

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

William J. O’Shaughnessy, Esq.
Cynthia S. Betz, Esq.
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Of Counsel:
Dominick A. Conde, Esq.
William E. Solander, Esq.
Peter D. Shapiro, Esq.
Vishal C. Gupta, Esq.
FITZPATRICK, CELLA,
HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104
(212) 218-2100

Attorneys for Plaintiffs,
SANOFI-AVENTIS U.S. LLC,
SANOFI-AVENTIS and DEBIOPHARM S.A.

_____)	
SANOFI-AVENTIS U.S. LLC,)	
SANOFI-AVENTIS,)	
DEBIOPHARM S.A.,)	
)	
Plaintiffs,)	CIVIL ACTION NO.:
)	
v.)	
)	
STRIDES, INC.,)	
ONCO THERAPIES LIMITED,)	
STRIDES ARCOLAB LIMITED,)	
)	
)	
Defendants.)	
_____)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi-Aventis U.S. LLC, Sanofi-Aventis and Debiopharm S.A. (hereinafter, “Plaintiffs”), by way of Complaint against Strides, Inc., Onco Therapies Limited, and Strides Arcolab Limited allege as follows:

THE PARTIES

1. Sanofi-Aventis is a corporation organized and existing under the laws of France, having its principal place of business at 54, rue La Boétie, 75008 Paris France. Sanofi-Aventis is a global innovator healthcare company whose core therapeutic areas are oncology, diseases of the central nervous system, cardiovascular disease, and internal medicine.

2. Sanofi-Aventis U.S. LLC is the U.S. subsidiary of Sanofi-Aventis, and is a corporation incorporated under the laws of the state of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Debiopharm S.A. (“Debiopharm”) is a corporation, existing under the laws of Switzerland, having its principal place of business at Forum “après-demain” Chemin Messidor 5-7, Case postale 5911, CH - 1002 Lausanne, Switzerland. Debiopharm develops innovative and life-saving pharmaceuticals.

4. On information and belief, Strides, Inc. (“Strides USA”) is a corporation registered to do business in New Jersey and maintaining an authorized agent and/or office at 201 South Main St., Suite #3, Lambertville, New Jersey 08530.

5. On information and belief, Onco Therapies Limited (“Onco”) is a corporation organized under the laws of India, having corporate offices at Strides House, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka 560076, India.

6. On information and belief, Strides Arcolab Limited (“Arcolab”) is a corporation organized under the laws of India, having corporate offices at Strides House, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka 560076, India.
7. On information and belief, Onco is a fully owned subsidiary of Arcolab.
8. On information and belief, Strides USA is an agent, affiliate or subsidiary of Onco.
9. On information and belief, Strides USA is an agent, affiliate or subsidiary of Arcolab.
10. On information and belief, Arcolab conducts business through and with Strides USA.
11. On information and belief, Onco conducts business through and with Strides USA.
12. On information and belief, Arcolab, Onco and/or Strides USA are in the business of manufacturing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies, and which include a generic version of Sanofi-Aventis’s injectable oxaliplatin products.
13. On information and belief, Strides assembled and caused to be filed with the United States Food and Drug Administration (“FDA”), pursuant to 21 U.S.C. § 355(j), Abbreviated New Drug Application (“ANDA”) No. 091358 concerning a proposed drug product, oxaliplatin injection (5mg/mL), in 10 mL, 20mL and 40mL vials.
14. On information and belief, Strides assembled and caused to be filed with the United States Food and Drug Administration (“FDA”), pursuant to 21 U.S.C. § 355(j),

Abbreviated New Drug Application (“ANDA”) No. 200979 concerning a proposed drug product, oxaliplatin for injection in 50 mg/vial and 100 mg/vials.

15. On information and belief, Arcolab, and Onco, acting alone or in concert, caused, actively encouraged, and/or directed Strides USA to file ANDA Nos. 091358 and 200979 with the FDA, and/or participated in the work related to the submission of ANDA Nos. 091358 and 200979.

16. Strides USA, Arcolab and Onco are referred to hereinafter, collectively, as “Strides”.

JURISDICTION AND VENUE

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

18. Strides USA is subject to personal jurisdiction in New Jersey because it maintains its principal place of business in New Jersey and maintains continuous and systematic contacts with this judicial district.

19. Arcolab is subject to personal jurisdiction in New Jersey because it maintains continuous and systematic contacts with this judicial district. Arcolab has conducted and continues to conduct business, directly, or through its subsidiaries, including Strides USA and Onco, in this judicial district. On information and belief, Arcolab, directly, or through its subsidiaries, manufactures, markets and sells generic drugs throughout the United States and the District of New Jersey.

20. In the alternative, Arcolab is subject to jurisdiction in the United States under the principles of general jurisdiction, and specifically in New Jersey pursuant to Fed. R.

Civ. P. 4(k)(2). Arcolab has contacts with the United States by, *inter alia*, its having filed an ANDA with the FDA through its subsidiary corporations, Strides USA and Onco.

21. Onco, a wholly owned subsidiary of Arcolab, is subject to personal jurisdiction in New Jersey because it maintains continuous and systematic contacts with this judicial district. Onco has conducted and continues to conduct business, directly, or through its parent company, Arcolab, and affiliate or subsidiary company, Strides USA, in this judicial district. On information and belief, Onco manufactures, markets and/or sells generic drugs throughout the United States and the District of New Jersey.

22. In the alternative, Onco is subject to jurisdiction in the United States under the principles of general jurisdiction, and specifically in New Jersey pursuant to Fed. R. Civ. P. 4(k)(2). Onco has contacts with the United States by, *inter alia*, its having filed an ANDA with the FDA.

23. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 (b), (c), (d) and 28 U.S.C. § 1400(b).

COUNT 1
INFRINGEMENT OF U.S. PATENT NO. 5,338,874

24. Plaintiffs repeat and reallege paragraphs 1-23 above as if fully set forth herein.

25. Sanofi-Aventis U.S. LLC holds approved new drug applications (“NDA”) 21-492 and 21-759 for Eloxatin[®], the active ingredient of which is oxaliplatin. Eloxatin[®] is approved for the treatment of colorectal cancer.

26. Debiopharm is the owner of United States Patent No. 5,338,874 (“the ’874 patent”) (attached as “Exhibit A”). Sanofi-Aventis is the exclusive licensee of the ’874 patent.

27. On information and belief, Strides submitted to the FDA ANDA Nos. 200979 and 091358 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and sale of injectable oxaliplatin formulations.

28. On information and belief, Strides made, and included in ANDA Nos. 200979 and 091358, a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '874 patent is invalid and/or unenforceable. On or about February 21, 2012, Strides sent Plaintiffs notice of that certification pursuant to 21 U.S.C. § 355(j)(2)(B).

29. By filing its ANDA Nos. 200979 and 091358 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its proposed drug products before the expiration of the '874 patent, Strides committed acts of infringement under 35 U.S.C. §271(e)(2).

30. Further, the commercial manufacture, use, offer for sale, sale and/or importation of the generic oxaliplatin products for which Strides seeks approval in its ANDA Nos. 200979 and 091358 will infringe one or more claims of the '874 patent under 35 U.S.C. § 271.

COUNT 2:
INFRINGEMENT OF U.S. PATENT NO. 5,716,988

31. Plaintiffs repeat and reallege paragraphs 1-30 above as if fully set forth herein.

32. Debiopharm is the owner of United States Patent No. 5,716,988 (“the '988 patent”) (attached as “Exhibit B”). Sanofi-Aventis is the exclusive licensee of the '988 patent.

33. On information and belief, Strides submitted to the FDA ANDA No. 091358 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and sale of Strides's generic oxaliplatin formulations.

34. On information and belief, Strides made, and included in ANDA No. 091358, certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '988 patent is not infringed, invalid and/or unenforceable. On or about February 21, 2012, Strides sent Plaintiffs notice of those certifications pursuant to 21 U.S.C. § 355(j)(2)(B).

35. By filing its ANDA No. 091358 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its proposed drug products before the expiration of the '988 patent, Strides committed acts of infringement under 35 U.S.C. §271(e)(2).

36. Further, the commercial manufacture, use, offer for sale, sale and/or importation of the generic oxaliplatin products for which Strides seeks approval in its ANDA No. 091358 will infringe one or more claims of the '988 patent under 35 U.S.C. § 271.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request:

A. Judgment that Strides, Inc., Onco Therapies Limited, and Strides Arcolab Limited have infringed one or more claims of the '874 patent by filing ANDA Nos. 091358 and 200979 relating to Strides's generic oxaliplatin products;

B. Judgment that Strides, Inc., Onco Therapies Limited, and Strides Arcolab Limited have infringed one or more claims of the '988 patent by filing ANDA No. 091358 relating to Strides's generic oxaliplatin products;

C. A permanent injunction restraining and enjoining Strides, Inc., Onco Therapies Limited, and Strides Arcolab Limited and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of generic oxaliplatin products as claimed in the '874 patent and/or '988 patent;

D. A declaration that the effective date of any approval of the ANDA Nos. 091358 and 200979 relating to Strides's generic oxaliplatin formulations be a date which is not earlier than the expiration date of the '874 patent plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

E. A declaration that the effective date of any approval of the ANDA No. 091358 relating to Strides's generic oxaliplatin formulations be a date which is not earlier than the expiration date of the '988 patent plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

F. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, expenses, and disbursements of this action, and;

G. Such other and further relief as the Court may deem just and proper.

Dated: April 5, 2012

Respectfully submitted,

By: /s/ William J. O'Shaughnessy
William J. O'Shaughnessy, Esq.
Cynthia S. Betz, Esq.
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Phone: (973) 622-4444
Fax: (973) 624-7070

Attorneys for Plaintiffs,
SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS, and
DEBIOPHARM S.A.

Of Counsel:

Dominick A. Conde, Esq.

William E. Solander, Esq.

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1290 Avenue of the Americas

New York, New York 10104

(212) 218-2100