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Paper 9
Entered: February 8, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUSTIBAL LLC,
Petitioner,

v.

BAYER HEALTHCARE LLC,
Patent Owner.

Case IPR2016-01490
Patent 8,637,553 B2

Before LORA M. GREEN, RAMA G. ELLURU, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Fustibal LLC. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–16 of U.S. Patent No. 8,637,553 B2 (Ex. 1001, "the '553 Patent"). Paper 1 ("Pet."). Bayer Healthcare LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 6 and 35 C.F.R. § 42.4(a).

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see* 37 C.F.R. §§ 42.4, 42.108. Upon considering the Petition and the Preliminary Response, we exercise our discretion under 35 U.S.C. § 325(d) to decline Petitioner's request for institution of an *inter partes* review based on some grounds. In addition, we determine that Petitioner has not shown a reasonable likelihood that it would prevail in showing the unpatentability of any of the challenged claims. Accordingly, we decline to institute an *inter partes* review of claims 1–16 of the '530 Patent.

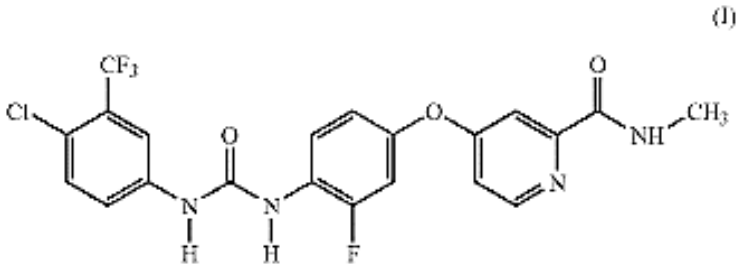
A. Related Applications and Proceedings

The '553 Patent to Boyer et al., issued from Application No. 10/895,985 ("the '985 Application"), filed July 22, 2004, and claims benefit of priority to Provisional Applications No. 60/489,102 and 60/540,326 filed July 23, 2003 and Feb. 2, 2004, respectively. Ex. 1001, [21], [60]. Patent Owner identifies a continuation application of the '985 Application, Application No. 13/669,103, as pending. *See* Paper 3, 2.

Patent Owner states that the '553 Patent has been asserted in the following district court proceedings: *Bayer HealthCare LLC v. Teva Pharm. USA, Inc.*, No. 1:16-01221-LPS (D. Del.) and *Bayer HealthCare LLC v. Apotex, Inc.*, No. 1:16-01222-LPS (D. Del.). Paper 8, 2. According to Petitioner, "the development of regorafenib (the claimed compound of the '553 Patent)" is at issue in *Onyx Pharms. Inc. v. Bayer Corp.*, Case No. C 09-2145 (EMC) (N.D. Cal. Oct 17, 2011). Pet. 1–2; *see* Prelim. Resp. 9–10 & n.4.

B. The '553 Patent and Relevant Background

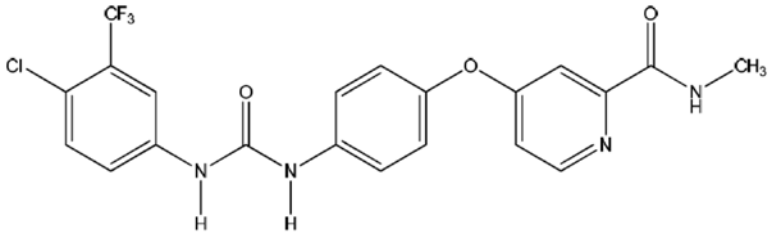
The '553 Patent is generally directed to "[a] compound of Formula I (reproduced below): salts thereof, prodrugs thereof, metabolites thereof, [and] pharmaceutical compositions containing such a compound." Ex. 1001, Abstract.



Formula 1 depicts the compound regorafenib, to which the '553 Patent is directed. The Specification describes compounds of Formula I as "potent inhibitor[s of] raf kinase, VEGFR kinase, p38 kinase, and PDGFR kinase, which are all molecular targets of interest for the treatment and prevention of osteoporosis, inflammatory disorders, hyper-proliferative disorders, and angiogenesis disorders, including cancer." *Id*. at 9:10–17.

The compound of Formula I (regorafenib), is the active ingredient in the anti-cancer drug STIVARGA®, marketed by Bayer HealthCare Pharmaceuticals Inc. for the treatment of certain types of colorectal cancer. *See* Pet. 4, Prelim. Resp. 1, 5; Ex. 2001,[1] 1, 11. Patent Owner points out that the discovery of regorafenib was preceded by the kinase inhibitor sorafenib, which has the following structure.

[1] STIVARGA® prescribing information dated June 2016.

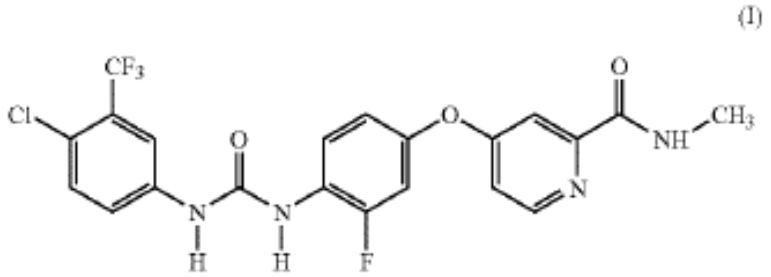


The above structure depicts the structure of sorafenib. Sorafenib is the active ingredient in the drug product NEXAVAR®, indicated for the treatment of certain renal, hepatocellular, and thyroid cancers. Prelim. Resp. 5; Ex. 2004[2], 1, 16; *see* Pet. 5.

C. Challenged Claims

Representative claim 13 recites:

13. A compound of Formula (I)



The remaining claims relate to salts, stereoisomers, and metabolites of the above compound.

D. The Asserted Prior art and Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 4):

Ground	Reference(s)	Basis	Claims
1	Riedl[3]	§ 102	1–16
2	Riedl	§ 103	1–16

[2] NEXAVAR® prescribing information revised November 2013.
[3] Riedl et al., WO 00/42012 A1, published July 20, 2000.

Ground	Reference(s)	Basis	Claims
3	Riedl, Ahern,[4] and Park[5]	§ 103	1–16
4	Riedl and Park	§ 103	1–16
5	Aherne and Park	§ 103	1–16

Petitioner also relies on the Declaration of Brian Shoichet, Ph.D. ("Shoichet Declaration"). Ex. 1008. As an initial matter, Patent Owner contends that Dr. Shoichet's Declaration should be accorded no weight because it fails to either state that it is made under penalty of perjury pursuant to 28 U.S.C. § 1764 or contain the affirmation prescribed in 37 C.F.R. § 1.68. Prelim. Resp. 19–20, 33. Although we agree with Patent Owner that the Shoichet Declaration is facially defective, at this stage of the proceeding, we decline to give the Declaration "no weight" on that basis.

E. Prosecution History Leading to the Issuance of the '553 Patent

Applicants disclosed Riedl in an Information Disclosure Statement dated March 18, 2008. Ex. 2005, 193. In allowing the then-pending claims, the Examiner's Reasons for Allowance provided that:

> After a thorough search, the closest prior art, WO 00/42012 to Riedl, et al. was found to teach similar phenyl-urea derivatives as kinase inhibitors. However, the WO document fails to teach or render obvious the instant claimed compounds according to Formula (I), and does not fairly suggest their salts or pharmaceutical compositions.

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[4] Aherne et al., *Finding the needle in the haystack: why high-throughput screening is good for your health*, 4(4) BREAST CANCER RES. 148–154, © 2002 BioMed Central Ltd.

[5] Park et al., *Metabolism of Fluorine-Containing Drugs*, 41 ANN. REV. PHARMACOL. TOXICOL, 443–70, © 2001 Annual Reviews.

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