

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

***In the Inter Partes Review (IPR) of***

**U.S. Patent No. 6,858,650**

**DECLARATION OF DEFOREST MCDUFF, Ph.D.**

I, DeForest McDuff, Ph.D., declare as follows:

**I. Introduction**

**A. Qualifications**

1. I am a Vice President of Intensity Corporation and an expert in applied business economics, with more than ten years of experience in consulting, finance, and economic research. I provide expert witness testimony and consulting in a variety of areas, including lost profits, reasonable royalties, unjust enrichment, commercial success, finance, statistics, valuation, and business optimization.

2. My expertise and experience span a variety of topics, including intellectual property, competition, antitrust, finance, labor, employment, and class action. My work in intellectual property spans the life sciences (including pharmaceuticals, biotechnology, diagnostics, and medical devices), electronics (including consumer electronics, semiconductors, computers, and telecommunications), and has included projects on a diverse range of other

industries (such as scuba diving equipment, golf clubs, and contact lenses). I frequently provide expertise and analysis in evaluating commercial success in the pharmaceutical industry.

3. I earned my Ph.D. in economics from Princeton University. At Princeton, I received a National Science Foundation Graduate Research Fellowship for academic research studying economic and statistical properties of housing markets and financial derivatives. I have published research in several peer-reviewed academic journals. I graduated *summa cum laude* with undergraduate degrees in economics and mathematics from the University of Maryland.

4. My curriculum vitae, provided in Exhibit 1034, contains more details on my background, experience, publications, and prior expert testimony.

**B. Scope of Work**

5. Intensity Corporation has been retained by Wiley Rein LLP on behalf of Torrent Pharmaceuticals Limited in connection with my work in this matter. Intensity Corporation is being compensated at a rate of \$725 per hour for my work and at lower rates for time spent by others on my team. The compensation of Intensity Corporation is not dependent on the substance of my testimony or the outcome of this matter.

6. For this declaration, I was asked to evaluate aspects of commercial success, from an economic perspective, as it pertains to Toviaz (fesoterodine) and

U.S. Patent No. 6,858,650 (collectively, “the patent-at-issue”). This declaration is a statement of my opinions in this matter and the basis and reasons for those opinions. In forming the opinions expressed in this declaration, I have relied upon my education, experience, and knowledge of the subjects discussed. In connection with my work in this matter, I interviewed Steven E. Patterson, Ph.D., Professor and Associate Director at the Center for Drug Design, University of Minnesota, on January 22, 2016, including discussion of: (1) the patent-at-issue, and (2) similarities and differences between Toviaz and Detrol/Detrol LA (tolterodine). I have also reviewed and relied upon documents and other materials that are cited herein. This declaration is identical in substance to the declaration that I filed in the *inter partes* review captioned *Mylan Pharmaceuticals Inc., et al. v. UCB Pharma GmbH*, IPR2016-00510 (“the Mylan IPR”), other than the fact that Torrent is only seeking review of the ‘650 patent.

7. This declaration summarizes only my current opinions, which are subject to change depending upon additional information and/or analysis. I and others working under my direction prepared the exhibits as summaries of the information I reviewed and relied upon. The entirety of my declaration, including exhibits and referenced materials, supplies the basis for my analysis and conclusions. The organizational structure of the declaration is for convenience. To the extent that facts, economic analysis, and other considerations overlap, I

generally discuss such issues only once for the sake of brevity. Neither the specific order in which each issue is addressed nor the organization of my declaration or exhibits affects the ultimate outcome of my analysis.

## **II. Background**

### **A. Overactive bladder**

8. Overactive bladder (“OAB”) is a condition primarily characterized by the sudden urge to urinate.<sup>1</sup> Additional symptoms of OAB include a high frequency of urination throughout the day, awakening multiple times to urinate at night, and urge incontinence, the involuntary loss of urine following an urgent need to urinate.<sup>2</sup> According to the Urology Care Foundation, approximately 33 million Americans are afflicted with OAB, including as many as 30% of men and 40% of women.<sup>3</sup>

9. There are various treatment options for OAB, including behavioral interventions, medications, Botox bladder injections, nerve stimulation, and in severe cases, surgery.<sup>4</sup> Behavioral interventions include exercises to strengthen the

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<sup>1</sup> Mayo Clinic Website, Overactive Bladder, Definition, <http://www.mayoclinic.org/diseases-conditions/overactivebladder/basics/definition/con-20027632> (accessed 1/15/2016). Urology Care Foundation Website, What Is Overactive Bladder (OAB)?, <http://www.urologyhealth.org/urologic-conditions/overactive-bladder-%28oab%29> (accessed 1/15/2016).

<sup>2</sup> Mayo Clinic Website, Overactive Bladder, Symptoms, <http://www.mayoclinic.org/diseases-conditions/overactivebladder/basics/symptoms/con-20027632> (accessed 1/15/2016).

<sup>3</sup> Urology Care Foundation Website, What Is Overactive Bladder (OAB)?, <http://www.urologyhealth.org/urologic-conditions/overactive-bladder-%28oab%29> (accessed 1/15/2016).

<sup>4</sup> Mayo Clinic Website, Overactive Bladder, Treatments and Drugs, <http://www.mayoclinic.org/diseases-conditions/overactivebladder/basics/treatment/con-20027632> (accessed 1/15/2016).

pelvic floor muscle, maintaining a healthy weight, limiting fluid consumption, and wearing absorbent pads, among others.<sup>5</sup> As of January 2016, nine branded prescription drugs are approved by the FDA to treat OAB, including: Botox (onabotulinumtoxin), Detrol (tolterodine tartrate), Detrol LA (tolterodine tartrate), Ditropan XL (oxybutynin chloride), Enablex (darifenacin), Gelnique (oxybutynin chloride), Myrbetriq (mirabegron), Oxytrol (oxybutynin), Toviaz (fesoterodine fumarate), and Vesicare (solifenacin succinate).<sup>6</sup> At this time, available generic drugs include: oxybutynin chloride, oxybutynin chloride extended release, tolterodine tartrate, tolterodine tartrate extended release, trospium chloride, and trospium chloride extended release.<sup>7</sup>

## **B. Toviaz (fesoterodine)**

10. Toviaz is an extended-release tablet containing fesoterodine fumarate.<sup>8</sup> Fesoterodine transforms in the body to release the active metabolite 5-

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<sup>5</sup> Mayo Clinic Website, Overactive Bladder, Treatments and Drugs, <http://www.mayoclinic.org/diseases-conditions/overactivebladder/basics/treatment/con-20027632> (accessed 1/15/2016).

<sup>6</sup> NIH Website, DailyMed Label Search Results for Overactive Bladder, <http://dailymed.nlm.nih.gov/dailymed/search.cfm?adv=1&query=34067-9%3A%28overactive+bladder%29&searchdb=all&labeltype=all&pagesize=200&audience=professional&page=1&sortby=alphabetically> (accessed 1/20/2016).

<sup>7</sup> NIH Website, DailyMed Label Search Results for Overactive Bladder, <http://dailymed.nlm.nih.gov/dailymed/search.cfm?adv=1&query=34067-9%3A%28overactive+bladder%29&searchdb=all&labeltype=all&pagesize=200&audience=professional&page=1&sortby=alphabetically> (accessed 1/20/2016).

Flavoxate is also used to treat symptoms of OAB, though it is not indicated for the treatment of OAB. See: Hesch, Kristen (2007), "Agents for Treatment of Overactive Bladder: A Therapeutic Class Review," *Proceedings (Baylor University Medical Center)* 20(3): 307–314, at 307.

<sup>8</sup> Toviaz Label, 10/31/2008, at 1.

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