IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

98-7164 CIV-FERGUSON

ELAN CORPORATION, PLC,

Plaintiff,

v.

ANDRX PHARMACEUTICALS, INC.

Defendant.

MAGISTRATE JUDGE SNOW

Case No.:

CLERK U.S. DIST. CT. S.D. OF FLA. - FTL
98 OCT 23 PM 2:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Elan Corporation, PLC ("Elan"), by its undersigned counsel, brings this action for patent infringement against Defendant Andrx Pharmaceuticals, Inc. ("Andrx"). This action relates to a patent covering a pharmaceutical formulation having an active ingredient known by the generic name naproxen. Plaintiff Elan alleges the following:

1. Plaintiff Elan is an Irish corporation having its corporate offices and principal place of business at Lincoln House, Lincoln Place, Dublin 2, Ireland. Plaintiff Elan is engaged in the business of researching, developing, manufacturing and selling pharmaceutical products throughout the world.

2. Upon information and belief, Defendant Andrx is a Florida corporation having its corporate offices and principal place of business at 4001 S.W. 47th Avenue, Ft. Lauderdale, Florida, 33314.

3. This patent infringement action arises under 35 U.S.C. §§ 271(e) and 281-283. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a). Venue is proper under 28 U.S.C. § 1391(c) and 1400(b).

COUNT FOR PATENT INFRINGEMENT

4. United States Letters Patent No. 5,637,320 ("the '320 patent"), entitled "Controlled Absorption Naproxen Formulation for Once-Daily Administration," was duly and legally issued by the United States Patent and Trademark Office on June 10, 1997, and expires on June 10, 2014. A copy of the '320 patent is attached hereto as Exhibit A.

5. Plaintiff Elan is the owner of the '320 patent.

6. The '320 patent claims a formulation for once-daily oral administration containing naproxen or a pharmaceutically acceptable salt of naproxen, such as naproxen sodium. Plaintiff Elan manufactures and sells such a once-daily naproxen formulation, which is marketed in the United States under the name Naprelan®.

7. Upon information and belief, Defendant Andrx filed with the United States Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") under 21

U.S.C. § 355(j) to obtain approval for Defendant Andrx to commercially manufacture, use and sell alleged generic equivalents of Naprelan®. Defendant Andrx seeks FDA approval to market its naproxen sodium controlled release tablets before the expiration date of the '320 patent. The FDA assigned Andrx's ANDA the number 75-416.

8. Upon information and belief, Defendant Andrx also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that none of the claims of the '320 patent will be infringed by the manufacture, use or sale of Andrx's naproxen sodium controlled release tablets.

9. On or about September 10, 1998, Plaintiff Elan received from Defendant Andrx a letter purporting to be a Notice of Certification under 21 C.F.R. § 314.95, informing Plaintiff Elan of Defendant Andrx's ANDA submission and corresponding certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV). A copy of this Notice is attached hereto as Exhibit B.

10. Under 35 U.S.C. § 271(e)(2)(A), Defendant Andrx's submission to the FDA of an ANDA to obtain approval for the commercial manufacture, use or sale of its naproxen sodium controlled release tablets before the expiration of the '320 patent was an act of infringement of the '320 patent.

RELIEF

WHEREFORE, Plaintiff Elan demands judgment as follows:

(a) finding that Defendant Andrx's naproxen sodium controlled release tablets for which it seeks FDA approval will infringe at least claim 1 of the '320 patent;

(b) ordering pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval by the FDA of Defendant Andrx's naproxen sodium controlled release tablets be a date not earlier than the date of the expiration of the '320 patent on June 10, 2014;

(c) granting injunctive relief pursuant to 35 U.S.C. § 271(e)(4)(B) against Defendant Andrx, prohibiting the commercial manufacture, use or sale of its naproxen sodium controlled release tablets until the expiration of the '320 patent on June 10, 2014;

(d) awarding Plaintiff Elan attorney's fees pursuant to 35 U.S.C. § 285, costs of suit, and any further and additional relief as this Court deems just and proper.

Dated: October 23, 1998

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFF
ELAN CORPORATION, PLC

ADDITIONAL

ATTACHMENTS

NOT

SCANNED

PLEASE REFER TO COURT FILE

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I (a) PLAINTIFFS
Elan Corporation, PLC

DEFENDANTS
Andrx Pharmaceuticals, Inc.

98-7164 CIV-FERGUSON

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF _____ (EXCEPT IN U.S. PLAINTIFF CASES)

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT FL (IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

ATTORNEYS (IF KNOWN) MAGISTRATE JUDGE SNOW

A/Broward/98-7164/WD7/LSS

(d) CIRCLE COUNTY WHERE ACTION AROSE:
DADE, MONROE, BROWARD, PALM BEACH, MARTIN, ST. LUCIE, INDIAN RIVER, OKEECHOBEE, HIGHLANDS

II. BASIS OF JURISDICTION (PLACE AN X IN ONE BOX ONLY)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN X IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) (For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY.) 35 USC §§271(e), 281-283. This an action by plaintiff against defendant for patent infringement.

IVa. 5 days estimated (for both sides) to try entire case.

V. NATURE OF SUIT (PLACE AN X IN ONE BOX ONLY)

A CONTRACT
☐ 110 Insurance
☐ 120 Marine
☐ 130 Miller Act
☐ 140 Negotiable Instrument
☐ 150 Recovery of Overpayment & Enforcement of Judgment
☐ 151 Medicare Act
B ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
B ☐ 153 Recovery of Overpayment of Veteran's Benefits
☐ 160 Stockholders' Suits
☐ 190 Other Contract
☐ 195 Contract Product Liability

A REAL PROPERTY
☐ 210 Land Condemnation
B ☐ 220 Foreclosure
☐ 230 Rent Lease & Ejectment
☐ 240 Torts to Land
☐ 245 Tort Product Liability
☐ 290 All Other Real Property

A TORTS
PERSONAL INJURY
☐ 310 Airplane
☐ 315 Airplane Product Liability
☐ 320 Assault, Libel & Slander
☐ 330 Federal Employers' Liability
☐ 340 Marine
☐ 345 Marine Product Liability
☐ 350 Motor Vehicle
☐ 355 Motor Vehicle Product Liability
☐ 360 Other Personal Injury
PERSONAL INJURY
☐ 362 Personal Injury—Med Malpractice
☐ 365 Personal Injury—Product Liability
☐ 368 Asbestos Personal Injury Product Liability
PERSONAL PROPERTY
☐ 370 Other Fraud
B ☐ 371 Truth in Lending
☐ 380 Other Personal Property Damage
☐ 385 Property Damage Product Liability

A CIVIL RIGHTS
☐ 441 Voting
☐ 442 Employment
☐ 443 Housing/ Accommodations
☐ 444 Welfare
☐ 440 Other Civil Rights

B PRISONER PETITIONS
☐ 510 Motions to Vacate Sentence
Habeas Corpus:
* ☐ 530 General
☐ 535 Death Penalty
* ☐ 540 Mandamus & Other
☐ 550 Civil Rights
*A or B

B FORFEITURE/PENALTY
☐ 610 Agriculture
☐ 620 Other Food & Drug
☐ 625 Drug Related Seizure of Property 21 USC 881
☐ 630 Liquor Laws
☐ 640 R.R. & Truck
☐ 650 Airline Regs
☐ 660 Occupational Safety/Health
☐ 690 Other

A LABOR
☐ 710 Fair Labor Standards Act
B ☐ 720 Labor/Mgmt. Relations
☐ 730 Labor/Mgmt. Reporting & Disclosure Act
☐ 740 Railway Labor Act
☐ 790 Other Labor Litigation
B ☐ 791 Empl. Ret. Inc Security Act

A BANKRUPTCY
☐ 422 Appeal 28 USC 158
☐ 423 Withdrawal 28 USC 157

A PROPERTY RIGHTS
☐ 820 Copyrights
☐ 830 Patent
☐ 840 Trademark

B SOCIAL SECURITY
☐ 861 HIA (1395ff)
☐ 862 Black Lung (923)
☐ 863 DIWC/DIWW (405(g))
☐ 864 SSID Title XVI
☐ 865 RSI (405(g))

A FEDERAL TAX SUITS
☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 871 IRS—Third Party 26 USC 7609

A OTHER STATUTES
☐ 400 State Reapportionment
☐ 410 Antitrust
☐ 430 Banks and Banking
B ☐ 450 Commerce/ICC Rates/etc.
☐ 460 Deportation
☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 810 Selective Service
☐ 850 Securities/Commodities/ Exchange
☐ 875 Customer Challenge 12 USC 3410
☐ 891 Agricultural Acts
☐ 892 Economic Stabilization Act
☐ 893 Environmental Matters
☐ 894 Energy Allocation Act
☐ 895 Freedom of Information Act
☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 950 Constitutionality of State Statutes
* ☒ 890 Other Statutory Actions (If Antitrust, then A)

VI. ORIGIN (PLACE AN X IN ONE BOX ONLY)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Refiled ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION ☐ UNDER F.R.C.P. 23 DEMAND $ Injunctive relief Check YES only if demanded in complaint: JURY DEMAND: ☐ YES ☒ NO

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 10/23/98 SIGNATURE OF ATTORNEY OF RECORD

UNITED STATES DISTRICT COURT
S/F I-2
DPV 6/90

FOR OFFICE USE ONLY: Receipt No. 514809 Amount: $150.00
Date Paid: 10-23-98 M/ifp: _____