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

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) C.A. No. 16-1221 (LPS)
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## STIPULATION AND ORDER REGARDING INFRINGEMENT

Plaintiffs Bayer HealthCare LLC and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") and Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") hereby STIPULATE, and request that the Court ORDER, as follows:

- 1. The regorafenib oral tablets that are the subject of Apotex's Abbreviated New Drug Application ("ANDA") No. 209765 (including any amendments or supplements thereto) ("Apotex's ANDA Product") infringe each of claims 1, 3, 6, 8, and 13 and 14 of U.S. Patent No. 8,637,553 ("the '553 patent"), provided that the claim at issue is not proven invalid or unenforceable;
- 2. The use of Apotex's ANDA Product in accordance with its labeling infringes each of claims 10, 11, and 12 of the '553 patent, provided that the claim at issue is not proven invalid or unenforceable;
- 3. Apotex will induce infringement of each of claims 10, 11, and 12 of the '553 patent, provided that the claim at issue is not proven invalid or unenforceable, through sale of Apotex's ANDA Product;



- 4. Apotex's ANDA Product infringes each of claims 1-4, 9-14, and 18-20 of U.S. Patent No. 9,458,107 ("the '107 patent"), provided that the claim at issue is not proven invalid or unenforceable;
- 5. As a result of the stipulation of infringement set forth herein, Bayer and Apotex (together "the Parties") agree that no supplementation to Apotex's responses to Bayer's Interrogatory Nos. 1-2 is required. In addition, as a result of the stipulation of infringement set forth herein, the Parties agree that Apotex will produce neither the closed portion of the Drug Master File for the regorafenib active pharmaceutical ingredient ("API") used in Apotex's ANDA Product, nor any samples of either its finished ANDA Product or the API used in its ANDA product that were requested by Bayer. Further, as a result of the stipulation of infringement set forth herein, Bayer withdraws its Interrogatories Nos. 7-8 as to Apotex.
- 6. As a result of the stipulation of infringement set forth herein, Bayer agrees that it will not take any individual depositions of Apotex employees other than Kiran Krishnan. In addition, as a result of the stipulation of infringement set forth herein, Bayer will withdraw topics 4, 12, 14, 15, 16, 17, 18, 19, 20, 21, and 22 as listed in Attachment A of Plaintiff's Notice of Deposition Pursuant to Federal Rule of Civil Procedure 30(b)(6) that was served on Apotex.
- 7. Nothing in this stipulation shall preclude Apotex from pursuing any properly pleaded and disclosed defense contesting the validity and/or enforceability of any claim of the '553 and/or the '107 patent(s).

Bayer and Apotex make this stipulation without prejudice to or waiver of their rights on any appeal of any judgment of this Court, except with respect to the matters of infringement as stipulated herein.



### IT IS HEREBY STIPULATED:

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/s/ Derek J. Fahnestock

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Attorneys for Defendants Apotex Corp. and Apotex Inc.

SO ORDERED this da	of, 2018.	
	United States District Judge	

