Paper No. ___
Filed: May 15, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATIORIES, LTD.,
Petitioner,

v.

AVENTIS PHARMA S.A.,
Patent Owner.

Case IPR2016-00712
Patent 8,927,592

PETITIONER MYLAN LABORATORIES LIMITED'S MOTION FOR OBSERVATIONS REGARDING THE CROSS-EXAMINATION OF DR. ALTON OLIVER SARTOR

In accordance with: (i) The Trial Practice Guide, and (ii) the Scheduling Order (Paper 10) as modified by the parties (Paper 49), Petitioner hereby submits the instant Motion for Observations Regarding the Cross- Examination Testimony of Dr. Alton Oliver Sartor, taken on May 8, 2017, after Petitioner filed its last substantive paper. The transcript of this testimony has been filed as EX1098.

1. In EX1098 at 357:25-358:22, Dr. Sartor agreed that, with respect to post-docetaxel mCRPC patients treated with cabazitaxel according to claims 31-34, "the difference between 2007 and 2017 is knowledge that you have in your head"—specifically, the knowledge "that cabazitaxel is an effective drug." This supports Petitioner's argument that Aventis's claim construction renders claims 31-34 unpatentable under 35 U.S.C. §101 because the alleged "inventive step" is knowledge that the prior art method works (Paper 44 ("Opp.") at 6), as well as to Petitioner's argument that Aventis's claim construction merely recites knowledge of an inherent property that cannot distinguish over the prior art (*id.* at 8-10).

2. In EX1098 at 377:12-24, Dr. Sartor agreed that his interpretation of the claims implied that "knowledge … of TROPIC data is necessary in order to have the intention of increasing survival for Claims 31, 32, 33, and 34" in both 2007 and 2017. This contradicts Aventis's position that "Aventis does not assert that the claims require FDA approval or a phase III study." Paper 52 ("PO Reply") at 1 n.1; *see also* Opp. at 1-2 (arguing that Aventis's construction requires

"knowledge of statistical population data" from, *e.g.*, a phase III study). It also supports Petitioner's 101 and inherency arguments described in obs. 1 above.

3. In EX1098 at 360:11-363:14, Dr. Sartor stated that under his interpretation of claim 31, an IV technician or a nurse who carried out each step of claim 31 would nonetheless not be capable of practicing the claim, because they would lack the knowledge that he contends is required to have an intention to increase survival. This supports Petitioner's arguments that Aventis's claim construction renders claims 31-34 indefinite under 35 U.S.C. §112 and unpatentable under 35 U.S.C. §101 because the metes and bounds of the claims are not clear, and the claims are directed to a mental state *per se*. *See* Opp. at 2-3, 5-6.

4. In EX1098 at 400:22-401:24, Dr. Sartor stated that if a post-docetaxel patient treated with cabazitaxel lived for 9 months, he would "attribute cabazitaxel to have treated with success," that death within 5 months would only be "a little grayer." This supports Petitioner's arguments that the observed successes of cabazitaxel in Mita (*see* Pet. at 54-55, EX1002 at ¶¶103, 225 (citing EX1012 at 727, describing an objective response to 25 mg/m^2 cabazitaxel in a post-docetaxel mCRPC patient whose disease did not progress until the eighth 3-week cycle—i.e., 6 months of progression-free survival)) and Pivot (*see* Pet. at 49, citing EX1010 at 1547 (reporting median overall survival of 12.3 months in taxane-resistant metastatic breast cancer patients receiving cabazitaxel); *see also* Mot. to Amd. at

12 (admitting Pivot showed 12.3 month overall survival in taxane-resistant metastatic breast cancer patients)), as reported in Attard and Beardsley, would lead a person of ordinary skill to have a reasonable expectation that cabazitaxel treatment would increase the survival of at least some patients with mCRPC that had progressed during or after treatment with docetaxel. *See* Opp. at 11; *see also* EX1043 at ¶45; Pet. at 33-34, 49, 54; EX1002 at ¶¶69-70, 103, 133, 183-84.

5. In EX1098 at 429:8-431:3, Dr. Sartor stated, "I believe it is entirely possible that some physicians believed, in a subjective manner, that they could have benefit from participating in the [TROPIC study]." Dr. Sartor further clarified that "it is possible that the study could have enrolled patients because physicians wanted the patients to receive cabazitaxel." *Id.* This testimony supports Petitioner's argument that "physicians were enrolling their patients in a phase III trial of the taxane cabazitaxel with an intention … of prolonging the life of at least some patients." Opp. at 10.

6. In EX1098 at 348:23-349:3, Dr. Sartor testified that the phrase "administering to a patient in need thereof" simply means that the patient is "a patient who needs to have their survival prolonged." In EX1098 at 431:4-17. Sartor testified that "virtually all" patients with mCRPC that has progressed during or after treatment with docetaxel are in need of a method of increasing survival. This testimony supports Petitioner's claim construction that the preamble "at most

gives a more generic description of the patient" and that any post-docetaxel mCRPC patient receiving treatment in 2008 had a recognized need for increased survival. Opp. at 3.

7. In EX1098 at 447:6-448:17, Dr. Sartor testified that a physician could only have the intent to increase survival alleged by Aventis to be required by claim 31 if the physician had taken additional steps not recited in claim 31 to determine that the patient met the inclusion criteria of the TROPIC study. This testimony demonstrates that Aventis's construction of claim 31 would render the claim unpatentable under 35 U.S.C. § 112 paragraphs 1 and 2. *See* Opp. at 5-6.

8. In EX1098 at 451:13-452:14, 453:9-455:14, Dr. Sartor testified that a physician in 2017 could not form the intent allegedly required to practice claim 31 in a post-docetaxel mCRPC patient if the patient had also been treated with any of a number of drugs, including Zytiga, Xofigo, mitoxantrone, and Xtandi. This testimony demonstrates that Aventis's construction of claim 31 would render the claim unpatentable under 35 U.S.C. § 112 paragraphs 1 and 2. *See* Opp. at 5-6. Additionally, this testimony is relevant to the question of commercial success (*see* Mot. to Amd. at 25; Opp. at 25; *see also* EX2149, ¶¶21-22, 27-30; EX1044, ¶¶23, 34-51, 68-69) because it indicates that, under Aventis's claim construction, most uses of Jevtana® in post-docetaxel mCRPC patients do not fall within the scope of the claims because they occur subsequent to treatment with Zytiga, Xofigo, or

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.