Paper No. ____
Filed: June 21, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LIMITED.,
Petitioner,

v.

AVENTIS PHARMA S.A.,
Patent Owner.

Case IPR2016-00712
Patent No. 8,927,592

PETITIONER MYLAN'S REPLY BRIEF ON REMAND PURSUANT TO PAPER NO. 108

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The record is replete with evidence that a POSA would have had a reasonable expectation of success in practicing the obvious method of the proposed claims—evidence which Patent Owner ("PO") mischaracterizes or ignores. In doing so, PO also obfuscates the standard for reasonable expectation of success by (1) not asserting that the claims require survival data, successful clinical trials, or FDA approval; while, at the same time, (2) criticizing Petitioner's evidence for not including data from a successful phase III trial. PO's obfuscation cannot avoid a determination of unpatentability.

I. Petitioner Established Reasonable Expectation of Success.

Applying the Federal Circuit's claim construction, both experts' testimony support reasonable expectation of success. As Dr. Seth testified, it would have been obvious to treat docetaxel-resistant DRmCRPC patients by administering cabazitaxel and prednisone "for the purpose of increasing patient survival." EX1002 ¶¶ 47, 84, 86, 90, 116, 120-22, 132, 163, 183; EX1043 ¶10. Dr. Seth sent his patients to the TROPIC study before the critical date expecting them to benefit from a better chance of living longer by controlling their disease if they received cabazitaxel. EX2258, 26:9-37:25 ("most of [us] knew that anything would be better than mitoxantrone"). Dr. Sartor conceded physicians may have intended to increase survival of their patients. Paper 84, 3, 7-8; EX1098, 342:3-9, 355:17-21, 429:8-431:3. PO's argument (at 14) that oncologists enrolled patients despite a

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death at 30 mg/m^2 shows the likelihood of success outweighed these risks.

Reasonable expectation of success in the context of this patent necessarily means the intended tumor control and survival increase will not occur for most patients. EX1001, 11:57; EX1002, ¶¶ 44, 47, 215; Paper 3, 20, 56-57; Paper 43, 14. PO argues physicians could only "hope" cabazitaxel would work, but for a particular "patient in need" there is still today only a hope of success. EX1043 ¶38.

Relying on *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636 (Fed. Cir. 2017), PO incorrectly argues the Federal Circuit "required" proof of a reasonable expectation of actual results based on an intent element. *Id.* at 646-47 (court noting defendants "accepted" framework, not holding it was required). *Watson* did not, and had no occasion to, overrule *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.* 821 F.3d 1359, 1367-68 (Fed. Cir. 2016) (quantitative removal "of no moment" to reasonable expectation because not a claim limitation). Because the claim element is an intention, reasonable expectation of success must be proven for having an intention, not for achieving the intended result.

PO relies on *Watson* and *Genzyme Corp. v. Dr. Reddy's Labs.*, 716 Fed. App'x 1006, 1007 (Fed. Cir. Dec. 18, 2017) to argue there was no reasonable expectation cabazitaxel would increase survival. But unlike those cases—in which the prior art affirmatively taught the drug was unlikely to work (*Watson*) or where neither the targeted receptor nor any receptor in its family had ever been shown to

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