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 Teva Pharmaceuticals USA, Inc. pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure.

At the time of the deposition, Teva shall designate one or more of its directors, officers, managing agents, or other persons who will testify on behalf of Teva as to all information known or reasonably available to Teva 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

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July 12, 2018



ATTACHMENT A

INSTRUCTIONS AND DEFINITIONS

- 1. As used herein, the terms "you," "your," "yours," and "Teva" mean 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.
- 2. As used herein, "Apotex" means 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.
- 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, "Teva's ANDA Product" shall be construed to include any product that is the subject of Abbreviated New Drug Application ("ANDA") No. 209728, 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:

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

(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, "Teva's Notice Letter" means the Notice Letter sent from Teva to Bayer on or about November 22, 2016.



- 12. As used herein, the term "834 patent" means United States Patent No. 7,351,834.
- 13. As used herein, the term "553 patent" means United States Patent No. 8,637,553.
- 14. As used herein, the term "124 patent" means United States Patent No. 8,680,124.
- 15. As used herein, the term "107 patent" means United States Patent No. 9,458,107.
- 16. As used herein, the term "Patents-in-Suit" means the '834, '553, '124, and '107 patents.
- 17. 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 Teva 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. 209728, the information considered in reaching that decision, and the individuals and entities involved in that decision.
- 3. Why Teva chose to file an ANDA for a generic regorafenib product in addition to an ANDA for a generic sorafenib product.
- 4. All patent certifications in connection with ANDA No. 209728, any amendments or supplements thereto, which individuals were involved in the patent certifications, and what information was considered.
- 5. The contents of the proposed labeling for Teva's ANDA Product, the decision-making as to the contents of the proposed label for Teva's ANDA Product, which individuals



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