IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFFS BAYER HEALTHCARE LLC AND BAYER HEALTHCARE PHARMACEUTICALS INC.'S OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

This claim-construction dispute involves two claim terms—"an effective amount" and "a subject who has been treated with imatinib"—recited in U.S. Patent No. 8,680,124 ("the '124 patent"). The '124 patent is one of four patents asserted by Plaintiffs Bayer HealthCare LLC and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Plaintiffs" or "Bayer") against Defendant Teva Pharmaceuticals USA, Inc. ("Teva") and relates to certain methods of using regorafenib, the active pharmaceutical ingredient in Bayer's Stivarga® drug product.

Neither disputed claim term requires elaborate construction. The specification expressly defines "effective amount" to mean "the amount of [regorafenib] which is effective to treat any symptom or aspect of the cancer." The claim language also makes clear that "an effective amount" can be used to treat a "malignant" or "benign" gastrointestinal stromal tumor. Bayer therefore proposes that the phrase "an effective amount" should be construed to mean "an amount which is effective to treat any symptom or aspect of the cancer *or the tumor*." As for the phrase "a subject who has been treated with imatinib," the claim language and specification confirm that it means exactly what it says. It therefore does not require further construction.

Despite the straightforward nature of the claim-construction exercise here, Teva (1) proposes a lengthy, complex, and unsupported construction for "an effective amount," and (2) imports a limitation into "a subject who has been treated with imatinib" that improperly restricts the meaning of that phrase to circumstances where the subject's cancer has developed resistance to imatinib. Neither construction is warranted. Accordingly, this Court should adopt Bayer's proposed constructions.

II. BACKGROUND

This Hatch-Waxman Act case concerns Bayer's Stivarga® drug product. As set forth in more detail in the FDA-approved labeling, Stivarga® is an anti-cancer drug approved to treat

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