

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

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

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**DEFENDANTS’ OPENING CLAIM CONSTRUCTION BRIEF**

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## I. INTRODUCTION

Defendant Teva Pharmaceuticals USA, Inc., submits this Opening Claim Construction Brief pursuant to paragraph 12 of the Court's Scheduling Order (ECF 20). Of the four asserted patents, the parties disagree on the construction of two terms, both of which are found in the claims of U.S. Patent No. 8,680,124 ("the '124 patent"). The parties agree that these terms can be construed without resorting to extrinsic evidence, leaving the Court with the task of determining which construction "stays true to the claim language and most naturally aligns with the patent's description of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005). Teva's constructions, which are taken directly from the inventors' written description of their invention, readily accomplish that objective. In contrast, Bayer asks the Court to construe the terms more broadly than what is supported by the specification. The Court should adopt Teva's proposed constructions, which are the most faithful to the intrinsic evidence.

## II. STATEMENT OF FACTS

This patent infringement lawsuit arises under the Hatch-Waxman Act, and involves four patents listed in the Orange Book for regorafenib, a drug sold under the brand name Stivarga<sup>®</sup>. Stivarga<sup>®</sup> is indicated for, *inter alia*, treatment of patients with certain forms of gastrointestinal stromal tumors (GIST) who have been previously treated with imatinib mesylate and sunitinib malate. Stivarga<sup>®</sup> is administered as a tablet containing regorafenib.

The only patent containing disputed claim terms, the '124 patent, is entitled "Treatment of Cancers with Acquired Resistance to KIT Inhibitors," and issued on March 25, 2014. The asserted claims of the '124 patent are generally directed to methods of treating certain cancers by administering an effective amount of regorafenib, identified as 4{4-[3-(4-chloro-3-

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