## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

| BAYER HEALTHCARE LLC and        | )                        |
|---------------------------------|--------------------------|
| BAYER HEALTHCARE                | )                        |
| PHARMACEUTICALS INC.,           | )                        |
|                                 | )                        |
| Plaintiffs,                     | )                        |
|                                 | ) C.A. No. 16-1221 (LPS) |
| v.                              | ) CONSOLIDATED           |
|                                 | )                        |
| TEVA PHARMACEUTICALS USA, INC., | )                        |
| et al.,                         | )                        |
|                                 | )                        |
| Defendants.                     | )                        |

## NOTICE OF DEPOSITION PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 30(b)(6)

PLEASE TAKE NOTICE that commencing on July 30, 2018, at the law office of Williams & Connolly LLP, 725 Twelfth Street, NW, Washington, DC 20005, or at such time and place that is agreed upon by the parties, Plaintiffs Bayer HealthCare LLC and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer"), through their attorneys, will take the deposition of Apotex Corp. and Apotex Inc. (collectively, "Apotex") pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure.

At the time of the deposition, Apotex shall designate one or more of its directors, officers, managing agents, or other persons who will testify on behalf of Apotex as to all information known or reasonably available to Apotex regarding the subject matters set forth in Attachment A.

The deposition will take place upon oral examination before a notary public or other person authorized to administer oaths, will be recorded by stenographic and/or sound-and-video means, and will continue from day to day until completed. You are invited to attend and participate.



MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Anthony D. Raucci

Jack B. Blumenfeld (#1014) Derek J. Fahnestock (#4705) Anthony D. Raucci (#5948) 1201 North Market Street P.O. Box 1347 Wilmington, DE 19899 (302) 658-9200 jblumenfeld@mnat.com dfahnestock@mnat.com araucci@mnat.com

Attorneys for Plaintiffs Bayer HealthCare LLC and Bayer HealthCare Pharmaceuticals Inc.

### OF COUNSEL:

Bruce R. Genderson Adam L. Perlman Dov P. Grossman Jessica B. Rydstrom Seth R. Bowers Ben Picozzi WILLIAMS & CONNOLLY LLP 725 Twelfth St. NW Washington, DC 20005 (202) 434-5000

July 12, 2018



#### ATTACHMENT A

## **INSTRUCTIONS AND DEFINITIONS**

- 1. As used herein, the terms "you," "your," "yours," and "Apotex" mean jointly and severally defendants Apotex Corp., Apotex Inc., their officers, directors, employees, divisions, parent companies, subsidiaries, affiliates, and predecessors or successors-in-interest, any joint venture to which they may be a party, consultants, agents, and accountants, including any person who served in any such capacity at any time.
- 2. As used herein, "Teva" means jointly and severally defendant Teva Pharmaceuticals USA, Inc., its officers, directors, employees, divisions, parent companies, subsidiaries, affiliates, and predecessors or successors-in-interest, any joint venture to which it may be a party, consultants, agents, and accountants, including any person who served in any such capacity at any time.
- 3. As used herein, the term "including" means "including but not limited to" or "including without limitation."
- 4. As used herein, the terms "and" as well as "or" shall be construed either disjunctively or conjunctively, and references shall be construed either as singular or plural, as necessary to bring within the scope of these topics any information that might otherwise be construed to be outside their scope.
- 5. As used herein, the term "all" shall be construed to mean all or any, and the term "any" shall be construed to mean all or any.
- 6. As used herein, the term "communication" means any transmission of any information from one person to another, including, without limitation, by personal meeting, telephone, facsimile, electronic transmission, including electronic mail, and teleconference.



- 7. As used herein, "Apotex's ANDA Product" shall be construed to include any product that is the subject of Abbreviated New Drug Application ("ANDA") No. 203085, as well as the active pharmaceutical ingredient drug substance(s) identified therein, including but not limited to any generic equivalent of Stivarga®.
  - 8. As used herein, "regorafenib" shall mean the compound of the formula:

$$CI \xrightarrow{CF_3} O \xrightarrow{N} NH \xrightarrow{CH_3}$$

(also known as, *inter alia*, 4{4-[3-(4-chloro-3-trifluoromethylphenyl)-ureido]-3-fluorophenoxy}-pyridine-2-carboxylic acid methylamide), or any salt form (including, but not limited to a hydrochloride salt) of the compound, or any solvate (including, but not limited to, any hydrate) of any of the aforementioned, or any polymorph of the aforementioned, or any other form of any of the aforementioned, or any mixture of two or more of the aforementioned, and includes but is not limited to the active pharmaceutical ingredient ("API") in Stivarga®.

- 9. As used herein, the term "FDA" means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners, and laboratories.
- 10. As used herein, the terms "person" and "entity" mean any natural person and any other cognizable entity, including, without limitation, corporations, proprietorships, partnerships, joint ventures, businesses, consortiums, clubs, associations, foundations, governmental agencies or instrumentalities, societies, and orders.
- 11. As used herein, "Apotex's Notice Letters" means the Notice Letters sent from Apotex to Bayer on or about November 8, 2016 and March 17, 2017.



- 12. As used herein, the term "553 patent" means United States Patent No. 8,637,553.
- 13. As used herein, the term "107 patent" means United States Patent No. 9,458,107.
- 14. As used herein, the term "Patents-in-Suit" means the '553 and '107 patents.
- 15. The use of the singular form of any word includes the plural and vice versa, as necessary to bring within the scope of these topics any information or documents and things that might otherwise be construed to be outside their scope.

### **TOPICS**

- 1. The process by which Apotex identified regorafenib as a candidate for a potential Abbreviated New Drug Application and which individuals and entities were involved in that process.
- 2. The decision to file ANDA No. 203085, the information considered in reaching that decision, and the individuals and entities involved in that decision.
- 3. All patent certifications in connection with ANDA No. 203085, any amendments or supplements thereto, which individuals were involved in the patent certifications, and what information was considered.
- 4. The contents of the proposed labeling for Apotex's ANDA Product, the decision-making as to the contents of the proposed label for Apotex's ANDA Product, which individuals and entities were involved in the decision-making, and the contents of any discussions related in any way to the decision-making.
  - 5. The projected sales and market share of Apotex's ANDA Product.
  - 6. The indications for Apotex's ANDA Product.
  - 7. Apotex's pricing practices as they pertain to Apotex's ANDA Product.
  - 8. Apotex's anticipated profits and/or losses from sale of Apotex's ANDA Product.



# DOCKET

# Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

#### **LAW FIRMS**

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

#### **FINANCIAL INSTITUTIONS**

Litigation and bankruptcy checks for companies and debtors.

## **E-DISCOVERY AND LEGAL VENDORS**

Sync your system to PACER to automate legal marketing.

