

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CANCER RESEARCH)	
TECHNOLOGY LIMITED and)	
SCHERING CORPORATION,)	
)	
Plaintiffs,)	C.A. No. _____
)	
v.)	
)	
BARR LABORATORIES, INC., and)	
BARR PHARMACEUTICALS, INC.,)	
)	
Defendants.)	

COMPLAINT

Plaintiffs Cancer Research Technology Limited and Schering Corporation for their Complaint herein, aver 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.

THE PARTIES

2. Plaintiff Cancer Research Technology Limited is a limited liability company organized and existing under the laws of the United Kingdom, having its principal place of business at Sardinia House, Sardinia Street, London, WC2A 3NL, England. Cancer Research Technology Limited was formerly known as Cancer Research Campaign Technology Limited. In October 2002, Cancer Research Campaign Technology Limited underwent a name change to Cancer Research Technology Limited (hereinafter "CRT").

3. Plaintiff Schering Corporation (“Schering”) is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 2000 Galloping Hill Rd., Kenilworth, NJ 07033-0530.

4. Upon information and belief, defendant Barr Laboratories, Inc. is a corporation, organized and existing under the laws of the State of Delaware, having its principal place of business at 223 Quaker Rd., Pomona, New York, 10970, with a registered agent for service of process at 2711 Centerville Road, Suite 400, Wilmington, DE 19808. Upon information and belief, Barr Laboratories, Inc. is currently doing business in this Judicial District by making and shipping, and using, offering to sell or selling, or causing others to use, offer to sell or sell, pharmaceutical products in this Judicial District.

5. Upon information and belief, defendant Barr Pharmaceuticals, Inc. is a corporation, organized and existing under the laws of the State of Delaware, having its principal place of business at 223 Quaker Rd., Pomona, New York, 10970, with a registered agent for service of process at 2711 Centerville Road, Suite 400, Wilmington, DE 19808. Upon information and belief, Barr Pharmaceuticals, Inc. is currently doing business in this Judicial District by making and shipping, and using, offering to sell or selling, or causing others to use, offer to sell or sell, pharmaceutical products in this Judicial District.

6. Upon information and belief, Barr Laboratories, Inc. is a wholly owned subsidiary of Barr Pharmaceuticals, Inc., and the two companies have common officers and directors.

7. Upon information and belief, the acts of Barr Laboratories, Inc. were done at the direction of, with the authorization of, and/or with the cooperation, participation, and/or assistance of, and at least in part for the benefit of Barr Pharmaceuticals, Inc. Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. are referred to collectively as “Barr.”

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

9. This Court has personal jurisdiction over Barr by virtue of, *inter alia*: (1) its presence in Delaware, and (2) its systematic and continuous contacts in Delaware.

10. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENT-IN-SUIT

11. CRT is the owner by assignment of all right, title, and interest in United States Patent No. 5,260,291, entitled “TETRAZINE DERIVATIVES” (“the ‘291 patent”), a copy of which is attached hereto as Exhibit A, which patent contains one or more claims covering the compound, composition and method of use of TEMODAR[®].

12. The ‘291 patent was duly and legally issued November 9, 1993, naming Edward Lunt, Malcolm F.G. Stevens, Robert Stone, Kenneth R.H. Wooldridge and Edward S. Newlands as the inventors, and naming Cancer Research Campaign Technology Limited as the assignee.

13. Schering has an exclusive license from CRT under the ‘291 patent to make, have made, use and sell temozolomide, the drug substance in TEMODAR[®].

14. Plaintiffs have all rights to sue and recover for past infringement of the ‘291 patent.

ACTS GIVING RISE TO THE ACTION

15. Plaintiff Schering is the holder of an approved New Drug Application (“NDA”), No. 21-029, for the manufacture and sale of temozolomide for the treatment of adult

patients with newly diagnosed glioblastoma multiforme and for the treatment of adult patients with refractory anaplastic astrocytoma. Schering markets and sells this compound and composition in the United States under the trade name TEMODAR[®] (temozolomide) Capsules (“TEMODAR[®]”), in 5 mg, 20 mg, 100 mg, 140 mg, 180 mg and 250 mg dosage forms. The 5 mg, 20 mg, 100 mg and 250 mg dosage forms of TEMODAR[®] were approved by the FDA in August 1999. The 140 mg and 180 mg dosage forms of TEMODAR[®] were approved by the FDA in October 2006.

16. Upon information and belief, Barr submitted Abbreviated New Drug Application (“ANDA”) No. 78-879 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, or importation of temozolomide capsules, 5 mg, 20 mg, 100 mg and 250 mg, a generic version of TEMODAR[®], before the expiration date of the ‘291 patent.

17. Upon information and belief, Barr’s ANDA No. 78-879 contains information to show that temozolomide capsules, 5 mg, 20 mg, 100 mg and 250 mg (a) are bioequivalent to TEMODAR[®], (b) have the same active ingredient as TEMODAR[®], (c) have the same route of administration, dosage form, and strength as TEMODAR[®], and (d) have the same, or substantially the same, proposed labeling as TEMODAR[®].

18. Upon information and belief, the compound and composition of Barr’s temozolomide capsules, 5 mg, 20 mg, 100 mg and 250 mg, are the subject of claims 1-3, 5-7, 11-13, and 27 of the ‘291 patent.

19. In a letter dated June 8, 2007, addressed to Schering-Plough Corporation, Barr sent notice “pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act” (“the ANDA Notice”). Schering-Plough received the ANDA Notice on June 13, 2007.

20. The ANDA Notice does not provide any valid basis for concluding that the '291 patent is invalid, unenforceable and/or not infringed.

21. Upon information and belief, Barr's submission of ANDA No. 78-879 was an act of infringement of one or more claims of the '291 patent, under the United States Patent Laws, 35 U.S.C. § 271(e)(2).

22. Upon information and belief, Barr's manufacture, use, sale, offer for sale, and/or importation of temozolomide capsules, 5 mg, 20 mg, 100 mg and 250 mg, will infringe, contribute to the infringement of, and/or induce the infringement of claims 1-3, 5-7, 11-13, and 27 of the '291 patent.

23. Upon information and belief, Barr has been aware of the existence of the '291 patent, but nevertheless has been and is now infringing claims 1-3, 5-7, 11-13, and 27 of the '291 patent. This case is "exceptional," as that term is set forth in 35 U.S.C. § 285.

24. The acts of infringement by Barr set forth above will cause CRT and Schering irreparable harm for which they have no adequate remedy at law, including irreparable harm within the state of Delaware and this Judicial District, and will continue unless preliminarily and permanently enjoined by this Court.

RELIEF

WHEREFORE, CRT and Schering pray for judgment against defendants as follows:

- A. Adjudging that the '291 patent is valid and enforceable;
- B. Adjudging that Barr has infringed claims 1-3, 5-7, 11-13, and 27 of the '291 patent, and that the use, sale, offer for sale, manufacture and/or importation by Barr of temozolomide capsules, if marketed, would infringe, induce infringement of, and/or contribute to infringement of claims 1-3, 5-7, 11-13, and 27 of the '291 patent;

C. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Barr's ANDA No. 78-879, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date that is not earlier than the date of expiration of the '291 patent, including any extensions;

D. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, Barr, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors or assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product that infringes claims 1-3, 5-7, 11-13, and 27 of the '291 patent, including any extensions;

E. Awarding CRT and Schering monetary relief if Barr commercially uses, offers for sale, sells, manufactures, or imports any drug product that infringes or induces or contributes to the infringement of claims 1-3, 5-7, 11-13 and 27 of the '291 patent within the United States prior to the expiration of that patent, including any extensions, and that such monetary relief be awarded to CRT and Schering with prejudgment interest;

F. Declaring this an exceptional case and awarding CRT and Schering their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

G. Awarding CRT and Schering such other and further relief as this Court may deem just and proper.

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