

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

LUPIN PHARMACEUTICALS, INC., *et al.*, *

Plaintiffs, *

v. * Civil Action No. RDB-15-1281

CRAIG RICHARDS, *

Defendant. *

* * * * *

MEMORANDUM OPINION

In this case, Plaintiffs Lupin Pharmaceuticals, Inc.¹ (“Lupin Pharmaceuticals”) and Lupin, Ltd. (“Lupin India”) (collectively, “the Lupin Plaintiffs”) seek to enjoin Defendant Craig Richards, the Attorney General of Alaska, (“the Attorney General”) from issuing a civil investigative demand (“CID”) to the Lupin Plaintiffs and from applying Alaskan antitrust law to the Lupin Plaintiffs. The Attorney General has moved to dismiss this action, arguing that this Court should abstain from exercising its jurisdiction under the abstention doctrine established in *Younger v. Harris*, 401 U.S. 37 (1971). The parties’ submissions have been reviewed, and this Court held a hearing on June 26, 2015 on the Motion. *See* Local Rule 105.6 (D. Md. 2014). For the reasons that follow, Defendants Craig Richards’ Motion to Dismiss (ECF No. 23) is GRANTED, and this case is DISMISSED.

BACKGROUND

¹ Lupin Pharmaceuticals, Inc is a Virginia corporation with its headquarters and principal place of business located in Baltimore, Maryland. Pls.’ Comp. ¶ 10. Lupin Pharmaceuticals distributes prescription medications to American customers and is a wholly owned subsidiary of co-Plaintiff Lupin, Ltd. (“Lupin India”). *Id.*

This Court accepts as true the facts alleged in plaintiff's complaint. *See Aziz v. Alcolac, Inc.*, 658 F.3d 388, 390 (4th Cir. 2011). This dispute arose out of issues pertaining to two drugs, Loestrin FE 24 and Effexor XR. These drugs are manufactured and sold by Warner-Chilcott and Wyeth, respectively, and those companies hold patents on the drugs. *See* Compl., ¶ 16. The Lupin Plaintiffs allege that neither Lupin Pharmaceuticals, Inc. nor Lupin, Ltd.² ("Lupin India") had rights to sell the drugs or approval to sell generic versions. *Id.* The Lupin Plaintiffs had filed applications with the Food & Drug Administration ("FDA") in 2006 and 2009 to sell generic versions of the respective drugs, but the brand manufacturers sued the Lupin Plaintiffs for declaratory judgments stating that the sale of such generics would violate their patents.³ *Id.* at ¶ 17. The Lupin Plaintiffs settled the patent claims in 2009 and 2010 respectively. *Id.* at ¶¶ 17-18.

² Lupin India is incorporated in India and has its headquarters and principal place of business in Mumbai, India. Pls.' Compl. ¶ 11. Lupin India develops and manufactures branded and generic drugs in India.

³ Specifically, the Lupin Plaintiffs alleged:

Neither LPI nor Lupin India has ever sold Loestrin or Effexor nor have they ever obtained approval from the Food and Drug Administration ("FDA") to sell generic versions of those products. On September 30, 2006, Plaintiffs filed with the FDA an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of Effexor. On March 13, 2007, Wyeth, the branded manufacturer of Effexor, sued SPI for a declaratory judgment that LPI's generic version of Effexor would infringe Wyeth's patent. Wyeth and LPI settled the litigation on May 11, 2009.

. . . On July 30, 2009, LPI filed an ANDA seeking FDA approval of a generic version of Loestrin. On September 9, 2009, Warner-Chilcott, the branded manufacturer of Loestrin, sued LPI for a declaratory judgment that LPI's generic version of Loestrin would infringe Warner Chilcott's patent. Warner-Chilcott and LPI settled the litigation on October 10, 2010.

Pls.' Compl. ¶¶ 17-18.

On February 3, 2015, pursuant to Alaska Stats. §§45.50.592⁴ and 45.50.495, Attorney General Richards issued separate civil investigative demands (CIDs) to Lupin

⁴ Section 45.50.592 states in full:

- (a) If the attorney general determines that a person is in possession, custody, or control of documentary evidence, wherever situated, that the attorney general believes to be relevant to an investigation authorized in AS 45.50.590, the attorney general may execute in writing and cause to be served on that person an investigative demand requiring the person to produce the documentary material, and permit inspection and copying.
- (b) Each demand must
 - (1) state the specific statute the alleged violation of which is under investigation, and the general subject matter of the investigation;
 - (2) describe, with reasonable specificity so as fairly to indicate the material demanded, the documentary material to be produced;
 - (3) prescribe a return date within which the documentary material is to be produced; and
 - (4) identify the state employees or representatives to whom the documentary material is to be made available for inspection and copying.
- (c) A demand may not
 - (1) require the production of documentary material that would be privileged from disclosure if demanded by a subpoena duces tecum issued by a court of the state; or
 - (2) contain a requirement that would be unreasonable or improper if contained in a subpoena duces tecum issued by a court of the state; however, this does not limit the power of the attorney general to require production of documents located outside the state that pertain to matters affecting the state.
- (d) The demand may be served by the attorney general or the designee of the attorney general by
 - (1) delivering a copy of it to the person to be served or, if the person is not a natural person, to an officer of the person to be served;
 - (2) delivering a copy of it to a place of business in the state of the person to be served; or
 - (3) mailing by registered or certified mail a copy of it addressed to the person to be served at a place of business in the state or, if the person has no place of business in the state, to the principal office or place of business of the person.
- (e) Documentary material produced pursuant to a demand, or copies of it, unless otherwise ordered by a superior court for good cause shown, may not be produced for inspection or copying by, nor may its contents be disclosed to, anyone other than an authorized employee of the state without the consent of the person who produced the material. However, under those

Pharmaceuticals, Inc., and Lupin, Ltd., demanding production of three categories of documents related to the two drugs. *Id.* at ¶ 21. The CIDs state that “[t]he Attorney General seeks to determine whether the pharmaceutical manufacturers subject to [the CID]

reasonable terms and conditions the attorney general prescribes, copies of the documentary material shall be available for inspection and copying by the person who produced the material or an authorized representative of that person. The attorney general, or a designee, may use copies of the documentary material as the attorney general or designee considers necessary in the enforcement of AS 45.50.562-45.50.598, including presentation before a court; however, material that contains trade secrets may not be presented except with the approval of the court in which the action is pending after adequate notice to the person furnishing the material.

(f) At any time before the return date specified in the demand, or within 20 days after the demand has been served, whichever period is shorter, a petition to extend the return date for, or to modify or set aside a demand issued under (a) of this section, stating good cause, may be filed in the superior court for the judicial district where the parties reside. A petition by a person on whom a demand is served, stating good cause, to require the attorney general or another person to act in accordance with the requirements of (c) of this section, and all other petitions in connection with a demand, may be filed in the superior court for the judicial district in which the person on whom the demand is served resides.

(g) A person on whom a demand is served under this section shall comply with the terms of the demand unless otherwise provided by an order of court issued in response to a petition filed under (f) of this section. A person who, with intent to avoid, prevent, or obstruct compliance, in whole or in part, with an investigative demand under this section, removes from any place, conceals, withholds, or destroys, mutilates, alters, or by any other means falsifies, documentary material in the possession, custody, or control of a person that is the subject of a demand duly served on any person, or who otherwise wilfully disobeys any such demand, is guilty of a misdemeanor, and is punishable upon conviction by a fine of not more than \$5,000, or by imprisonment for a term of not more than one year, or by both. Failure of the state to serve the demand properly under (d) of this section is a defense to prosecution under this subsection, but invalidity of the demand under (b) or (c) of this section is not a defense, and that invalidity may be tested only in an action under (f) of this section to modify or set aside the demand.

(h) Nothing in this section impairs the authority of the attorney general or a designee to lay before a grand jury of this state evidence concerning a violation of AS 45.50.562 - 45.50.596, to invoke the power of a court to compel the production of evidence before a grand jury, or to file a civil complaint or criminal information alleging a violation of AS 45.50.562 - 45.50.596.

violated Alaska state law by entering into a settlement agreement that terminated ongoing patent litigation regarding the brand name drug listed herein, and thereby delaying generic entry into the marketplace,” in potential violation of Alaska antitrust and consumer protection statutes. *See* Mem. Supp. Mot. Dismiss 1-2, ECF No. 23-1. The CIDs originally required production of responsive documents within sixty days. *Id.* at 2. The Lupin Plaintiffs allege that the scope of the CIDs included filings with the Federal Trade Commission (“FTC”) and Department of Justice (“DOJ”), documents produced in the patent litigations, documents discussing the validity of the patents, and agreements between Lupin and the branded manufacturers. Pls.’ Compl. ¶ 21.

Alaska law provides that the subject of a CID may within 20 days of service file a petition in Alaska Superior Court stating good cause why the CID should be modified or set aside. Alaska Stat. §45.50.592(f). The Lupin Plaintiffs declined to file any petition requesting modification of the CID. It is undisputed, however, that the Lupin Plaintiffs requested to extend the time for compliance with the CIDs; the Attorney General granted those requests. Thus, the deadline to produce documents responsive to the CIDs was May 4, 2015. Pls.’ Compl. ¶23.

Instead of complying with or objecting to the CIDs, the Lupin Plaintiffs filed the present action on the May 4 deadline, and filed the Motion for Preliminary Injunction (ECF No. 4) on the following day. The Complaint requests that this Court immediately issue a permanent injunction restraining Defendant from issuing civil investigative demands (CIDs) to Plaintiffs in connection with the Attorney General’s investigation of Plaintiffs’ compliance with Alaskan Antitrust laws, and from applying those state laws to Plaintiffs. Plaintiffs also

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