UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

BRISTOL -MYERS SQUIBB COMPANY,
Plaintiff

v.

MYLAN TECHNOLOGIES, INC.,
Defendant

Docket No. 2:01-CV-18

COMPLAINT

NOW COMES, Plaintiff Bristol-Myers Squibb Company ("BMS"), for its Complaint herein against Defendant Mylan Technologies, Inc. ("Mylan"), hereby avers, upon knowledge with respect to BMS and upon information and belief as to all other matters, as follows:

NATURE OF ACTION

1. This is an action for patent infringement. BMS owns a patent relating to buspirone hydrochloride (or buspirone), the active ingredient in BuSpar®, a novel drug used in the treatment of anxiety disorders and the short-term relief of the symptoms of anxiety. Mylan has infringed that patent.

PARTIES

2. BMS is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 345 Park Avenue, New York, NewYork. BMS is a diversified, worldwide health and personal care company whose businesses include medicines and nutritionals. BMS is a leading maker of innovative

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therapies for cancer; cardiovascular, metabolic and infectious diseases; and central nervous system and dermatological disorders.

3. Mylan is a foreign corporation registered with the State of Vermont and has its principal place of business at 110 Lake Street, St Albans, Vermont. Mylan Technologies, Inc. is a wholly owned subsidiary of Mylan Laboratories, Inc. and an affiliate of Mylan Pharmaceuticals, Inc. Mylan Technologies Inc. manufactures transdermal drug delivery systems and holds patents to enhance the generic and branded divisions of Mylan Laboratories, Inc.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

5. Mylan is subject to personal jurisdiction in this Court. Mylan resides in Vermont, has its principal place of business in Vermont, transacts business in Vermont and has engaged in tortious conduct in Vermont. Mylan's contact with Vermont, its activities in Vermont, and the contacts and activities imputable to Mylan are sufficient to support a personal judgment against it.

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

CLAIM FOR RELIEF

7. BMS holds the new drug application ("NDA") for, and markets and sells, BuSpar®, the active ingredient in which is buspirone.

8. On November 21, 2000, the United States Patent and Trademark Office issued United States Patent No. 6,150,365 (the "'365 patent" or "patent"), which is assigned to BMS.

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9. The patent claims a method of using buspirone. The sole claim in the '365 patent provides:

> A process for ameliorating an undesirable anxiety state in a mammal comprising systemic administration to the mammal of an effective but non-toxic anxiolytic dose of 6-hydroxy-8-[4-[4-(2-pyrimidinyl)-piperazinyl]-butyl]-8-azaspiro[4.5]-7,9-dione or a pharmaceutically acceptable acid addition salt or hydrate thereof.

(Col. 16, lines 27-32 (emphasis added).) The named compound is 6-hydroxy buspirone and is a metabolite of buspirone.

10. The patent specification expressly defines two methods of systemic administration of an effective, non-toxic anxiolytic dose of [6-hydroxy-buspirone]: (i) direct administration of 6-hydroxy-buspirone itself (Col. 10, lines 19-27), and (ii) oral administration of a precursor or prodrug form of 6-hydroxy-buspirone such as buspirone (Col. 11, line 64 to Col. 12, line 5).

11. As required by law, BMS timely submitted information relating to the '365 patent to the FDA for listing in an FDA publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluations", commonly known as the "Orange Book". See 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53(d)(3). The FDA thereafter listed the '365 patent in the Orange Book.

12. Upon information and belief, Mylan submitted to the FDA an abbreviated new drug application ("ANDA"), No. 76-008, seeking approval to engage in the commercial manufacture, use and sale of 30 mg doses of generic buspirone.

13. When a generic manufacturer files an ANDA seeking approval of a generic version of a drug for which unexpired patents are listed in the Orange Book, it must file

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a certification with respect to each listed patent. 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

14. Upon information and belief, Mylan filed "paragraph IV" certifications with respect to the '365 patent, contending that its proposed generic buspirone will not infringe the patent or that the patent is invalid. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

15. Inclusion of a paragraph IV certification in an ANDA is deemed an act of infringement. 35 U.S.C. § 271(e)(2). The statute, referring to an ANDA containing a paragraph IV certification, states: "It shall be an act of infringement to submit an application under [21 U.S.C. § 355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of [the] drug . . . before the expiration of [the] patent". Id.

16. Thus, by filing a paragraph IV certification with respect to the '365 patent, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2). Moreover, the commercial manufacture, use, offer for sale, sale or importation of the buspirone products for which it seeks approval in ANDA No. 76-008 will infringe the '365 patent.

17. On December 8, 2000, BMS received notice from Mylan that it had submitted a paragraph IV certification, relating to its 30 mg buspirone hydrochloride products, with respect to the '365 patent. Once a paragraph IV certification has been served, a pioneer drug company has a 45-day window in which to commence patent litigation. 21 U.S.C. § 355(j)(5)(B)(iii). If the pioneer company chooses to do so, then an automatic stay goes into effect, barring the approval of the generic drug until the

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earlier of the expiration of 30 months or a judicial decision of noninfringement or invalidity. Id.

18. BMS commenced this suit within the 45-day window.

19. Accordingly, BMS is entitled to the relief provided by 35 U.S.C. § 271(e)(4).

PRAYER FOR RELIEF

WHEREFORE, BMS respectfully requests the following relief:

A. Judgment that Mylan has infringed the '365 patent by filing the aforementioned ANDA and paragraph IV certification relating to Mylan's 30 mg. buspirone hydrochloride products;

B. A permanent injunction restraining and enjoining Mylan 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 30 mg buspirone hydrochloride products for use in the methods covered by the '365 patent;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Mylan's 30mg. buspirone hydrochloride products be a date which is not earlier than the August 5, 2019 expiration date of the '365 patent; and

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

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DATED at Montpelier, Vermont, this 18th day of January, 2001.

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