



JS 44  
(Rev. 12/96)

# 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**

Biovail Laboratories, Inc.

Puerto Rico

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

**DEFENDANTS**

JUDGE CASTILLO

TorPharm, Inc.

**02C 6216**

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT

(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)

Eric C. Cohen, Esq. (312) 655-1500  
Welsh & Katz, Ltd.  
120 S. Riverside Plaza, 22nd Floor  
Chicago, Illinois 60606

ATTORNEYS (IF ANY)

**DOCKETED**  
MAGISTRATE JUDGE BOBRICK  
AUG 30 2002

**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)

- |   |                            |                            |   |                            |                            |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
|   | PTF                        | DEF                        |   | PTF                        | DEF                        |
| Citizen of This State                   | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State                | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

**IV. ORIGIN**

(PLACE AN "X" IN ONE BOX ONLY)

- 1 Original Proceeding
- 2 Removed from State Court
- 3 Remanded from Appellate Court
- 4 Reinstated or Reopened
- 5 Transferred from another district (specify)
- 6 Multidistrict Litigation
- 7 Appeal to District Judge from Magistrate Judgment

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

| CONTRACT   | TORTS  | FORFEITURE/PENALTY   | BANKRUPTCY   | OTHER STATUTES   |
|--|--|--|--|--|
| <input type="checkbox"/> 110 Insurance<br><input type="checkbox"/> 120 Marine<br><input type="checkbox"/> 130 Miller Act<br><input type="checkbox"/> 140 Negotiable Instrument<br><input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment<br><input type="checkbox"/> 151 Medicare Act<br><input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans)<br><input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits<br><input type="checkbox"/> 160 Stockholders' Suits<br><input type="checkbox"/> 165 Other Contract<br><input type="checkbox"/> 195 Contract Product Liability | <b>PERSONAL INJURY</b><br><input type="checkbox"/> 310 Airplane<br><input type="checkbox"/> 315 Airplane Product Liability<br><input type="checkbox"/> 320 Assault, Libel & Slander<br><input type="checkbox"/> 330 Federal Employers' Liability<br><input type="checkbox"/> 340 Marine<br><input type="checkbox"/> 345 Marine Product Liability<br><input type="checkbox"/> 350 Motor Vehicle<br><input type="checkbox"/> 355 Motor Vehicle Product Liability<br><input type="checkbox"/> 360 Other Personal Injury<br><br><b>PERSONAL INJURY</b><br><input type="checkbox"/> 362 Personal Injury - Med. Malpractice<br><input type="checkbox"/> 365 Personal Injury - Product Liability<br><input type="checkbox"/> 368 Asbestos Personal Injury Product Liability<br><br><b>PERSONAL PROPERTY</b><br><input type="checkbox"/> 370 Other Fraud<br><input type="checkbox"/> 371 Truth in Lending<br><input type="checkbox"/> 380 Other Personal Property Damage<br><input type="checkbox"/> 385 Property Damage Product Liability | <input type="checkbox"/> 610 Agriculture<br><input type="checkbox"/> 620 Other Food & Drug<br><input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881<br><input type="checkbox"/> 630 Liquor Laws<br><input type="checkbox"/> 640 R.R. & Truck<br><input type="checkbox"/> 650 Airline Regs.<br><input type="checkbox"/> 680 Occupational Safety/Health<br><input type="checkbox"/> 690 Other | <input type="checkbox"/> 422 Appeal 28 USC 158<br><input type="checkbox"/> 423 Withdrawal 28 USC 157<br><br><b>PROPERTY RIGHTS</b><br><input type="checkbox"/> 620 Copyrights<br><input checked="" type="checkbox"/> 630 Patent<br><input type="checkbox"/> 640 Trademark<br><br><b>SOCIAL SECURITY</b><br><input type="checkbox"/> 661 HIA (1395ff)<br><input type="checkbox"/> 662 Black Lung (923)<br><input type="checkbox"/> 663 DIWC/DIWW (405(g))<br><input type="checkbox"/> 664 SSID Title XVI<br><input type="checkbox"/> 665 RSI (405(g)) | <input type="checkbox"/> 400 State Reapportionment<br><input type="checkbox"/> 410 Antitrust<br><input type="checkbox"/> 430 Banks and Banking<br><input type="checkbox"/> 450 Commerce/ICC Rates/etc.<br><input type="checkbox"/> 460 Deportation<br><input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations<br><input type="checkbox"/> 610 Selective Service<br><input type="checkbox"/> 650 Securities/Commodities/Exchange<br><input type="checkbox"/> 675 Customer Challenge 12 USC 3410<br><input type="checkbox"/> 691 Agricultural Acts<br><input type="checkbox"/> 692 Economic Stabilization Act<br><input type="checkbox"/> 693 Environmental Matters<br><input type="checkbox"/> 694 Energy Allocation Act<br><input type="checkbox"/> 695 Freedom of Information Act<br><input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice<br><input type="checkbox"/> 650 Constitutionality of State Statutes<br><input type="checkbox"/> 690 Other Statutory Actions |
| REAL PROPERTY  | CIVIL RIGHTS   | PRISONER PETITIONS   |  |  |
| <input type="checkbox"/> 210 Land Condemnation<br><input type="checkbox"/> 220 Foreclosure<br><input type="checkbox"/> 230 Rent Lease & Ejectment<br><input type="checkbox"/> 240 Torts to Land<br><input type="checkbox"/> 245 Tort Product Liability<br><input type="checkbox"/> 290 All Other Real Property   | <input type="checkbox"/> 441 Voting<br><input type="checkbox"/> 442 Employment<br><input type="checkbox"/> 443 Housing/Accommodations<br><input type="checkbox"/> 444 Welfare<br><input type="checkbox"/> 440 Other Civil Rights   | <input type="checkbox"/> 510 Motion to Vacate Sentence Habeas Corpus:<br><input type="checkbox"/> 530 General<br><input type="checkbox"/> 535 Death Penalty<br><input type="checkbox"/> 540 Mandamus & Other<br><input type="checkbox"/> 550 Civil Rights<br><input type="checkbox"/> 555 Prison Condition   | <input type="checkbox"/> 710 Fair Labor Standards Act<br><input type="checkbox"/> 720 Labor/Mgmt Relations<br><input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act<br><input type="checkbox"/> 740 Railway Labor Act<br><input type="checkbox"/> 790 Other Labor Litigation<br><input type="checkbox"/> 791 Empl. Ret. Inc Security Act   | <b>FEDERAL TAX SUITS</b><br><input type="checkbox"/> 670 Taxes (U.S. Plaintiff or Defendant)<br><input type="checkbox"/> 671 IRS - Third Party 26 USC 7609   |

**VI. CAUSE OF ACTION**

(CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY)

35 U.S.C. Section 271 (e)(2) - Patent Infringement

**VII. REQUESTED IN COMPLAINT**

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint

JURY DEMAND:  YES  NO

VIII. This case  is not a refiling of a previously dismissed action.

is a refiling of case number \_\_\_\_\_, previously dismissed by Judge \_\_\_\_\_

DATE

SIGNATURE OF ATTORNEY OF RECORD

8/30/2002

*Eric C. Cohen*

UNITED STATES DISTRICT COURT

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IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

JUDGE CASTILLO

BIOVAIL LABORATORIES, INC. )  
a corporation of Barbados, )  
 )  
Plaintiff, )  
 )  
vs. )  
 )  
TORPHARM, INC., a Canadian )  
Corporation, )  
 )  
Defendant. )

MAGISTRATE JUDGE BOBRICK  
No.: **02C 6216**

Judge:

**DOCKETED**

AUG 30 2002

02 AUG 30 11:02 AM  
U.S. DISTRICT COURT

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff, Biovail Laboratories, Inc., for its complaint against TorPharm, Inc.,  
allege as follows:

**JURISDICTION, VENUE, AND PARTIES**

1. This is an action by Biovail Laboratories, Inc. ("Biovail") for infringement of U.S. Patent No. 5,529,791 and U.S. Patent No. 5288,505, and is brought against Defendant TorPharm, Inc. (TorPharm), under 35 U.S.C. §271(e)(2). This infringement action arises under the Patent Laws because TorPharm has filed, pursuant to 21 U.S.C. §355(j), an Abbreviated New Drug Application ("ANDA") Number 76-395 with the Federal Food and Drug Administration ("FDA") for a Diltiazem HCl Capsules Type TZ (Diltiazem Hydrochloride Extended-Release Capsules USP) 120mg, 180mg, 240mg, 300mg and 360mg. Under 35 U.S.C. §271(e)(2), "[i]t shall be an act of infringement to submit an [ANDA] 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."

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2. Plaintiff Biovail is a corporation organized and existing under the laws of Barbados and has a place of business in Carolina, Puerto Rico.

3. Defendant TorPharm is a corporation organized and existing under the laws of Canada, and has a principal place of business at 50 Steinway Blvd, Toronto, Ontario, M9W 6Y3, Canada.

4. This action arises under the patent laws of the United States of America and specifically under 35 U.S.C. §271(e)(2). Jurisdiction is founded on 28 U.S.C. §§ 1331 and 1338(a). Defendant TorPharm has a registered agent for the service of process in this District. This Court has personal jurisdiction over TorPharm and venue is proper in this Court under 28 U.S.C. §§1391(c) and 1400(b).

**BIOVAIL'S NEW DRUG APPLICATION AND  
BIOVAIL'S RIGHTS UNDER THE '791 PATENT**

5. U.S. Patent No. 5,529,791 (hereinafter "the '791 patent") was lawfully granted on June 25, 1996 to and Galephar P.R. Inc., Ltd. ("Galephar"), the assignee of the named inventors, Arthur M. Deboeck and Phillippe R. Baudier.

6. U.S. Patent No. 5,288,505 (hereinafter "the '505 patent") was lawfully granted on February 22, 1994 to Galephar, the assignee of the named inventors, Arthur M. Deboeck and Phillippe R. Baudier.

7. Biovail is the exclusive licensee of the '791 patent and the '505 patent under an Agreement effective September 10, 1995, which remains in full force and effect, and has the exclusive right to sublicense others and to sue for infringement.

8. Biovail sought and received approval from the United States Food and Drug Administration ("FDA") to manufacture, market and sell an extended release diltiazem-containing drug product known commercially as TIAZAC®, which is listed along with

the '791 patent in the FDA's book of Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") under its active ingredient, Diltiazem Hydrochloride.

9. Biovail sought and received approval from the United States Food and Drug Administration ("FDA") to manufacture, market and sell an extended release diltiazem-containing drug product known commercially as Diltiazem HCl, which is listed along with the '791 patent and the '505 patent in the FDA's book of Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") under its active ingredient, Diltiazem Hydrochloride.

**TORPHARM'S ACT OF PATENT INFRINGEMENT  
UNDER 35 U.S.C. §271(e)(2)**

10. TorPharm advised Biovail by a letter which bears the date July 16, 2002 (but which was apparently mailed on July 19, 2002), that it had filed Abbreviated New Drug Application ("ANDA") No. 76-395 with the Federal Food and Drug Administration ("FDA") for Diltiazem HCl Capsules Type TZ (Diltiazem Hydrochloride Extended-Release Capsules USP) 120mg, 180mg, 240mg, 300mg and 360mg. TorPharm's letter, however, did not identify any New Drug Application or reference listed drug. The letter stated that TorPharm had certified to the FDA (pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification")), that the '791 patent "will not be infringed by the manufacture, use, or sale of Diltiazem HCl Capsules Type TZ (Diltiazem Hydrochloride Extended-Release Capsules USP) 120mg, 180mg, 240mg, 300mg and 360mg". TorPharm's letter did not provide "a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed", as is

required by 21 U.S.C. §355(j)(2)(B)(i) and (ii), but alleged only in conclusory terms that its proposed ANDA product would not infringe the '791 patent. Biovail received TorPharm's letter on July 22, 2002.

11. After a reasonable opportunity for further investigation or discovery, there is likely to be evidence that TorPharm has infringed the '791 patent under 35 U.S.C. §271(e)(2), by seeking approval under its ANDA No. 76-395 with a Paragraph IV certification to engage in the commercial manufacture, use, sale or offer for sale of its proposed ANDA product prior to the expiration of the '791 patent.

12. After a reasonable opportunity for further investigation or discovery, there is likely to be evidence that TorPharm has infringed the '505 patent under 35 U.S.C. §271(e)(2), by seeking approval under ANDA No. 76-395 to engage in the commercial manufacture, use, sale or offer for sale of its proposed ANDA product prior to the expiration of the '505 patent.

13. After a reasonable opportunity for further investigation or discovery, there is likely to be evidence that TorPharm has offered to sell or import into the United States an approved drug under ANDA No. 76-395.

**RELIEF REQUESTED**

**WHEREFORE**, Plaintiff prays for judgment as follows:

- A. A judgment that Torpharm has infringed valid U.S. Patent Nos. 5,529,791 and 5,288,505 under 35 U.S.C. §271(e)(2);
- B. Pursuant to 35 U.S.C. §271(e)(4)(C), for an award of damages for TorPharm's offer to sell or import an approved drug under ANDA No. 76-395;

- C. For an award of the costs and expenses in this action; and,
- D. For such further and other relief as this Court may deem just and proper.

Dated: August 30, 2001



Eric C. Cohen  
Robert B. Breisblatt  
James P. White  
Charles R. Krikorian  
WELSH & KATZ, LTD.  
120 South Riverside Plaza – 22<sup>nd</sup> Floor  
Chicago, Illinois 60606

Attorneys for Plaintiff  
Biovail Laboratories, Inc.