# 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 U.S. Patent No. 8,927,592

DECLARATION OF MICHAEL E. TATE REGARDING EXHIBITS 2170, 2171, 2172, and 2179



Aventis Exhibit 2235

## I. Introduction

1. My name is Michael E. Tate. I am the same Michael E. Tate that submitted an expert declaration concerning secondary considerations relating to the obviousness of subject matter claimed in U.S. Patent No. 8,927,592 on December 23, 2016, Exhibit 2149. I respectfully submit this declaration based on my personal knowledge in support of Patent Owner's Exhibits 2170, 2171, 2172, and 2179 that were cited in my December 23, 2016 declaration.

## **II.** Exhibit 2172

2. The Red Book provides drug pricing and product information published by Truven Health Analytics.<sup>1</sup> It is reported to be one of the oldest sources of drug information in the United States.<sup>2</sup> It is routinely used and relied on in the pharmaceutical industry, and I and others at Charles River Associates have relied on the Red Book in providing consultation regarding intellectual property in the context of strategy, licensing, valuation, and/or litigation consulting.

<sup>&</sup>lt;sup>2</sup> RED BOOK From Thomson Reuters Continues Providing Average Wholesale Prices for Drugs as Others Stop Supplying This Important Data, PR Newswire (April 8, 2010), http://www.prnewswire.com/news-releases/red-book-from-thomson-reuters-continues-providing-average-wholesale-prices-for-drugs-as-others-stop-supplying-this-important-data-90250542.html (Exh. 2237).



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<sup>&</sup>lt;sup>1</sup> *RED BOOK: A Comprehensive, Consistent Drug Pricing Resource*, Truven Health Analytics, available at http://micromedex.com/products/product-suites/clinical-knowledge/redbook (Exh. 2236).

- 3. The Red Book is an online-only electronic database available at the following URL: http://micromedex.com/products/product-suites/clinical-knowledge/redbook (Exh. 2236). The website states that the information is regularly updated to reflect current pricing.<sup>3</sup> A user must purchase a license to access the database. After signing in, the user can search for particular drugs or products. Search results display the product name, active ingredient, manufacturer, and pricing, among other information. Search results can be exported to an electronic spreadsheet file.
- 4. Exhibit 2172 contains true and accurate information exported from the Red Book Online database on December 14, 2016. On that date, the Red Book online database was searched for the drugs Xtandi®, Zytiga®, Xofigo®, and Jevtana®. The search results were each exported as electronic spreadsheets. The spreadsheets were combined and converted into a PDF file, and stamped for this proceeding as Exh. 2172.
- 5. Exhibit 2238 is a true and accurate screenshot of the search result on the Red Book Online website for Xtandi® conducted on January 9,

<sup>&</sup>lt;sup>3</sup> *RED BOOK: A Comprehensive, Consistent Drug Pricing Resource*, Truven Health Analytics, available at http://micromedex.com/products/product-suites/clinical-knowledge/redbook (Exh. 2236).



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- 2017.<sup>4</sup> This is an example of what the Red Book Online displays prior to exporting the search result as a spreadsheet.
- 6. Exhibit 2239 is a true and accurate screenshot of the search result on the Red Book Online website for Zytiga® conducted on January 9, 2017.<sup>5</sup> This is an example of what the Red Book Online displays prior to exporting the search result as a spreadsheet.
- 7. Exhibit 2240 is a true and accurate screenshot of the search result on the Red Book Online website for Xofigo® conducted on January 9, 2017.<sup>6</sup> This is an example of what the Red Book Online displays prior to exporting the search result as a spreadsheet.
- 8. Exhibit 2241 is a true and accurate screenshot of the search result on the Red Book Online website for Jevtana® conducted on January 9, 2017.<sup>7</sup> This is an example of what the Red Book Online displays prior to exporting the search result as a spreadsheet.
- 9. Exhibit 2242 is a true and accurate copy of "Understanding RED BOOK Online Search Results," a guide by Truven Health Analytics on

<sup>&</sup>lt;sup>7</sup> The price for Jevtana® has not changed since December 14, 2016.



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<sup>&</sup>lt;sup>4</sup> The price for Xtandi® has increased \$552.83/month since December 14, 2016, but this does not change my conclusions in the expert report.

<sup>&</sup>lt;sup>5</sup> The price for Zytiga® has not changed since December 14, 2016.

<sup>&</sup>lt;sup>6</sup> The price for Xofigo® has not changed since December 14, 2016.

searching the Red Book, available at

http://www.micromedexsolutions.com/micromedex2/4.36.0/WebHelp/RED\_BOO K/Search\_Results/RED\_BOOK\_Search\_Results.htm.

## III. Exhibits 2170, 2171, and 2179

- 10. I understand that Exhibits 2170, 2171, and 2179 are Sanofi marketing documents that describe the market share of Jevtana®.<sup>8</sup> This understanding has been further confirmed by the Declaration of Art Lathers (Exhibit 2231). I understand that Sanofi relies on these market share reports in the course of its business.<sup>9</sup>
- 11. Slide 32 of Exhibit 2171 is titled "Methodology," and sets forth how data is collected for market share. Slides 28-31 describe the panel of physicians. Slides 36-37 provide further information about data collection and reporting. Slides 38-46 display the "Prostate Cancer Treatment Survey." Upon review of Exhibits 2170 and 2171, I have no reason to believe that the market share data reported was collected in a different way than reported in Exhibit 2171 at slide 32.

<sup>&</sup>lt;sup>9</sup> Exhibit 2231 at  $\P$ ¶2-3.



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<sup>&</sup>lt;sup>8</sup> Exhibit 2231 ¶¶3-4.

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