,862
7,465,800
7,468,363
7,723,361
7,855,217
7,893,045
7,968,569
7,977,357
8,058,443
8,143,286
8,188,118
8,193,219
8,198,262
8,198,306
8,207,200
8,263,637
8,410,136
8,431,598
8,440,194

13. During prosecution before the United States Patent and Trademark Office ("PTO") of each of the 22 above-listed patents, Celgene cited the '346 patent to the PTO. Many of the 22 above-listed patents concern cancer treatment with thalidomide or a thalidomide analogue, either alone or in combination with another anti-cancer agent.

The Orange Book

14. The United States Food and Drug Administration ("FDA") maintains a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly called the "Orange Book." The Orange Book identifies drug products approved on the basis of safety and effectiveness. For approved drug products, the Orange Book includes patent and exclusivity data. Drug-product manufacturers provide the FDA with patent information for their respective drug products, which the FDA then includes in the Orange Book.

Alkeran®

15. The FDA approved Alkeran® in 1964. Alkeran® is a drug product containing melphalan. Melphalan is an alkylating agent that is active against certain cancers. Alkeran® now has the following FDA-approved indications: the palliative treatment of multiple myeloma and for the palliation of non-resectable epithelial carcinoma of the ovary. A true and correct copy of the Alkeran® prescribing information is attached as Exhibit B.

16. Alkeran® is approved for oral administration as 2-mg tablets.

17. From 2003 to 2009, Celgene distributed, promoted, and sold Alkeran® under a Celgene label.

18. Celgene has made and still makes prescribing information for Alkeran® available on Celgene's website, i.e., at http://www.celgene.com/pdfs/AlkeranPI_Tablet.pdf. See attached Exhibit B.

Thalomid®

19. Celgene offers to sell and sells a drug product containing thalidomide under the trade name Thalomid®.

20. The FDA approved Thalomid® in 1998. Thalomid® now has the following FDA-approved indications: the treatment of multiple myeloma in combination with dexamethasone, the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum ("ENL") (an inflammatory complication of leprosy or Hansen's disease), and as a maintenance therapy for prevention and suppression of the cutaneous manifestations of erythema nodosum leprosum recurrence. A true and correct copy of the Thalomid® prescribing information is attached as Exhibit C.

21. The Thalomid® prescribing information specifies some of the 22 Celgene-owned patents identified above, such as U.S. Patent Nos. 7,230,012 and 7,723,361, which reference the '346 patent. See attached Exhibit C.

22. Thalomid® is approved for oral administration as 50-mg, 100-mg, 150-mg, and 200-mg capsules.

23. Except for Thalomid®, the FDA has not approved any drug product containing thalidomide. Thus, only Celgene can sell a drug product containing thalidomide in the United States.

24. For Thalomid®, the Orange Book lists some of the 22 Celgene-owned patents identified above, such as U.S. Patent Nos. 7,230,012 and 7,723,361, which reference the '346 patent.

Revlimid®

25. Celgene offers to sell and sells a drug product containing lenalidomide under the trade name Revlimid®. Lenalidomide is a thalidomide analogue.

26. The FDA approved Revlimid® in 2005. Revlimid® now has the following FDA-approved indications: the treatment of multiple myeloma in combination with dexamethasone, transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes ("MDS") associated with a chromosome 5q deletion abnormality with or without additional cytogenetic abnormalities, and mantle cell lymphoma ("MCL") in patients whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. A true and correct copy of the Revlimid® prescribing information is attached as Exhibit D.

27. The Revlimid® prescribing information specifies some of the 22 Celgene-owned patents identified above, such as U.S. Patent Nos. 7,465,800, 7,468,363, 7,855,217, and 7,968,569, which reference the '346 patent. See attached Exhibit D.

28. Revlimid® is approved for oral administration as 2.5-mg, 5-mg, 10-mg, 15-mg, 20-mg, and 25-mg capsules.

29. Except for Revlimid®, the FDA has not approved any drug product containing lenalidomide. Thus, only Celgene can sell a drug product containing lenalidomide in the United States.

30. For Revlimid®, the Orange Book lists some of the 22 Celgene-owned patents identified above, such as U.S. Patent Nos. 7,465,800, 7,468,363, 7,855,217, and 7,968,569, which reference the '346 patent.

Multiple Myeloma

31. Multiple myeloma is a type of cancer.

32. The Multiple Myeloma Research Foundation ("MMRF") has described multiple myeloma as follows:

> Multiple myeloma (also known as myeloma or plasma cell myeloma) is [a] progressive hematologic (blood) disease. It is a cancer of the plasma cell, an important part of the immune system that produces immunoglobulins (antibodies) to help fight infection and disease. Multiple myeloma is characterized by excessive numbers of abnormal plasma cells in the bone marrow and overproduction of intact monoclonal immunoglobulin (IgG, IgA, IgD, or IgE) or Bence-Jones protein (free monoclonal light chains). Hypercalcemia, anemia, renal damage, increased susceptibility to bacterial infection, and impaired production of normal immunoglobulin are common clinical manifestations of multiple myeloma. It is often also characterized by diffuse osteoporosis, usually in the pelvis, spine, ribs, and skull.

http://www.themmrf.org/living-with-multiple-myeloma/newly-diagnosed-patients/what-is-multiple-myeloma/

33. Multiple myeloma has also been described as follows:

> Each year in the United States, nearly 22,000 people are diagnosed with multiple myeloma, a cancer of the bone marrow. Bone marrow contains plasma cells, a type of white blood cell that

> is an important part of the immune system, which protects the body from infection.
>
> Normally, plasma cells make up less than 5 percent of the blood cells in the bone marrow. For reasons not completely understood, plasma cells can grow out of control. When they do, they are referred to as myeloma cells. These myeloma cells can fill up the bone marrow and damage the bone. Over time, they collect and form tumors in several (multiple) areas of the bones. That is why this cancer is called "multiple" myeloma.

http://www.cancercare.org/publications/12-treatment_update_multiple_myeloma.

34. The National Comprehensive Cancer Network ("NCCN") is an alliance of over twenty cancer centers in the United States, most of which are designated by the National Cancer Institute (one of the National Institutes of Health) as comprehensive cancer centers. The NCCN seeks to improve the quality, effectiveness, and efficiency of cancer care.

35. The NCCN promulgates oncology guidelines and chemotherapy templates to improve the use of drugs for cancer care. Those guidelines and templates are widely recognized and applied as the standard of care in oncology in the United States.

36. Since approximately 2008, the NCCN has identified the use of the combination of melphalan, prednisone, and thalidomide ("MPT") as an appropriate therapy for some patients with multiple myeloma.

37. The FDA has not approved the use of the combination of melphalan, prednisone, and thalidomide to treat any patients with multiple myeloma.

38. Since approximately 2012, the NCCN has identified the use of the combination of melphalan, prednisone, and lenalidomide ("MPL") as an appropriate therapy for some patients with multiple myeloma.

39. The FDA has not approved the use of the combination of melphalan, prednisone, and lenalidomide to treat any patients with multiple myeloma.

40. Even though not approved by the FDA, the use of the combination of melphalan, prednisone, and thalidomide has become a primary therapy for many patients with multiple myeloma, and the use of the combination of melphalan, prednisone, and lenalidomide has more recently become a primary therapy for many patients with multiple myeloma.

The FDA Regulates Promotional Activities

41. The FDA does not regulate the practice of medicine. So doctors may prescribe approved drug products for unapproved or off-label uses, e.g., for any purposes doctors consider medically appropriate.

42. The term "off-label" refers to the use of an approved drug product for any purpose or in any manner other than what the product's labeling (or package insert) specifies. Off-label use includes treating a condition not indicated in the labeling, treating an indicated condition at a different dose or frequency than specified in the labeling, or treating a different patient population (e.g., treating a child when the product is approved only for treating adults).

43. The FDA does regulate promotional practices for drug products, e.g., through the Office of Prescription Drug Promotion (formerly the Division of Drug Marketing, Advertising and Communications). Under the Food, Drug, and Cosmetic Act ("FDCA"), drug-product manufacturers may market drug products only for FDA-approved uses.

44. The Food and Drug Administration Modernization Act of 1997 created an exception to the prohibition against off-label marketing. Drug-product manufacturers may now provide doctors with publications concerning unapproved or off-label uses in response to unsolicited requests. But requests that are prompted in any way by manufacturers or their representatives are not unsolicited requests.

45. The FDA has identified the following examples, among others, of improper promotional activities relating to requests for information about unapproved uses:

> If a firm's sales representative mentions a use of a product that is not reflected in the product's approved labeling and invites a health care professional to request more information, resulting requests would be considered solicited requests.
>
> If a representative of a firm, such as a medical science liaison or paid speaker (e.g., key opinion leader), presents off-label use data at a company-sponsored promotional event (e.g., a dinner) and attendees then ask or submit requests for more information, these requests would be considered solicited requests.
>
> If a firm issues to health care professionals business reply cards that are intended for use in requesting off-label information, presents statements or contact information in promotional pieces in a manner that solicits requests for off-label medical or scientific information (e.g., "Product X continues to be evaluated in more than 50 trials in a broad range of conditions and patients" and "Call 1-800-… for more information"), or displays a commercial exhibit panel suggesting a new indication (e.g., a sign that reads "Coming Soon, a new use for Product X"), requests made in response to these types of prompts would be considered solicited requests.
>
> If a firm provides a phone number, e-mail address, uniform resource locator (URL), or username that is a word, alpha phrase, or alpha representation implying the availability of off-label information for its product, requests using this phone number, e-mail address, URL, or username would be considered solicited requests.

Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (Dec. 2011).

Promotional Activities Influence Prescribing Decisions

46. Upon information and belief, prescription drug sales are sensitive to promotional activities. Various studies have shown that promotional activities by drug-product manufacturers significantly affect prescribing decisions by doctors.

47. A 2000 review article states, "The present extent of physician-industry interactions appears to affect prescribing and professional behavior ...." A. Wazana, "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?" 283 JOURNAL OF THE AM. MED. ASS'N No. 3, 373-380, at 373 (Jan. 2000). A 2008 article notes that the Wazana review article

"found evidence of consistent and strong causality over a wide range of industry-physician interactions and a dose-response relationship in all interactions, where it was investigated, demonstrating that marketing efforts to influence prescribing do indeed work." G. Kyle et al., "Pharmaceutical Company Influences on Medication Prescribing and Their Potential Impact on Quality Use of Medicines," 33 JOURNAL OF CLINICAL PHARMACY & THERAPEUTICS 553-559, at 554 (2008). That 2008 article also notes that "many professional organizations worldwide representing doctors and pharmacists have developed professional practice guidelines for their members to increase awareness of the influence of pharmaceutical industry marketing on prescribing and other decisions." *Id*. at 558.

48. A 2005 publication states, "Increased promotion is associated with increased medicines sales, promotion influences prescribing more than doctors realise, and doctors rarely acknowledge that promotion has influenced their prescribing." P. Norris et al., "Reviews of Materials in the WHO/HAI Database on Drug Promotion: What Impact Does Pharmaceutical Promotion Have on Behavior?" at 54 (2005), available at http://apps.who.int/medicinedocs/pdf/s8109e/s8109e.pdf.

49. A 2005 article reports that "systematic reviews of the literature confirmed a direct relationship between the frequency of contact with [pharmaceutical company] reps and the likelihood that physicians will behave in ways favorable to the pharmaceutical industry." H. Brody, "The Company We Keep: Why Physicians Should Refuse to See Pharmaceutical Representatives," 3 ANNALS OF FAMILY MEDICINE No. 1, 82-85, at 83 (Jan.-Feb. 2005).

50. A 2005 review article regarding marketing in the pharmaceutical industry explains that the word "detailing" in that industry refers to marketing efforts direct toward doctors by personal selling through sales representatives. P. Manchanda et al., "The Effects and

Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review," 5 YALE JOURNAL OF HEALTH POLICY, LAW & ETHICS 785-822, at 785-86 (May 2005). That 2005 review article then reports that "detailing ... affects physician prescription behavior in a positive and significant manner." *Id*. at 787. That 2005 review article also reports that detailing "has an impact on prescription behavior via both a subjective and an objective path." *Id*. at 810.

51. With regard to interactions with sales representatives, a 2010 review article reports that most of the studies considered found "an association with increased prescribing of the promoted drug" and visits by sales representatives. G. Spurling et al., "Information from Pharmaceutical Companies and the Quality, Quantity, and Cost of Physicians' Prescribing: A Systematic Review," 7 PLOS MEDICINE No. 10, 1-22, at 4 (Oct. 2010). More generally, that 2010 review article notes that most of the studies considered "found associations between exposure [to pharmaceutical company information] and higher frequency of prescribing." *Id*. at 1.

52. A medical school has observed that the pharmaceutical industry spends billions of dollars "each year in direct marketing to physicians, including detailing by drug reps, journal ads, samples, and gifts with the ultimate goal of changing prescribing behavior. Studies have shown that even small gifts influence prescribing behavior, and that marketing leads to increased formulary requests and decreased use of generic medications." See "Industry Conflict of Interest Policy," available at http://brown.edu/academics/medical/student-affairs/policy-and-procedure/industry-conflict-interest-policy (footnotes omitted).

53. Further, there is evidence that the availability of free samples leads doctors to prescribe the corresponding drug product. *See, e.g.*, L. Chew et al., "A Physician Survey of the Effect of Drug Sample Availability on Physicians' Behavior," 15 JOURNAL OF GEN. INTERNAL

MED. 478-483 (2000). A 2005 publication states, "Samples stimulate prescribing." P. Norris et al., "Reviews of Materials in the WHO/HAI Database on Drug Promotion: What Impact Does Pharmaceutical Promotion Have on Behavior?" at 55 (2005), available at http://apps.who.int/medicinedocs/pdf/s8109e/s8109e.pdf.

Celgene's Promotional Activities

54. Upon information and belief, the FDA's Division for Drug Marketing, Advertisement and Communication sent Celgene at least one warning letter reporting that Celgene engaged in improper marketing activities by stating or suggesting that Thalomid® is safe and effective for an unapproved use, e.g., by utilizing press releases to promote Thalomid®.

55. Upon information and belief, Celgene sales representatives have contacted doctors and communicated (orally and/or in writing) the advantages and benefits of Celgene's products, e.g., by answering questions concerning Celgene's products.

56. Upon information and belief, at various times from 2003 to at least 2009 Celgene sales representatives have discussed with doctors the use of Alkeran® to treat cancers and have encouraged doctors to prescribe Alkeran® to treat cancers, including multiple myeloma.

57. Upon information and belief, at various times from 1998 to the present Celgene sales representatives have discussed with doctors the use of Thalomid® to treat cancers and have encouraged doctors to prescribe Thalomid® to treat cancers, including multiple myeloma.

58. Upon information and belief, at various times from 2005 to the present Celgene sales representatives have discussed with doctors the use of Revlimid® to treat cancers and have encouraged doctors to prescribe Revlimid® to treat cancers, including multiple myeloma.

59. Upon information and belief, Celgene has employed individuals having backgrounds in science under the job title "medical liaison" or "medical science liaison" or "medical affairs representative" or something similar as part of its medical affairs division.

Upon information and belief, these medical liaisons or representatives have discussed with doctors the use of Alkeran®, Thalomid®, and/or Revlimid® to treat cancers and have encouraged doctors to prescribe Celgene products to treat cancers, including multiple myeloma.

60. Upon information and belief, Revlimid® has been marketed or promoted much more than Thalomid® since 2005. Upon information and belief, some doctors have been reluctant to prescribe Revlimid® for some patients due to the significantly higher price of Revlimid® compared to Thalomid®, and Celgene still sells substantial quantities of Thalomid®.

61. Upon information and belief, various publications from about 2005 through at least 2012 have reported favorable results from clinical trials that involved the use of melphalan and prednisone together with thalidomide or lenalidomide to treat patients with multiple myeloma. Those publications include:

> A. Palumbo et al., "Oral Melphalan, Prednisone, and Thalidomide for Newly Diagnosed Patients with Myeloma," 104 CANCER 1428-1433 (Oct. 2005)
>
> A. Palumbo et al., "Oral Melphalan and Prednisone Chemotherapy plus Thalidomide Compared with Melphalan and Prednisone Alone in Elderly Patients with Multiple Myeloma: Randomised Controlled Trial," 367 THE LANCET No. 9513, 825-831 (Mar. 2006)
>
> A. Palumbo et al., "Intravenous Melphalan, Thalidomide and Prednisone in Refractory and Relapsed Multiple Myeloma," 76 EUROPEAN JOURNAL OF HAEMATOLOGY 273-277 (Apr. 2006)
>
> T. Facon et al., "Melphalan and Prednisone plus Thalidomide Versus Melphalan and Prednisone Alone or Reduced-Intensity Autologous Stem Cell Transplantation in Elderly Patients with Multiple Myeloma (IFM 99-06): A Randomised Trial," 370 THE LANCET No. 9594, 1209-1218 (Oct. 2007)
>
> A. Palumbo et al., "Melphalan, Prednisone, and Lenalidomide Treatment for Newly Diagnosed Myeloma: A Report from the GIMEMA—Italian Multiple Myeloma Network," 25 JOURNAL OF CLINICAL ONCOLOGY No. 28, 4459-4465 (Oct. 2007)

C. Hulin et al., "Melphalan-Prednisone-Thalidomide (MP-T) Demonstrates a Significant Survival Advantage in Elderly Patients ≥75 Years with Multiple Myeloma Compared with Melphalan-Prednisone (MP) in a Randomized, Double-Blind, Placebo-Controlled Trial, IFM 01/01," 110 BLOOD No. 11, 31a Abstract #75 (Nov. 2007)

A. Palumbo et al., "Oral Melphalan, Prednisone, and Thalidomide in Elderly Patients with Multiple Myeloma: Updated Results of a Randomized Controlled Trial," 112 BLOOD No. 8, 3107-3114 (Oct. 2008)

A. Palumbo et al., "Melphalan, Prednisone, and Lenalidomide for Newly Diagnosed Myeloma: Kinetics of Neutropenia and Thrombocytopenia and Time-to-Event Results," 9 CLINICAL LYMPHOMA, MYELOMA & LEUKEMIA No. 2, 145-150 (Apr. 2009)

C. Hulin et al., "Efficacy of Melphalan and Prednisone plus Thalidomide in Patients Older than 75 Years with Newly Diagnosed Multiple Myeloma: IFM 01/01 Trial," 27 JOURNAL OF CLINICAL ONCOLOGY No. 22, 3664-3670 (Aug. 2009)

A. Palumbo et al., "Continuous Lenalidomide Treatment for Newly Diagnosed Multiple Myeloma," 366 NEW ENGLAND JOURNAL OF MEDICINE No. 10, 1759-1769 (May 2012)

M. Offidani et al., "Phase II Study of Melphalan, Thalidomide and Prednisone Combined with Oral Panobinostat in Patients with Relapsed/Refractory Multiple Myeloma," 53 LEUKEMIA & LYMPHOMA No. 3, 1722-1727 (Sept. 2012)

62. Upon information and belief, Celgene, its representatives, and/or its agents have provided doctors with publications (e.g., in the form of reprints) that reported favorable results from one or more clinical trials that involved the use of melphalan and prednisone together with thalidomide or lenalidomide to treat patients with multiple myeloma.

63. Upon information and belief, Celgene has issued press releases about favorable results from clinical trials that involved the use of melphalan and prednisone together with thalidomide or lenalidomide to treat patients with multiple myeloma.

64. Upon information and belief, Celgene has issued press releases about regulatory authorities in countries outside the United States that approved the use of the combination of melphalan, prednisone, and thalidomide to treat patients with multiple myeloma.

65. Upon information and belief, Celgene, its representatives, and/or its agents have provided doctors with NCCN information or materials relating to the use of melphalan-prednisone-thalidomide therapy and/or melphalan-prednisone-lenalidomide therapy to treat patients with multiple myeloma.

66. Upon information and belief, Celgene has provided—and continues to provide—various doctors with funding or compensation, e.g., through a Celgene consultancy, advisory board/committee, or speaker bureau and/or as honoraria. Upon information and belief, some doctors who received payments from Celgene have reported favorable results from clinical trials that involved the use of melphalan and prednisone together with thalidomide or lenalidomide to treat patients with multiple myeloma at medical society meetings, such as meetings of the American Society of Hematology and/or the American Society of Clinical Oncology.

67. Upon information and belief, United States Attorneys in various judicial districts and various state attorneys general started investigations in 2011 and 2012 concerning Celgene's promotion of Thalomid® and Revlimid® for unapproved uses. The use of Thalomid® without dexamethasone to treat multiple myeloma constitutes an unapproved use. The use of Thalomid® in combination with melphalan and prednisone to treat multiple myeloma constitutes an unapproved use. The use of Revlimid® without dexamethasone to treat multiple myeloma constitutes an unapproved use. The use of Revlimid® in combination with melphalan and prednisone to treat multiple myeloma constitutes an unapproved use.

Melphalan-Prednisone-Thalidomide (MPT) and Melphalan-Prednisone-Lenalidomide (MPL) Therapy for Multiple Myeloma

68. Upon information and belief, less than approximately 15,000 new cases of multiple myeloma were diagnosed in the United States in 2004.

69. Upon information and belief, more than approximately 20,000 new cases of multiple myeloma were diagnosed in the United States in 2012.

70. Upon information and belief, the American Cancer Society has estimated that more than 22,000 new cases of multiple myeloma will be diagnosed in the United States in 2013.

71. Upon information and belief, the use of melphalan (Alkeran®) and prednisone together with thalidomide (Thalomid®) to treat multiple myeloma increased disproportionately to the number of new cases of multiple myeloma in the United States from the early 2000s to the mid 2000s.

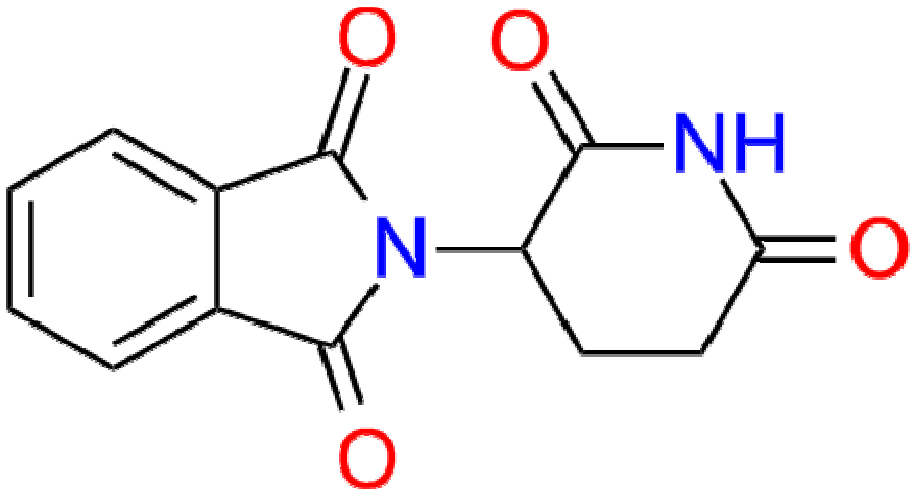
72. Upon information and belief, the use of melphalan (Alkeran®) and prednisone together with lenalidomide (Revlimid®) to treat multiple myeloma increased disproportionately to the number of new cases of multiple myeloma in the United States from the mid 2000s to the present.

73. Upon information and belief, Celgene, its representatives, and/or its agents have marketed or promoted Revlimid® much more than Thalomid® since 2005.

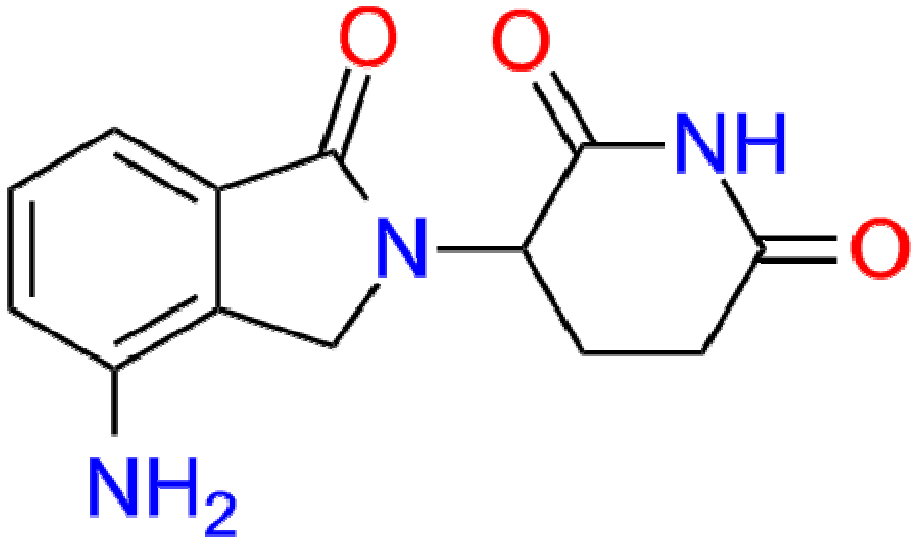
74. Upon information and belief, the disproportionate increases in the use initially of thalidomide (Thalomid®) and subsequently of lenalidomide (Revlimid®) in combination with melphalan (Alkeran®) and prednisone to treat multiple myeloma resulted—at least in part—from efforts by Celgene, its representatives, and/or its agents to encourage doctors to treat multiple myeloma with these drug products.

Similarities Between Thalidomide and Lenalidomide

75. Thalidomide can be represented by the following chemical structure:



76. Lenalidomide can be represented by the following chemical structure:



77. Thalidomide and lenalidomide have similar chemical structures. Lenalidomide is a thalidomide analogue.

78. Thalidomide and lenalidomide have similar mechanisms of action.

79. Both thalidomide and lenalidomide function to induce cancer cell death and/or impede new cancer cell formation. Both drugs achieve this function by acting on biological

pathways to (1) increase biological substances that promote cancer cell death, (2) decrease biological substances that aid cancer cell survival, and/or (3) stimulate the immune system. Both drugs result in a reduction in the number of cancer cells.

Celgene's Infringement of the Patent in Suit

80. Andrulis restates and realleges the preceding paragraphs in this Complaint.

81. One or more claims of the '346 patent literally or through equivalence cover the use of either thalidomide (Thalomid®) or lenalidomide (Revlimid®) in combination with melphalan (Alkeran®) to treat cancers.

82. Doctors who use either thalidomide (Thalomid®) or lenalidomide (Revlimid®) in combination with melphalan (Alkeran®) to treat cancers directly infringe one or more claims of the '346 patent literally or through equivalence.

83. This action seeks monetary damages from and injunctive relief against Celgene, who, upon information and belief, has promoted the use of thalidomide (Thalomid®) and lenalidomide (Revlimid®) in combination with melphalan (Alkeran®) to treat cancers.

84. Upon information and belief, Celgene has directly infringed, induced infringement of, and/or contributed to infringement of one or more claims of the '346 patent, both literally and under the doctrine of equivalents, by making, using, selling, and/or offering for sale Thalomid® and Revlimid® for use with an alkylating agent, e.g., melphalan, to treat cancers, e.g., multiple myeloma. By doing so, Celgene has violated 35 U.S.C. § 271.

85. Upon information and belief, Celgene has actively induced others, e.g., doctors, to directly infringe one or more claims of the '346 patent. Since at least the receipt of this Complaint, Celgene has acted with knowledge, or at least with willful blindness of the fact, that the induced acts constitute infringement of the '346 patent. Upon information and belief, Celgene has intended to cause direct infringement by others, e.g., doctors. Upon information and

belief, Celgene has taken affirmative steps to induce infringement by, among other things, communicating (orally and/or in writing) the advantages or benefits of using thalidomide (Thalomid®) and lenalidomide (Revlimid®) in combination with melphalan (Alkeran®) to treat cancers. Thus, Celgene has aided, abetted, urged, or encouraged others, e.g., doctors, to directly infringe one or more claims of the '346 patent, and Celgene has affirmatively and specifically intended to cause direct infringement.

86. Upon information and belief, Celgene's acts of infringement of the '346 patent have been willful and deliberate. Since at least the receipt of this Complaint, Celgene has acted with an objectively high likelihood that its actions constituted infringement of the '346 patent by refusing to take a license and continuing to make, sell, and/or promote thalidomide (Thalomid®) and lenalidomide (Revlimid®) in combination with melphalan (Alkeran®) to treat cancers. The objectively defined risk was either known to Celgene or so obvious that it should have been known to Celgene.

87. Celgene's infringement of the '346 patent has damaged Andrulis in an amount to be determined, but in no event less than a reasonable royalty.

88. Celgene's infringement of the '346 patent has caused Andrulis to suffer irreparable harm. Celgene's infringement will continue unless enjoined by the Court. Andrulis has no adequate remedy at law and is entitled to preliminary and permanent injunctions prohibiting Celgene from infringing the '346 patent.

Prayer for Relief

WHEREFORE, Andrulis requests a judgment:

(a) declaring that Celgene has infringed the '346 patent under 35 U.S.C. § 271;

(b) declaring that Celgene's infringement has been willful and deliberate;

(c) awarding damages adequate to compensate for Celgene's infringement of the '346 patent, but in no event less than a reasonable royalty, and awarding increased damages due to Celgene's willful and deliberate infringement;

(d) awarding interest on all damages;

(e) preliminarily and permanently enjoining Celgene, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Celgene from infringing the '346 patent;

(f) declaring this an exceptional case under 35 U.S.C. § 285 and awarding Andrulis its attorneys' fees;

(g) awarding Andrulis its costs and expenses; and

(h) granting such other and further relief as the Court deems just and proper.

Jury Demand

Andrulis demands a jury trial on all issues so triable by right.

Dated: October 2, 2013

/s/ Kenneth L. Dorsney

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