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UNITED STATES DISTRICT COURT  
 NORTHERN DISTRICT OF CALIFORNIA  
 OAKLAND DIVISION

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 ASTELLAS PHARMA INC., and BOEHRINGER  
 INGELHEIM PHARMACEUTICALS, INC.

Plaintiffs,

v.

IMPAX LABORATORIES, INC.

Defendant.  
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COMPLAINT FOR PATENT INFRINGEMENT

FILED  
 2008 JUL 18 11:10:57  
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1                                    **COMPLAINT FOR PATENT INFRINGEMENT**

2                    Plaintiffs Astellas Pharma Inc. and Boehringer Ingelheim Pharmaceuticals,  
3    Inc. (hereinafter collectively “Plaintiffs”), for their Complaint for patent infringement  
4    herein against defendant Impax Laboratories, Inc., allege as follows:

5                                    **PARTIES**

6                    1.        Astellas Pharma Inc. (“Astellas”) is a corporation organized and  
7    existing under the laws of Japan, having a principal place of business at 3-11,  
8    Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo 103-8411, Japan.

9                    2.        Boehringer Ingelheim Pharmaceuticals Inc. (“BIPI”) is a corporation  
10   organized and existing under the laws of Delaware, having a principal place of business at  
11   900 Ridgebury Road, Ridgefield, Connecticut 06877-0368.

12                   3.        On information and belief, Defendant Impax Laboratories, Inc.  
13   (“Impax”) is a corporation organized and existing under the laws of Delaware, having a  
14   principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

15                                    **JURISDICTION AND VENUE**

16                   4.        This action arises under the patent laws of the United States of  
17   America. This Court has jurisdiction over the subject matter of this action under  
18   28 U.S.C. §§ 1331 and 1338(a).

19                   5.        Venue is proper in this judicial district pursuant to 28 U.S.C.  
20   §§ 1391(b) and (c), and 28 U.S.C. § 1400(b); Impax is subject to personal jurisdiction  
21

1 based on information and belief that Impax's principle place of business is within this  
2 judicial jurisdiction and it has regular and systematic business contacts within this judicial  
3 jurisdiction.

#### 4 **INTRADISTRICT ASSIGNMENT**

5 6. Pursuant to Civil L.R. 3-2(c), this patent infringement action may be  
6 assigned on a district-wide basis. Because Impax's corporate headquarters are located in  
7 the County of Alameda, Plaintiffs are filing this Complaint in the Oakland Division.

#### 8 **CLAIM FOR PATENT INFRINGEMENT**

9 7. Plaintiff BIPI holds an approved new drug application ("NDA") No.  
10 20-579 for Flomax<sup>®</sup> capsules (0.4 mg), which tablets contain the active ingredient  
11 tamsulosin HCl. Flomax<sup>®</sup> capsules are approved by the United States Food and Drug  
12 Administration ("FDA") for the treatment of the signs and symptoms of benign prostatic  
13 hyperplasia ("BHP"). Flomax<sup>®</sup> capsules are sold in the United States by BIPI.

14 8. The active ingredient in the Flomax<sup>®</sup> capsules, tamsulosin HCl, is  
15 known chemically as (-)-(R)-5-[2-[[2-(2-ethoxyphenoxy) ethyl]amino]propyl]-2-  
16 methoxybenzenesulfonamide, monohydrochloride or (-)-(R)-5-{2-[2-(2-  
17 ethoxyphenoxy)ethylamino]-2-methylethyl}-2-methoxybenzenesulfonamide  
18 hydrochloride.

19 9. Astellas is the owner of United States Patent No. 4,703,063 ("the  
20 '063 patent"). The '063 patent was duly and legally issued on October 27, 1987.

1           10.    Astellas was formed as a result of the merger of Yamanouchi  
2   Pharmaceutical Co., Ltd. ("Yamanouchi") of Tokyo, Japan and Fujisawa Pharmaceutical  
3   Co., Ltd. of Osaka, Japan. The '063 patent was initially assigned to Yamanouchi, which  
4   subsequently became Astellas after the merger.

5           11.    The '063 patent claims, *inter alia*, tamsulosin and pharmaceutical  
6   compositions containing it. A true copy of the '063 patent is attached hereto as Exhibit  
7   A.

8           12.    On information and belief, Impax submitted to the FDA an  
9   abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j),  
10   seeking approval to engage in the commercial manufacture, use, and sale of tamsulosin  
11   HCl 0.4 mg capsules.

12           13.    On information and belief, Impax submitted its ANDA to the FDA  
13   for the purpose of obtaining approval to engage in the commercial manufacture, use, or  
14   sale of its tamsulosin HCl 0.4 mg capsules before the expiration of the '063 patent.

15           14.    On information and belief, Impax made, and included in its ANDA,  
16   a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") that, in its  
17   opinion and to the best of its knowledge, the '063 patent is invalid or will not be  
18   infringed.

19           15.    On information and belief, on or about June 5, 2008, Impax sent a  
20   Notice Letter, purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and  
21

1 the FDA regulations relating thereto, to Astellas Pharma U.S. Inc., Astellas, BIPI and  
2 Boehringer Ingelheim Corp.

3 16. By filing the ANDA under 21 U.S.C. § 355(j) for the purpose of  
4 obtaining approval to engage in the commercial manufacture, use, or sale of its proposed  
5 tamsulosin HCl 0.4 mg capsules before the expiration of the '063 patent, Impax has  
6 committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial  
7 manufacture, use, offer for sale, sale and/or importation of tamsulosin, tamsulosin HCl  
8 and/or the generic tamsulosin HCl 0.4 mg capsules for which Impax seeks approval in its  
9 ANDA will also infringe one or more claims of the '063 patent.

10 17. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4),  
11 including an Order of this Court that the effective date of any approval of the  
12 aforementioned ANDA, relating to Impax's tamsulosin HCl 0.4 mg capsules, shall be a  
13 date which is not earlier than October 27, 2009, the current expiration date of the '063  
14 patent, or any later date of exclusivity to which Plaintiffs are or become entitled. Further,  
15 Plaintiffs are entitled to an award of damages for any commercial sale or use of  
16 tamsulosin HCl 0.4 mg capsules, and any act committed by Impax with respect to the  
17 subject matter claimed in the '063 patent, which act is not within the limited exclusions of  
18 35 U.S.C. § 271(e)(1).

19 18. This is an exceptional case and Plaintiffs are entitled to an award of a  
20 reasonable attorney fee under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs respectfully request the following relief:

A. Judgment that Impax has infringed one or more claims of the '063 patent by filing the aforesaid ANDA relating to Impax's tamsulosin HCl 0.4 mg capsules;

B. A permanent injunction restraining and enjoining Impax and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of tamsulosin HCl 0.4 mg capsules as claimed in the '063 patent;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Impax's tamsulosin HCl 0.4 mg capsules be a date which is not earlier than the expiration of the '063 patent, or any later date of exclusivity to which Plaintiffs are or become entitled;

D. Damages from Impax for any commercial activity constituting infringement of the '063 patent;

E. An award to Plaintiffs of the costs and a reasonable attorney fee in this action; and

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



1 Dated: July 17, 2008

By:



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