

THE UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,  
Petitioners,

v.

SENJU PHARMACEUTICAL CO., LTD.,  
Patent Owner

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Case IPR2015-01097

Patent 8,754,131 B2

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**DECLARATION OF JOHN C. JAROSZ**

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I, John C. Jarosz, do hereby declare, under penalty of perjury, as follows.

**I. INTRODUCTION**

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

**A. Assignment**

2. I have been retained as an expert on behalf of Senju Pharmaceutical Co. Ltd. (“Senju” or “Patent Owner”) as well as Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp. (collectively, “Bausch & Lomb”) in connection with the above captioned *inter partes* review (“IPR”) proceeding before the United States Patent and Trademark Office Patent Trial and Appeal Board (“PTAB”).

3. I understand that the PTAB has granted the petition of Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, “Lupin” or “Petitioners”) to institute an IPR regarding claims 1-30 of U.S. Patent No. 8,754,131 (the “131 patent”) on obviousness grounds. That IPR was assigned Case No. IPR2015-01097.

4. I understand that the PTAB has granted the petitions of the Petitioners to institute separate IPRs regarding claims 1-30 of U.S. Patent No. 8,669,290 (the “290 patent”), claims 1-30 of U.S. Patent No. 8,927,606 (the “606 patent”), and claims 1-27 of U.S. Patent No. 8,871,813 (the “813 patent”)



on obviousness grounds. Those IPRs were assigned Case Nos. IPR2015-01099, IPR2015-01100, and IPR2015-01105, respectively.

5. I understand that Senju is the assignee of the '131 patent and that Shirou Sawa and Shuhei Fujita are the named inventors of the patent.
6. I understand that the '131 patent describes and claims compositions of the active ingredient bromfenac sodium ("bromfenac") and the surfactant tyloxapol.<sup>1</sup> I further understand that Prolensa® embodies compositions claimed in the '131 patent.
7. I have been asked by Counsel for Patent Owner to assess whether Prolensa® has been a marketplace success, and whether such success is attributable to the inventions claimed in the '131 patent.

**B. Qualifications**

8. I am a Managing Principal of Analysis Group, Inc. ("Analysis Group") and Director of the firm's Washington, DC office. Analysis Group is an economic, financial, and strategy consulting firm with offices in Beijing, China; Boston, MA; Chicago, IL; Dallas, TX; Denver, CO; Los Angeles, CA; Menlo Park, CA; Montreal, Quebec; New York, NY; San Francisco, CA; and Washington, DC. We provide research and analysis in a

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<sup>1</sup> I understand that a surfactant is a substance that, when added to a liquid, reduces the surface tension of that liquid.

variety of business, litigation, and regulatory settings, and have particular expertise in intellectual property (“IP”) matters, having been engaged in numerous matters involving patents, trademarks, copyrights, trade secrets, and unfair competition.

9. I am an economist whose specialty is IP valuation, monetary relief assessment, and the economics of commercial success. I have been involved in more than 350 such engagements spanning a broad range of industries and technologies, including a variety of engagements covering pharmaceutical products. I received a J.D. from the University of Wisconsin and an M.A. in Economics from Washington University in St. Louis, where I completed most of the requirements for a Ph.D. in Economics. I also hold a B.A. in Economics and Organizational Communication from Creighton University in Omaha. I am a member of several professional associations, including the Licensing Executives Society. I have been a speaker and instructor many times on a variety of financial, economic, and valuation topics, most having to do with IP protection.

10. A copy of my curriculum vitae is provided as Appendix I. It includes a more detailed description of my educational background and professional experience.

**C. Compensation**

11. My firm has billed the Patent Owner on a time-and-materials basis for my work and that of my colleagues. My hourly billing rate is \$665. I also have directed the efforts of other staff members of Analysis Group, whose hourly billing rates range from \$265 to \$425. My compensation is not, in any way, dependent on the outcome of this proceeding or on the substance of my opinion.

**D. Evidence Considered**

12. In undertaking my study and arriving at my conclusions and opinions, I have relied upon the materials cited here, and considered my own knowledge, experience, and research, as well as additional information from a variety of sources that an expert economist would routinely consider in performing this undertaking. I specifically relied upon the materials cited and, although at times I refer to only selected portions of a cited reference, it should be understood that I have considered and relied upon all relevant aspects of such cited reference.
13. In connection with the opinions and conclusions contained in this declaration, I also considered revenue, prescription, and promotional expenditure data provided by IMS Health (“IMS”). [REDACTED]
- [REDACTED]



14. IMS reports manufacturer gross sales data, but does not report manufacturer net sales data. IMS does not collect the rebates, discounts, returns and other bottom-line discounts from or to the manufacturer that go into calculating the amount that a manufacturer or supplier ultimately receives. The data that IMS does collect measures sales into retail and non-retail outlets, and represents the actual prices that were charged to the outlet (*i.e.*, the retail pharmacy, mail pharmacy, clinic, etc.) to acquire the pharmaceutical products as seen on the purchase invoices. The gross sales that IMS does report allow for comparisons across competing drugs and across time. This comparative information is extraordinarily useful to pharmaceutical companies in the real world, and to courts and panels in litigations addressing commercial success.

15. Appendix 2 through Appendix 13 provide a summary of the voluminous IMS data relating to Prolensa® that I considered. I and others working under my direction and supervision prepared these appendices.

**E. Summary of Opinions**

16. Based upon my review and analysis of the evidence received to date, it is my opinion that Prolensa® has achieved substantial marketplace success in the United States. It is also my opinion that there is a nexus between the

marketplace success of Prolensa® and the claims of the '131 patent. In short, the claims of the '131 patent at issue here have been a commercial success.

17. A number of facts demonstrate that Prolensa® has been a marketplace success. Prolensa®'s revenues and prescriptions grew substantially after its commercial launch in April 2013. In its first ten quarters of commercial availability, Prolensa® has been prescribed approximately 1.4 million times in the U.S., generating \$246.9 million in revenue. (Appendix 13.) Prolensa® achieved this success despite being introduced into a marketplace in which at least six branded drugs and three generic drugs had already received U.S. Food and Drug Administration ("FDA") approval to treat similar indications as Prolensa®. (*See, e.g.*, Appendix 2.) Since its introduction, Prolensa® has achieved the second highest share of revenues and prescriptions among branded drugs with similar indications as Prolensa®. (Appendix 3; Appendix 6.)

18. A number of facts demonstrate that there is a causal nexus between the success of Prolensa® and the claimed features of the '131 patent. The patent describes and claims compositions of the active ingredient bromfenac and the surfactant tyloxapol. Specifically, certain claims of the '131 patent disclose stable aqueous liquid compositions of the active ingredient

bromfenac and the surfactant tyloxapol, which is the technology embodied in the drug Prolensa®. (Ex. 2082, at ¶178.) I understand that these compositions have a lower, more natural pH level with improved ocular penetration relative to other bromfenac formulations, allowing Prolensa® to deliver the same clinical efficacy, but using a lower concentration of the active ingredient bromfenac [REDACTED] relative to other bromfenac formulations. The reduced concentrations of active ingredient [REDACTED], as well as the lower pH, result in an improved side effect profile relative to other nonsteroidal anti-inflammatory drug (“NSAID”) formulations, with no stinging or burning. The lower pH and reduced side effects make Prolensa® more comfortable to use relative to other NSAID formulations and enhance patient compliance. [REDACTED]

[REDACTED] As explained by Dr. Trattler, the development of Prolensa® was “highly significant to the field of ophthalmology and cataract surgery.” (Ex. 2116, at ¶51.) The claimed features of the ’131 patent have been a critical driver of the success of Prolensa®. That is, Prolensa® is consistently marketed based on the benefits made possible by the ’131 patent.

19. Bausch & Lomb’s patterns of promotional expenditures on Prolensa®



are consistent with those for competing drugs with similar indications that became commercially available around the same time as Prolensa®. (Appendix 12.) Specifically, the patterns of Bausch & Lomb's promotional expenditures as a percent of gross sales are consistent with promotional expenditure patterns for Ilevro®, which was commercially released six months prior to Prolensa®. (Appendix 12.) And the success of Prolensa® is not attributable to any pricing advantages, because it has none.

## **II. BACKGROUND**

### **A. Parties to the *Inter Partes* Review**

#### **1. Senju**

20. Senju is a pharmaceutical company that operates out of Osaka, Japan. (Ex. 2194; Ex. 2195.) Senju manufactures a number of different prescription and over-the-counter drugs, specializing in the development of eye care products and ear, nose, and throat treatments. (Ex. 2194; Ex. 2196.) Senju is the original assignee of the '131 patent. (Ex. 1002.)

#### **2. Bausch & Lomb**

21. Bausch & Lomb Incorporated is a manufacturer of eye care products headquartered in Rochester, New York. (Ex. 2186.) Originally incorporated as Bausch & Lomb Optical Company, the company changed its name to Bausch & Lomb Incorporated in 1960. (Ex. 2186.) Bausch & Lomb

Incorporated is a subsidiary of Bausch & Lomb Holdings Incorporated (“Bausch & Lomb Holdings”). (Ex. 2186.)

22. I understand that Bausch & Lomb Pharma Holdings Corp. is the licensee of the ’131 patent from Senju and is a wholly-owned subsidiary of Bausch & Lomb Incorporated.

23. In 2007, Bausch & Lomb Holdings was acquired by the private equity firm Warburg Pincus PLC (“Warburg”) for \$4.5 billion, including \$3.67 billion in cash and the assumption of \$830 million in debt. (Ex. 2212.) As a result of this acquisition, Bausch & Lomb Holdings stock was delisted from the New York Stock Exchange on October 26, 2007. (Ex. 2212.)

24. On June 6, 2012, Bausch & Lomb Holdings acquired ISTA Pharmaceutical, Inc. (“ISTA”), a manufacturer of eye drugs, in a \$465.5 million all-cash transaction.<sup>2</sup> (Ex. 2237, at 52. *See also*, Ex. 2208; Ex. 2210.) As a result of the acquisition, Bausch & Lomb Holdings gained ownership of four prescription eye care products, including Bromday® (a once-daily bromfenac formulation that was first launched in November 2010), as well as several eye care products in various stages of development, including Prolensa®. (Ex. 2185, at 5-6; Ex. 2208; Ex. 2210.) Also on June 6, 2012, Bausch & Lomb Incorporated submitted a New Drug Application (“NDA”)

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<sup>2</sup> Purchase price is net of cash acquired.



to the FDA seeking approval for Prolensa®. (Ex. 2152.)

25. On August 5, 2013, Warburg sold Bausch & Lomb Holdings to Valeant Pharmaceuticals International, Inc. (“Valeant”) for approximately \$8.7 billion, including \$4.2 billion to repay Bausch & Lomb’s existing debt. (Ex. 2205; Ex. 2236, at 10-K page 33.) Following the acquisition, Bausch & Lomb Holdings retained its name and became a division of Valeant, and Valeant’s existing ophthalmology business was integrated into Bausch & Lomb Holdings. (Ex. 2184.)

### **3. Lupin**

26. Lupin Ltd. was founded in 1968. (Ex. 2259.) Headquartered in Mumbai, India, Lupin Ltd. is a pharmaceutical company that develops generic and branded formulations as well as active pharmaceutical ingredients. (Ex. 2260; Ex. 2261.) Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Ltd. based in Baltimore, Maryland that aims to develop generic and branded pharmaceutical products for the U.S. market. (Ex. 2262; Ex. 2263.) I understand that Lupin Ltd. submitted Abbreviated New Drug Application (“ANDA”) No. 206027 seeking approval to sell a generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa®. (Ex. 2007, at 3-4; Ex. 2008, at 3-4; Ex. 2009, at 3-4; Ex. 2010, at 4-5.) I understand that Lupin’s ANDA for generic bromfenac ophthalmic

solution was submitted three months after Prolensa® received FDA approval in April 2013. (Ex. 2082, at ¶207.)

#### **B. Cataract Treatments**

27. A cataract is a congenital or degenerative clouding of the lens of the eye that affects vision. (Ex. 2067, at 606.) Early symptoms include loss of contrast, glare, needing more light to see well, and problems distinguishing dark blue and black. (Ex. 2067, at 606.) Cataracts are the leading cause of blindness worldwide, and affect more than 20 million Americans over the age of 40. (Ex. 2052, at 447.)

28. Cataracts develop slowly over time, and occur as a result of aging or other risk factors such as trauma, smoking and alcohol use, under-nutrition, exposure to x-rays, or other factors. (Ex. 2067, at 606.) If external treatments such as corrective eyeglasses or long-term pupillary dilation do not sufficiently improve eyesight, the next option is surgery. (Ex. 2067, at 607.) Cataract surgery is one of the most commonly performed operations in the world. (Ex. 2052, at 447.) During cataract surgery, the clouded lens is removed from the eye and typically replaced with a plastic or silicone intraocular lens. (Ex. 2067, at 606-07.)

#### **C. Post-Surgery Options**

29. A wide range of medications are approved for use in treating

inflammation (and pain) following cataract surgery. The two most common types are NSAIDs and corticosteroids. (*See, e.g.*, Ex. 2153, at 5; Ex. 2155.) NSAIDs and corticosteroids treat inflammation by different mechanisms. (Ex. 2116, at ¶23.) They act on different enzymes that cause post-surgical inflammation and, thus, mediate post-surgical inflammation in different ways. (Ex. 2116, at ¶23.) Moreover, NSAIDs and corticosteroids exhibit different side effect profiles. (Ex. 2116, at ¶23.)

30. In addition to the NSAID bromfenac (the active ingredient in Prolensa®), the FDA has approved three major topical ophthalmic NSAIDs for use in the treatment of post-cataract surgery inflammation and, in some cases, pain:<sup>3</sup> 1) diclofenac sodium; 2) ketorolac tromethamine; and 3) nepafenac. (*See, e.g.*, Ex. 2153, at 5; Ex. 2155.)

### **1. Non-Bromfenac NSAIDs**

#### **a. Diclofenac Sodium**

31. Diclofenac sodium is sold under the brand name Voltaren® as a 0.1

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<sup>3</sup> The IMS data for USC 61420 (ophthalmic NSAIDs) includes a fourth additional NSAID, flurbiprofen sodium, and its branded form Ocufer®. However, according to Dr. Trattler, Ocufer® has never been approved by the FDA for the treatment of inflammation or pain following cataract surgery. (Ex. 2116, at ¶25.) To be conservative, the appendices to this declaration show totals and relative shares that include Ocufer®/generic flurbiprofen sodium and that exclude Ocufer®/generic flurbiprofen sodium.

percent concentration ophthalmic solution and a 1 percent topical gel. (Ex. 2162; Ex. 2166.) Generic versions of diclofenac sodium are available in solution and topical gel formulations. (Ex. 2170; Ex. 2171.)

32. Voltaren® solution first received FDA approval in March 1991. (Ex. 2162.) Diclofenac sodium ophthalmic solution is indicated for the treatment of inflammation following cataract surgery, and is administered four times per day through an eye drop. (Ex. 2057.)

**b. Ketorolac Tromethamine**

33. Ketorolac tromethamine is sold in 0.4 percent, 0.45 percent, and 0.5 percent ophthalmic solution formulations under the brand names Acular LS®, Acuvail®, and Acular®, respectively.<sup>4</sup> (Ex. 2161; Ex. 2163; Ex. 2167.) Generic versions of ketorolac tromethamine are available in solution formulations with varying concentrations. (Ex. 2168; Ex. 2169.)

34. Acular® first received FDA approval in November 1992. (Ex. 2161.) Acular LS® and Acuvail® received FDA approval in May 2003 and July 2009, respectively. (Ex. 2163; Ex. 2167.) Acular® and Acular LS® are

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<sup>4</sup> The IMS data for USC 61420 (ophthalmic NSAIDs) includes a fourth form of Acular®, known as Acular PF®. According to Dr. Trattler, Acular PF® was not indicated for the treatment of inflammation or pain following cataract surgery. (Ex. 2116, at ¶29.) To be conservative, the appendices to this declaration show totals and relative shares that include Acular PF® and that exclude Acular PF®.

administered four times per day, while Acuvail® is administered twice per day. (Ex. 2155, at 18; Ex. 2193.) Ketorolac tromethamine is indicated for the treatment of inflammation and pain following cataract surgery, and is administered through an eye drop. (Ex. 2060; Ex. 2183; Ex. 2240.)

### **c. Nepafenac**

35. Nepafenac is sold as a 0.1 percent concentration ophthalmic suspension under the brand name Nevanac® and as a 0.3 percent concentration ophthalmic suspension under the brand name Ilevro®. (Ex. 2165; Ex. 2178.)

36. Nevanac® and Ilevro® first received FDA approval in August 2005 and October 2012, respectively. (Ex. 2165; Ex. 2178.) Nevanac® is administered three times per day, while Ilevro® is administered once per day. (Ex. 2155, at 18; Ex. 2193.) Nepafenac is indicated for the treatment of inflammation and pain following cataract surgery and is administered through an eye drop. (Ex. 2241.)

### **2. Corticosteroids**

37. Various corticosteroids have been approved for the treatment of post-operative inflammation and, in some cases, pain. These treatments include loteprednol etabonate 0.5 percent ophthalmic solution, sold under the brand name Lotemax®; difluprednate 0.05 percent ophthalmic solution, sold under the brand name Durezol®; and rimexolone 1 percent ophthalmic suspension,

sold under the brand name Vexol®. (Ex. 2153, at 5; Ex. 2155.)

38. Although NSAIDs and corticosteroids can both be used to treat post-operative ophthalmic inflammation and pain, they represent distinct drug classes. (Ex. 2155.) According to Dr. Trattler, NSAIDs and corticosteroids act on different enzymes that cause post-surgical inflammation and, thus, mediate the major inflammatory response following surgical trauma in different ways. (Ex. 2116, at ¶23.)

39. An October 2014 review, done by Dr. Line Kessel *et al.*, of existing research comparing the effectiveness of NSAIDs and corticosteroids in treating inflammation following cataract surgery found that NSAIDs are more effective in controlling inflammation and recommended the use of NSAIDs over corticosteroids to prevent inflammation. (Ex. 2202, at 1922.) Additionally, NSAIDs and corticosteroids have different side effect profiles when used to treat ocular inflammation. (Ex. 2116, at ¶23; Ex. 2119.) The superior performance and different side effect profile of NSAIDs relative to corticosteroids are also consistent with Bausch & Lomb's Prolensa® marketing and promotional materials, which focus almost exclusively on NSAIDs with only passing mentions of corticosteroids. (*See, e.g.*, Ex. 2220; Ex. 2221; Ex. 2226.)

40. The relevant competitive marketplace for Prolensa® includes



ophthalmic NSAIDs that are indicated for the treatment of inflammation or inflammation and pain following cataract surgery.<sup>5</sup> It does not include corticosteroids.<sup>6</sup>

**D. Prolensa®**

41. I understand that Prolensa® embodies the relevant claims of the '131 patent. (Ex. 2082, at ¶178.) Approved by the FDA on April 5, 2013, Prolensa® is a once-daily, sterile, topical, NSAID indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. (Ex. 1049; Ex. 2176.) Prolensa® contains a 0.07 percent concentration of the active NSAID bromfenac. (Ex. 1049.) Prolensa® is formulated using tyloxapol as a surfactant. (Ex. 1049.)

5 [REDACTED]

[REDACTED] However, the IMS data for USC 61420 (ophthalmic NSAIDs) also includes Voltaren® and generic diclofenac sodium, which are also indicated for the treatment of inflammation following cataract surgery. (Ex. 2057.) I have included Voltaren® and generic diclofenac sodium in my analysis.

6 [REDACTED]

Prolensa® was first commercially available in April 2013. (Ex. 2211.)

Prolensa® is administered through an eye drop. (Ex. 1049.)

### **1. Earlier Bromfenac Products**

42. In July 2000, bromfenac was approved for use in Japan and was marketed by Senju under the name Bronuck. (Ex. 2224; [REDACTED] ISTA acquired the ophthalmic rights to bromfenac under a license from Senju in May 2002. (Ex. 2229.) On March 24, 2005, ISTA received U.S. FDA approval for Xibrom®, a twice-daily topical NSAID for the treatment of ocular inflammation following cataract surgery. (Ex. 2164; Ex. 2213; Ex. 2223.) Xibrom® contains a 0.09 percent concentration of the active NSAID bromfenac, and uses polysorbate 80 as a surfactant. (Ex. 2164; Ex. 2190; Ex. 2213.) Xibrom® was first commercially available in the second quarter of 2005. (Ex. 2213; *see also*, Appendix 2; Appendix 5.) In January 2006, the FDA expanded the approved Xibrom® indications to include the treatment of pain following cataract surgery. (Ex. 2189; Ex. 2223.)
43. On October 16, 2010, ISTA received FDA approval for Bromday®, a once-daily topical NSAID for the treatment of ocular inflammation and pain following cataract surgery. (Ex. 2164; Ex. 2188; Ex. 2223.) Like Xibrom®, Bromday® contains a 0.09 percent concentration of the active NSAID bromfenac, and uses polysorbate 80 as a surfactant; however Bromday® is



dosed once a day compared to twice daily for Xibrom®. (Ex. 1009; Ex. 2164; Ex. 2188.) Bromday® was first launched commercially in November 2010. (Ex. 2185.)

44. The first generic version of Xibrom® was launched in May 2011 by Mylan under a development and supply agreement with Coastal Pharmaceuticals. (Ex. 2214; Ex. 2242.) Subsequently, several additional generic pharmaceutical companies, including Paddock LLC, Luitpold, Apotex Inc., and Hi-Tech Pharmacal, launched generic bromfenac 0.09 percent ophthalmic solutions, including generic versions of Bromday. (Ex. 2172; Ex. 2173; Ex. 2174; Ex. 2175; Ex. 2177; Ex. 2238; Ex. 2239.)

## **2. ISTA's Acquisition by Bausch & Lomb**

45. Bausch & Lomb (which, at the time, was owned by Warburg) paid \$465.5 million to acquire ISTA in June 2012.<sup>7</sup> (Ex. 2208; Ex. 2210; Ex. 2237, at 52.) At the time of the acquisition, ISTA had Prolensa® in its product pipeline. (Ex. 2210.) Ten months after Bausch & Lomb's acquisition of ISTA, in preparation for the sale of Bausch & Lomb, Warburg filed an S-1 statement with the U.S. Securities and Exchange Commission ("SEC") in which it identified the fair value of Bromday® and Prolensa® at \$297.9 million, or approximately 64 percent of the \$465.5 million acquisition price

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<sup>7</sup> Purchase price is net of cash acquired.

for ISTA.<sup>8</sup> (Ex. 2237, at 53.)

### **3. Development and Launch of Prolensa®**

46. On June 6, 2012, the same day that Bausch & Lomb's acquisition of ISTA was completed, Bausch & Lomb submitted NDA No. 203168 to the FDA seeking approval for Prolensa®. (Ex. 2152.) On April 5, 2013, the FDA approved Prolensa® for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. (Ex. 1049; Ex. 2176.) Like Bromday®, Prolensa® is a once-daily topical NSAID. (Ex. 1049; Ex. 1009.) However Prolensa® contains a lower concentration of bromfenac than Bromday® (0.07 percent vs. 0.09 percent), and uses tyloxapol rather than polysorbate 80 as the surfactant. (Ex. 1049; Ex. 1009.)

#### **E. Patented Technology**

47. The '131 patent, entitled "Aqueous Liquid Preparation Containing 2-Amino-3-(4-Bromobenzoyl)Phenylacetic Acid," was filed on January 28, 2014 and issued to Senju on June 27, 2014. (Ex. 1002.) The Abstract of the patent provides,

An aqueous liquid preparation of the present invention containing 2-amino-3-(4-bromobenzoyl)phenylacetic acid or its pharmacologically acceptable salt or a hydrate thereof, an alkyl aryl polyether alcohol type polymer such as tyloxapol, or a

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<sup>8</sup> \$297.9 million / \$465.5 million = 64.0 percent.

polyethylene glycol fatty acid ester such as polyethylene glycol monostearate is stable. Since even in the case where a preservative is incorporated into said aqueous liquid preparation, the preservative exhibits a sufficient preservative effect for a long time, said aqueous liquid preparation in the form of an eye drop is useful for the treatment of blepharitis, conjunctivitis, scleritis, and postoperative inflammation. Also, the aqueous liquid preparation of the present invention in the form of a nasal drop is useful for the treatment of allergic rhinitis and inflammatory rhinitis (e.g. chronic rhinitis, hypertrophic rhinitis, nasal polyp, etc.). (Ex. 1002, at 1.)

48. I understand that certain claims of the '131 patent are directed to stable aqueous liquid preparations of 2-Amino-3-(4-bromobenzoyl)phenylacetic acid (also known as bromfenac) and the surfactant tyloxapol, which is the technology embodied in the drug Prolensa®. (Ex. 1002, at 3; Ex. 2082, at ¶178.)

49. I understand that Petitioners contend that U.S Patent Nos. 4,910,225 (the "'225 patent") and 5,891,913 (the "'913 patent") constitute prior art to the '131 patent. I understand that the '225 patent relates to compositions of bromfenac and polysorbate 80, while the '913 patent relates to compositions of diclofenac and tyloxapol. Xibrom® and Bromday®, which are products that use the active ingredient bromfenac, use polysorbate 80 as the surfactant. (Ex. 1009; Ex. 2190.) However, I understand that the Patent Owner contends that Xibrom® and Bromday® do not constitute prior art to the '131 patent. I further understand that Bronuck does not constitute prior

art to the '131 patent because it was not marketed in the United States prior to January 21, 2003. I also understand that there are no commercial products that use the active ingredient diclofenac potassium and the surfactant tyloxapol in order to treat inflammation or pain following cataract surgery.<sup>9</sup> (Ex. 2153, at 5.)

50. I understand that the compositions of bromfenac and tyloxapol disclosed and claimed in the '131 patent result in a formulation to treat inflammation or pain following cataract surgery that has a lower, more natural pH level with improved ocular penetration relative to other bromfenac formulations, allowing Prolensa® to deliver the same clinical efficacy, but using a lower concentration of the active ingredient bromfenac and a lower concentration of surfactant relative to other bromfenac formulations. (Ex. 2116, at ¶¶40-42; Ex. 2119; Ex. 2223; [REDACTED] [REDACTED] The reduced concentrations of active ingredient [REDACTED], as well as the lower pH, result in an improved side effect profile relative to other NSAID formulations, with no stinging or burning. (Ex. 2116, at ¶¶39-41.) The lower pH and reduced side effects make Prolensa® more comfortable to use relative to other NSAID formulations and enhance patient compliance.

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<sup>9</sup> Voltaren® uses diclofenac sodium as the active ingredient, but does not contain tyloxapol. (Ex. 2057.)

(Ex. 2116, at ¶39-40.) [REDACTED]

[REDACTED]

[REDACTED]

### **III. FRAMEWORK OF ANALYSIS**

51. To assess the commercial success of the inventions described in the claims of the '131 patent, I performed a two-part analysis. First, I examined whether the product embodying the patented inventions has been successful in the marketplace. As part of this analysis, I considered information related to the competitive landscape as well as the absolute and relative performance of Prolensa®.

52. Second, I evaluated the nexus between the success of the product embodying the '131 patent and the benefits and advantages made possible by the patented inventions. For this assessment, I identified the primary benefits and advantages of the patented inventions, particularly in relation to other ophthalmic NSAIDs indicated for the treatment of inflammation or inflammation and pain following cataract surgery, and examined the extent to which these benefits and advantages contributed to the marketplace success of the product.

53. It is my understanding that “commercial success” is a legal construct that has been established through case law. I understand that the commercial

success of the product must be due to the merits of the claimed invention beyond what is readily available in the prior art. (*J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997).)

54. I also understand that in order for there to be a finding of commercial success, it is not necessary that the patent owner sell every conceivable embodiment of the claims in the patent. Additionally, I understand that the commercial success analysis does not require that the patented features of the invention be the only reason for a product's success. Instead, the features must be a motivating (or important) factor. In this way, the existence of other demand drivers does not negate a showing of commercial success as long as there is proof that the success was a direct result of the claimed invention. That is, a causal correlation (or "nexus") must exist between the merits of the invention and the marketplace success of the product.

55. From an economic perspective, this makes sense because demand for any product, pharmaceutical or not, is driven by a host of factors, not just one. (*See, e.g., Ex. 2234, at 49.*) There is no product, pharmaceutical or not, for which consumers and suppliers agree that there is a single, or even primary, driver of demand, much less agree to what that driver is. A showing of commercial success appears to be consistent with the basic laws of demand and marketplace realities; the patent must be shown to be a



motivating (or important) factor in the purchase decision. The existence of other demand drivers does not negate a showing of commercial success.

#### **IV. COMMERCIAL SUCCESS OF THE '131 PATENT**

56. Prolensa® has been a marketplace success, as demonstrated by its overall level of sales and prescriptions as well as its share relative to other competing branded and generic ophthalmic NSAIDs. Prolensa® achieved its competitive position and sales success despite the existence of numerous established branded and generic ophthalmic NSAIDs that are indicated for the treatment of inflammation or inflammation and pain following cataract surgery.<sup>10</sup> Moreover, there is a nexus between the marketplace success of Prolensa® and the claims of the '131 patent.

##### **A. Marketplace Success**

###### **1. Absolute Performance of Prolensa®**

57. As noted above, Prolensa® received FDA approval and was made

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<sup>10</sup> Neither the law nor economics requires that there be only one commercially successful product in a particular marketplace. If that were the case, then numerous products that have achieved significant sales would be, by definition, deemed commercially unsuccessful. For example, under such a standard, Pepsi Cola, Diet Coke, Mountain Dew, Dr. Pepper, Sprite, and numerous other carbonated soft drinks would be deemed commercially unsuccessful because each accounts for a smaller share of U.S. carbonated soft drink sales than their competitor Coca Cola. (Ex. 2315.)

commercially available as of April 2013. (Ex. 2176; Ex. 2211.) Since its launch, sales of Prolensa® have been substantial, according to data from the market research firm IMS. As shown in Appendix 13, total U.S. gross sales increased from \$16.5 million in the third quarter of 2013 (Prolensa®'s first full quarter) to \$31.2 million in the third quarter of 2015. Prolensa® gross sales in the third quarter of 2015 were higher than in any prior quarter. (Appendix 13.)

58. U.S. Prolensa® gross sales totaled \$44.3 million in 2013, during its first nine months in the marketplace. (Appendix 13.) In 2014, U.S. gross sales were \$111.3 million. (Appendix 13.) In total, since its approval in April 2013 and through the third quarter of 2015, Prolensa® has generated \$246.9 million in U.S. gross sales during its first ten quarters. (Appendix 13.)

59. The number of Prolensa® prescriptions<sup>11</sup> in the U.S. also has increased significantly. As reflected below, total Prolensa® prescriptions

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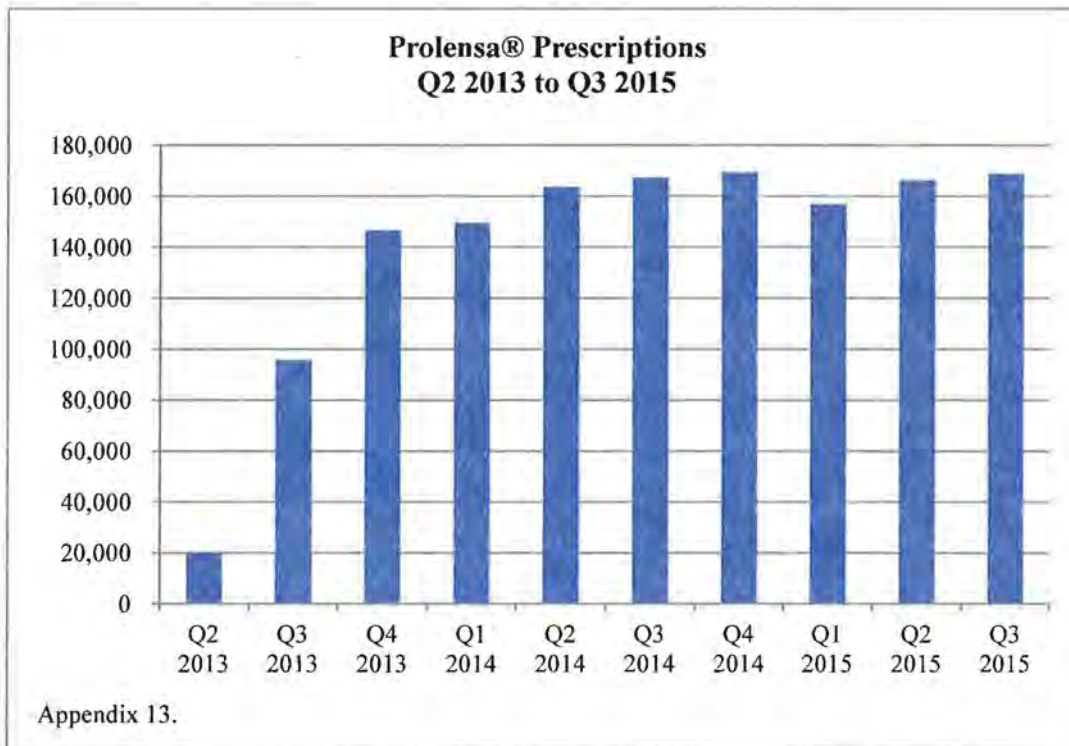
<sup>11</sup> I understand that IMS's National Prescription Audit ("NPA") prescription data are collected from a "universe of retail, standard mail service, specialty mail service and long-term care pharmacies" and omit data from hospital pharmacies. (Ex. 2192.) Accordingly, IMS data may understate the usage of post-operative inflammation drugs such as Prolensa® and other competing NSAIDs.



grew from approximately 20,000 in the second quarter of 2013 (the first quarter in which Prolensa® was commercially available), to approximately 96,000 in the third quarter of 2013 (Prolensa®'s first full quarter of commercial availability), to approximately 164,000 in the second quarter of 2014. (Appendix 5.) This is a growth rate of over 71 percent during Prolensa®'s first four full quarters of commercial availability (*i.e.*, the third quarter of 2013 to the second quarter of 2014).<sup>12</sup> Between the second quarter of 2013 and the third quarter of 2015, the peak number of Prolensa® prescriptions was 169,388, which occurred in the fourth quarter of 2014. (Appendix 13.)

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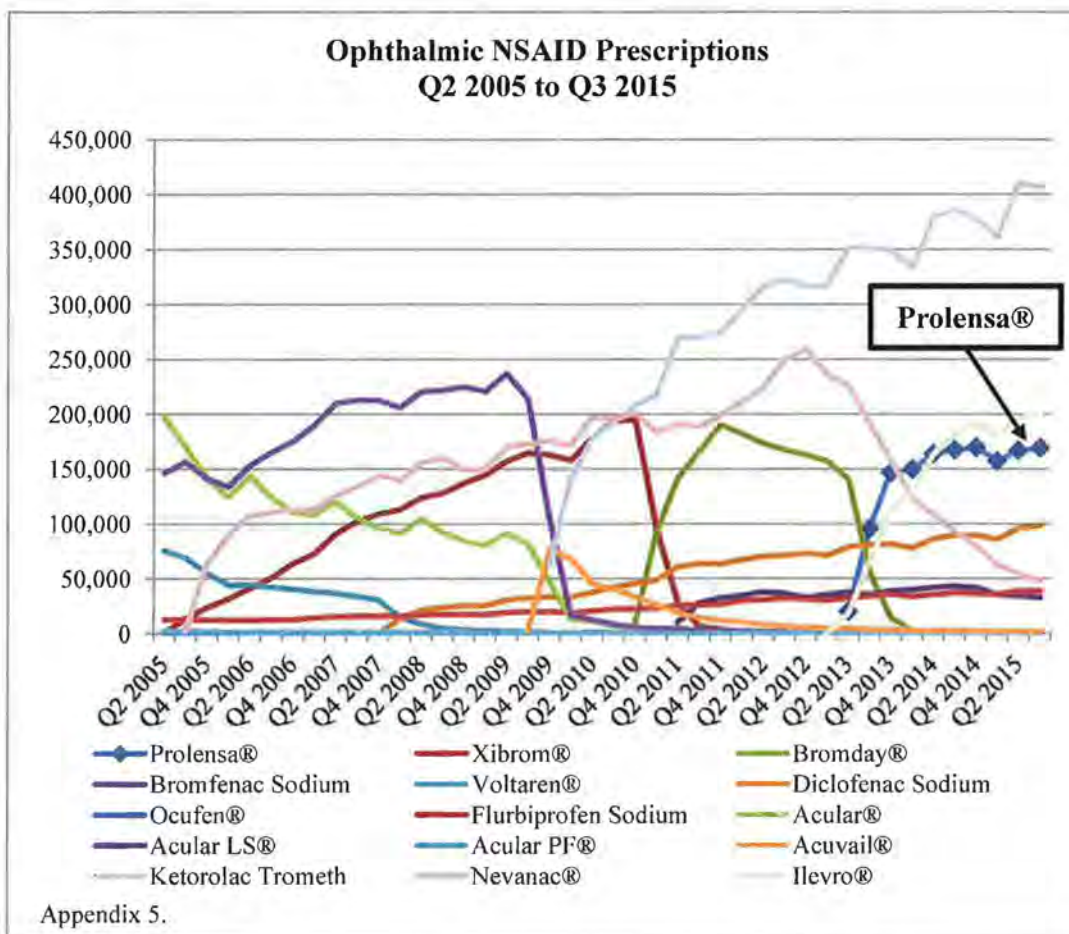
<sup>12</sup> Calculated as 163,653 total prescriptions / 95,546 total prescriptions – 1 = 71.3 percent. (Appendix 5.)



60. Since the second quarter of 2014, the number of ophthalmic NSAID prescriptions has remained relatively flat, falling in the narrow range of 983,000 to 1,002,000 for five of the six most recent quarters.<sup>13</sup> (Appendix 5.) In those same five quarters, Prolensa®’s prescriptions fell in the range of 163,000 to 169,000 each quarter, as reflected below. (Appendix 5.) In the first quarter of 2015, the only quarter since the second quarter of 2014 in which Prolensa® prescriptions fell outside this range (totaling 157,000), prescriptions for ophthalmic NSAIDs in general were down (totaling 919,000). (Appendix 5.) Thus, based on the number of prescriptions,

<sup>13</sup> Total includes the additional NSAIDs Ocufen®, generic flurbiprofen sodium, and Acular PF®.

Prolensa® has achieved a consistent level of sales, in spite of entering relatively late into a relatively crowded field. Compared with other, and older, ophthalmic NSAIDs, it has done very well, as reflected below.



61. Annual U.S. Prolensa® prescriptions totaled approximately 262,000 in 2013 and approximately 650,000 in 2014. (Appendix 13.) Since its approval in April 2013 and through the third quarter of 2015, there have been approximately 1.4 million prescriptions for Prolensa® dispensed in the U.S. (Appendix 13.) These prescriptions account for nearly 3.5 million

milliliters of Prolensa® sold in the U.S. (Appendix 13.)

## **2. Relative Performance of Prolensa®**

### **a. Initially**

62. The success of Prolensa® is significant in light of the timing of its entry and the marketplace in which it competes. Bausch & Lomb received FDA approval for Prolensa® in April 2013. (Ex. 2176. *See also*, Ex. 2218.) However, this was more than two decades after the March 1991 approval of Voltaren® and the November 1992 approval of Acular®. (Ex. 2161; Ex. 2162.) Acular LS®, Nevanac®, and Acuvail® were subsequently approved between 2003 and 2009. (Ex. 2163; Ex. 2165; Ex. 2167.) Additionally, Ilevro® received approval in October 2012, six months prior to Prolensa®'s approval. (Ex. 2178.)
63. Numerous generic NSAIDs were also available at the time of Prolensa®'s approval and commercial launch. Generic ophthalmic solutions of diclofenac sodium (the active ingredient in Voltaren®) and ketorolac tromethamine (the active ingredient in Acular®), were approved in December 2007 and November 2009, respectively. (Ex. 2161; Ex. 2162; Ex. 2168; Ex. 2169; Ex. 2170.) Moreover, the first generic version of bromfenac was launched in May 2011 by Mylan and Coastal Pharmaceuticals. (Ex. 2214; Ex. 2242.) Thus, by the time Prolensa® received FDA approval, on April 5, 2013, at least six branded drugs and three generic drugs, including



generic bromfenac, had already received FDA approval to treat similar indications as Prolensa®. (Ex. 2176.)

64. This environment suggests two potential challenges for Prolensa®. First, it is well established in the economics literature that late entry typically reduces the market share that a product can attain. (Ex. 2157, at 645, 655.) This relationship may be even more pronounced in the pharmaceutical industry, where habit weighs strongly in prescription and consumption decisions. (Ex. 2142, at 349, 363, 367.) In other words, if doctors are used to prescribing one form of a drug, they will be reluctant to switch to a different treatment unless there is a compelling reason to do so, and the longer they have been prescribing a particular formulation, the less likely they are to switch to a new formulation. (*See, e.g.*, Ex. 2142, at 367-68.) Here, despite the fact that Prolensa® was a late entrant, it quickly generated substantial sales, thus demonstrating the popularity and acceptance of the patented technology in the marketplace. As shown in Appendix 3 and Appendix 6, in the fourth quarter of 2013, which was Prolensa®'s second full quarter of commercial availability, Prolensa® accounted for approximately 31.3 percent of the total gross sales and 16.2 percent of the total prescriptions of ophthalmic NSAIDs indicated for the treatment of inflammation or

inflammation and pain following cataract surgery.<sup>14</sup>

65. Second, the availability of generics within a class of medications tends to generate resistance from insurance companies regarding the coverage of branded drugs on formularies, which tends to put branded drugs at a competitive disadvantage to generics within the same general class. In this regard, Prolensa® has had to compete with generic NSAIDs that have been available since at least 2007, including generic bromfenac, which has been available since May 2011. (Ex. 2170; Ex. 2242.)

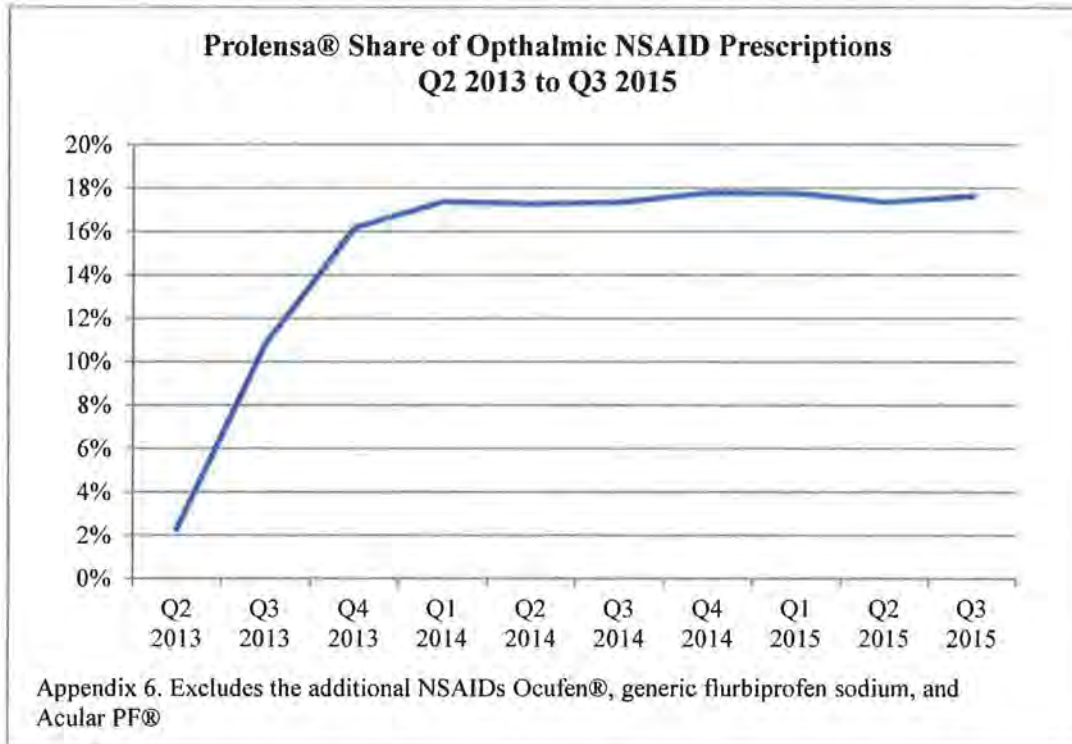
**b. Over Time**

66. Despite entering a very crowded business, within its first few quarters of availability, Prolensa® captured a substantial share of prescriptions of ophthalmic NSAIDs indicated for the treatment of inflammation or inflammation and pain following cataract surgery.
67. According to IMS, since the second quarter of 2013, Prolensa® has accounted for 15.3 percent of total U.S. prescriptions of ophthalmic NSAIDs indicated for the treatment of inflammation or inflammation and pain

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<sup>14</sup> When adjusted to include the additional NSAIDs Ocufer®, generic flurbiprofen sodium, and Acular PF®, Prolensa® accounted for approximately 31.1 percent of total gross sales and 15.6 percent of total prescriptions. (Appendix 4; Appendix 7.)

following cataract surgery.<sup>15</sup> (Appendix 6.) Since the fourth quarter of 2013, Prolensa®’s second full quarter of commercial availability, Prolensa®’s share of competing U.S. ophthalmic NSAID prescriptions has ranged from 16.2 percent to 17.8 percent each quarter, as reflected below.<sup>16</sup> (Appendix 6.)



68. Since the second quarter of 2013, Prolensa®’s 15.3 percent of U.S.

<sup>15</sup> When adjusted to include the additional NSAIDs Ocufer®, generic flurbiprofen sodium, and Acular PF®, Prolensa® accounted for approximately 14.7 percent of total prescriptions. (Appendix 7.)

<sup>16</sup> When adjusted to include the additional NSAIDs Ocufer®, generic flurbiprofen sodium, and Acular PF®, Prolensa®’s share of competing U.S. ophthalmic NSAID prescriptions since the fourth quarter of 2013 has ranged from 15.6 percent to 17.1 percent each quarter. (Appendix 7.)

prescriptions of ophthalmic NSAIDs indicated for the treatment of inflammation or inflammation and pain following cataract surgery is third highest among all competing ophthalmic NSAIDs during this period, behind generic ketorolac tromethamine and only 0.4 percent lower than the branded drug Ilevro®. (Appendix 6.) In the third quarter of 2015, Prolensa® accounted for 17.6 percent of competing U.S. ophthalmic NSAID prescriptions.<sup>17</sup> (Appendix 6.)

69. The marketplace success of Prolensa® is further evident from an analysis of the total U.S. sales relative to other ophthalmic NSAIDs with similar indications. Prolensa®'s share of the competing U.S. ophthalmic NSAID gross revenues since its launch in the second quarter of 2013 is 29.0 percent, essentially tied with Ilevro® for the highest among all ophthalmic NSAIDs indicated for the treatment of inflammation or inflammation and pain following cataract surgery.<sup>18</sup> (Appendix 3.) Since the fourth quarter of

<sup>17</sup> [REDACTED]

<sup>18</sup> When adjusted to include the additional NSAIDs Ocufer®, generic flurbiprofen



2013, Prolensa®'s second full quarter of commercial availability, Prolensa®'s share of the competing U.S. ophthalmic NSAID gross revenues has ranged from 31.3 percent to 33.5 percent each quarter. (Appendix 3.) In the third quarter of 2015, Prolensa® accounted for 32.3 percent of total U.S. gross revenues from prescriptions of ophthalmic NSAIDs indicated for the treatment of inflammation or inflammation and pain following cataract surgery. (Appendix 3.)

70. Thus, based on the number of prescriptions as well as gross revenue, Prolensa® has achieved a consistent level of sales and a consistent share, in spite of entering relatively late into a relatively crowded field.

**c. Third-Party Perceptions**

71. A variety of third parties have noted that the sales and profits of Prolensa® have been, and are forecasted to be, substantial. The views of industry analysts represent objective evidence of performance for the simple fact that those analysts are *not* associated with Bausch & Lomb. This evidence is used as one of many lenses through which to assess the commercial success of Prolensa®.

72. In May 2012, SunTrust Robinson Humphrey projected a \$400 million potential market size for Prolensa® starting in 2013. (Ex. 2154, at 3.) Based on sodium, and Acular PF®, Prolensa® accounted for approximately 28.8 percent of total gross sales. (Appendix 4.)

on data from IMS, Prolensa® has already generated \$246.9 million in gross revenue through its first ten quarters of U.S. commercial sales, and sales have reached new quarterly highs in each of the three most recent quarters. (Appendix 13.)

73. The SunTrust Robinson Humphrey sales forecast is consistent with forecasts from other market analysts. For example, a February 2014 research report from HSBC Global Research forecasted that Prolensa® sales would reach \$100 million per year within two to three years. (Ex. 2026.) Notably, this analyst report is available on Petitioners' website.

74. A June 2014 report from UBS forecasted Prolensa® sales of \$91.4 million in 2014 and \$111 million in 2015. (Ex. 2204, at 14.) Data from IMS shows that U.S. gross sales of Prolensa® totaled \$111.3 million in 2014, and \$91.3 million through the first three quarters of 2015, which is on pace to exceed these third-party forecasts. (Appendix 13.)

75. More recent forecasts have projected continued growth in Prolensa® sales in the coming years. For example, an October 2015 report by UBS projected Prolensa® sales to reach \$173.8 million annually by 2020. (Ex. 2203, at 7.)

76. Industry analysts have noted that Prolensa®'s sales success is a driver for Valeant's (the parent company to Bausch & Lomb) overall company

growth. For instance, a July 2015 report from CIBC noted that Valeant's "[o]rganic growth continues to come in well above expectations" and that this outperformance was being driven by several U.S. drugs, including Prolensa®. (Ex. 2235, at 3.)

**d. Licensing Activity**

77. The Patent Owner here has entered into several licenses covering the '131 patent. On or around May 14, 2015, the Patent Owner entered into a confidential settlement and license agreement with Apotex Inc. and Apotex Corp (collectively, "Apotex") covering the '131 patent, as well as four other patents owned by Patent Owner – the '290 patent, the '813 patent, the '606 patent, and U.S. Patent No. 8,129,431 (the "'431 patent"). (Ex. 2027.) The license was entered into in settlement of existing litigation between the parties. According to the Stipulated Consent Judgment and Injunction issued by the court in that litigation, Apotex stipulated that the patents at issue in that litigation, including the '131 patent, were valid, enforceable, and would be infringed by the generic product that is the subject of Apotex's ANDA 207334. (Ex. 2027.) I understand that the subject of Apotex's ANDA 207334 was a generic formulation of Prolensa®.

78. On or around June 4, 2015, the Patent Owner entered into a confidential settlement and license agreement with Paddock Laboratories,

LLC; L. Perrigo Company; and Perrigo Company (collectively, “Paddock”) covering the ’131 patent, as well the ’431 patent, the ’290 patent, the ’813 patent, and the ’606 patent. (Ex. 2028.) The license was entered into in settlement of existing litigation between the parties. According to the Stipulated Consent Judgment and Injunction issued by the court in that litigation, Paddock stipulated that the patents at issue in that litigation, including the ’131 patent, were valid, enforceable, and would be infringed by the generic product that is the subject of Paddock’s ANDA 207584. (Ex. 2028.) I understand that the subject of Paddock’s ANDA 207584 was a generic formulation of Prolensa®.

79. On or around June 30, 2015, the Patent Owner entered into a confidential settlement and license agreement with Metrics, Inc.; Coastal Pharmaceuticals, Inc.; Mayne Pharma Group Limited; and Mayne Pharma (USA), Inc. (collectively, “Metrics”) covering the ’131 patent, as well the ’431 patent, the ’290 patent, the ’813 patent, and the ’606 patent. (Ex. 2029.) The license was entered into in settlement of existing litigation between the parties. According to the Stipulated Consent Judgment and Injunction issued by the court in that litigation, Metrics stipulated that the patents at issue in that litigation, including the ’131 patent, were valid, enforceable, and would be infringed by the generic product that is the subject of Metrics’ ANDA

206257. (Ex. 2029.) I understand that the subject of Metrics' ANDA 206257 was a generic formulation of Prolensa®.

80. The Patent Owner has entered into at least three licenses in which the licensees have stipulated that the '131 patent is valid and enforceable and would be infringed by a generic version of Prolensa®. Despite the fact that I did not have access to the full terms of the confidential license agreements, relevant information about each license agreement was available through the stipulated consent judgment and injunction orders. And these orders reveal that each of the licensees admitted that the '131 patent is valid, enforceable, and would be infringed by the generic sale of the products that were the subject of their respective ANDAs. The words and actions indicate that the '131 patent is both relevant and important to the manufacture and sale of Prolensa®.

**B. Causal Nexus**

**1. Benefits of the Patented Inventions**

81. I understand that the patented inventions enable a number of benefits. I understand that the compositions of bromfenac and tyloxapol disclosed and claimed in the '131 patent result in a formulation that has a lower, more natural pH level with improved ocular penetration relative to other bromfenac formulations used to treat inflammation or inflammation and pain

following cataract surgery, allowing Prolensa® to deliver the same clinical efficacy, but using a lower concentration of the active ingredient bromfenac and a lower concentration of surfactant relative to other bromfenac formulations. (Ex. 2116, at ¶¶40-42; Ex. 2119; Ex. 2223; [REDACTED])

[REDACTED] The reduced concentrations of active ingredient [REDACTED] as well as the lower pH, result in an improved side effect profile relative to other NSAID formulations, with no stinging or burning. (Ex. 2116, at ¶¶39-41.)

The lower pH and reduced side effects make Prolensa® more comfortable to use relative to other NSAID formulations and enhance patient compliance. (Ex. 2116, at ¶39-40.) [REDACTED]

[REDACTED]

[REDACTED]

82. Prior to the commercial release of Prolensa®, available ophthalmic NSAID treatments for inflammation or inflammation and pain following cataract surgery (including Xibrom® and Bromday®) often resulted in painful burning and stinging when applied to a patient's eye. (Ex. 2116, at ¶36.)

83. I understand that Prolensa® is characterized by a lower concentration of active ingredient and surfactant as well as improved ocular penetration relative to other bromfenac formulations because of its unique formulation,



which includes tyloxapol. This improved formulation results in a drug that is more comfortable to apply than other available treatments. I understand that Prolensa® has a pH level that is lower than other bromfenac formulations and closer to the pH level of natural tears, and that Prolensa® was not reported to cause any burning or stinging in patients. (Ex. 2116, at ¶¶39-40.)

84. According to Dr. Williams, the benefits that result from combining bromfenac with tyloxapol instead of polysorbate 80 were unexpected. (Ex. 2082, at ¶65.) Specifically, according to Dr. Williams, tyloxapol's ability to chemically stabilize bromfenac was unexpected, since substituting one non-ionic surfactant for another (*e.g.*, substituting tyloxapol for polysorbate 80) would not have been expected to affect chemical stability at all. (Ex. 2082, at ¶191.) Instead, according to Dr. Williams, the use of tyloxapol instead of polysorbate 80 resulted in "vastly superior chemical stability." (Ex. 2082, at ¶191.) The unexpected improvement in stability permitted formulating Prolensa® with a [REDACTED] and a significant reduction in pH level, which resulted in a lower concentration of bromfenac without any reduction in efficacy. (Ex. 2082, at ¶¶203-05.)

**a. Clinical Importance of the Benefits**

85. The benefits of pharmaceuticals are evaluated by patients and intermediaries. An intermediary is usually the prescribing physician. As

discussed in Dr. Trattler's declaration, physicians consider the efficacy, safety, and side effects of treatments when making their prescribing decisions. (Ex. 2116, at ¶¶37-42.) Moreover, physicians consider the likelihood that patients will be willing and able to comply with the prescribed course of treatment in the face of possible side effects when making their prescribing decisions. (Ex. 2116, at ¶39-40.)

86. As described above, other available ophthalmic NSAIDs for the treatment of inflammation or inflammation and pain following cataract surgery were known to result in painful burning and stinging. (Ex. 2116, at ¶36.) These side effects have a negative impact on patient compliance, increasing the risk of developing serious post-operative complications, such as cystoid macular edema, and resulting in prolonged post-operative pain. (Ex. 2116, at ¶¶36, 39.)

87. Prolensa®'s formulation results in a lower, more natural pH level and improved ocular penetration of the active ingredient bromfenac relative to other bromfenac formulations used to treat inflammation or inflammation and pain following cataract surgery, enabling the use of a relatively low concentration of bromfenac. (Ex. 2116, at ¶¶40-41.) As a result, patients who use Prolensa® experience a reduced exposure of surgically compromised tissue to the active drug ingredient, without a loss of efficacy.

(Ex. 2116, at ¶41.) According to several studies, limiting ocular exposure to a medication may result in a reduced incidence of adverse events. (Ex. 2119; Ex. 2228, at 26.) Notably, the advanced formulation of Prolensa® relative to Bromday® allows Prolensa® to achieve the same clinical efficacy as Bromday® with a more favorable side effect profile and a lower concentration of the active ingredient bromfenac while maintaining once-daily dosing. This is in contrast to nepafenac, the only other NSAID approved for once-daily dosing, in which a lower concentration of active ingredient is associated with more frequent dosing requirements. (Ex. 2119.) Specifically, the once-daily formulation of nepafenac contains triple the drug concentration compared with the alternative, three-times-daily formulation. (Ex. 2119.)

88. Moreover, as discussed above, Prolensa® exhibits a superior side effect profile, with no reported burning or stinging, relative to other available ophthalmic NSAIDs with similar indications. This superior side effect profile makes it easier for patients to adhere to their prescribed treatment schedule, reducing the risk of post-operative complications and prolonged pain. (Ex. 2116, at ¶39.) These benefits represent a significant improvement over prior ophthalmic NSAIDs that exhibited unfavorable side effect profiles, drug concentrations, and/or dosing schedules. As one medical

study noted, “[t]he lower concentration of bromfenac 0.07% combined with its once-daily dosing may help further improve patient adherence and compliance.” (Ex. 2119.)

89. Dr. Trattler described the development of Prolensa® as “highly significant to the field of ophthalmology and cataract surgery.” (Ex. 2116, at ¶51.) Prolensa® was the first available ophthalmic NSAID to treat inflammation or inflammation and pain following cataract surgery without the presence of painful burning or stinging upon use. (Ex. 2116, at ¶51.) The improvements that resulted from the advanced formulation of Prolensa® relative to other bromfenac formulations have “substantially benefited patients.” (Ex. 2116, at ¶50.) For many reasons, Dr. Trattler has concluded that Prolensa® is his “drug of choice in treating post-operative pain and inflammation” in his patients and that he “routinely prescribe[s] Prolensa® because, among other reasons, its lack of burning and stinging makes it more comfortable to patients, which fosters patient compliance.” (Ex. 2116, at ¶¶41, 51.)

90. Dr. Steven Silverstein, founder of the Silverstein Eye Centers in Kansas City, Missouri, praised the benefits of the advanced formulation, noting that Prolensa® “provides powerful and rapid control of inflammation and pain following cataract surgery, confirming the potency of this NSAID

and the benefits of the new formulation.” (Ex. 2218.)

91. Additionally, Dr. Rajesh Rajpal, a leading cataract surgeon, described how the improved comfort and superior side effect profile of Prolensa® is particularly important for elderly patients, on whom cataract surgery is typically performed. (Ex. 2116, at ¶59.) According to Dr. Rajpal, varying dosing schedules and burning or stinging sensations can lead to higher patient non-compliance, particularly in elderly patients. (Ex. 2116, at ¶59.)

92. From an economic perspective, the fact that six generic drug companies, including the Petitioners here, have demonstrated a desire and intent (or, in economic terms, a “revealed preference”) to offer a generic version of Prolensa® is very strong evidence that Prolensa® is believed by the Petitioners to be a commercial success. (Ex. 2082, at ¶¶206-07.) Petitioners could have chosen to formulate and offer for sale a generic version of Xibrom®, the twice-daily bromfenac 0.09 percent solution developed by ISTA that uses polysorbate 80 as a surfactant and that has been off patent and without marketing exclusivity since January 2009, or Bromday®, the once-daily bromfenac 0.09 percent solution developed by ISTA that uses polysorbate 80 as a surfactant and that is currently off patent. (Ex. 2158; Ex. 2181; Ex. 2199, at 7.) Petitioners also could have chosen to formulate and offer for sale a generic version of any number of different



topical ophthalmic NSAIDs used to treat inflammation or inflammation and pain resulting from cataract surgery, such as Voltaren® gel, Voltaren® solution, or Acular® solution. (Ex. 2161; Ex. 2162; Ex. 2166; Ex. 2179; Ex. 2180; Ex. 2182.) None of these other NSAIDs are currently protected by patents or subject to any exclusivity, and the Petitioners could file an ANDA for these products without incurring the risk and expense of litigation.<sup>19</sup>

93. From a business perspective, it would make little sense for the Petitioners to invest substantial resources in pursuit of such a generic product and the pursuit of regulatory approval (not to mention participating in this IPR) unless they believed that the underlying branded product has been and will continue to be a commercial success. Prescription drug categories vary across a number of dimensions, including the number of available branded and generic drugs, the length of time that drugs have been commercially available, the distribution of shares among competing drugs, the number of potential users for the competing drugs, the potential for profitable generic entry, and numerous other dimensions. The decision

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<sup>19</sup> I am not aware of whether the Petitioners have filed an ANDA for any other topical ophthalmic NSAIDs or corticosteroids. Even if they have, the choice to pursue an ANDA for Prolensa® suggests that Petitioners recognize that there is incremental value associated with offering once-daily bromfenac 0.07 percent solution formulation.



whether to pursue a generic version of a branded drug must weigh all of these factors across all potential drug categories to identify the best uses of the generic manufacturer's resources. Those opportunities that do not present a sufficient return on investment will not be pursued.

94. Here, the decision to pursue generic copies of Prolensa®, as opposed to another ophthalmic NSAID, including Bromday®, or another drug category altogether, indicates that the generic manufacturers anticipate the potential return on investment from generic copies of Prolensa® to be positive, and likely higher than other opportunities. This potential return on investment is a function of numerous factors, which include the number of potential users as well as Prolensa®'s likely share, historical sales, and advantages relative to other ophthalmic NSAIDs. If the potential return on investment were not sufficiently high – that is, if the potential sales and profits that could be transferred from Prolensa® to the generic manufacturers were not sufficiently high – then the generic manufacturers would be better served to invest their time, effort, and money in pursuing generic forms of other drugs (including drugs in other categories) that offer a better return.

95. Moreover, the fact that Petitioners are seeking approval of a generic form of Prolensa® indicates that they believe that there are specific

advantages to the claims of the '131 patent that differentiate Prolensa® from other bromfenac formulations and from other competing ophthalmic NSAIDs. If that were not the case (*i.e.*, if Prolensa® were not considered to be a commercially successful product by the Petitioners), one would not expect the Petitioners to seek to introduce a generic version of the product, as there are myriad other competing ophthalmic NSAIDs, including two bromfenac formulations, for which generic drugs could be pursued instead of Prolensa®.

**b. Marketing Importance of the Benefits**

96. It is expected that Bausch & Lomb, or any company for that matter, would highlight numerous product features in its marketing materials. The presence of product features that are not attributed to the '131 patent is not surprising, as Bausch & Lomb does not claim that the benefits attributable to the '131 patent are the *only* benefits that Prolensa® provides to patients.

97. As discussed above, my understanding is that a commercial success analysis does not require that the patented features of the invention be the *only* reason for a product's success. Instead, the features must be a motivating (or important) factor. Here, the Prolensa® marketing materials highlight numerous product features that are attributable to the '131 patent – the lower pH level, use of a lower concentration of active ingredient and

surfactant with no loss of efficacy, and improved side effect profile – in addition to product features that are not.

**i. Healthcare Professionals**

98. Prolensa® marketing and promotional materials include presentations that highlight Prolensa®’s advanced formulation and the benefits resulting from compositions of bromfenac and tyloxapol that are described in the ’131 patent. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]


[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



99. Prolensa® marketing and promotional materials also include

presentations delivered by practicing eye doctors and presentations developed for medical discussion groups. For example, Dr. Mitchell A. Jackson, founder and director of Jacksoneye, developed a presentation entitled “Selecting an NSAID for Cataract Surgery: What Really Matters” for the Annual American Society of Cataract and Refractive Surgery Symposium in April 2013. (Ex. 2211; Ex. 2221.) In the presentation, Dr. Jackson discussed Prolensa®’s “advanced formulation” and associated patient comfort levels, as well as the lower, more physiological pH level that enabled improved corneal penetration and thus a lower concentration of bromfenac. (Ex. 2221, at 7-8, 15, 18, 25-26.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



100.





[REDACTED]

101. Several Prolensa® presentations designed for medical audiences refer to the results of medical research evaluating the effectiveness of Prolensa®’s lower concentration formulation, including the Phase III clinical trials. (*See, e.g.*, [REDACTED]; Ex. 2221, at 19-25; [REDACTED].) Results from the Phase III clinical trials as well as other medical research related to Prolensa® have been presented at medical industry meetings, including the November 2012 Annual Meeting of the American Academy of Ophthalmology and the May 2013 Association for Research in Vision and Ophthalmology Annual Meeting in Seattle, Washington. (Ex. 2223; Ex. 2224; Ex. 2227.) Materials prepared for these meetings noted that the advanced or modified formulation “facilitates intraocular penetration, thereby allowing a lower medication load while maintaining clinical efficacy with once daily dosing” and the “bromfenac 0.07% formulation has been

shown to improve the penetration into ocular tissues thereby allowing for a lower concentration with comparable tissue concentrations to those seen with Bromday.” (Ex. 2223; Ex. 2224; Ex. 2227.)

102. Other marketing and promotional materials geared towards the medical community include the Prolensa® formulary kit. The introduction to the formulary kit notes several of the benefits of the claimed inventions, including that Prolensa® “has an advanced formulation that facilitates corneal penetration” and “offers ocular comfort and convenience with [once-daily dosing].” (Ex. 2219.)

**ii. Other Audiences**

103. Since its launch in April 2013, Bausch & Lomb marketing and promotional materials aimed at other audiences also have publicized the claimed features of the invention and their benefits, including Prolensa®’s advanced formulation (including tyloxapol), lower and more natural pH level, improved corneal penetration, proven efficacy, lower concentration of active ingredients, and enhanced comfort relative to other compositions. That is, the marketing of Prolensa® is closely linked to the relevant claims of the ’131 patent.

104. Various Prolensa® information sheets and marketing materials describe Prolensa® as having an “advanced formulation [that] delivers

corneal penetration” and “[p]roven efficacy at a lower concentration than Bromday®.” (Ex. 2217; Ex. 2222; Ex. 2231.) Prolensa® information sheets also describe the improved side effect profile, noting that Prolensa® is “[d]esigned for ocular comfort and convenience.” (Ex. 2217; Ex. 2231.) Information sheets also highlight the lower, more physiological pH level that facilitates corneal penetration. (Ex. 2231.) Several Prolensa® marketing materials specifically noted the inclusion of tyloxapol among the ingredients. (*See, e.g.*, Ex. 2217; Ex. 2225.) Pages from several of these documents, which describe Prolensa®’s advanced formulation, proven efficacy at a lower concentration of active ingredient, comfort, and lower, more physiological pH level, are shown below.

## INTRODUCING PROLENSA™ (bromfenac ophthalmic solution) 0.07% Powered for penetration

### PRODUCT INFORMATION

<b>NAME AND INDICATION</b>	PROLENSA™ (bromfenac ophthalmic solution) 0.07% is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.
<b>DESCRIPTION</b>	A sterile, topical NSAID for ophthalmic use.
<b>FILL SIZES</b>	1.6 mL in a 7.5-mL container and 3 mL in a 7.5-mL container.
<b>NDC</b>	1.6 mL [24208-602-01]; 3 mL [24208-602-03]
<b>DELIVERY</b>	Solution
<b>ACTIVE INGREDIENT</b>	Bromfenac
<b>INACTIVE INGREDIENTS</b>	Boric acid, edetate disodium, povidone, sodium borate, sodium sulfite, xylocaine, sodium hydroxide to adjust pH, and Water for Injection, USP.
<b>PRESERVATIVE</b>	Benzalkonium chloride 0.005%
<b>HOW SUPPLIED</b>	White low-density polyethylene (LDPE) dropper tip and a 15-mm polypropylene (PP) cap.
<b>DOSE</b>	Instill one drop into the affected eye on the day of surgery, and through the first 14 days post-surgery.
<b>A/B RATING</b>	There is no A/B bioequivalent for PROLENSA.



### PACKAGING SPECIFICATIONS

<b>STORAGE CONDITIONS</b>	Store at 59°F to 77°F (15°C-25°C)	
<b>SELLING UNIT DIMENSIONS</b>	<b>Fill</b>	<b>Dimensions</b>
	5 g	1 1/2" x 1 1/4" x 3 1/2" (H)
<b>SHIPPING CASE DIMENSIONS</b>	<b>Pack</b>	<b>Dimensions</b>
	144	13 1/2" x 10 1/2" x 7"

### PRICING AND ORDER INFORMATION

<b>Phone orders</b> 1.800.323.0000	<b>Fax orders</b> 1.888.386.1222
<b>WAC</b> \$170.63 (either size, same WAC)	<b>NDC</b> 24208-602-01 24208-602-03

\*TERMS AND CONDITIONS: Approved by FDA. Prescription only. For use in the United States only. PROLENSA is a registered trademark of Bausch + Lomb. All other trademarks are the property of their respective owners. © 2010 Bausch + Lomb. All rights reserved. For more information, visit [www.bausch.com](http://www.bausch.com). Please see important risk information on reverse.

For the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

## PROLENSA™: Potency and penetration with QD efficacy<sup>1,2</sup>

### FORMULATED TO FACILITATE CORNEAL PENETRATION

- Advanced formulation delivers corneal penetration<sup>1,3</sup>
- Proven efficacy at a lower concentration than BROMDAY® (bromfenac ophthalmic solution) 0.09%<sup>1,4</sup>

### POWERED FOR EFFICACY

- Powerful clearance—More than twice as many patients achieved complete clearance of postoperative inflammation vs vehicle at Day 15 (45.5% vs 20.2%;  $P < 0.0001$ )<sup>1,2</sup>
- Rapid resolution—Rapid reduction of inflammation following cataract surgery<sup>2</sup>
- Pain free at Day 1—Approximately 4 of 5 patients were pain free at Day 1<sup>2\*</sup>

### DESIGNED FOR COMFORT AND CONVENIENCE

- Designed for ocular comfort and convenience with QD efficacy<sup>1,2</sup>
- No shaking required; solution delivers consistent dose in each drop<sup>1,5</sup>

Visit [www.bausch.com](http://www.bausch.com)

For product-related questions and concerns, call 1.800.323.0000

### IMPORTANT RISK INFORMATION ABOUT PROLENSA\*

#### Indications and Usage

PROLENSA™ (bromfenac ophthalmic solution) 0.07% is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

#### Dosage and Administration

Instill one drop into the affected eye once daily beginning 1 day prior to surgery, continued on the day of surgery, and through the first 14 days post-surgery.

#### Warnings and Precautions

- Sulfite allergic reactions
- Slow or delayed healing
- Potential for cross-sensitivity
- Increased bleeding of ocular tissues
- Corneal effects, including keratitis
- Contact lens wear

#### Adverse Reactions

The most commonly reported adverse reactions in 3%–8% of patients were anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and blurred vision.

Please see complete information about PROLENSA™ in the accompanying full Prescribing Information.

\*Risk of PROLENSA™ (bromfenac ophthalmic solution) 0.07% is discussed in the full Prescribing Information.

References: 1. PROLENSA™ (bromfenac ophthalmic solution) 0.07% vs. BROMDAY® (bromfenac ophthalmic solution) 0.09% in the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. JAMA. 2010;303:1000-1007. 2. PROLENSA™ (bromfenac ophthalmic solution) 0.07% vs. vehicle in the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. JAMA. 2010;303:1008-1015. 3. PROLENSA™ (bromfenac ophthalmic solution) 0.07% vs. vehicle in the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. JAMA. 2010;303:1016-1023. 4. PROLENSA™ (bromfenac ophthalmic solution) 0.07% vs. BROMDAY® (bromfenac ophthalmic solution) 0.09% in the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. JAMA. 2010;303:1024-1031. 5. PROLENSA™ (bromfenac ophthalmic solution) 0.07% vs. vehicle in the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. JAMA. 2010;303:1032-1039.

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**BAUSCH + LOMB**

**PROLENSA™**  
(bromfenac ophthalmic solution) 0.07%

(Ex. 2217.)



## PROLENSA™: Powered for penetration

ADVANCING THE FORMULATION TO FACILITATE CORNEAL PENETRATION<sup>1,2</sup>

**The PROLENSA™ Effect**

**The Halogenation Effect**

Halogenated with bromine for potency<sup>3</sup>

To enhance mucinolytic capabilities from 0.1% to 0.07% (vehicle preserved)

**The pH Effect**

Lower pH increases lipophilicity<sup>4,5</sup>

Adapted to pH shifts to enhance drug delivery capacity of bromine brominated drug delivery

**PROLENSA™**

FACILITATES CORNEAL PENETRATION<sup>6</sup>

- Advanced formulation delivers corneal penetration<sup>6,7</sup>
- Proven efficacy at a lower concentration<sup>1</sup>

**IMPORTANT RISK INFORMATION ABOUT PROLENSA™**

**Indications and Usage**  
 PROLENSA™ (bromfenac ophthalmic solution) 0.07% is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

**Warnings and Precautions**

• Sulfite allergy reactions	• Increased bleeding of ocular tissues
• Slow or delayed healing	• Corneal edema, including keratitis
• Potential for cross-reactivity	• Contact lens wear

Please see full Prescribing Information for PROLENSA™ inside pocket.

**Study design:** This study compared PROLENSA™ 0.07% to vehicle 0.07% in patients who had undergone cataract surgery. The study was a randomized, double-masked, parallel-group, comparative study. The study was conducted in the United States and Canada.

## PROLENSA™: Powered for efficacy

**Powerful Clearance**

**INFLAMMATION CLEARANCE AT DAY 15<sup>1,2</sup>**

Primary endpoint: Complete clearance of cells and flare<sup>3</sup>

Endpoint	PROLENSA	Vehicle
Complete clearance (cells and flare)	46%	20%
Additional proscribed endpoint: Zero to trace cells	80%	47%

*>2x as many patients had complete clearance (P<0.001)*

*of patients had zero to trace cells (P<0.001)*

**Rapid Resolution**

**INFLAMMATION REDUCTION FOLLOWING CATARACT SURGERY<sup>1,2</sup>**

Mean Summed Ocular Inflammation Score (SSOIS) at each visit

Day	PROLENSA	Vehicle
Day 1	~1.5	~1.5
Day 3	~0.8	~1.2
Day 4	~0.5	~1.0
Day 15	~0.2	~0.8

**Pain Free at Day 1**

Approximately 4 of 5 patients were pain free at Day 1<sup>1,2</sup>

• 78.8% vs 49.5% with vehicle; P<0.0001

**DESIGNED FOR COMFORT AND CONVENIENCE**

- More physiologic pH<sup>4,5</sup>
- Ocular comfort with convenient OTC dosing demonstrated in PROLENSA™-treated eyes<sup>1</sup>
  - Patients reported less foreign body sensation and photophobia, and had less redness vs vehicle<sup>8</sup>

<sup>1</sup>See PROLENSA™ Prescribing Information for full details on efficacy and safety. <sup>2</sup>See PROLENSA™ Prescribing Information for full details on efficacy and safety. <sup>3</sup>See PROLENSA™ Prescribing Information for full details on efficacy and safety. <sup>4</sup>See PROLENSA™ Prescribing Information for full details on efficacy and safety. <sup>5</sup>See PROLENSA™ Prescribing Information for full details on efficacy and safety. <sup>6</sup>See PROLENSA™ Prescribing Information for full details on efficacy and safety. <sup>7</sup>See PROLENSA™ Prescribing Information for full details on efficacy and safety. <sup>8</sup>See PROLENSA™ Prescribing Information for full details on efficacy and safety.

**PROLENSA™**  
**(bromfenac ophthalmic solution) 0.07%**

(Ex. 2231, at 2-3.)

105. Press releases also highlight the benefits enabled by the compositions described in the '131 patent. For example, ISTA's March 2012 press release about Prolensa® noted that Prolensa®'s advanced formulation "enhances

the penetration of bromfenac into ocular tissue, allowing us to lower the concentration of bromfenac, while maintaining the convenience of once-daily use.” (Ex. 2230.) Bausch & Lomb’s April 8, 2013 press release announcing the FDA approval for Prolensa® described the “benefits of the new formulation,” including Prolensa®’s “high degree of efficacy and ocular comfort” and how Prolensa®’s “formulation [is] designed to facilitate ocular penetration” which “allows for a lower concentration of bromfenac.” (Ex. 2218.) Similarly, Bausch & Lomb’s April 17, 2013 press release noted that Prolensa®’s “advanced formulation allows for a lower concentration of the active ingredient, bromfenac, while maintaining the convenience of once daily dosing.” (Ex. 2211.)

**c. Third-Party Perceptions**

106. Third-party observers also have highlighted the significance of Prolensa®’s improved formulation as covered by the ’131 patent. And a number of practicing ophthalmologists have discussed the advantages of Prolensa® relative to other available ophthalmic NSAIDs.
107. According to Dr. Trattler, Prolensa® “is widely recognized in the medical community as a major improvement on existing therapies for its efficacy in treating inflammation post cataract surgery while maintaining a favorable side effect profile.” (Ex. 2116, at ¶54.) Moreover, according to Dr.



Trattler and Dr. Williams, Prolensa® has received widespread acclaim in the medical community and in medical journals. (Ex. 2116, at ¶60; Ex. 2082, at ¶65.)

108. Other recent articles discuss how Prolensa® offers advantages over prior generation NSAIDs. Dr. Eric Donnenfeld, Clinical Professor of Ophthalmology at NYU Medical Center, pointed out that newer generation NSAIDs, such as Prolensa®, are extremely potent, safer, better tolerated, and more effective than prior generation NSAIDs, and are “reformulated to achieve additional penetration into the eye [and are] very gentle on the ocular surface.” (Ex. 2160; Ex. 2191.) Similarly, Dr. Elizabeth Davis, Managing Partner of Minnesota Eye Consultants and Adjunct Clinical Professor at the University of Minnesota, noted that she prefers Prolensa® to other available NSAIDs because “[i]t has anesthetic properties, so it is very comfortable to take.” (Ex. 2191.)

109. In addition, a 2013 study by Dr. Thomas R. Walters *et al.* concluded that Prolensa®’s “advanced formulation of bromfenac, with a lower concentration of active ingredient, has a similar efficacy profile as higher concentrations of bromfenac” and that Prolensa® “could be a valuable addition to surgeons’ standard of care after cataract surgery.” (Ex. 2228, at 31.)

## 2. Promotional Activities

110. Demand for a product, pharmaceutical or not, is driven by a host of factors, not just one.<sup>21</sup> (*See, e.g.*, Ex. 2234, at 49.) Promotional efforts, such as journal advertising, samples, physician detailing, and coupons, along with physicians' habits, and insurance formulary restrictions, among other things, all have contributed to demand for Prolensa®. However, the existence of these demand drivers does not negate the fact that the patented inventions, *i.e.* compositions of the active ingredient bromfenac and the surfactant tyloxapol, are a critical set of factors that contribute to the demand for Prolensa®. Indeed, the patented inventions have been a motivating factor behind Prolensa®'s marketplace success.

### a. Informative and Persuasive Advertising

111. The type and extent of advertising for any product or service varies depending on the nature of the promoted goods and/or services. Advertising can be either informative or persuasive. Informative advertising notifies consumers of a product's existence and its characteristics, while persuasive advertising seeks to create what economists refer to as "spurious product differentiation." (Ex. 2201, at 1705-06.) Research on pharmaceutical

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<sup>21</sup> It is my understanding that to prove a patent is commercially successful does not require that the patented features be the only reason for a product's success. Instead, the patented feature must be a motivating factor.

promotion has found that pharmaceutical promotion is primarily informative with respect to choices among differentiated drugs, but it is persuasive with respect to undifferentiated drugs. (Ex. 2143, at 2.)

112. These findings are consistent with the notion that prescription drugs are “experience goods” that must be tried in order to assess the quality of the product. Promotion for experience goods seeks to inform customers of the product’s existence and to encourage them to try the product, but following trial, the physician’s and consumer’s own experience with the product will dictate future consumption decisions. According to Professor Berndt of the Massachusetts Institute of Technology,

Clearly, prescription drugs are predominantly experience goods... Moreover, since physicians primarily make prescribing decisions, much pharmaceutical marketing is focused on them, with detailers providing information and free samples to physicians to encourage them to experiment with their product. (Ex. 2148, at 110-11.)

113. In other words, the goal of promotion in the pharmaceutical industry is to encourage physicians and patients to try a drug in order to experience the drug first-hand. Indeed, patients and prescribers must be made aware of the existence and benefits of a drug’s advantages, and pharmaceutical promotion fulfills this role.

**b. Pharmaceutical Demand Factors**

114. Economic studies of pharmaceutical markets indicate, not

surprisingly, that demand is driven by many factors, including product characteristics (such as efficacy, dosing, and favorable side effect profiles), relative prices, promotional efforts, and various other factors, including formulary status and published clinical results.<sup>22</sup> (*See, e.g.*, Ex. 2150, at 149-53; Ex. 2151, at 310-13; Ex. 2198, at 456-57; Ex. 2209, at 551, 573, 586.) Those studies show, for the most part, that each factor has a positive effect on pharmaceutical sales. And they show that these factors are often inter-related; that is, strategies (results) on one front are often correlated with strategies (results) on another.

115. Marketing alone does not and cannot explain a drug's success, and will not cause a physician to prescribe a drug. Instead, physicians are influenced by a number of factors, including clinical and scientific evidence on the safety, efficacy, and side effects of the drug. Physicians will not prescribe a drug unless it is safe, is effective, and offers benefits to patients that other drugs do not.

**i. Impact of Product Characteristics**

116. There is no dispute that Bausch & Lomb has promoted Prolensa®.

But the existence of promotional efforts does not negate a link between the

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<sup>22</sup> Insurance companies and health maintenance organizations ("HMOs") may impact the purchase decision through their use of formularies. (*See, e.g.*, Ex. 2145, at 169, 186; Ex. 2147, at 30-33; Ex. 2200, at 130-33.)

marketplace success of Prolensa® and the benefits of the claimed inventions. There is well-established literature about the two-way relationship between promotional efforts and product characteristics, which holds here. (*See, e.g.*, Ex. 2149, at 3, 17.) Substantial promotional efforts are generally undertaken for those products that are perceived to exhibit favorable product characteristics. As Guha, Li, and Scott observed,

[P]harmaceutical companies are more likely to invest in substantial marketing efforts for drugs with superior therapeutic benefits. Therefore, the level of marketing effort a pharmaceutical company invests in a drug and the impact of marketing on its success typically depend on the underlying therapeutic benefits of the drug. (Ex. 2232, at 3.)

117. According to Professor Berndt,

Marketing provides technology-transfer information to patients and providers on efficacy in the treatment of specific medical disorders based on clinical trial data; the incidence of side effects, adverse interactions, and contraindications; pharmacokinetic properties involving half-life and dosage; and, in the naturalistic environment outside the clinical trial setting, effectiveness information on post-launch product surveillance evidence, actual dosages, off-label usage (when appropriate), subpopulation differentials, tolerability, and cost-effectiveness. (Ex. 2148, at 111-12.)

118. In another paper, Professor Berndt and his co-authors noted that “drug marketing is largely a matter of providing information about the existence and usefulness of the product....” (Ex. 2151, at 296.) And Guha, Li, and Scott observed that “[m]arketing performs an important role in



disseminating clinical and therapeutic information about a drug.” (Ex. 2232, at 3.)

119. Since its launch in April 2013, Bausch & Lomb’s marketing and promotional materials have publicized the claimed features of the inventions and their benefits, including Prolensa®’s advanced formulation (including tyloxapol), lower and more natural pH level, improved corneal penetration, proven efficacy, lower concentration of active ingredients, and enhanced comfort relative to other compositions. Companies typically feature messages in their promotional materials that they believe will resonate with clinicians. Bausch & Lomb’s numerous references to the benefits of the patented inventions (including use of tyloxapol) suggest that the company believed that the provision of such information was important to physicians.

#### **ii. Impact of Product Quality**

120. Economic studies of pharmaceutical demand reveal that the level of promotion is a function of product quality. (Ex. 2149.) A study done by Professor Berndt and his colleagues showed that promotion responds positively to product improvements, including new FDA indications and other science-based events. (Ex. 2149, at 17.) The failure to acknowledge this relationship results in an overstatement of the distinct impact of promotional efforts on sales.



121. While promotion often is an important factor in driving product sales, it is no guarantee of marketplace success. Products may lose market share (over time) or not gain as much as expected, despite intense promotional efforts by manufacturers. If a drug has weaknesses relative to other available drugs, even a substantial promotional campaign cannot create sales or preserve market share. Promotion succeeds only if the underlying product provides actual benefits. According to Mogelesky,

In the end, though, no matter how wonderful an incentive [to a physician] may be, it's the scientific research behind a medication that's the bottom line.... 'The incentives will help you along, but the scientific backing of the drug is what's really going to help the physician decide.' (Ex. 2146, at 104-05.)

122. A study by Professors Mizik and Jacobson found that

[A]lthough detailing and free drug samples have a positive and statistically significant association with the number of new prescriptions issued by a physician, the magnitudes of the effects are modest. As such, our results challenge the two dominant views and support the contention that, rather than being easy marks, physicians are tough sells. (Ex. 2207, at 1705.)

123. In the present context, promotional efforts likely encouraged ophthalmologists (or medical professionals more generally) to try Prolensa® with their patients. But on-going prescribing of these products by these professionals has required satisfaction with the results achieved by the treatments, particularly in light of the availability of a variety of branded and

generic alternatives. In short, if patients were dissatisfied with the product prescribed, the medical professionals would not continue prescribing the product, regardless of the amount of promotion offered by the manufacturers. “Ultimately, the therapeutic benefits of a drug, and not marketing, are likely to determine whether or not it is a commercial success.” (Ex. 2232, at 2.)

**c. Impact of Promotional Efforts**

124. Substantial promotional efforts are undertaken for those products that are perceived to exhibit favorable product characteristics, even for those products that have the same active ingredient as a prior product, and marketing for pharmaceuticals may vary due to a number of factors, including “the stage in the product life cycle, order of entry effects, and the arrival of new information about the drug.” (*See, e.g.*, Ex. 2149, at 3, 17; Ex. 2232, at 3.) The decision to strongly promote a drug is based on numerous factors. As Guha, Li, and Scott observed “[f]ailing to properly control for these relevant factors in an economic analysis may erroneously lead to the conclusion that the marketing of a particular drug is excessive. Such conclusions cannot credibly undermine the link between the patented features and the commercial success of a drug.” (Ex. 2232, at 4.)

125. As discussed above, Mizik and Jacobson found that firm marketing,

such as detailing and free drug samples, has a positive and statistically significant impact on the number of prescriptions issued, but that the magnitudes of the effects are modest. (Ex. 2207, at 1704-05.) However, as also noted above, from an economic perspective, Bausch & Lomb would not devote significant resources to the marketing and promotion of Prolensa® unless it were rational to do so (*i.e.*, it would generate profits that justified the investment). At the time of Prolensa®'s launch in April 2013, Bromday® was the third most prescribed ophthalmic NSAID indicated for the treatment of inflammation following cataract surgery, behind only generic ketorolac tromethamine and branded Nevanac®, accounting for approximately 19.1 percent of total prescriptions as of the first quarter of 2013.<sup>23</sup> (Appendix 6.) Moreover, Bromday® had achieved the third most total prescriptions and at least a 19.1 percent share of competing ophthalmic NSAIDs in each of the eight quarters leading up to the April 2013 launch of Prolensa®.<sup>24</sup> (Appendix 6.) Despite the continued marketplace success of Bromday®, ISTA and Bausch & Lomb invested resources and effort into

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<sup>23</sup> When adjusted to include the additional NSAIDs Ocufer®, generic flurbiprofen sodium, and Acular PF®, Bromday® accounted for approximately 18.4 percent of total prescriptions in the first quarter of 2013 (Appendix 7.)

<sup>24</sup> The eight quarters include the second quarter of 2011 through the first quarter of 2013.

supporting Prolensa®. (Ex. 2199, at 4.) Bausch & Lomb's investment in resources to promote Prolensa® – despite the fact that another ISTA/Bausch & Lomb bromfenac product, Bromday®, was already available – is consistent with a belief that Prolensa® possessed favorable product characteristics, and that the provision of that information would be relevant to clinicians.

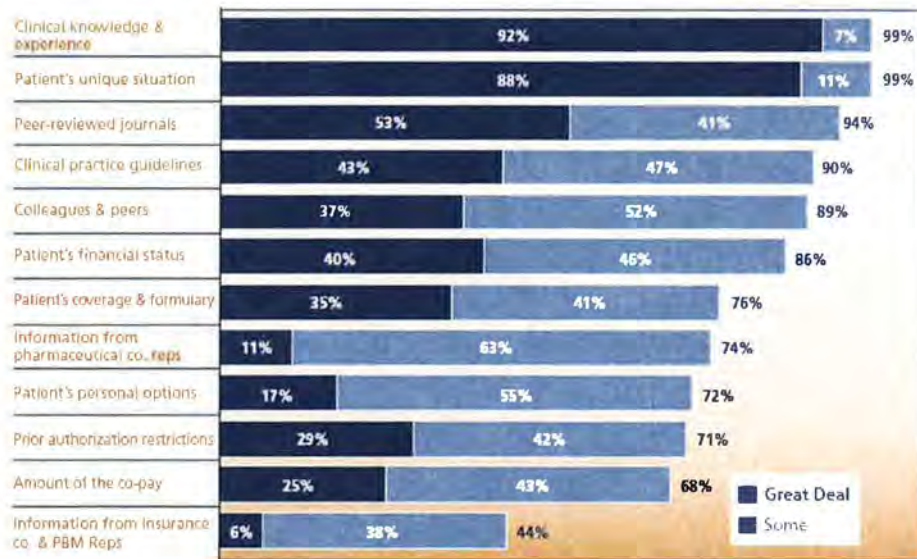
126. Other research explains that physicians consider information from multiple sources when deciding what to prescribe, including manufacturer marketing efforts and patient requests. (Ex. 2297, at 1699-700.) The impact of marketing efforts, though, can have positive *or negative* effects on prescribing behavior. (Ex. 2297, at 1699.) And the impact of marketing efforts on prescribing behavior is moderated by drug characteristics. (Ex. 2297, at 1699.) In other words, the effectiveness of marketing is impacted by the quality and characteristics of the drug being marketed. The effectiveness can also vary by brand. (Ex. 2297, at 1699.) Thus, physicians are informed by marketing efforts, but also consider information about the quality and effectiveness of the drug, as well as patient requests, when deciding what to prescribe. (Ex. 2297, at 1699.) Marketing spending alone will not cause a physician to prescribe a drug if the drug does not offer clinical benefits to patients.



127. These results are consistent with the results of a number of other industry surveys on the factors that influence physician prescribing behavior. (Ex. 2298, at 3-4.) For example, a 2008 study by KRC Research asked over 500 physicians the extent to which they considered 12 different factors in their prescribing decisions. As shown in the chart below, “Information from pharmaceutical company reps” ranked eighth, behind factors such as “Clinical knowledge and experience,” “Patient’s unique situation,” “Peer-reviewed journals,” and “Patient’s coverage and formulary.” (Ex. 2298, at 3.)

**CHART 1: Factors Physicians Consider in Prescribing Medicines**

*Percent Saying Great Deal or Some Influence on Prescribing Decisions*



*Source: Pharmaceutical Research and Manufacturers of America, KRC Research: Survey of Physicians' Opinions About Pharmaceutical and Biotech Research Company Activities and Information, n=501, 2008.*

128. Other surveys found that only 13 percent of physicians considered

information from pharmaceutical companies to be “very important” and only 14 percent considered pharmaceutical sales representatives to have a “major impact” on their prescribing decisions. (Ex. 2298, at 3-4.)

129. There are numerous examples of pharmaceutical products that were supported by significant marketing expenditures and advertising campaigns, but, despite such significant marketing efforts, fell far short of expectations.

- Xeljanz® (rheumatoid arthritis). Launched in 2012, Xeljanz® was the seventh most marketed drug in 2014 with total marketing spending of over \$160 million. (Ex. 2299.) Sales in 2014 totaled \$308 million, an increase of 170 percent over 2013, however sales fell well short of peak sales expectations of \$3 billion per year. (Ex. 2299.)
- Eliquis® (deep vein thrombosis and pulmonary embolism). Launched in 2012, Eliquis® was approved for additional indications in August 2014. (Ex. 2300; Ex. 2301.) The 2013 marketing spending was approximately \$116 million, and in 2014, Eliquis® was the third most marketed drug, with total marketing spending of \$219 million. (Ex. 2302.)<sup>25</sup> The 2013 sales fell well short of expectations, causing 2014 sales projections to be

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<sup>25</sup> According to FiercePharmaMarketing, “Eliquis’ paid media spending topped \$219 million, an increase of 89% year over year.” Calculated as \$219 million / 1.89 = \$115.9 million.



revised down by 60 percent. (Ex. 2303; Ex. 2304.) Sales in 2014 totaled \$774 million, ahead of the downward revised 2014 expectations, but still well short of pre-launch expectations of \$3 to \$5 billion annually. (Ex. 2301; Ex. 2302; Ex. 2303; Ex. 2304; Ex. 2305.)

- Horizant® (restless leg syndrome). GlaxoSmithKline partnered with XenoPort on Horizant®, paying XenoPort \$75 million upfront with another \$500 million in potential milestone payments. (Ex. 2306.) GlaxoSmithKline was reported to have 500 sales representatives working on promoting Horizant® to physicians following Horizant®'s 2011 launch. (Ex. 2307.) Initial sales were disappointing, with quarterly sales of only \$1.3 million in the first quarter of commercial availability. (Ex. 2306.) Sales stayed low, totaling, for example, \$1.6 million in Q3 2012. (Ex. 2308.) In Q1 2014, XenoPort spent \$8 million on marketing to generate only \$220,000 in sales. (Ex. 2309.)
- Rogaine® (hair loss). Upjohn introduced Rogaine in September 1988, and shortly thereafter launched a \$20 million marketing campaign. (Ex. 2310.) 1989 U.S. sales were initially projected to exceed \$300 million; however, during the first three months of 1989, sales reached only \$11 million. (Ex. 2310.)

#### **d. Impact of Price**

130. Brand name drugs are typically more expensive than generic drugs in both absolute terms and in terms of the co-payments for which the patients are responsible. Health insurance plans that cover prescription drugs frequently have tiers that require different co-payments for brand name and generic drugs. (*See, e.g.*, Ex. 2144, at 61-62; Ex. 2233, at 120-21.) These differences in co-payments, along with managed care techniques, such as prior-authorization requirements and the common pharmacy practice of filling brand name prescriptions with generic substitutes when available, tend to drive patients away from brand name drugs like Prolensa® and towards generics. (*See, e.g.*, Ex. 2144, at 61-62; Ex. 2233, at 120-21.)
131. Since Prolensa®'s commercial launch in the second quarter of 2013, Prolensa® has sold for an average price of approximately \$176 per prescription, based on gross sales. (Appendix 9.) This price is slightly higher than the average price per prescription for the two branded nepafenac compositions, Nevanac® and Ilevro®, but lower than the average price per prescription for each of the branded ketorolac tromethamine compositions. (Appendix 9.)
132. However, the difference in gross price per prescription may be impacted by differences in dosing regimens and unit volumes (*i.e.*, bottle

sizes). For example, Prolensa®, Bromday®, and Ilevro® are the only branded drug compositions approved for once-daily dosing, while each of the other branded drugs requires multiple doses to be administered daily. (Ex. 2155, at 18; Ex. 2193.) Prescriptions can also vary in the volume of drug prescribed. For example, Prolensa® is available in 1.6mL and 3mL bottles, while Acuvail® is sold in packs of 30 single-use vials containing 0.4mL of liquid each, for a total volume of 12mL. (Ex. 1049; Ex. 2183.) Thus, another approach to comparing Prolensa®'s price to other competing ophthalmic NSAIDs is to examine the gross price per milliliter of drug. Bausch & Lomb has sold nearly 3.5 million milliliters of Prolensa® in the U.S., generating \$246.9 million in gross sales since the second quarter of 2013. (Appendix 13.) On this basis, the average price of Prolensa® per milliliter, \$71, is in the middle of the range of average prices seen in other branded drugs with similar indications, with several competing branded ophthalmic NSAIDs selling for lower average prices than Prolensa®. (Appendix 10.)

133. These gross prices, as noted earlier, reflect sales into retail and non-retail outlets and represent the actual prices that were charged to the outlet (*i.e.*, the retail pharmacy, mail pharmacy, clinic, etc.) to acquire the pharmaceutical products as seen on the purchase invoices. They do not

account for rebates, coupons, or other discounts that can reduce the price paid by the consumer. However, data on coupons, rebates, and other discounts from other companies who manufactures competing drugs are generally not publicly available. In the absence of data on the discounts provided by other companies, it is unclear how Prolensa® discount programs compare with those available for competing ophthalmic NSAIDs. However, assuming that discounts as a percentage of gross sales prices are approximately the same across manufacturers, an analysis of relative pricing across competing drugs based on net prices would be consistent with an analysis of relative pricing across competing drugs based on gross prices.<sup>26</sup>

134. That notwithstanding, Prolensa®'s average gross price per prescription and average gross price per milliliter are both consistent with other competing ophthalmic NSAIDs. It does not appear that Prolensa®'s marketplace success is due to lower prices relative to other competing branded ophthalmic NSAIDs.

135. My analysis of the IMS data also shows that Prolensa® has sold at premiums, and in some cases significant premiums, relative to available generic ophthalmic NSAIDs with similar indications, including bromfenac,

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<sup>26</sup> Moreover, and importantly, I understand that a demonstration of commercial success does not require a showing of internal profitability.

diclofenac sodium, and ketorolac tromethamine, since Prolensa®'s commercial launch in the second quarter of 2013. (Appendix 9; Appendix 10.) In recent quarters, the disparity between the gross price of Prolensa® and generic bromfenac has grown considerably. Between the third quarter of 2014 and the third quarter of 2015, Prolensa® has been priced between 22.4 percent and 62.1 percent higher than generic bromfenac.<sup>27</sup> When compared against other competing generic ophthalmic NSAIDs, the Prolensa® price premium is significantly higher.<sup>28</sup> Despite Prolensa®'s higher prices relative to available generics, including generic bromfenac, it has been able to capture a substantial share of ophthalmic NSAID prescriptions. (Appendix 6.)

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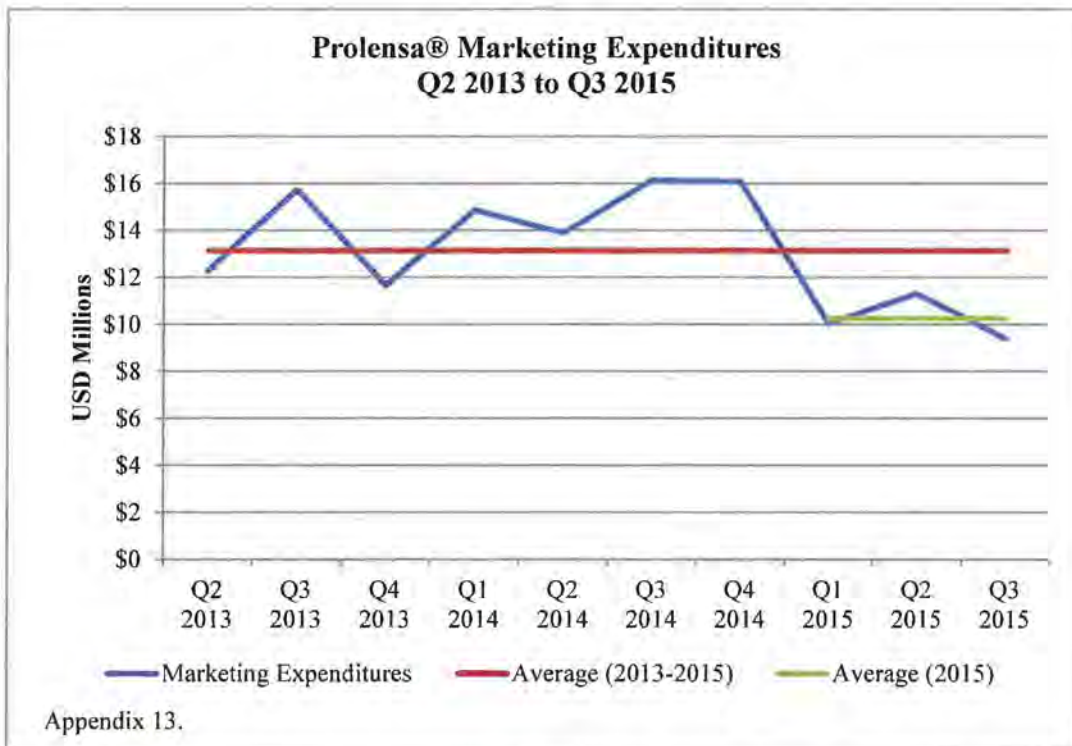
<sup>27</sup> In the fourth quarter of 2014, the gross prices of Prolensa® and generic bromfenac were \$168.10 and \$137.38 per prescription, respectively, representing a Prolensa® price premium of 22.4 percent. In the third quarter of 2015, the most recent quarter for which data are available, the prices of Prolensa® and generic bromfenac were \$184.61 and \$113.88 per prescription, respectively, representing a Prolensa® price premium of 62.1 percent. (Appendix 9.)

<sup>28</sup> In the third quarter of 2015, for example, Prolensa® sold for a gross price of \$184.61 per prescription, compared with \$8.15 per prescription for generic diclofenac sodium, \$12.32 per prescription for generic flurbiprofen sodium, and \$18.15 per prescription for generic ketorolac tromethamine. (Appendix 9.)



### 3. Promotional Spending

136. Since the second quarter of 2013 and through the third quarter of 2015, Bausch & Lomb's U.S. marketing expenditures for Prolensa® have totaled \$131.3 million. (Appendix 13.) As reflected below, during this period, Bausch & Lomb's U.S. marketing expenditures related to Prolensa® have ranged from \$9.4 million to \$16.1 million in each quarter, peaking in the third quarter of 2014. (Appendix 13.) In the third quarter of 2015, Bausch & Lomb invested \$9.4 million in U.S. marketing related to Prolensa®, its smallest quarterly marketing investment to date. (Appendix 13.)



137. As shown in Appendix 12, Bausch & Lomb's Prolensa® promotional

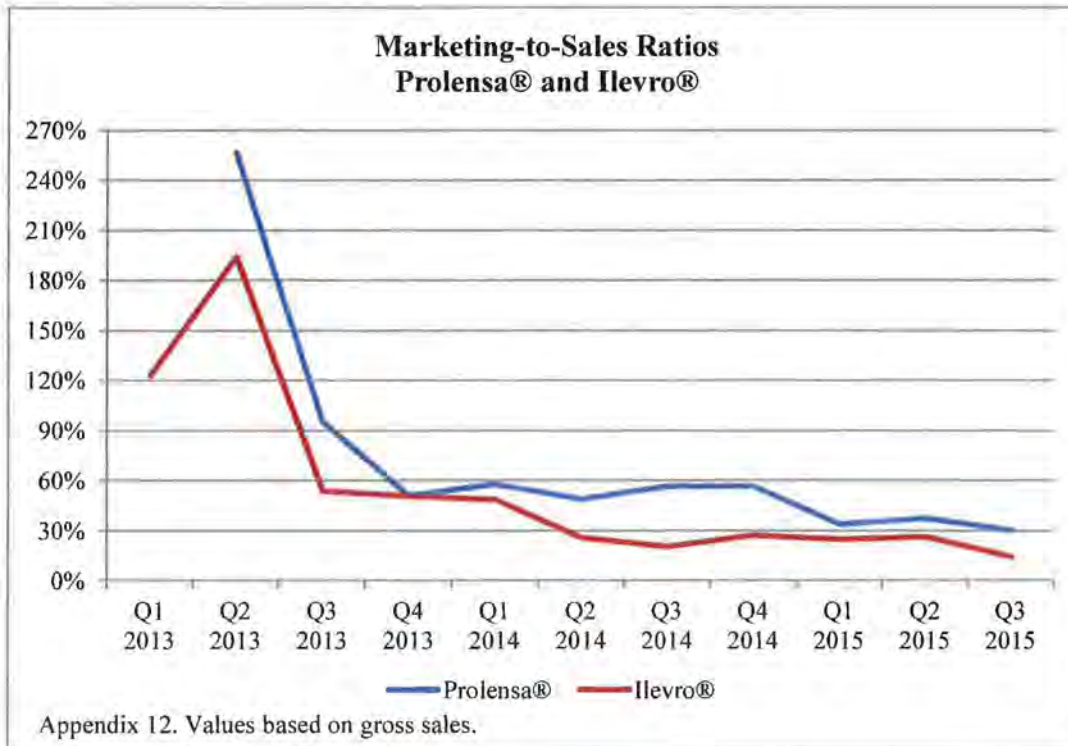


spending as a percentage of its total gross sales is 53.2 percent since the commercial launch of Prolensa® in April 2013 through the third quarter of 2015. During this same period, promotional spending data are not available for several of the other branded ophthalmic NSAIDs indicated for the treatment of inflammation or inflammation and pain following cataract surgery. However, to the extent that manufacturers invested in promotional spending for these other drugs, it is notable that many of these NSAIDs received FDA approval much earlier than Prolensa®, which was approved in April 2013. (Ex. 2176. *See also*, Ex. 2218.) Voltaren® and Acular® received FDA approval more than 20 years before the commercial launch of Prolensa®. (Ex. 2161; Ex. 2162.) Similarly, Acular LS®, Nevanac®, and Acuvail® received FDA approval in 2003, 2005, and 2009, respectively. (Ex. 2163; Ex. 2165; Ex. 2167.) The only competing ophthalmic NSAID that received FDA approval around the same time as Prolensa® was Ilevro®, which was approved in October 2012, six months prior to Prolensa®. (Ex. 2178.)

138. Notably, Prolensa® and Ilevro® – the two most recent ophthalmic NSAIDs indicated for the treatment of inflammation or inflammation and pain following cataract surgery that were introduced to the marketplace – each exhibit a higher ratio of promotional spending to gross sales compared

with other competing ophthalmic NSAIDs in the last three years. This is to be expected, considering that Prolensa® and Ilevro® are the two newest entrants into this crowded marketplace where other available treatment options had been promoted for many years prior to their launch.

139. For Ilevro®, total promotional spending as a percent of gross sales was 29.3 percent during this period. (Appendix 12.) However, both Ilevro® and Prolensa® exhibit similar patterns in which promotional spending as a percent of gross sales was high for several quarters before falling significantly in recent quarters. (Appendix 12.) It appears that promotional expenditure patterns related to Prolensa® are consistent with promotional spending patterns for Ilevro®, the only other competing NSAID for which recent promotional spending data are available, as reflected below.



140. Moreover, Prolensa® and Ilevro® entered into a crowded marketplace, as discussed above. More marketing resources are required in order to compete in a more crowded marketplace. According to Professor Berndt,

... many of these new products will be entering therapeutic classes with one or more existing products, and it is well known that marketing-to-sales ratios tend to be successively higher for subsequent entrants that have to overcome others' early-mover advantages. (Ex. 2148, at 112.)

141. These numbers are also consistent with industry data that the marketing-to-sales ratio generally is high following the launch of a drug. As Guha, Li, and Scott observed, “[p]harmaceutical marketing-to-sales ratios vary over the product life cycle. They are typically highest immediately

following the launch of a new branded drug when the manufacturer must undertake a substantial effort to inform physicians of the existence and therapeutic benefits of the product.” (Ex. 2232, at 4.)

142. Upfront spending can be substantial because, once commercialized, pharmaceutical products typically require several years to reach peak sales. Fischer *et al.* examined data on the length of time to reach peak sales in various categories of pharmaceutical products, and found that “for 80% of the brands time-to-peak-sales amounts to four years or longer.” (Ex. 2311, at 440.) According to one text,

[n]egative cash flow outlays occur through [the R&D] period and for the first few years after launch. Cash flows then become positive and escalate rapidly to year 10. Most of the drugs in the sample had post-launch patent lifetimes in the range of 9 to 14 years. (Ex. 2314, at 36.)

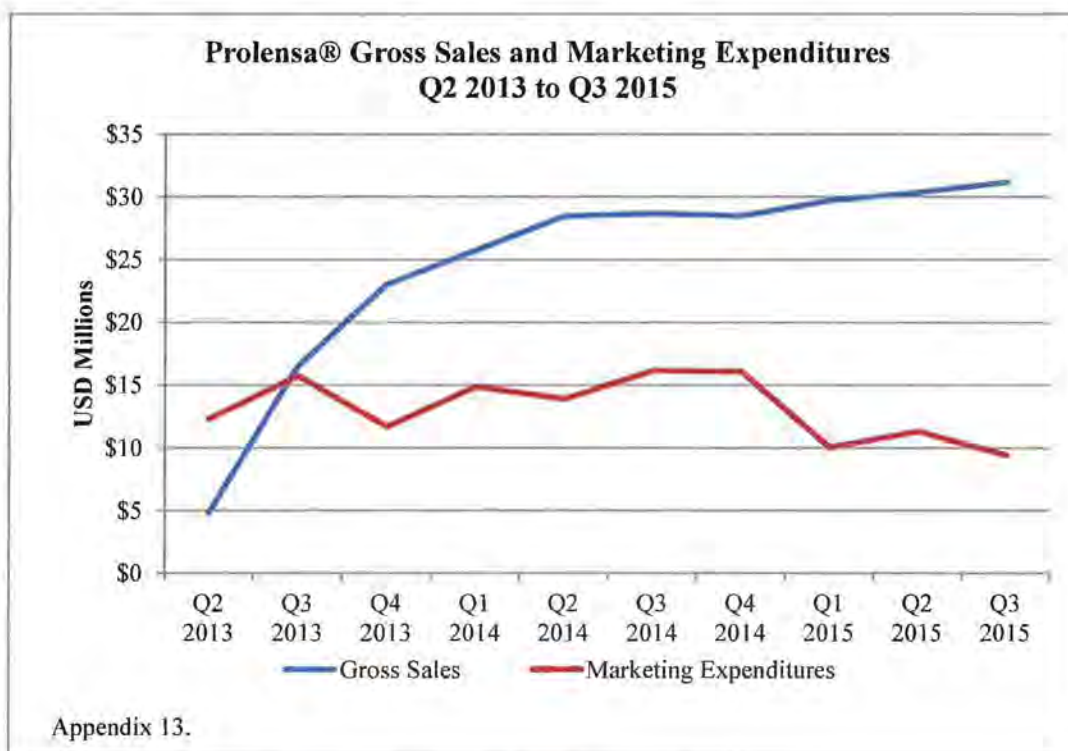
143. With the long run in mind, companies, particularly in the pharmaceutical area, typically invest heavily in marketing immediately following the launch of a new product in order to lay the groundwork for future success. (Ex. 2312, at 288; Ex. 2313, at 177.) According to Osinga, Leeftang, and Wieringa,

[o]ur empirical results suggest that drug manufacturers should use physician-oriented marketing in the periods right after an introduction of a brand because during these periods, both persistent and temporary marketing effects are significant and largest in effect size. Later, manufacturers should decrease the brand's marketing expenditures because the effects become

insignificant or only marginally effective. These recommendations correspond to the spending patterns actually observed for many brands. (Ex. 2313, at 183.)

144. Similarly, it is not surprising that, over time, those same companies tend to invest less and less in marketing, while maintaining, or usually increasing, sales. In fact, that is exactly the pattern seen in the sales and expenditures related to Prolensa®. As reflected below, Bausch & Lomb's marketing expenditures on Prolensa® declined significantly from the fourth quarter of 2014 to the first quarter of 2015, and quarterly marketing expenditures in the first quarter through the third quarter of 2015 represent the three lowest quarterly expenditures since Prolensa®'s launch in April 2013. Moreover, gross sales of Prolensa® during these three quarters were the three highest quarterly totals since Prolensa®'s launch.





145. In short, Prolensa® marketing expenditures, though substantial, have been neither unexpected nor extraordinary. It appears that Bausch & Lomb has undertaken substantial efforts to inform the marketplace about the benefits and advantages of Prolensa®. Many of those benefits and advantages flow from the '131 patent. Marketing without the strength of the underlying science would be ineffective and unwise, and would have few long-lasting benefits.

## V. CONCLUSION

146. Based upon my review and analysis of the evidence received to date, it is my opinion that Prolensa® has achieved substantial marketplace success in the United States. It is also my opinion that there is a nexus between the

marketplace success of Prolensa® and the claims of the '131 patent. In short, the claims of the '131 patent at issue here have been a commercial success.

147. A number of facts demonstrate that Prolensa® has been a marketplace success. Prolensa®'s revenues and prescriptions grew substantially after its commercial launch in April 2013. In its first ten quarters of commercial availability, Prolensa® has been prescribed approximately 1.4 million times in the U.S., generating \$246.9 million in revenue. (Appendix 13.) Prolensa® achieved this success despite being introduced into a marketplace in which at least six branded drugs and three generic drugs had already received FDA approval to treat similar indications as Prolensa®. (*See, e.g.*, Appendix 2.) Since its introduction, Prolensa® has achieved the second highest share of revenues and prescriptions among branded drugs with similar indications as Prolensa®. (Appendix 3; Appendix 6.)

148. A number of facts demonstrate that there is a causal nexus between the success of Prolensa® and the claimed features of the '131 patent. The patent describes and claims compositions of the active ingredient bromfenac and the surfactant tyloxapol. Specifically, certain claims of the '131 patent disclose stable aqueous liquid compositions of the active ingredient bromfenac and the surfactant tyloxapol, which is the technology embodied

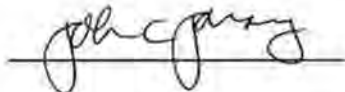
in the drug Prolensa®. (Ex. 2082, at ¶178.) I understand that these compositions have a lower, more natural pH level with improved ocular penetration relative to other bromfenac formulations, allowing Prolensa® to deliver the same clinical efficacy, but using a lower concentration of the active ingredient bromfenac and a lower concentration of surfactant relative to other bromfenac formulations. The reduced concentrations of active ingredient [REDACTED], as well as the lower pH, result in an improved side effect profile relative to other NSAID formulations, with no stinging or burning. The lower pH and reduced side effects make Prolensa® more comfortable to use relative to other NSAID formulations and enhance patient compliance. [REDACTED]

[REDACTED]. As explained by Dr. Trattler, the development of Prolensa® was “highly significant to the field of ophthalmology and cataract surgery.” (Ex. 2116, at ¶51.) The claimed features of the ’131 patent have been a critical driver of the success of Prolensa®. That is, Prolensa® is consistently marketed based on the benefits made possible by the ’131 patent.

149. Bausch & Lomb’s patterns of promotional expenditures on Prolensa® are consistent with those for competing drugs with similar indications that became commercially available around the same time as Prolensa®.

(Appendix 12.) Specifically, the patterns of Bausch & Lomb's promotional expenditures as a percent of gross sales are consistent with promotional expenditure patterns for Ilevro®, which was commercially released six months prior to Prolensa®. (Appendix 12.) And the success of Prolensa® is not attributable to any pricing advantages, because it has none.

150. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

A handwritten signature in black ink, appearing to read "John C. Jarosz", is written over a horizontal line.

John C. Jarosz  
February 23, 2016

## APPENDIX 1

### JOHN C. JAROSZ Managing Principal

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John Jarosz, a Managing Principal of Analysis Group, Inc., specializes in applied microeconomics and industrial organization. He has performed research, given economic testimony and provided strategy consultation in intellectual property, licensing, commercial damages, and antitrust matters, including:

- Evaluation of damages in patent, copyright, trade secret, trademark and unfair competition cases. The types of damages have included lost profits, reasonable royalties, price erosion, unjust enrichment, accelerated market entry and prejudgment interest.
- Evaluation of injunctive relief and commercial success in a variety of intellectual property court settings.
- Strategy consultation regarding the nature and value of technology, methods to share technology and reasonable compensation terms.
- Analysis and testimony regarding patent misuse and copyright misuse defenses, particularly concerning market definition and market power.
- General commercial damages testimony in a variety of cases and across numerous industries.

Mr. Jarosz received a J.D. from the University of Wisconsin. Mr. Jarosz holds an M.A. in Economics from Washington University in St. Louis, where he was a Ph.D. candidate and completed most of the program requirements. He also holds a B.A. in Economics and Organizational Communication from Creighton University in Omaha, Nebraska.

Prior to joining Analysis Group, Mr. Jarosz was a Director with Putnam, Hayes & Bartlett, Inc. Before that, he was a Senior Analyst with Richard J. Barber Associates, a Section Supervisor with Mutual of Omaha Insurance and a Research Analyst with the Center for the Study of American Business.

### EDUCATION

J.D.	University of Wisconsin
M.A. & Ph.D. candidate	Economics, Washington University, St. Louis
B.A.	Economics and Organizational Communication, Creighton University



## PROFESSIONAL ASSOCIATIONS/MEMBERSHIPS

- American Economic Association
- American Law and Economics Association
- American Bar Association (Sections: Intellectual Property, Antitrust and Litigation)
- State Bar of Wisconsin (Section: Intellectual Property)
- American Intellectual Property Law Association (Sections: Federal Litigation, Licensing, Trade Secrets and Antitrust)
- Licensing Executives Society
  - Former Chair, Valuation and Taxation Committee
  - Former Member, Certified Licensing Professional Exam Writing Team
- Former Advisory Board - *The IP Litigator*
- Former Columnist (Damage Awards) - *The IP Litigator*
- Omicron Delta Epsilon (International Honor Society in Economics)
- Association of University Technology Managers
- Certified Licensing Professional
- Intellectual Property Owners Association (Committee: Damages and Injunctions)
- 2011 Presidential Rank Review Board
- Referee, Journal of Forensic Economics
- The Sedona Conference (Sections: Best Practices in Patent Litigation, Patent Damages and Remedies)
- IAM Patent 1000 (2014, 2015): The World's Leading Patent Practitioners - Economic Experts
- IP Law360: Voices of the Bar

## TESTIMONIAL EXPERIENCE

### Patent Cases – Damages

- **BroadSoft, Inc. v. Callwave Communications, LLC**  
*United States District Court, District of Delaware (Case No. 13-cv-0711-RGA)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to telecommunications call processing.
- **Advanced Video Technologies, LLC v. Blackberry, LTD. and Blackberry Corporation**  
*United States District Court, Southern District of New York (Case No. 1:11-cv-06604-CM-RLE)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to video compression and decompression.

- **Drone Technologies, Inc. v. Parrot S.A. and Parrot, Inc.**  
*United States District Court, Western District of Pennsylvania (Case No. 2:14-cv-0111)*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to drone technology.
- **Bayer CropScience AG and Bayer CropScience NV v. Dow AgroSciences LLC, Mycogen Plant Science Inc., Agrigenetics, Inc. d/b/a Mycogen Seeds LLC, and Phytogen Seed Company, LLC**  
*International Chamber of Commerce (Case No. 18892/VRO /AGF)*  
Arbitration hearing testimony and expert report: damages associated with alleged breach of contract and patent infringement involving genetically modified seed.
- **CertusView Technologies, LLC v. S &N Locating Services LLC and S & N Communications, Inc.**  
*United States District Court, Eastern District of Virginia, Norfolk Division (Case No. 2:13 –cv-346 (MSD/LRL))*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to creation of electronic sketches for utility location purposes.
- **Ecolab USA Inc. and Kleantech Systems, LLC v. Diversey, Inc.**  
*United States District Court for the District of Minnesota (Civil Action No. 12-cv-1984 (SRN/JJG))*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving products covering the monitoring of hospital cleaning.
- **Everlight Electronics Co. Ltd., and Emcore Corporation v. Nichia Corporation and Nichia America Corporation v. Everlight Americas, Inc.**  
*United States District Court, Eastern District of Michigan, Southern Division (Case No.4:12-cv-11758 GAD-MKM)*  
Trial and deposition testimony, expert report and declaration: commercial success, lost profits, reasonable royalty, and prejudgment interest involving patents directed to LEDs.
- **Source Search Technologies, LLC v. Kayak.com, Inc.**  
*United States District Court, District of New Jersey (Case No. 2:11-cv-03388-FSH-MAH)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to online exchanges.
- **Universal Electronics, Inc. v. Universal Remote Control, Inc.**  
*United States District Court, Central District of California, Southern Division (Case No.SACV12-329AG (JPRx))*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to universal remotes.
- **Prowess, Inc. v. RaySearch Laboratories AB, et al.**  
*United States District Court, District of Maryland (Case No. 11 CV 1357 (WDQ))*  
Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to treatment planning software for radiation therapy.
- **JDS Therapeutics, LLC and Nutrition 21, LLC v. Pfizer Inc., Wyeth LLC, Wyeth Consumer Healthcare Ltd., and Wyeth Consumer Healthcare LLC**  
*United States District Court, Southern District of New York (Case No.1:12-cv-09002-JSR)*  
Deposition testimony and expert report: commercial success, reasonable royalty, and unjust enrichment involving patents and trade secrets directed to the use of chromium picolinate in multi-vitamins.

- **comScore, Inc. v. Moat, Inc.**  
*United States District Court, Eastern District of Virginia, Norfolk Division (Case No. 2:12CV695-HCM/DEM, Lead Case 2:12CV351-HCM/DEM)*  
Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to online analytics.
- **Impulse Technology Ltd. v. Microsoft Corporation, Electronic Arts, Inc., Ubisoft Holdings, Inc., and Konami Digital Entertainment Inc.**  
*United States District Court, District of Delaware (Case No. 11-586-RGA-CJB)*  
Deposition testimony and expert report: reasonable royalty involving patents directed to video game motion detection functionalities.
- **LendingTree, LLC v. Zillow, Inc., NexTag, Inc., and Adchemy, Inc.**  
*United States District Court, Western District of North Carolina, Charlotte Division (Case No. 3:10-cv-439-FDW-DCK)*  
Trial and deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to internet loan matching systems.
- **Network Protection Sciences, LLC v. Fortinet, Inc.**  
*United States District Court, Northern District of California (Case No. 3:12-cv-01106-WHA)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to network security systems.
- **Shurtape Technologies, LLC and Shurtech Brands, LLC v. 3M Company**  
*United States District Court, Western District of North Carolina (Case No. 5:11-cv-00017)*  
Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to painter's tape.
- **Abbott Biotechnology Ltd. and AbbVie, Inc. v. Centocor Ortho Biothec, Inc.**  
*United States District Court, District of Massachusetts (Case No. 09-40089-FDS)*  
Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to the treatment of rheumatoid arthritis.
- **Wi-LAN Inc. v. Alcatel-Lucent USA Inc.; Telefonaktiebolaget LM Ericsson; Ericsson Inc.; Sony Mobile Communications AB; Sony Mobile Communications (USA) Inc.; HTC Corporation; HTC America, Inc.; Exedeia Inc.; LG Electronics, Inc.; LG Electronics Mobilecomm U.S.A., Inc.; and LG Electronics U.S.A., Inc.**  
*United States District Court, Eastern District of Texas (Case No. 6:10-CV-521-LED)*  
Trial and deposition testimony, affidavit, and expert report: reasonable royalty and prejudgment interest involving patents directed to wireless telecommunication systems.
- **Epos Technologies Ltd.; Dane-Elec S.A.; Dane-Elec Memory S.A.; and Dane-Elec Corporation USA v. Pegasus Technologies Ltd. and Luidia, Inc.**  
*United States District Court, District of Columbia (Case No. 07-cv-00416-WMN)*  
Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to digital pen products.
- **Life Technologies Corporation; Applied Biosystems, LLC; Institute for Protein Research; Alexander Chetverin; Helena Chetverina; and William Hone v. Illumina, Inc. and Solexa, Inc.**  
*United States District Court, Southern District of California (Case No. 3:11-cv-00703)*  
Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to DNA amplification and sequencing technology.

- **TomTom, Inc. v. Michael Adolph**  
*United States District Court, Eastern District of Virginia (Case No. 6:10-CV-521-LED)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to automotive navigation systems.
- **Carl B. Collins and Farzin Davanloo v. Nissan North America, Inc. and Nissan Motor Co., Ltd.**  
*United States District Court, Eastern District of Texas, Marshall Division (Case No. 2:11-cv-00428-JRG)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to automotive engines.
- **I.E.E. International Electronics & Engineering, S.A. and IEE Sensing, Inc. v. TK Holdings, Inc.**  
*United States District Court, Eastern District of Michigan (Case No. 2:10-cv-13487)*  
Deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents directed to capacitive sensing used in automotive seats.
- **St. Clair Intellectual Property Consultants, Inc. v. Acer, Inc., et al./Microsoft Corporation v. St. Clair Intellectual Property Consultants, Inc.**  
*United States District Court, District of Delaware (Case No. 09-354-JJF, 09-704-JJF and 10-282-LPS)*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to power management, bus configuration and card slot technology in laptops and desktops.
- **CardioFocus, Inc. v. Xintec Corporation (d/b/a Convergent Laser Technologies); Trimedyne, Inc.; and Cardiogenesis Corporation**  
*United States District Court, District of Massachusetts (Case No. 1:08-cv-10285 NMG)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to laser devices used for the treatment of advanced coronary artery disease.
- **Avocent Redmond Corp. v. Raritan Americas, Inc.**  
*United States District Court, Southern District of New York (Case No. 10-cv-6100 (PKC)(JLC))*  
Deposition testimony and expert report: lost profits, lost royalties, reasonable royalty and prejudgment interest involving a patent and contract directed to software and hardware products and technologies that provide connectivity and centralized management of IT infrastructure through KVM switches.
- **Frontline Placement Technologies, Inc. v. CRS, Inc.**  
*United States District Court, Eastern District of Pennsylvania (Case No. 2:07-CV-2457)*  
Deposition testimony and expert report: lost profits, lost royalties, reasonable royalty and prejudgment interest involving a patent and contract directed to automated substitute fulfillment software.
- **Novozymes A/S and Novozymes North America, Inc. v. Danisco A/S; Genecor International Wisconsin, Inc.; Danisco US Inc.; and Danisco USA Inc.**  
*United States District Court, Western District of Wisconsin (Case No. 10-CV-251)*  
Trial and deposition testimony and expert report and expert declaration: lost profits, reasonable royalty, prejudgment interest and irreparable harm involving a patent directed to alpha-amylases used for fuel ethanol.



- **Triangle Software, LLC v. Garmin International, Inc.; Garmin USA, Inc.; TomTom, Inc.; and Volkswagen Group of America, Inc.**  
*United States District Court, Eastern District of Virginia, Alexandria Division (Case No. 1:10-CV-01457-CMH-TCB)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to providing personal navigation device functionality.
- **Northeastern University and JARG Corporation v. Google, Inc.**  
*United States District Court, Eastern District of Texas, Marshall Division (Case No. 2:07-cv-486(CE))*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to internet index and search technology.
- **Bissell Homecare, Inc. v. Dyson, Inc.**  
*United States District Court, Western District of Michigan (Case No. 1:08-cv-724)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to vacuum cleaner collection and discharge.
- **Toshiba Corporation v. Imation Corp.; Moser Baer India Ltd; Glyphics Media, Inc.; Ritek Corp.; Advanced Media, Inc.; CMC Magnetics Corp.; Hotan Corp.; and Khypermedia Corp.**  
*United States District Court, Western District of Wisconsin (Case No. 3:09-cv-00305-slc)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to DVDs.
- **Affinity Labs of Texas, LLC. v. BMW North America, LLC, et al.**  
*United States District Court, Eastern District of Texas, Lufkin Division (Case No. 9:08-CV-00164-RC)*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to connecting a portable audio player to an automobile sound system.
- **Regents of the University of Minnesota v. AGA Medical Corp.**  
*United States District Court, District of Minnesota (Case No. 0:07-cv-04732 (PJS/RLE))*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to septal occlusion devices.
- **Ethicon Endo-Surgery, Inc. v. Hologic Inc. and Suros Surgical Systems, Inc.**  
*United States District Court, Southern District of Ohio, Western Division (Case No. 07-cv-00834)*  
Trial and deposition testimony and expert report: lost profits and reasonable royalty involving patents directed to biopsy equipment and methods, and the biopsy of soft tissue.
- **Humanscale Corp. v. CompX International, Inc. and CompX Waterloo**  
*United States District Court, Eastern District of Virginia, Richmond Division (Case No. 3:09-CV-86-JRS)*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to keyboard support mechanisms.
- **Carl Zeiss Vision GMBH and Carl Zeiss Vision International GMBH v. Signet Armorlite, Inc.**  
*United States District Court, Southern District of California (Case No. 09-CV-0657-DMS (POR))*  
Trial testimony and deposition testimony and expert report: lost profits, reasonable royalty, and lost licensing fees involving a patent directed to progressive eyeglass lenses.
- **ShopNTown LLC v. Landmark Media Enterprises, LLC**  
*United States District Court, Eastern District of Virginia, Norfolk Division (Case No. 2:08CV564)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to rental matching systems over the internet.
- **Cerner Corp. v. Visicu, Inc.**



*United States District Court, Western District of Missouri, Western Division (Case No. 04-1033-CV-W-GAF)*

Trial and deposition testimony and expert report: lost profits and reasonable royalty involving patents directed to electronic ICU monitoring systems.

- **Sanofi-Aventis Canada Inc.; Schering Corp.; and Sanofi-Aventis Deutschland GmbH v. Apotex/Novopharm Limited**  
*Federal Court of Canada (Case No. T-1161-07/T-161-07)*  
Trial testimony and expert report: lost profits and reasonable royalty involving a patent directed to hypertension treatment.
- **C2 Communications Technologies, Inc. v. Qwest Communications Corp; Global Crossing Telecommunications, Inc.; and Level 3 Communications, LLC**  
*United States District Court, Eastern District of Texas, Marshall Division (Case No. 2-06CV-241 TJW)*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to carrying PSTN calls via Voice over Internet Protocol.
- **Siemens AG v. Seagate Technology**  
*United States District Court, Central District of California, Southern Division (Case No. SA CV 06-788 JVS (ANx))*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to hard disk drive technology.
- **Siemens Medical Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.**  
*United States District Court, District of Delaware (Case No. 07-190-SLR)*  
Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to medical scanner technology.
- **Aventis Pharma, S.A. v. Baxter Healthcare Corp.**  
*Arbitration*  
Arbitration hearing and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to hemophilia treatment.
- **Every Penny Counts, Inc. v. Bank of America Corp. and Bank of America, N.A.**  
*United States District Court, Middle District of Florida, Fort Myers Division (Case No. 2:07-CV-42-FTM-29SPC)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to the Keep the Change debit card program.
- **DEKALB Genetics Corp. v. Syngenta Seeds, Inc.; Golden Harvest Seeds, Inc.; Sommer Bros. Seed Co.; JR Robinson Seeds, Inc.; and Garst Seed Co.**  
*United States District Court, Eastern District of Missouri (Case No. 4:06CV01191MLM)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to genetically modified corn.
- **International Flora Technologies, Ltd. v. Clarins U.S.A.**  
*United States District Court, District of Arizona (Case No. 2:06-CV-01371-ROS)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to skin care products.

- **Howmedica Osteonics Corp. v. Zimmer, Inc.; Centerpulse Orthopedics, Inc. (formerly known as Sulzer Orthopedics, Inc.); and Smith & Nephew, Inc.**  
*United States District Court, District of New Jersey (Case No.05-0897 (WHW))*  
Deposition testimony and expert report; lost profits, reasonable royalty, and prejudgment interest involving a patent directed to hip implant technology.
- **Elan Pharma International, Ltd. v. Abraxis Bioscience, Inc.**  
*United States District Court, District of Delaware (Case No.06-438-GMS)*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to nanotechnology drug delivery.
- **Mobile Micromedia Solutions LLC v. Nissan North America, Inc.**  
*United States District Court, Eastern District of Texas, Texarkana Division (Case No.505-CV-230)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to automotive entertainment systems.
- **Nichia Corp. v. Seoul Semiconductor, Ltd. and Seoul Semiconductor, Inc.**  
*United States District Court, Northern District of California (Case No. 3:06-CV-00162-MMC (JCS))*  
Trial and deposition testimony and expert report: reasonable royalty, unjust enrichment, and prejudgment interest involving patents directed to light emitting diodes.
- **NetRatings, Inc. v. WebSideStory, Inc.**  
*United States District Court, Southern District of New York (Case No. 06-CV-878(LTS)(AJP))*  
Deposition testimony and expert report: reasonable royalty involving technology directed to internet audience measurement and analysis.
- **Ernest K. Manders, M.D. v. McGhan Medical Corp.**  
*United States District Court, Western District of Pennsylvania (Case No. 02-CV-1341)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to implantable tissue expanders.
- **Source Search Technologies, LLC v. LendingTree, Inc.; IAC/InterActiveCorp; and ServiceMagic, Inc.**  
*United States District Court, District of New Jersey (Case No. 2:04-CV-4420)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to online exchanges.
- **The Boeing Co. v. The United States**  
*United States Court of Federal Claims (Case No. 00-705 C)*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to a process for aging aluminum lithium alloys used for space shuttle external tanks.
- **Bridgestone Sports Co., Ltd. and Bridgestone Golf, Inc. v. Acushnet Co.**  
*United States District Court, District of Delaware (Case No. 05-132-(JJF))*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to cores, intermediate layers and covers of golf balls.
- **Dyson Technology Ltd. and Dyson, Inc. v. Maytag Corp.**  
*United States District Court, District of Delaware (Case No. 05-434-GMS)*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to upright cyclonic vacuum cleaners.

- **Verizon Services Corp. and Verizon Laboratories, Inc. v. Vonage Holdings Corp. and Vonage America, Inc.**  
*United States District Court, Eastern District of Virginia (Case No. 1:06CV682)*  
Trial and deposition testimony and expert report: permanent injunction, lost profits, and reasonable royalty involving patents directed to a voice over internet protocol (“VoIP”) platforms.
- **Hitachi, LTD v. BorgWarner, Inc.**  
*United States District Court, District of Delaware (Case No. 05-048-SLR)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to automotive cam shaft technology.
- **Innogenetics N.V. v. Abbott Laboratories**  
*United States District Court, Western District of Wisconsin (Case No. 05-C-0575-C)*  
Trial and deposition testimony and expert report: reasonable royalty involving a patent directed to HCV genotyping.
- **O2 Micro International v. Monolithic Power Systems, Inc.**  
*United States District Court, Northern District of California (Case No. 04-02000 CW; 06-02929 CW)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to AC to DC power converter circuits used for backlights.
- **Solvay Solexis, Inc. v. 3M Co.; 3M Innovative Properties Co.; and Dyneon LLC**  
*United States District Court, District of New Jersey (Case No. 04-06162 (FSH/PS))*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to low temperature fluoroelastomers.
- **Target Technology Co., LLC v. Williams Advanced Materials, Inc., et al.**  
*United States District Court, Central District of California (Case No. SACV04-1083 DOC (MLGx))*  
Deposition testimony and expert report: reasonable royalty and design-around alternatives involving a patent directed to silver alloy sputtering targets for DVDs.
- **Metrologic Instruments, Inc. v. Symbol Technologies, Inc.**  
*United States District Court, District of New Jersey (Case No. 03cv2912 (HAA))*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to bar code scanners.
- **Eaton Corp. v. ZF Meritor, LLC**  
*United States District Court, Eastern District of Michigan (Case No. 03-74844)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to truck clutches and transmissions.
- **Meritor Transmission Corp. v. Eaton Corp.**  
*United States District Court, Western District of North Carolina (Case No. 1:04-CV-178)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to truck transmissions.
- **Monsanto Co. v. Syngenta Seeds, Inc.**  
*United States District Court, District of Delaware (Case No. 04-305-SLR)*  
Deposition testimony and expert report: reasonable royalty involving patents directed to genetically modified corn seed.
- **Indiana Mills & Manufacturing, Inc. v. Dorel Industries, Inc.**  
*United States District Court, Southern District of Indiana (Case No. 1:04-CV-1102)*  
Deposition testimony and expert report: damages and profits associated with alleged contract breach and patent infringement involving technology directed to automobile child restraint systems.
- **Paice LLC v. Toyota Motor Corp.**

*United States District Court, Eastern District of Texas, Marshall Division (Case No. 2-04CV-211) (DF)*

Deposition testimony and expert report: reasonable royalty involving patents directed to hybrid-electric powertrain systems.

- **GTECH Corp. v. Scientific Games International**  
*United States District Court, District of Delaware (Case No. 04-0138)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to a system and method for distributing lottery tickets.
- **WEDECO UV Technologies, Inc. v. Calgon Carbon Corp.**  
*United States District Court, District of New Jersey (Case No. 01-924)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to treatment of potable water with UV light.
- **Khyber Technologies Corp. v. Casio, Inc; Everex Systems, Inc.; Hewlett-Packard Co.; and Hewlett-Packard Singapore PTE. LTD.**  
*United States District Court, District of Massachusetts (Case No. 99-CV-12468-GAO)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to audio playback for portable electronic devices.
- **Air Liquide America, L.P. v. P.H. Glatfelter Co.**  
*United States District Court, Middle District of Pennsylvania (Case No. 1:CV-04-0646)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to the use of ozone bleaching of pulp.
- **Gary J. Colassi v. Cybex International, Inc.**  
*United States District Court, District of Massachusetts (Case No. 02-668-JEL/JGL)*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to treadmill support decks.
- **Medinol Ltd. v. Guidant Corp. and Advanced Cardiovascular Systems, Inc.**  
*United States District Court, Southern District of New York (Case No. 03 C iv.2604 (SAS))*  
Deposition testimony and expert report: reasonable royalty analysis and prejudgment interest involving patents directed to connectors for coronary and peripheral stents.
- **Donner, Inc. v. American Honda Motor Co.; McDavid Plano-Acura, L.P.; and The Beaumont Co.**  
*United States District Court, Eastern District of Texas, Texarkana Division (Case No.F:03-CV-253)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to automobile entertainment systems.
- **Nonin Medical, Inc. v. BCI, Inc.**  
*United States District Court, Fourth Division of Minnesota (Case No.02-668-JEL/JGL)*  
Deposition testimony and expert report: reasonable royalty, lost profits, and prejudgment interest involving patents directed to finger clip pulse oximeters.
- **Stryker Trauma S.A. and Howmedica Osteonics Corp. v. Synthes (USA)**  
*United States District Court, District of New Jersey (Case No.01-CV 3879 (DMC))*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to snap-fit external fixation systems.



- **Michael Foods, Inc. and North Carolina State University v. Rose Acre Farms, Inc.**  
*United States District Court, Eastern District of North Carolina Western Division (Case No.5:02-CV-477-H(3))*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to extended shelf life eggs.
- **Waters Technologies Corp.; Waters Investments, Ltd.; Micromass UK Ltd.; and Micromass, Inc. v. Applera Corp.**  
*United States District Court, District of Delaware (Case No.02-1285-GMS)*  
Deposition testimony and expert report: lost profits, price erosion, reasonable royalty, and prejudgment interest involving a patent directed to mass spectrometer ionization sources.
- **Medtronic Sofamor Danek, Inc. v. Gary K. Michelson, M.D. and Karlin Technology, Inc.**  
*United States District Court, Western District of Tennessee (Case No. 01-2373 GV)*  
Trial and deposition testimony and expert report: damages and profits associated with alleged contractual breaches, tortious interference and intentional negligent representations involving spinal implants.
- **Matsushita Electric Industrial Co. Ltd. v. Cinram International, Inc.**  
*United States District Court, District of Delaware (Case No.01-882-SLR)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest covering patents directed to aspects of bonding substrates together to form optical discs, such as DVDs.
- **Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp. and Schering Corp.**  
*United States District Court, District of New Jersey (Case No. 96-CV-04047)*  
Trial and deposition testimony and expert report: lost profits, reasonable royalty, price erosion, and prejudgment interest involving a patent directed to porcine vaccine (PRRS) products.
- **Arris International and Randall A. Holliday v. John Mezzalingua and Associates, Inc. d/b/a PPC**  
*United States District Court, District of Colorado (Case No. 01-WM-2061)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to coaxial cable connectors.
- **Promega Corp. v. Applera Corp.; and Lifecodes Corp., and its Subsidiaries Cellmark Diagnostics, Inc.; and Genomics International Corp.**  
*United States District Court, Western District of Wisconsin (Case No. 01-C-0244-C)*  
Deposition testimony and expert report: lost profit rate, reasonable royalty, and prejudgment interest involving a patent directed to DNA sequencing technology.
- **Alcon Laboratories, Inc. and Alcon Manufacturing, Ltd. v. Pharmacia Corp.; Pharmacia & Upjohn Co.; and The Trustees of Columbia University in the City of New York**  
*United States District Court, Southern District of New York (Case No. 01-Civ.2989 (WHP))*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to compositions for treatment of glaucoma.
- **Pharmacia Corp.; Pharmacia AB; Pharmacia Enterprises S.A.; and Pharmacia & Upjohn Co. v. Alcon Laboratories, Inc.**  
*United States District Court, Southern District of New York (Case No. 01-070-SLR)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to compositions for treatment of glaucoma.



- **Takata Corp. v. AlliedSignal, Inc. and Breed Technologies, Inc.**  
*United States District Court, District of Delaware (Case No. 98-94-MMS)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest covering patents and trade secrets directed to seatbelt retractors.
- **Chiron Corp. v. Genentech, Inc.**  
*United States District Court, Eastern District of California (Case No. S-00-1252 WBS GGH)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest covering a patent directed to the active ingredient in an anti-cancer drug.
- **Greene, Tweed of Delaware, Inc. v. DuPont Dow Elastomers, LLC**  
*United States District Court, Eastern District of Pennsylvania (Case No. 00-CV-3058)*  
Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent covering perfluorelastomeric seals used in semiconductor fabrication applications.
- **Streck Laboratories v. Beckman Coulter, Inc.**  
*United States District Court, District of Nebraska (Case No. 8:99CV473)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents covering hematology testing equipment.
- **Adobe Systems Inc. v. Macromedia, Inc.**  
*United States District Court, District of Delaware (Case No. 00-743-JJF)*  
Trial and deposition testimony and expert report: reasonable royalty involving patents covering computer video and audio software.
- **Dictaphone Corp. v. Nice Systems, Ltd.**  
*United States District Court, District of Connecticut (Case No. 3:00-CV-1143)*  
Deposition testimony and expert report: lost profits, price/margin erosion, reasonable royalty, and prejudgment interest involving patents covering digital logger systems.
- **Metrologic Instruments, Inc. v. PSC, Inc.**  
*United States District Court, District of New Jersey (Case No. 99-CV-04876)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents covering bar code scanning equipment.
- **Genzyme Corp. v. Atrium Medical Corp.**  
*United States District Court, District of Delaware (Case No. 00-958-RRM)*  
Trial testimony and expert report: lost profits and price/margin erosion involving patents covering chest drainage systems.
- **Norian Corp. v. Stryker Corp.**  
*United States District Court, Northern District of California (Case No. C-01-0016 (WHA))*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent covering bone cement.
- **John Mezzalingua Associates, Inc., d/b/a PPC v. Antec Corp.**  
*United States District Court, Middle District of Florida (Case No. 3:01-CV-482-J-25 HTS)*  
Deposition testimony and expert report: disgorgement of profits involving a design patent covering a coaxial cable connection.
- **Rockwell Automation Technologies, LLC v. Spectra-Physics Lasers, Inc. and Opto Power Corp.**  
*United States District Court, District of Delaware (Case No. 00-589-GMS)*  
Deposition testimony and expert report: reasonable royalty involving a patent covering a process for producing semiconductor epitaxial films.
- **Tanashin Denk Co., Ltd. v. Thomson Consumer Electronics, Inc.**

*United States District Court, Southern Division of Indiana (Case No. IP 99-836-C Y/G)*

Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents covering cassette tape drives.

- **Medtronic Sofamor Danek, Inc. et al. v. Osteotech**  
*United States District Court, Western Division of Tennessee (Case No. 99-2656-GV)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents covering the instruments and method of inserting a spinal inter-body fusion device.
- **Heimann Systems GmbH v. American Science and Engineering, Inc.**  
*United States District Court, District of Connecticut (Case No. 00 CV 10276 (WGY))*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to mobile X-ray examining apparatus.
- **Omega Engineering, Inc. v. Cole-Parmer Instrument Co.; Davis Instrument Manufacturing Co., Inc.; Dwyer Instruments, Inc.; and Raytek Corp.**  
*United States District Court, District of Connecticut (Case Nos. 3:98 CV 00733 (JCH), 3:98 CV 02052 (JCH) and 3:98 CV 02276 (JCH))*  
Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents and alleged unfair competitive practices directed to portable infrared thermometers.
- **Particle Measuring Systems, Inc. v. Rion Co., Ltd.**  
*United States District Court, District of Colorado (Case No. 99-WM-1433)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to a device and method for optically detecting particles in fluid.
- **The University of Colorado Foundation Inc., et al. v. American Cyanamid Co.**  
*United States District Court, District of Colorado (Case No. 93-K-1657)*  
Trial and deposition testimony and expert report: measure and amount of prejudgment interest in a patent infringement, fraud and unjust enrichment case covering prenatal vitamin formulations.
- **Gleason Works v. Oerlikon Geartec AG and Liebherr-America, Inc.**  
*United States District Court, Western District of New York (Case No. 98-CV-6275 L)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to bevel gear-cutting machines.
- **Amersham Pharmacia v. PE Corp.**  
*United States District Court, Northern District of California (Case No. C 97-04203-TEH)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to a method of using energy transfer reagents in a DNA sequencing system.
- **Ziarno v. The American Red Cross, et al.**  
*United States District Court, Northern District of Illinois (Case No. 99 CIV 3430)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to online/internet fundraising.
- **Applied Medical Resources Corp. v. Core Dynamics, Inc.**  
*United States District Court, Central District of California (Case No. SACV 99-748-DOC (ANx))*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to surgical trocars.

- **Bell Communications Research, Inc. v. Fore Systems, Inc.**  
*United States District Court, District of Delaware (Case No. 98-586 JJJ)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest covering patents directed to telecommunications technology (ATM over SONET networks).
- **Newell Operating Co. (EZ Painter Co.) v. Linzer Products Corp.**  
*United States District Court, Eastern District of Wisconsin (Case No. 98-C-0864)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest covering a patent directed to a method for manufacturing polypropylene paint roller covers.
- **Dow Chemical Co. v. Sumitomo Chemical Co., Ltd. and Sumitomo Chemical America, Inc.**  
*United States District Court, Eastern District of Michigan (Case No. 96-10330-BC)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest covering a patent directed to a method for manufacturing cresol epoxy novalac resins used in integrated circuit encapsulation.
- **Insight Development Corp. v. Hewlett-Packard Co.**  
*United States District Court, Northern District of California (Case No. C 98 3349 CW)*  
Deposition testimony and expert report: damages and profits associated with alleged contract breaches, patent, copyright and trade secret misappropriation/infringement and unfair competition involving digital image processing and transmission, including that over the internet.
- **Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer Inc. and Centre National De La Recherche Scientifique**  
*United States District Court, Southern District of New York (Case No. 95 Civ. 8833)*  
Deposition testimony and expert report: reasonable royalty covering a patent directed to semi-synthetic processes for manufacturing an anti-cancer drug.
- **Pactiv Corp. v. S.C. Johnson & Son, Inc.**  
*United States District Court, Northern District of Illinois (Case No. 98 C 2679)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to zipper closure mechanisms for home storage bags.
- **Dr. Harry Gaus v. Conair Corp.**  
*United States District Court, Southern District of New York (Case No. 94-5693 (KTD) (FM))*  
Trial and deposition testimony and expert report: reasonable royalty and prejudgment interest covering a patent directed to hazard prevention devices used with electrical hair dryers.
- **Neogen Corp. v. Vicam, L.P., et al.**  
*United States District Court, Middle District of Florida (Case No. 97-405-CIV-T-23B)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest covering a patent and a variety of tort claims directed to aflatoxin testing equipment.
- **Surety v. Entrust**  
*United States District Court, Eastern District of Virginia (Case No. 99-203-A)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest covering a patent directed to digital time stamping.
- **Sofamor Danek Holdings, Inc., et al. v. United States Surgical Corp., et al.**  
*United States District Court, Western District of Tennessee (Case No. 98-2369 GA)*  
Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent covering the method of inserting a spinal inter-body fusion device.

- **Molten Metal Equipment Innovation, Inc. v. Metaullics**  
*United States District Court, Northern District of Ohio (1:97-CV2244)*  
Trial testimony and expert report: lost profits, reasonable royalty, and prejudgment interest covering a patent directed to submersible molten metal pumps.
- **AcroMed Corp. v. Sofamor Danek Group, Inc.**  
*United States District Court, Northern District of Ohio (Case No. 1:93-CV01184)*  
Trial and deposition testimony and expert report: lost profits and prejudgment interest involving patents directed to spinal implant devices.
- **BIC Corp. v. Thai Merry Co., Ltd.**  
*United States District Court, Central District of California (Case No. 98 CIV. 2113 (DLC))*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to disposable cigarette lighters.
- **Synsort Inc. v. Michael Wagner; Cambridge Algorithm; ICF Kaiser Intl. Inc., et al.**  
*United States District Court, Northern District of Georgia (Case No. 1:93-CV-2247-JEC)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to data sorting software.
- **Shell Oil Co. v. ICI Americas, Inc. and P.E.T Processors, LLC**  
*United States District Court, Eastern District of Louisiana (Case No. 97-3526 Section "K")*  
Deposition testimony and expert report: lost profits and reasonable royalty involving a patent directed to a process to manufacture solid stated polyethylene naphthalene.
- **Pall Corp. v. Hemasure Inc. and Lydall, Inc.**  
*United States District Court, Eastern District of New York (Case No. CV-96-436 (TCP/ETB), Case No. 96-5620 (LDW/VVP))*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to prestorage leukodepletion devices.
- **Mentor H/S, Inc. v. Medical Device Alliance, Inc.; Lysonix, Inc.; and Misonix, Inc.**  
*United States District Court, Central District of California (Case No. CV97-2431 WDK (BQRx))*  
Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to ultrasonic liposuction.
- **Hyundai Electronics Industries Co., Ltd. v. NEC Corp. and NEC Electronics, Inc.**  
*United States District Court, Eastern District of Virginia (Case No. 97-2030A, Case No. 97-2031A, Case No. 98-118-A)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to semiconductor technology.
- **Hitachi, LTD. v. Samsung Display Devices Co., LTD.; Samsung Display Devices, Inc.; Samsung Electronics Co., LTD.; Samsung Electronics America, Inc.; and Office Depot, Inc.**  
*United States District Court, Eastern District of Virginia (Case No. 97-1988-A)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving patents directed to various aspects of cathode ray tubes.
- **Stairmaster Sports/Medical Products, a Limited Partnership v. Groupe Procycle, Inc. and Procycle USA, Inc.**  
*United States District Court, District of Delaware (Case No. 97-396 MMS)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to stair climbing fitness equipment.



- **Angelo Mongiello's Children, LLC v. Pizza Hut, Inc.**  
*United States District Court, Eastern District of New York (Case No. 95 CV 4601)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest involving a patent directed to a method for forming pizza shells.
- **BTG v. Magellan Corp.; BTG v. Trimble Navigation**  
*United States District Court, Eastern District of Pennsylvania (Case No. 96-CV-7551/Case No. 96-CV-5084 (HB))*  
Deposition testimony and expert reports: reasonable royalty, prejudgment interest, value of inventory on hand, preparation and investments made and business commenced (as of patent reissuance) involving a patent directed to secret or secure communications technology employed in global positioning system products.
- **Micro Chemical, Inc. v. Lextron, Inc.**  
*United States District Court, District of Colorado (Case No. 88-Z-499)*  
Trial and deposition testimony and expert report: lost profits, price erosion, reasonable royalty, and prejudgment interest involving a patent directed to feed additive weigh/mix dispensing machines.
- **Thai Merry Co., Ltd.; Honson Marketing Group, Inc.; and Calico Brands, Inc. v. BIC Corp.**  
*United States District Court, Central District of California (Case No. 96-5256 WJR (BORx))*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to child-resistant disposable cigarette lighters.
- **Radco, Inc. v. Shell Oil Co.; Foster Wheeler USA Corp.; Lyondell-Citgo Refining Co., LLC; Petro-Chem Development Co, Inc.; and Marathon Oil Co.**  
*United States District Court, Northern District of Oklahoma (Case No. 93-C 1102)*  
Deposition testimony and expert report: reasonable royalty involving a patent directed to coker heater refinery equipment.
- **Beloit Corp. v. Valmet Corp., et al.**  
*United States District Court, Western District of Wisconsin (Case No. 96-C-0087-C)*  
Trial testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to the dryer section of paper making machines.
- **Burke, Inc. v. Everest & Jennings, Inc. et al./Burke, Inc. v. Invacare Corp.**  
*United States District Court, California Central District (Case No. 89-2613 (KMW)/Case No. 90-787 (KMW))*  
Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest over a patent directed to three wheel motorized scooter technology.
- **Bauer Inc. v. Rollerblade, Inc.**  
*United States District Court, Eastern District of Virginia (Case No. 96-952-A)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to a hybrid stitched and molded skate boot design.
- **Mettler - Toledo A.G. v. Denver Instrument Co., et al.**  
*United States District Court, Eastern District of Virginia (Case No. 95-1055-A)*  
Deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving patents directed to analytical and precision balances.
- **Bristol-Myers Squibb Co. v. Abbott Laboratories**  
*United States District Court, Southern District of Indiana (Case No. EV 94-56-C)*  
Trial and deposition testimony and expert report: reasonable royalty involving a patent directed to a guiding device used in enteral delivery set assemblies.



- **Crown Equipment Corp. v. The Raymond Corp.**  
*United States District Court, Northern District of Ohio (Case No. 3:93CV7356)*  
Trial and deposition testimony and expert report: lost profits, reasonable royalty, and prejudgment interest involving a patent directed to lift truck technology.
- **Mitsubishi Kasei Corp.; and Mitsubishi Kasei America, Inc. v. Virgle Hedgcoth; and Mertec Licensing Technology**  
*United States District Court, Northern District of California (Case No. 94-1971 SAW (JSB))*  
Deposition testimony and expert report: reasonable royalty involving a patent directed to sputtered rigid disks used in personal computers.
- **Travelers Express Co. Inc. v. The Standard Register Co.**  
*United States District Court, District of Minnesota (Case No. 4-93-436)*  
Deposition testimony and expert report: lost profits, reasonable royalty, patent misuse, and prejudgment interest involving patents directed to money order dispensers.
- **Dow Chemical Co. v. The United States**  
*Court of Federal Claims (Case No. 19-83C)*  
Trial and deposition testimony: measure and amount of delay compensation in an eminent domain case over the taking of a patent directed to the back - filling of abandoned coal mines.

#### **Patent Cases – Injunctive Relief**

- **Integra Lifesciences Corporation, Integra Lifesciences Sales, LLC, Confluent Surgical, Inc., and Incept, LLC v. Hyperbranch Medical Technology, Inc.**  
*United States District Court, District of Delaware (Case No. 15-cv-00819)*  
Deposition testimony and expert report: preliminary relief involving patents directed to cranial and spinal dural repair sealants.
- **Antares Pharma, Inc. v. Medac Pharma, Inc., Medac GmbH, Becton Dickinson France S.A.S., and Becton, Dickinson and Company**  
*United States District Court, District of Delaware (C.A. No. 14-270-SLR)*  
Deposition testimony and expert report: irreparable harm, balance of hardships, and public interest involving patents directed to methotrexate autoinjector products.
- **Delavau, LLC v. J.M. Huber Corporation and J.M. Huber Micropowders Inc.**  
*United States District Court, District of New Jersey (Case No. 12-05378 (ES)(SCM))*  
Deposition testimony and expert declaration: preliminary injunctive relief involving patents directed to dietary calcium supplements.
- **Dyson Technology Limited and Dyson, Inc. v. Cornucopia Products, LLC**  
*United States District Court, District of Arizona (Case No. 2:12-cv-00924-ROS)*  
Hearing testimony and expert declaration: irreparable harm involving patents directed to bladeless fans.
- **Novozymes A/S and Novozymes North America, Inc. v. Danisco A/S; Genecor International Wisconsin, Inc.; Danisco US Inc.; and Danisco USA Inc.**  
*United States District Court, Western District of Wisconsin (Case No. 10-CV-251)*  
Trial and deposition testimony and expert report and expert declaration: lost profits, reasonable royalty, prejudgment interest and irreparable harm involving a patent directed to alpha-amylases used for fuel ethanol.

- **LifeWatch Services, Inc. and Card Guard Scientific Survival, LTD. v. Medicomp, Inc. and United Therapeutics Corp.**  
*United States District Court, Middle District of Florida, Orlando Division (Case No. 6:09-cv-1909-Orl-31DAB)*  
Hearing and deposition testimony and expert declaration: preliminary injunctive relief involving patents directed to ambulatory arrhythmia monitoring solutions.
- **Verizon Services Corp. and Verizon Laboratories, Inc. v. Vonage Holdings Corp. and Vonage America, Inc.**  
*United States District Court, Eastern District of Virginia (Case No. 1:06CV682)*  
Trial and deposition testimony and expert report: permanent injunction, lost profits and reasonable royalty involving patents directed to a voice over internet protocol (“VoIP”) platforms.
- **Riverwood International Corp. v. MeadWestvaco Corp.**  
*United States District Court, Northern District of Georgia (Case No. 1:03-CV-1672 (TWT))*  
Deposition testimony and expert report: irreparable harm involving a patent directed to 2x6 beverage cartons.

#### **Patent Cases – Commercial Success**

- **Innopharma Licensing, Inc., Innopharma Licensing LLC, Innopharma Inc., Innopharma LLC, Mylan Pharmaceuticals, Inc., and Mylan Inc. v. Senju Pharmaceutical Co., Ltd., Bausch & Lomb, Inc., and Bausch & Lomb Pharma Holdings Corp.**  
*The United States Patent and Trademark Office (Case IPR2015-00902 and Case IPR2015-00903); United States District Court, District of New Jersey (Case Nos. 14-cv-00667-JBS-KMW; 14-cv-04149-JBS-KMW; 14-cv-05144-JBS-KMW; 15-cv-00335-JBS-KMW; 14-cv-06893-JBS-KMW; and 15-cv-03240-JBS-KMW)*  
Deposition testimony and expert declaration: commercial success involving patents directed to nonsteroidal anti-inflammatory drugs (“NSAIDs”) used to treat post-cataract surgery inflammation and pain.
- **Arctic Cat, Inc., v. Polaris Industries, Inc.**  
*The United States Patent and Trademark Office (Case IPR2014-01427)*  
Deposition testimony and expert declaration: commercial success involving patents directed to side-by-side all-terrain vehicles.
- **Intendis GmbH, Intraseriv GmbH & Co. KG and Bayer Healthcare Pharmaceuticals Inc., v. Glenmark Generics Ltd. and Glenmark Generics Inc., USA.**  
*United States District Court, District of Delaware (Case No. 13-cv-421-SLR)*  
Trial and deposition testimony and expert report: commercial success involving a patent directed to the treatment of certain skin diseases.
- **Everlight Electronics Co. Ltd., and Emcore Corporation v. Nichia Corporation and Nichia America Corporation v. Everlight Americas, Inc.**  
*United States District Court, Eastern District of Michigan, Southern Division (Case No. 4:12-cv-11758 GAD-MKM)*  
Trial and deposition testimony, expert report and declaration: commercial success, lost profits, reasonable royalty, and prejudgment interest involving patents directed to LEDs.

- **Bayer Healthcare Pharmaceuticals, Inc. and Dow Pharmaceutical Sciences, Inc. v. River's Edge Pharmaceuticals, LLC, Teresina Holdings, LLC, Medical Products Laboratories, Inc. and Stayma Consulting Services, LLC**  
*United States District Court, Northern District of Georgia, Atlanta Division (Case No.11-cv-01634-RLV)*  
Deposition testimony and expert report: commercial success involving a patent directed to the treatment of certain skin diseases.
- **JDS Therapeutics, LLC and Nutrition 21, LLC v. Pfizer Inc., Wyeth LLC, Wyeth Consumer Healthcare Ltd., and Wyeth Consumer Healthcare LLC**  
*United States District Court, Southern District of New York (Case No.1:12-cv-09002-JSR)*  
Deposition testimony and expert report: commercial success, reasonable royalty, and unjust enrichment involving patents and trade secrets directed to the use of chromium picolinate in multi-vitamins.
- **Ferring, B.V. v. Watson Laboratories, Inc. – Florida, Apotex Inc., and Apotex Corp.**  
*United States District Court, District of Nevada (Case Nos.3:11-cv-00481-RCJ-VPC, 3:11-cv-00485-RCJ-VPC, 3:11-cv-00853-RCJ-VPC, 3:11-cv-00854-RCJ-VPC, 2:12-cv-01935-RCJ-VPC, and 2:12-cv-01941-RCJ-VPC)*  
Deposition testimony and expert report: commercial success involving patents directed to the treatment of menorrhagia.
- **Medicis Pharmaceutical Corporation; Dow Pharmaceutical Sciences, Inc.; and Alyzan, Inc. v. Actavis Mid Atlantic LLC**  
*United States District Court, District of Delaware (Case No. 11-CV-409)*  
Deposition testimony and expert report: commercial success involving a patent directed to delivery vehicles for treatment of dermatological disorders.
- **Galderma Laboratories, L.P.; Galderma S.A.; and Galderma Research & Development, S.N.C. v. Tolmar Inc.; and Actavia Mid Atlantic LLC**  
*United States District Court, District of Delaware (Case No. 10-cv-45 (LPS))*  
Trial and deposition testimony and expert report: commercial success involving a patent directed to treatment of dermatological disorders.
- **Pronova Biopharma Norge AS v. Teva Pharmaceuticals USA, Inc.; Apotex Corp. and Apotex Inc.; Par Pharmaceutical, Inc.; and Par Pharmaceutical Companies, Inc.**  
*United States District Court, District of Delaware (Case Nos. 09-286-SLR/09-304-SLR/09-305-SLR-MPT)*  
Trial and deposition testimony and expert report: commercial success covering patents directed to treatment of HDL cholesterol and hypertriglyceridemia.
- **Eli Lilly and Company v. Wockhardt Limited and Wockhardt USA, Inc.**  
*United States District Court, District of Indiana, Indianapolis Division (Case No. 1:08-cv-1547-WTL-TAB)*  
Deposition testimony and expert report: commercial success covering a patent directed to treatment of depression, anxiety and pain.
- **Acorda Therapeutics, Inc. v. Apotex Inc. and Apotex Corp.**  
*United States District Court, District of New Jersey (Case No. 2:07-cv-04937-JAG-MCA)*  
Trial and deposition testimony and expert report: commercial success covering a patent directed to treatment of spasticity.

- **Medeva Pharma Suisse A.G. and Proctor & Gamble Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.**  
*United States District Court, District of New Jersey (Case No. 3:07-CV-05165-FLW-TJB)*  
Deposition testimony and expert report: commercial success involving a patent directed to treatment of ulcerative colitis.
- **Otsuka Pharmaceutical Co., Ltd., Inc., et al. v. Sandoz, Inc., et al.**  
*United States District Court, District of New Jersey (Case No. 07-cv-01000)*  
Trial and deposition testimony and expert report: commercial success covering a patent directed to the active ingredient of an atypical antipsychotic drug.
- **Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd v. Novopharm Ltd.**  
*Canadian Federal Court (Case No. T-2175-04)*  
Trial testimony (written) and affidavit: commercial success covering a patent directed to the active ingredient of an anti-infective drug.
- **Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd v. The Minister of Health; and Apotex Inc.**  
*Federal Court of Canada (Case No. T-1508-05)*  
Deposition testimony and expert report: commercial success interest involving a patent directed to an anti-infective drug.
- **Ortho-McNeil Pharmaceutical, Inc., et al. v. Mylan Laboratories**  
*United States District Court, Northern District of West Virginia (Case No. 1:02CV32)*  
Trial and deposition testimony and expert report: commercial success covering a patent directed to the active ingredient of an anti-infective drug.
- **Elan Corp., PLC v. Andrx Pharmaceuticals, Inc.**  
*United States District Court, Southern District of Florida (Case No. 98-7164)*  
Trial and deposition testimony and expert report: commercial success covering a patent directed to controlled release dosing of a nonsteroid anti-inflammatory drug.

#### **Patent Cases – Other**

- **Travelers Express Co. Inc. v. The Standard Register Co.**  
*United States District Court, District of Minnesota (Case No. 4-93-436)*  
Deposition testimony and expert report: lost profits, reasonable royalty, patent misuse and prejudgment interest involving patents directed to money order dispensers.

#### **Trade Secret Cases**

- **In the Matter of Certain Sulfentrazone, Sulfentrazone Compositions, and Processes for Making Sulfentrazone (FMC (Complainant))**  
*United States International Trade Commission (Investigation No. 337-TA-914)*  
Trial and deposition testimony and expert report: irreparable harm, balance of hardships, and public interest involving a patent directed to a crop herbicide.
- **In the Matter of Certain Opaque Polymers (Organik Kimya (Respondent))**  
*United States International Trade Commission (Investigation No. 337-TA-883)*  
Deposition testimony and expert report: injury, independent economic valuation, and bond involving trade secrets used in the production of opaque polymers.



- **MacDermid, Inc. v. Cookson Group, plc, Cookson Electronics, Enthone, Inc., and David North**  
*United States Superior Court, Judicial District of Waterbury (Case No.x10-cv-09-5014518-d)*  
Deposition testimony and expert report: royalty and prejudgment interest involving the misappropriation of trade secrets directed to chemicals, materials, and technical services used in a possible corporate acquisition.
- **JDS Therapeutics, LLC and Nutrition 21, LLC v. Pfizer Inc., Wyeth LLC, Wyeth Consumer Healthcare Ltd., and Wyeth Consumer Healthcare LLC**  
*United States District Court, Southern District of New York (Case No.1:12-cv-09002-JSR)*  
Deposition testimony and expert report: commercial success, reasonable royalty, and unjust enrichment involving patents and trade secrets directed to the use of chromium picolinate in multi-vitamins.
- **E. I. du Pont de Nemours and Company v. Kolon Industries, Inc. and Kolon USA, Inc.**  
*United States District Court, Eastern District of Virginia, Richmond Division (Case No. 3:09CV58)*  
Trial and deposition testimony and expert report: unjust enrichment involving misappropriation of trade secrets directed to aramid fiber production.
- **CA, Inc.; Computer Associates Think, Inc.; Platinum Technology International, Inc.; and Platinum Technology IP, Inc., v. Rocket Software, Inc.**  
*United States District Court, Eastern District of New York (Case No. 07-CV-1476 (ADS)(MLO)*  
Deposition testimony and expert report: lost profits, unjust enrichment, price erosion and prejudgment interest involving copyrights and trade secrets related to DB2 software tools.
- **Sensormatic Electronics Corp. v. The TAG Co. US LLC; Phenix Label Co.; Dennis Gadonniex**  
*United States District Court, Southern District of Florida (Case No.06-81105-Civ-Hurley/Hopkins)*  
Trial and deposition testimony and expert report: unjust enrichment involving misappropriation of trade secrets directed to loss prevention systems.
- **Cogent Systems, Inc. v. Northrop Grumman Corp.**  
*California Superior Court, County of Los Angeles, Central District (Case No.BC332199)*  
Deposition testimony and expert report: reasonable royalty involving misappropriation of trade secrets directed to fingerprint identification technology.
- **Geomatrix, LLC and David A. Potts v. Infiltration Systems, Inc.**  
*Connecticut Superior Court, District of Middlesex at Middleton (Case No.MMX-CV-05-4004477 S)*  
Deposition testimony and expert disclosure: reasonable royalty involving misappropriation of trade secrets directed to leach field and septic tank technology.
- **McMahon Marketing v. Toyota Motor Sales**  
*California Superior Court, County of Los Angeles (Case No. BC317277)*  
Deposition testimony: damages and profits associated with trade secrets directed to a luxury hotel and automotive partnership.
- **Christopher Karol and Karol Designs, LLC v. Burton Corp.**  
*United States District Court, District of Vermont (Case No. 1:01-CV-178)*  
Deposition testimony and expert report: reasonable royalty and disgorgement of profits involving trade secrets and an NDA directed to snowboard boot and binding technology.
- **Takata Corp. v. AlliedSignal, Inc. and Breed Technologies, Inc.**  
*United States District Court, District of Delaware (Case No. 98-94-MMS)*  
Deposition testimony and expert report: reasonable royalty and prejudgment interest covering patents and trade secrets directed to seatbelt retractors.



- **Trimless-Flashless Design, Inc. v. Augat, Inc.; Thomas & Betts Corp.; and Tyco International, Ltd.**  
*United States District Court, Eastern District of Virginia (Case No. CA00-245-A)*  
Trial and deposition testimony and expert report: damages and profits associated with alleged breach of contract and misappropriation of trade secrets involving metallized particle interconnects used to connect microprocessors with mother boards.
- **Insight Development Corp. v. Hewlett-Packard Co.**  
*United States District Court, Northern District of California (Case No. C 98 3349 CW)*  
Deposition testimony and expert report: damages and profits associated with alleged contract breaches, patent, copyright and trade secret misappropriation/infringement and unfair competition involving digital image processing and transmission, including that over the internet.
- **DSC Communications Corp. v. DGI Technologies, Inc.**  
*United States District Court, Northern District of Texas (Case No. 3:94-CV-1047)*  
Trial testimony and expert report: reasonable royalty involving copyrights, trade secrets and unfair competition over telecommunications switching equipment.
- **Wayne State University; Lumigen Inc.; and A. Paul Schapp v. Irena Bronstein and Tropix Inc.**  
*State of Michigan Circuit Court, County of Wayne and Court of Claims (Case No. 88-804-627 CK/Case No. 88-11871CM)*  
Deposition testimony and expert report: unjust enrichment and lost profits involving trade secrets directed to chemiluminescence (medical detection) technology.

#### **Trademark Cases**

- **Katherine Dines v. Toys “R” Us-Delaware, Inc.**  
*United States District Court, District of Colorado (Case No. 12-cv-2279-PAB-KMT)*  
Deposition testimony and expert report: profits and prejudgment interest associated with trademark infringement involving a line of stuffed animal toys.
- **The Coryn Group II, LLC v. O.C. Seacrets, Inc.**  
*United States District Court, District of Maryland, Northern Division (Case No. 08-cv-02764-WDQ)*  
Trial testimony and expert report: profits and damages involving the use of “Secrets” trademark in the leisure resort business.
- **YSL Beauté v. Oscar de la Renta, Ltd.**  
*American Arbitration Association (Case No. 13 133 01389 08)*  
Arbitration hearing testimony and expert report: damages associated with alleged breach of contract and trademark infringement involving cosmetics, fragrances and beauty products.
- **Fishman Transducers, Inc. v. Stephen Paul d/b/a “Esteban” Davstar Productions and HSN Interactive LLC**  
*United States District Court, District of Massachusetts (Case No. 07-CA-10071 RCL)*  
Trial and deposition testimony and expert report: damages and profits associated with a trademark directed to guitar transducers.
- **ISP.NET, LLC d/b/a IQuest Internet v. Qwest Communications International, Inc.**  
*United States District Court, Southern District of Indiana, Indianapolis Division (Case No. IP01-0480 C B/S)*  
Deposition testimony and expert report: reasonable royalty, disgorgement of profits and prejudgment interest involving a trademark directed to internet service provision.

- **Fuel Clothing Co., Inc. v. Safari Shirt Co. d/b/a Fuel Clothing Co., Inc.**  
*United States District Court, Western District of Washington at Tacoma (Case No. CO5 5366 KJB)*  
Deposition testimony and expert report: economic harm involving a trademark directed to sports apparel logos.
- **Alpha International, Inc. v. General Foam Plastics Corp.**  
*United States District Court, Eastern District of North Carolina (Case No. 4:01-CV-142-H(3))*  
Deposition testimony and expert report: copyright infringement, trademark infringement, conversion and unjust enrichment involving bowling pin sets and ride-on toys.
- **Fuel TV, Inc. v. Fuel Clothing Co., Inc.**  
*United States District Court, Central District of California, Western Division (Case No. CV03-8248-ABC-VBKx)*  
Deposition testimony and expert report: economic harm involving infringement of trademark used in extreme sports applications.
- **AutoNation, Inc. v. Acme Commercial Corp., et al. (CarMax)**  
*United States District Court, Southern District of Florida (Case No. 96-6141)*  
Trial and deposition testimony and expert report: reasonable royalty associated with trademark infringement and unfair competition in the auto superstore business.

#### **Copyright Cases**

- **American Society for Testing and Materials d/b/a ASTM International; National Fire Protection Association, Inc.; and American Society of Heating, Refrigerating, and Air Conditioning Engineers, Inc. v. Public.Resource.org, Inc.**  
*United States District Court for the District of Columbia (Case No. 13-cv-01215-TSC)*  
Deposition testimony and expert report: harm and public interest involving copyrights and trademarks covering standards incorporated by reference into law.
- **Complex Systems, Inc. v. ABN AMRO Bank N.V.**  
*United States District Court, Southern District of New York (Case No. 08-cv-7497)*  
Deposition testimony and expert report: revenues and profits involving copyrighted trade finance software.
- **Shepard Fairey and Obey Giant Art, Inc. v. The Associated Press v. Shepard Fairey; Obey Giant Art, Inc.; Obey Giant LLC; Studio Number One, Inc.; and One 3 Two, Inc.**  
*United States District Court, Southern District of New York (Case No. 09-01123(AKH))*  
Deposition testimony and expert report: fair use, damages and profits involving copyrighted photograph of President Obama.
- **CA, Inc.; Computer Associates Think, Inc.; Platinum Technology International, Inc.; and Platinum Technology IP, Inc., v. Rocket Software, Inc.**  
*United States District Court, Eastern District of New York (Case No. 07-CV-1476 (ADS)(MLO))*  
Deposition testimony and expert report: lost profits, unjust enrichment, price erosion and prejudgment interest involving copyrights and trade secrets related to DB2 software tools.
- **Alpha International, Inc. v. General Foam Plastics Corp.**  
*United States District Court, Eastern District of North Carolina (Case No. 4:01-CV-142-H(3))*  
Deposition testimony and expert report: copyright infringement, trademark infringement, conversion and unjust enrichment involving bowling pin sets and ride-on toys.

- **Insight Development Corp. v. Hewlett-Packard Co.**  
*United States District Court, Northern District of California (Case No. C 98 3349 CW)*  
Deposition testimony and expert report: damages and profits associated with alleged contract breaches, patent, copyright and trade secret misappropriation/infringement and unfair competition involving digital image processing and transmission, including that over the internet.
- **First National Bank of Omaha v. Three Dimensions Systems Products, Inc.**  
*United States District Court, District of Nebraska (Case No. 8:98CV569)*  
Trial and deposition testimony and expert report: damages and profits associated with an alleged contract breach and copyright infringement involving financial services software.
- **Leslie Atkins v. Benson J. Fischer, et al.**  
*United States District Court, District of Columbia (Case No. 1:98CV00800)*  
Deposition testimony and expert report: damages and profits associated with copyright infringement covering beer label and packaging designs.
- **Wrench LLC v. Taco Bell Corp.**  
*United States District Court, Southern District of Michigan (Case No. 1:98-CV-45)*  
Trial and deposition testimony and expert report: unjust enrichment and actual damages involving chihuahua promotional campaign.
- **DSC Communications Corp. v. DGI Technologies, Inc.**  
*United States District Court, Northern District of Texas (Case No. 3:94-CV-1047)*  
Trial testimony and expert report: reasonable royalty involving copyrights, trade secrets and unfair competition over telecommunications switching equipment.

#### **Breach of Contract Cases**

- **Luminara Worldwide, LLC v. Shenzhen Liown Electronics Co., Ltd.**  
*State of Minnesota District Court, County of Hennepin Fourth Judicial District (Case No. 27-CV-14-16085)*  
Deposition testimony and expert report: damages associated with alleged breaches of contract and duty of good faith and fair dealing related to agreements to manufacture flameless candles.
- **ABS Holdings, Ltd. and ABS Global, Ltd. v. KT Corporation and KTSAT Corporation**  
*International Court of Arbitration of the International Chamber of Commerce*  
Arbitration hearing testimony and expert declaration: damages associated with alleged breaches of contract involving the sale and on-going operations of a satellite.
- **Bayer CropScience AG and Bayer CropScience NV v. Dow AgroSciences LLC, Mycogen Plant Science Inc., Agrigenetics, Inc. d/b/a Mycogen Seeds LLC, and Phytogen Seed Company, LLC**  
*International Chamber of Commerce (Case No. 18892/VRO /AGF)*  
Arbitration hearing testimony and expert report: damages associated with alleged breach of contract and patent infringement involving genetically modified seed.
- **Immunomedics Inc. v. Nycomed GmnH (n/k/a Takeda GmbH), Takeda Pharmaceutical Company Limited, and Takeda Pharmaceuticals International, Inc.**  
*International Center for Dispute Resolution*  
Arbitration hearing testimony and expert report: diminution of value associated with the delayed/failed development of a monoclonal antibody drug to treat various autoimmune diseases.

- **Avocent Redmond Corp. v. Raritan Americas, Inc.**  
*United States District Court, Southern District of New York (Case No. 10-cv-6100 (PKC)(JLC))*  
Deposition testimony and expert report: lost profits, lost royalties, reasonable royalty and prejudgment interest involving a patent and contract directed to software and hardware products and technologies that provide connectivity and centralized management of IT infrastructure through KVM switches.
- **General Assurance of America, Inc. v. Overby-Seawell Company**  
*United States District Court, Eastern District of Virginia, Alexandria Division (Case No. 1:11CV483)*  
Deposition testimony and expert report: damages and profits associated with obligations arising from a contract involving specialized insurance products.
- **Frontline Placement Technologies, Inc. v. CRS, Inc.**  
*United States District Court, Eastern District of Pennsylvania (Case No. 2:07-CV-2457)*  
Deposition testimony and expert report: lost profits, lost royalties, reasonable royalty and prejudgment interest involving a patent and contract directed to automated substitute fulfillment software.
- **Amkor Technology, Inc. v. Tessera, Inc.**  
*International Chamber of Commerce, International Court of Arbitration (Case No.166531/VRO)*  
Arbitration hearing and deposition testimony and expert report: royalty payments due under a contract directed to semiconductor packaging technology.
- **Max-Planck-Gesellschaft zur Förderung der Wissenschaften E. V.; Max-Planck-Innovation GmbH; and Alnylam Pharmaceuticals, Inc. v. Whitehead Institute for Biomedical Research; Massachusetts Institute of Technology; and the Board of Trustees of the University of Massachusetts**  
*United States District Court, District of Massachusetts (Case No. 2009-11116-PBS)*  
Deposition testimony and expert report: damages and profits associated with contracts covering the transfer and sharing of RNAi technology.
- **YSL Beauté v. Oscar de la Renta, Ltd.**  
*American Arbitration Association (Case No. 13 133 01389 08)*  
Arbitration hearing testimony and expert report: damages associated with alleged breach of contract and trademark infringement involving cosmetics, fragrances and beauty products.
- **IMTEC Imaging LLC v. CyberMed, Inc.**  
*JAMS Arbitration (Reference No.1410005418)*  
Arbitration hearing and deposition testimony and expert report: lost profits and development costs associated with the alleged breach of a contract involving a software license agreement directed to cone beam computed tomography machines used in dental applications.
- **Biosynexus, Inc. v. Glaxo Group Limited and MedImmune, Inc.**  
*New York Supreme Court, County of New York (Case No. 604485/05)*  
Deposition testimony and expert report: diminution of value associated with the delayed/failed development of a pediatric anti-infective drug.
- **Indiana Mills & Manufacturing, Inc. v. Dorel Industries, Inc.**  
*United States District Court, Southern District of Indiana (Case No. 1:04-CV-1102)*  
Deposition testimony and expert report: damages and profits associated with alleged contract breach and patent infringement involving technology directed to automobile child restraint systems.



- **ETEX Corp. v. Medtronic, Inc.; Medtronic International Limited; and Medtronic Sofamor Danek, Inc.**  
*CPR Institute for Dispute Resolution*  
Arbitration hearing and deposition testimony and expert report: lost revenues and profits associated with alleged contractual breaches and antitrust violations involving spinal implant materials.
- **Audiotext International, Ltd. and New Media Group, Inc. v. Sprint Communications Co., L.P.**  
*United States District Court, Eastern District of Pennsylvania (Case No.03-CV-2110)*  
Deposition testimony and expert report: non-delivery damages involving contracts covering resale of telecommunications services.
- **Medtronic Sofamor Danek, Inc. v. Gary K. Michelson, M.D. and Karlin Technology, Inc.**  
*United States District Court, Western District of Tennessee (Case No. 01-2373 GV)*  
Trial and deposition testimony and expert report: damages and profits associated with alleged contractual breaches, tortious interference and intentional negligent representations involving spinal implants.
- **Honeywell International, Inc. and GEM Microelectronic Materials LLC v. Air Products and Chemicals, Inc. and Ashland, Inc.**  
*Delaware Chancery Court, County of New Castle (Case No.20434-NC)*  
Trial and deposition testimony and expert report: lost profits associated with alleged contractual breach and tortious interference as well as irreparable harm inquiry involving a strategic alliance to provide electronic chemicals, gases and services to the semiconductor industry.
- **Christopher Karol; and Karol Designs, LLC v. Burton Corp.**  
*United States District Court, District of Vermont (Case No. 1:01-CV-178)*  
Deposition testimony and expert report: reasonable royalty and disgorgement of profits involving trade secrets and an NDA directed to snowboard boot and binding technology.
- **Interactive Return Service, Inc. v. Virginia Polytechnic Institute and State University, et al.**  
*Circuit Court for the City of Richmond (Case No.LM-870-3)*  
Deposition testimony: lost profits and lost licensing fees involving contracts to develop interactive/return path communications.
- **City of Hope National Medical Center v. Genentech, Inc.**  
*Superior Court, State of California, County of Los Angeles (Case No. BC215152)*  
Deposition testimony and expert report: damages associated with alleged breach of contract involving license fees for use of recombinant DNA technology.
- **Igen International, Inc. v. Roche Diagnostics GmbH**  
*United States District Court, Southern Division of Maryland (Case No. PJM 97-3461)*  
Trial and deposition testimony and expert report: damages and profits associated with an alleged breach of contract involving electrochemiluminescent detection technology used in DNA probe and immunoassay kits.
- **Trimless-Flashless Design, Inc. v. Augat, Inc.; Thomas & Betts Corp.; Tyco International, Ltd.**  
*United States District Court, Eastern District of Virginia (Case No.CA00-245-A)*  
Trial and deposition testimony and expert report: damages and profits associated with alleged breach of contract and misappropriation of trade secrets involving metallized particle interconnects used to connect microprocessors with mother boards.
- **New Industries Co. (Sudan) Ltd. v. PepsiCo, Inc.**  
*American Arbitration Association (Case No. 50 T 114 00001 95)*  
Arbitration hearing testimony and expert report: damages and profits associated with breaches of PepsiCo franchise agreement.
- **Insight Development Corp. v. Hewlett-Packard Co.**



*United States District Court, Northern District of California (Case No. C 98 3349 CW)*

Deposition testimony and expert report: damages and profits associated with alleged contract breaches, patent, copyright and trade secret misappropriation/infringement and unfair competition involving digital image processing and transmission, including that over the internet.

- **First National Bank of Omaha v. Three Dimensions Systems Products, Inc.**  
*United States District Court, District of Nebraska (Case No. 8:98CV569)*  
Trial and deposition testimony and expert report: damages and profits associated with an alleged contract breach and copyright infringement involving financial services software.
- **Computer Aid v. Hewlett-Packard**  
*United States District Court, Eastern District of Pennsylvania (Case No. (C-96-3085 (MHP))*  
Deposition testimony and expert report: appropriate discount rate and prejudgment interest rate involving a failed software development contract.
- **Wrench LLC v. Taco Bell Corp.**  
*United States District Court, Southern District of Michigan (Case No. 1:98-CV-45)*  
Trial and deposition testimony and expert report: unjust enrichment and actual damages involving chihuahua promotional campaign.
- **Kabushiki Kaisha Izumi Seiko Seiskusho v. Windmere Corp. et al.**  
*United States District Court, Southern District of Florida (Case No. 94-0803-CIV-MOORE)*  
Deposition testimony and expert declaration: lost revenues and lost profits in a breach of contract, fraud and antitrust case involving rotary shavers.

#### **Antitrust Cases**

- **Rambus Inc., v. Micron Technology, Inc.**  
*California Superior Court, County of San Francisco (Case No. 04-431105)*  
Deposition testimony and expert report: lost revenues and profits associated with alleged antitrust violations related to DRAM technology.
- **ETEX Corp. v. Medtronic, Inc.; Medtronic International Limited; and Medtronic Sofamor Danek, Inc.**  
*CPR Institute for Dispute Resolution*  
Arbitration hearing and deposition testimony and expert report: lost revenues and profits associated with alleged contractual breaches and antitrust violations involving spinal implant materials.
- **Kabushiki Kaisha Izumi Seiko Seiskusho v. Windmere Corp. et al.**  
*United States District Court, Southern District of Florida (Case No. 94-0803-CIV-MOORE)*  
Deposition testimony and expert declaration: lost revenues and lost profits in a breach of contract, fraud and antitrust case involving rotary shavers.
- **DSC Communications Corp. v. DGI Technologies, Inc.**  
*United States District Court, Northern District of Texas (Case No. 3:94-CV-1047)*  
Trial testimony and expert report: reasonable royalty involving copyrights, trade secrets and unfair competition over telecommunications switching equipment.
- **Travelers Express Co. Inc. v. The Standard Register Co.**  
*United States District Court, District of Minnesota (Case No. 4-93-436)*  
Deposition testimony and expert report: lost profits, reasonable royalty, patent misuse and prejudgment interest involving patents directed to money order dispensers.

#### **General Tort Cases**

- **General Assurance of America, Inc. v. Overby-Seawell Company**  
*United States District Court, Eastern District of Virginia, Alexandria Division (Case No.1:11CV483)*  
Deposition testimony and expert report: damages and profits associated with obligations arising from a contract involving specialized insurance products.
- **The Osage Tribe of Indians of Oklahoma v. The United States of America**  
*United States Court of Federal Claims (Case No. 99-550 L (into which is consolidated No. 00-169L))*  
Deposition testimony and expert declaration: present value interest from unpaid oil royalties.
- **Biosynexus, Inc. v. Glaxo Group Limited; and MedImmune, Inc.**  
*New York Supreme Court, County of New York (Case No. 604485/05)*  
Deposition testimony and expert report: diminution of value associated with the delayed/failed development of a pediatric anti-infective drug.
- **Bavarian Nordic A/S and Anton Mayr v. Acambis, Inc.**  
*United States District Court, District of Delaware (Case No. 05-614-SLR)*  
Deposition testimony and expert report: unjust enrichment and value of property associated with tortious conversion, unfair trade practices and unfair competition involving proprietary technology directed to vaccines.
- **Alpha International, Inc. v. General Foam Plastics Corp.**  
*United States District Court, Eastern District of North Carolina (Case No. 4:01-CV-142-H(3))*  
Deposition testimony and expert report: copyright infringement, trademark infringement, conversion and unjust enrichment involving bowling pin sets and ride-on toys.
- **Medtronic Sofamor Danek, Inc. v. Gary K. Michelson, M.D. and Karlin Technology, Inc.**  
*United States District Court, Western District of Tennessee (Case No. 01-2373 GV)*  
Trial and deposition testimony and expert report: damages and profits associated with alleged contractual breaches, tortious interference and intentional negligent representations involving spinal implants.
- **Honeywell International, Inc. and GEM Microelectronic Materials LLC v. Air Products and Chemicals, Inc. and Ashland, Inc.**  
*Delaware Chancery Court, County of New Castle (Case No.20434-NC)*  
Trial and deposition testimony and expert report: lost profits associated with alleged contractual breach and tortious interference as well as irreparable harm inquiry involving a strategic alliance to provide electronic chemicals, gases and services to the semiconductor industry.
- **Interactive Return Service, Inc. v. Virginia Polytechnic Institute and State University, et al.**  
*Circuit Court for the City of Richmond (Case No.LM-870-3)*  
Deposition testimony: lost profits and lost licensing fees involving contracts to develop interactive/return path communications.
- **Omega Engineering, Inc. v. Cole-Parmer Instrument Co.; Davis Instrument Manufacturing Co., Inc.; Dwyer Instruments, Inc.; and Raytek Corp.**  
*United States District Court, District of Connecticut (Case Nos.3:98 CV 00733 (JCH), 3:98 CV 02052 (JCH) and 3:98 CV 02276 (JCH))*  
Trial and deposition testimony and expert report: lost profits, reasonable royalty and prejudgment interest involving patents and alleged unfair competitive practices directed to portable infrared thermometers.

- **The University of Colorado Foundation Inc., et al. v. American Cyanamid Co.**  
*United States District Court, District of Colorado (Case No.93-K-1657)*  
Trial and deposition testimony and expert report: measure and amount of prejudgment interest in a patent infringement, fraud and unjust enrichment case covering prenatal vitamin formulations.
- **Hunter Group, Incorporated v. Susan Smith, et al.**  
*United States District Court, District of Maryland (Case No. 97-2218)*  
Trial and deposition testimony and expert report: lost enterprise value and lost profits associated with improper solicitation of enterprise resource planning software trainers.
- **William Aramony v. United Way of America et al.**  
*United States District Court, Southern District of New York (Case No. 96 Civ. 3962 (SAS))*  
Trial testimony and expert report: lost contributions and out-of-pocket losses surrounding the departure of United Way of America president.
- **Fox v. Fox**  
*State of Virginia, Circuit Court, Arlington County (Chancery No. 96-80)*  
Trial testimony (proffered) and expert report; prospective valuation of a patent portfolio involving lasers used for lithotripsy and angioplasty.
- **AutoNation, Inc. v. Acme Commercial Corp., et al. (CarMax)**  
*United States District Court, Southern District of Florida (Case No. 96-6141)*  
Trial and deposition testimony and expert report: reasonable royalty associated with trademark infringement and unfair competition in the auto superstore business.

#### **International Trade Cases**

- **In the Matter of Certain 3G Mobile Handsets and Components Thereof (Nokia (Respondent))**  
*(International Trade Commission Inv. No. 337-TA-613)*  
Trial and deposition testimony and expert report: economic evaluation of whether proposed license terms for certain wireless devices are discriminatory under a FRAND obligation and economic evaluation of hold-up and reverse hold-up.
- **In the Matter of Certain Sulfentrazone, Sulfentrazone Compositions, and Processes for Making Sulfentrazone (FMC (Complainant))**  
*United States International Trade Commission (Investigation No. 337-TA-914)*  
Trial and deposition testimony and expert report: irreparable harm, balance of hardships, and public interest involving a patent directed to a crop herbicide.
- **In the Matter of Certain Opaque Polymers (Organik Kimya (Respondent))**  
*United States International Trade Commission (Investigation No.337-TA-883)*  
Deposition testimony and expert report: injury, independent economic valuation, and bond involving trade secrets used in the production of opaque polymers.
- **In the Matter of Certain Wireless Devices with 3G and/or 4G Capabilities and Components Thereof (Nokia (Respondent))**  
*United States International Trade Commission (Investigation No.337-TA-868)*  
Trial and deposition testimony and expert report: economic evaluation of whether proposed license terms for certain wireless devices are discriminatory under a FRAND obligation, and economic evaluation of hold-up and reverse hold-up.

- **In the Matter of Certain Wireless Devices with 3G Capabilities and Components Thereof (Nokia (Respondent))**  
*United States International Trade Commission (Investigation No.337-TA-800)*  
Trial and deposition testimony and expert report: economic evaluation of whether proposed license terms for certain wireless devices are discriminatory under a FRAND obligation.
- **In the Matter of Certain Computing Devices with Associated Instruction Sets and Software (VIA Technologies, Inc., Centaur Technology, IP-First LLC (Complainants))**  
*United States International Trade Commission (Investigation No.337-TA-812)*  
Trial and deposition testimony and expert report: economic evaluation of domestic industry issues associated with importation of certain computing devices.
- **In the Matter of Certain Modified Vaccinia Ankara (“MVA”) Viruses and Vaccines and Pharmaceutical Compositions Based Thereon (Bavarian Nordic A/S (Complainant))**  
*United States International Trade Commission (Investigation No. 337-TA-550)*  
Deposition testimony and expert report: domestic industry and injury involving patents and proprietary technology directed to vaccines.

### **Malpractice Cases**

- **TattleTale Portable Alarm Systems, Inc. v. Calfee, Halter & Griswold LLP, et al.**  
*United States District Court, Southern District of Ohio, Eastern Division (Case No. 2:10-CV-226)*  
Deposition testimony and expert report: lost royalties associated with a law firm’s negligence in handling a patent directed to portable alarm systems.
- **Timothy Robinson and Whorl, LLC v. Cohen Mohr, LLP; Dan Duval; Perkins Coie, LLP; Perkins Coie, L.P.C.; Perkins Coie, D.C.P.C.; and Perkins Coie, California, P.C.**  
*State of Virginia, Circuit Court of Fairfax County (Case No. CL-2009-080)*  
Deposition testimony and expert report: lost value and prejudgment interest involving allegations of law firm’s negligence in securing an interest in intellectual property directed to biometric payment technology.
- **Frank Robertson and Cayvon, Inc. v. Nexsen Pruet Jacobs & Pollard, LLP**  
*South Carolina Common Pleas Court, Fifth Judicial Circuit, Richland (Case No. 2004-CP-40-5531)*  
Deposition testimony: lost profits associated with a law firm’s negligence in handling a patent directed to commercial nut-cracking machines.
- **Anodyne Corp. v. Klaas, Law, O’Meara & Malkin**  
*State of Colorado District Court, City and County of Denver (Case No. 97-CV-7129)*  
Trial testimony and expert report: lost licensing income and prejudgment interest associated with a law firm’s negligence in filing a patent application directed to wrappable flashlights.

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- “Patent Infringement Reasonable Royalty Damages: Apportion the Increment?” Asian Pacific American Bar Association of Silicon Valley, November 2015 (with William Rooklidge, Michael Chapman, and Richard Eichmann).
- “Patent Enforcement,” Guest Lecturer, George Washington University Law School, September 2015 (with Chuck Donohoe).
- “Commercial Success at the PTAB,” Strafford Publications CLE Webinar, August 2015 (with Michael Flibbert and Maureen Queler).
- “Patent Damages Developments in the US,” International Intellectual Property Law Association Global IP Summit, July 2015 (with Iain Connor and Ronald Courtney).
- “WG9 Panel: Development of a Preliminary Compensatory Damages Contentions (PCDCs) Process, Including the Drafting of Local Patent Damages Rules,” The Sedona Conference WG9 and WG10 Joint Midyear Meeting, May 2015 (with Marta Beckwith, Cathy Bissoon, Melissa Finocchio, Andrea Weiss Jeffries, and James Morando).
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- “Valuation and Taxation Roundtable Discussion -- Hands on Application of Valuation Tools,” Licensing Executives Society Winter Meeting, February 2005 (with Serge-Alain Wandji).
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- “Creative Thinking on Remedies,” Law Seminars International, Trademarks Transactions and Litigation Workshop, July 2003.
- “Industry Royalty Rates and Profitability: An Empirical Test of the 25% Rule,” Licensing Executives Society Annual Meeting (Workshop 3-L), October 2001 (with Carla Mulhern and Robert Vigil).
- “Patent vs. Trade Secret Protection after 18-Month Publication and Festo--Monetary Relief,” Licensing Executives Society Annual Meeting (Workshop 2-M), October 2001 (with Griffith Price, Jr., John Williamson and Robert Payne).
- “The Design-Around Defense in Lost Profits Litigation,” Patent Lawyers Club of Washington, May 2000.
- “Use of the 25% Rule in Valuing Intellectual Property,” Center for Continuing Education, Santa Clara, California, December 1999.
- “Extracting Value from Intellectual Assets: Valuation,” INTX Seminar -- On the Frontier of Intellectual Asset Management: The Strategic Management of Intellectual Assets, November 1999.
- “Internet Patents – Monetary Remedies,” American Intellectual Property Law Association Mid-winter Meeting – IP Law in Cyberspace, February 1999 (with R. Jeffrey Malinak).
- “Industry Royalty Rates and Profitability: An Empirical Test of the 25% Rule,” Licensing Executives Society Annual Meeting (Workshop 3-11), October 1998 (with Carla Mulhern).
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- “Valuation of Technology,” Technology Transfer Society Annual Meeting, July 1997.
- “The Valuation and Licensing of Intellectual Property,” Launchspace, December 1996 (with Robert Goldscheider).
- “Quantifying and Valuing Royalties for Intellectual Property,” The 5th Intellectual Property Institute for Corporate Counsel, May 1996.
- “Taxes and Damages,” CPA/Lawyer Relations Committee, DC Institute of CPAs -Legal and Financial Implications of Damages in Litigation, October 1995.
- “Estimating Lost Profits in Commercial Litigation,” Maryland Association of Certified Public Accountants, Litigation Support Service Conferences, May 1995.
- “Damages in Patent and Trademark Infringement,” Joint American Society of Appraisers and Canadian Institute of Chartered Business Valuators meeting, November 1994.

**APPENDIX 2  
OPHTHALMIC NSAIDS  
TOTAL SALES  
UNITED STATES**

	2005			2006				2007				
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Bromfenac Sodium Xibrom® Bromday® Prolensa® Bromfenac Sodium	\$372	\$1,331	\$2,094	\$3,304	\$5,083	\$5,602	\$6,875	\$7,673	\$9,717	\$10,687	\$11,693	
Diclofenac Sodium Voltaren® Diclofenac Sodium	\$5,238	\$4,843	\$3,910	\$3,423	\$3,617	\$3,368	\$3,223	\$3,541	\$3,532	\$3,217	\$2,913	
Flurbiprofen Sodium Ocufen® Flurbiprofen Sodium	\$73	\$66	\$60	\$59	\$56	\$52	\$46	\$44	\$45	\$35	\$34	
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail® Ketorolac Trometh	\$13,825	\$13,673	\$11,532	\$10,934	\$12,921	\$11,104	\$9,706	\$10,165	\$11,866	\$10,750	\$9,371	
Nepafenac Nevanac® Ilevro®		\$616	\$5,370	\$6,634	\$7,345	\$7,419	\$7,672	\$7,831	\$8,992	\$9,638	\$10,615	
<b>Total</b>	<b>\$31,833</b>	<b>\$31,513</b>	<b>\$32,970</b>	<b>\$34,111</b>	<b>\$40,588</b>	<b>\$39,482</b>	<b>\$40,512</b>	<b>\$47,522</b>	<b>\$50,356</b>	<b>\$51,017</b>	<b>\$51,155</b>	
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	\$30,818	\$30,575	\$32,066	\$33,337	\$39,703	\$38,679	\$39,670	\$42,324	\$49,311	\$50,211	\$50,375	
Total Xibrom®/Bromday®/Prolensa®	\$372	\$1,331	\$2,094	\$3,304	\$5,083	\$5,602	\$6,875	\$7,673	\$9,717	\$10,687	\$11,693	
	2008				2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium Xibrom® Bromday® Prolensa® Bromfenac Sodium	\$12,606	\$14,726	\$15,529	\$17,337	\$19,769	\$22,691	\$23,538	\$24,348	\$25,711	\$30,111	\$32,673	\$34,106
Diclofenac Sodium Voltaren® Diclofenac Sodium	\$1,532	\$931	\$594	\$444	\$398	\$344	\$186	\$117	\$99	\$90	\$64	\$59
Flurbiprofen Sodium Ocufen® Flurbiprofen Sodium	\$31	\$26	\$27	\$23	\$26	\$22	\$21	\$19	\$19	\$20	\$18	\$21
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail® Ketorolac Trometh	\$9,729	\$11,512	\$10,534	\$9,696	\$10,626	\$12,826	\$12,318	\$7,015	\$1,914	\$1,384	\$1,067	\$852
Nepafenac Nevanac® Ilevro®	\$15,594	\$17,868	\$17,905	\$17,888	\$20,849	\$23,031	\$21,650	\$9,755	\$1,485	\$1,050	\$953	\$929
	\$248	\$262	\$261	\$245	\$289	\$331	\$199	\$15	\$2	\$0	\$0	\$0
							\$1,556	\$13,692	\$11,407	\$3,723	\$5,251	\$3,743
							\$2,316	\$2,371	\$2,758	\$2,738	\$2,830	\$2,830
	\$10,691	\$12,564	\$12,847	\$11,392	\$12,926	\$14,547	\$15,729	\$16,723	\$17,815	\$20,506	\$20,633	\$22,945
<b>Total</b>	<b>\$31,549</b>	<b>\$39,021</b>	<b>\$38,792</b>	<b>\$38,026</b>	<b>\$65,941</b>	<b>\$74,891</b>	<b>\$76,368</b>	<b>\$75,118</b>	<b>\$62,054</b>	<b>\$62,730</b>	<b>\$64,493</b>	<b>\$68,610</b>
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	\$30,774	\$38,207	\$37,995	\$37,267	\$65,121	\$74,035	\$75,642	\$74,595	\$61,575	\$62,221	\$63,992	\$68,100
Total Xibrom®/Bromday®/Prolensa®	\$12,606	\$14,726	\$15,529	\$17,337	\$19,769	\$22,691	\$23,538	\$24,348	\$25,711	\$30,111	\$32,673	\$34,108





**APPENDIX 3**

**OPHTHALMIC NSAIDS  
SHARE OF TOTAL SALES  
EXCLUDING FLURBIPROFEN SODIUM PRODUCTS AND ACULAR PF®  
UNITED STATES**

	2005			2006			2007				
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium											
Xibrom®	1.9%	4.4%	6.5%	9.9%	12.8%	14.5%	17.3%	18.0%	19.6%	21.3%	23.2%
Bromday®											
Prolensa®											
Bromfenac Sodium											
Diclofenac Sodium											
Voltaren®	17.0%	15.8%	12.2%	10.3%	9.1%	8.7%	8.1%	8.3%	7.1%	6.4%	5.8%
Diclofenac Sodium	0.0%	0.0%	0.0%								
Ketorolac Trometh											
Acular®	51.4%	44.7%	36.0%	32.8%	32.5%	28.7%	24.5%	23.9%	24.0%	21.4%	19.0%
Acular LS®	29.8%	33.0%	27.9%	27.1%	26.5%	28.9%	30.7%	31.3%	31.1%	31.7%	30.9%
Acuvail®											
Ketorolac Trometh											
Nepafenac											
Nevanac®		2.0%	17.4%	19.9%	19.0%	19.2%	19.3%	18.4%	18.2%	19.2%	21.1%
Ilevro®											
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
<b>Total Xibrom®/Bromday®/Prolensa®</b>	<b>1.9%</b>	<b>4.4%</b>	<b>6.5%</b>	<b>9.9%</b>	<b>12.8%</b>	<b>14.5%</b>	<b>17.3%</b>	<b>18.0%</b>	<b>19.6%</b>	<b>21.3%</b>	<b>23.2%</b>

	2008				2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium												
Xibrom®	24.8%	25.3%	26.8%	30.3%	30.4%	30.6%	31.1%	32.6%	41.8%	48.4%	51.1%	50.1%
Bromday®												2.9%
Prolensa®												
Bromfenac Sodium												
Diclofenac Sodium												
Voltaren®	3.0%	1.6%	1.0%	0.8%	0.6%	0.5%	0.2%	0.2%	0.2%	0.1%	0.1%	0.1%
Diclofenac Sodium	1.2%	1.0%	1.0%	0.9%	0.8%	0.8%	0.9%	0.8%	1.3%	1.0%	1.0%	0.9%
Ketorolac Trometh												
Acular®	19.2%	19.8%	18.2%	16.9%	16.3%	17.3%	16.3%	9.4%	3.1%	2.2%	1.7%	1.3%
Acular LS®	30.7%	30.7%	30.9%	31.2%	32.0%	31.1%	28.6%	13.1%	2.4%	1.7%	1.5%	1.4%
Acuvail®							2.1%	18.4%	18.5%	9.2%	8.2%	5.5%
Ketorolac Trometh								3.1%	3.9%	4.4%	4.3%	4.2%
Nepafenac												
Nevanac®	21.1%	21.6%	22.2%	19.9%	19.8%	19.6%	20.8%	22.4%	28.9%	33.0%	32.2%	33.7%
Ilevro®												
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
<b>Total Xibrom®/Bromday®/Prolensa®</b>	<b>24.8%</b>	<b>25.3%</b>	<b>26.8%</b>	<b>30.3%</b>	<b>30.4%</b>	<b>30.6%</b>	<b>31.1%</b>	<b>32.6%</b>	<b>41.8%</b>	<b>48.4%</b>	<b>51.1%</b>	<b>53.0%</b>

**APPENDIX 3**

**OPHTHALMIC NSAIDS  
SHARE OF TOTAL SALES  
EXCLUDING FLURBIPROFEN SODIUM PRODUCTS AND ACULAR PF®  
UNITED STATES**

	2011				2012				2013			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium												
Xibrom®	32.2%	12.7%	0.3%	0.1%	0.0%	0.0%	0.0%	0.0%				
Bromday®	16.9%	26.7%	36.8%	42.0%	41.9%	41.7%	39.2%	38.3%	36.9%	30.7%	11.7%	0.4%
Prolensa®										6.2%	22.3%	31.3%
Bromfenac Sodium		6.2%	7.0%	7.4%	7.7%	8.0%	7.1%	7.1%	7.9%	8.5%	7.8%	9.1%
Diclofenac Sodium												
Voltaren®	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%				
Diclofenac Sodium	1.1%	1.3%	1.3%	1.2%	1.1%	1.1%	1.0%	1.0%	0.9%	1.0%	1.0%	1.0%
Ketorolac Trometh												
Acular®	1.3%	1.2%	1.3%	0.8%	0.7%	0.7%	0.6%	0.5%	0.6%	0.6%	0.6%	0.5%
Acular LS®	1.3%	1.2%	1.1%	0.6%	0.6%	0.5%	0.5%	0.4%	0.4%	0.3%	0.3%	0.6%
Acuvail®	4.6%	3.7%	3.7%	2.8%	2.5%	1.4%	1.3%	1.3%	1.4%	1.2%	1.1%	1.1%
Ketorolac Trometh	4.6%	6.1%	6.0%	5.4%	4.8%	4.9%	5.2%	4.5%	4.3%	4.7%	4.8%	4.7%
Nepafenac												
Nevanac®	37.9%	40.9%	42.4%	39.6%	40.6%	41.8%	45.1%	46.9%	46.4%	43.4%	37.7%	31.3%
Ilevro®									1.3%	3.5%	12.6%	20.1%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
<b>Total Xibrom®/Bromday®/Prolensa®</b>	<b>49.1%</b>	<b>39.4%</b>	<b>37.1%</b>	<b>42.1%</b>	<b>41.9%</b>	<b>41.7%</b>	<b>39.2%</b>	<b>38.3%</b>	<b>36.9%</b>	<b>36.8%</b>	<b>34.1%</b>	<b>31.6%</b>

	2014				2015			2013 Q2 -
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	2015 Q3
Bromfenac Sodium								
Xibrom®								
Bromday®	0.0%	0.0%	0.0%				0.0%	3.8%
Prolensa®	32.2%	33.5%	32.4%	31.4%	33.1%	31.5%	32.3%	29.0%
Bromfenac Sodium	10.1%	7.6%	6.3%	6.3%	5.0%	4.6%	3.9%	6.8%
Diclofenac Sodium								
Voltaren®								
Diclofenac Sodium	0.8%	0.8%	0.7%	0.7%	0.7%	0.6%	0.8%	0.8%
Ketorolac Trometh								
Acular®	0.5%	0.5%	0.3%	0.4%	0.4%	0.3%	0.3%	0.4%
Acular LS®	0.8%	0.5%	0.5%	0.3%	0.3%	0.3%	0.3%	0.4%
Acuvail®	1.0%	0.8%	0.7%	0.7%	0.6%	0.5%	0.5%	0.8%
Ketorolac Trometh	5.6%	6.1%	6.6%	7.0%	8.1%	8.2%	7.7%	6.5%
Nepafenac								
Nevanac®	24.3%	20.4%	18.9%	16.7%	14.5%	13.3%	12.0%	22.4%
Ilevro®	24.8%	29.8%	33.5%	36.5%	37.2%	40.7%	42.2%	29.1%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
<b>Total Xibrom®/Bromday®/Prolensa®</b>	<b>32.2%</b>	<b>33.6%</b>	<b>32.4%</b>	<b>31.4%</b>	<b>33.1%</b>	<b>31.5%</b>	<b>32.3%</b>	<b>32.8%</b>

Notes & Sources:  
From IMS Data.

**APPENDIX 4**  
**OPHTHALMIC NSAIDS**  
**SHARE OF TOTAL SALES**  
**UNITED STATES**

	2005			2006				2007					
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4		
Bromfenac Sodium													
Xibrom®	1.8%	4.2%	6.4%	9.7%	12.3%	14.2%	17.0%	17.7%	19.3%	20.9%	22.9%		
Bromday®													
Prolensa®													
Bromfenac Sodium													
Diclofenac Sodium													
Voltaren®	16.5%	15.4%	11.9%	10.0%	8.9%	8.5%	8.0%	8.2%	7.0%	6.3%	5.7%		
Diclofenac Sodium	0.0%	0.0%	0.0%										
Flurbiprofen Sodium													
Ocufen®	0.2%	0.2%	0.2%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%		
Flurbiprofen Sodium	1.9%	1.8%	1.8%	1.7%	1.4%	1.4%	1.4%	1.2%	1.1%	1.0%	1.0%		
Ketorolac Trometh													
Acular®	49.7%	43.4%	35.0%	32.1%	31.8%	28.1%	24.0%	23.5%	23.6%	21.1%	18.7%		
Acular LS®	28.8%	32.1%	27.2%	26.5%	26.0%	28.3%	30.1%	30.7%	30.6%	31.2%	30.5%		
Acular PF®	1.1%	0.9%	0.8%	0.4%	0.6%	0.5%	0.6%	0.6%	0.5%	0.5%	0.4%		
Acuvail®													
Ketorolac Trometh													
Nepafenac													
Nevanac®		2.0%	16.9%	19.4%	18.6%	18.8%	18.9%	18.1%	17.9%	18.9%	20.8%		
Ilevro®													
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	
<b>Total Xibrom®/Bromday®/Prolensa®</b>	<b>1.8%</b>	<b>4.2%</b>	<b>6.4%</b>	<b>9.7%</b>	<b>12.5%</b>	<b>14.2%</b>	<b>17.0%</b>	<b>17.7%</b>	<b>19.3%</b>	<b>20.9%</b>	<b>22.9%</b>		
	2008				2009				2010				
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Bromfenac Sodium													
Xibrom®	24.5%	25.0%	26.4%	29.9%	30.0%	30.3%	30.8%	32.4%	41.4%	48.0%	50.7%	49.7%	
Bromday®												2.9%	
Prolensa®													
Bromfenac Sodium													
Diclofenac Sodium													
Voltaren®	3.0%	1.6%	1.0%	0.8%	0.6%	0.5%	0.2%	0.2%	0.2%	0.1%	0.1%	0.1%	
Diclofenac Sodium	1.2%	1.0%	1.0%	0.9%	0.8%	0.8%	0.9%	0.8%	1.2%	1.0%	0.9%	0.9%	
Flurbiprofen Sodium													
Ocufen®	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
Flurbiprofen Sodium	1.0%	0.9%	0.9%	0.8%	0.8%	0.7%	0.7%	0.6%	0.7%	0.8%	0.7%	0.7%	
Ketorolac Trometh													
Acular®	18.9%	19.5%	17.9%	16.7%	16.1%	17.1%	16.1%	9.3%	3.1%	2.2%	1.7%	1.2%	
Acular LS®	30.3%	30.3%	30.5%	30.8%	31.6%	30.8%	28.3%	13.0%	2.4%	1.7%	1.5%	1.4%	
Acular PF®	0.5%	0.4%	0.4%	0.4%	0.4%	0.4%	0.3%	0.0%	0.0%	0.0%	0.0%		
Acuvail®							2.0%	18.2%	18.4%	9.1%	8.1%	5.5%	
Ketorolac Trometh								3.1%	3.8%	4.4%	4.2%	4.1%	
Nepafenac													
Nevanac®	20.7%	21.3%	21.9%	19.6%	19.6%	19.4%	20.6%	22.3%	28.7%	32.7%	32.0%	33.4%	
Ilevro®													
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	
<b>Total Xibrom®/Bromday®/Prolensa®</b>	<b>24.5%</b>	<b>25.0%</b>	<b>26.4%</b>	<b>29.9%</b>	<b>30.0%</b>	<b>30.3%</b>	<b>30.8%</b>	<b>32.4%</b>	<b>41.4%</b>	<b>48.0%</b>	<b>50.7%</b>	<b>52.6%</b>	



**APPENDIX 5**  
**OPHTHALMIC NSAIDS**  
**TOTAL PRESCRIPTIONS DISPENSED**  
**UNITED STATES**

	2005			2006			2007					
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Bromfenac Sodium Xibrom® Bromday® Prolensa® Bromfenac Sodium	600	13,740	23,501	31,592	41,103	50,459	63,451	72,685	90,594	101,857	108,760	
Diclofenac Sodium® Voltaren® Diclofenac Sodium	75,568 55	69,013 55	55,516 32	44,082 33	44,293 37	42,390 36	40,338 35	38,338 52	36,659 59	34,013 42	30,870 123	
Flurbiprofen Sodium Ocufen® Flurbiprofen Sodium	618 12,838	514 12,875	428 12,529	351 12,112	288 12,152	250 12,506	220 12,621	237 14,097	197 15,231	160 15,766	143 15,963	
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail® Ketorolac Trometh	196,666 146,012 2,158	169,940 156,442 1,937	140,995 141,129 1,593	124,312 133,694 1,322	143,440 152,922 1,203	124,279 164,849 1,079	109,932 174,756 1,097	107,601 189,568 1,138	120,281 209,493 1,241	105,270 212,394 1,120	95,905 212,399 1,021	
Nepafenac Nevanac® Ilevro®		2,425	63,620	89,154	107,574	109,839	113,173	113,153	125,062	133,510	145,825	
<b>Total</b>	<b>434,575</b>	<b>426,921</b>	<b>439,343</b>	<b>456,652</b>	<b>503,012</b>	<b>505,687</b>	<b>513,623</b>	<b>536,869</b>	<b>598,817</b>	<b>604,132</b>	<b>609,009</b>	
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	418,901	411,595	424,793	422,867	489,369	491,852	501,685	521,397	582,148	587,086	591,882	
Total Xibrom®/Bromday®/Prolensa®	600	13,740	23,501	31,592	41,103	50,459	63,451	72,685	90,594	101,857	108,760	
	2008				2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium Xibrom® Bromday® Prolensa® Bromfenac Sodium	112,864	123,782	127,727	137,019	144,225	156,857	164,430	162,483	157,832	178,029	193,676	194,501 8,853
Diclofenac Sodium Voltaren® Diclofenac Sodium	14,916 13,259	8,360 21,427	4,996 23,314	3,570 25,063	2,568 25,551	1,993 30,371	1,389 32,382	749 33,318	506 33,191	1,073 37,335	556 41,865	497 45,575
Flurbiprofen Sodium Ocufen® Flurbiprofen Sodium	132 15,979	152 17,040	117 17,273	102 17,632	95 17,162	92 18,875	60 19,727	69 19,923	76 18,859	87 20,403	75 21,980	76 22,378
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail® Ketorolac Trometh	91,058 205,743 1,060	104,202 220,330 1,222	91,797 221,588 1,148	84,386 224,808 928	80,469 220,469 931	90,919 236,737 983	81,974 213,690 716	47,775 105,795 238	13,122 17,001 97	10,827 12,558 48	6,558 8,263 10	4,636 5,584 11
Nepafenac Nevanac® Ilevro®	138,882	155,622	160,120	148,997	149,932	169,989	172,697	175,315	171,652	196,898	195,918	200,493
<b>Total</b>	<b>593,993</b>	<b>632,337</b>	<b>648,280</b>	<b>642,505</b>	<b>641,402</b>	<b>706,816</b>	<b>689,956</b>	<b>683,412</b>	<b>620,536</b>	<b>680,153</b>	<b>701,244</b>	<b>723,128</b>
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	576,822	633,923	629,742	623,843	623,214	686,866	669,453	663,182	601,504	659,615	679,179	700,663
Total Xibrom®/Bromday®/Prolensa®	112,864	123,782	127,727	137,019	144,225	156,857	164,430	162,483	157,832	178,029	193,676	203,354



**APPENDIX 5**  
**OPHTHALMIC NSAIDS**  
**TOTAL PRESCRIPTIONS DISPENSED**  
**UNITED STATES**

	2011				2012				2013			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Bromfenac Sodium</b>												
Xibrom®	95,438	27,807	6,298	3,533	1,447	430	191	123	75	42	41	28
Bromday®	92,043	141,205	166,058	189,768	181,996	172,731	167,038	162,501	157,013	140,052	55,783	14,282
Prolensa®										20,034	95,546	146,478
Bromfenac Sodium		9,825	27,724	32,276	34,430	37,983	36,507	32,559	35,178	37,983	35,530	38,646
<b>Diclofenac Sodium</b>												
Voltaren®	411	321	331	314	143	60	19	12	15	6	11	8
Diclofenac Sodium	48,498	60,656	63,533	63,204	67,124	70,027	71,211	72,651	71,006	78,614	80,741	81,315
<b>Flurbiprofen Sodium</b>												
Ocufer®	80	43	45	44	26	54	38	36	29	29	36	29
Flurbiprofen Sodium	22,379	25,679	26,057	26,434	29,626	30,584	32,125	31,069	29,838	32,593	34,002	35,481
<b>Ketorolac Trometh</b>												
Acular®	3,811	3,427	2,972	2,043	1,559	1,380	1,369	1,209	950	906	803	612
Acular LS®	4,228	3,993	2,898	2,432	1,979	1,573	1,405	1,183	1,055	1,053	779	1,180
Acular PF®	6	4	4	3		2						3
Acuvail®	25,757	18,579	14,161	11,788	10,321	8,152	6,687	5,873	5,204	4,508	3,799	3,568
Ketorolac Trometh	216,398	268,916	269,828	274,210	294,578	316,428	322,171	317,091	316,691	351,749	331,106	348,985
<b>Nepafenac</b>												
Nevanac®	183,278	190,396	187,851	198,900	211,339	223,823	249,947	259,078	235,601	225,549	191,233	157,975
Ilevro®									606	18,026	65,825	112,492
<b>Total</b>	<b>692,327</b>	<b>750,851</b>	<b>767,760</b>	<b>804,949</b>	<b>834,568</b>	<b>863,247</b>	<b>888,708</b>	<b>883,385</b>	<b>852,261</b>	<b>911,144</b>	<b>915,235</b>	<b>941,082</b>
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	669,862	725,125	741,654	778,468	804,916	832,607	856,545	852,280	823,394	878,522	881,197	905,569
Total Xibrom®/Bromday®/Prolensa®	187,481	169,012	172,356	193,301	183,445	173,181	167,229	162,624	157,088	160,128	151,370	160,788

	2014				2015			2013 Q2 - 2015 Q3
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	
<b>Bromfenac Sodium</b>								
Xibrom®	18	14	26	7	5			181
Bromday®	2,669	956	283	82	31	27	12	214,177
Prolensa®	149,409	163,653	167,241	169,388	156,919	166,337	168,902	1,403,907
Bromfenac Sodium	39,783	41,903	42,887	41,790	34,925	34,265	32,871	380,583
<b>Diclofenac Sodium</b>								
Voltaren®	11	10	4	4	2	5	9	70
Diclofenac Sodium	77,973	86,153	89,261	88,960	83,798	95,778	98,041	862,634
<b>Flurbiprofen Sodium</b>								
Ocufer®	31	21	14	23	28	28	19	258
Flurbiprofen Sodium	33,544	35,436	37,042	36,264	33,255	38,578	38,346	356,541
<b>Ketorolac Trometh</b>								
Acular®	656	704	621	682	572	596	523	6,677
Acular LS®	1,823	1,096	1,311	803	554	476	511	9,586
Acular PF®						1		4
Acuvail®	2,749	2,488	2,287	2,170	1,890	1,671	1,539	26,669
Ketorolac Trometh	332,870	378,926	385,938	378,108	360,990	409,254	407,274	3,705,200
<b>Nepafenac</b>								
Nevanac®	123,014	108,198	92,900	79,197	62,714	54,424	47,855	1,143,059
Ilevro®	128,970	163,527	181,744	191,610	179,481	195,995	200,985	1,438,655
<b>Total</b>	<b>893,520</b>	<b>983,087</b>	<b>1,001,559</b>	<b>989,088</b>	<b>919,164</b>	<b>997,435</b>	<b>996,887</b>	<b>9,548,201</b>
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	859,945	947,630	964,503	952,801	883,881	958,828	958,522	9,191,398
Total Xibrom®/Bromday®/Prolensa®	152,096	164,623	167,550	169,477	156,955	166,364	168,914	1,618,265

Notes & Sources  
From IMS Data

APPENDIX 6

OPHTHALMIC NSAIDS  
 SHARE OF TOTAL PRESCRIPTIONS DISPENSED  
 EXCLUDING FLURBIPROFEN SODIUM PRODUCTS AND ACULAR PF®  
 UNITED STATES

	2005			2006				2007			
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium											
Xibrom®	0.1%	3.3%	5.5%	7.5%	8.4%	10.3%	12.6%	13.9%	15.6%	17.3%	18.4%
Bromday®											
Prolensa®											
Bromfenac Sodium											
Diclofenac Sodium											
Voltaren®	18.0%	16.8%	13.1%	10.4%	9.1%	8.6%	8.0%	7.4%	6.3%	5.8%	5.2%
Diclofenac Sodium	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Ketorolac Trometh											
Acular®	46.9%	41.3%	33.2%	29.4%	29.3%	25.3%	21.9%	20.6%	20.7%	17.9%	16.2%
Acular LS®	34.9%	38.0%	33.2%	31.6%	31.2%	33.5%	34.8%	36.4%	36.0%	36.2%	35.9%
Acuvail®											
Ketorolac Trometh											
Nepafenac											
Nevanac®		0.6%	15.0%	21.1%	22.0%	22.3%	22.6%	21.7%	21.5%	22.7%	24.3%
Ilevro®											
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
Total Xibrom®/Bromday®/Prolensa®	0.1%	3.3%	5.5%	7.5%	8.4%	10.3%	12.6%	13.9%	15.6%	17.3%	18.4%

	2008				2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium												
Xibrom®	19.6%	19.5%	20.3%	22.0%	23.1%	22.8%	24.6%	24.5%	26.2%	27.0%	28.5%	27.8%
Bromday®												1.3%
Prolensa®												
Bromfenac Sodium												
Diclofenac Sodium												
Voltaren®	2.6%	1.4%	0.8%	0.6%	0.4%	0.3%	0.2%	0.1%	0.1%	0.2%	0.1%	0.1%
Diclofenac Sodium	2.3%	3.4%	3.7%	4.0%	4.1%	4.4%	4.8%	5.0%	5.5%	5.7%	6.2%	6.5%
Ketorolac Trometh												
Acular®	15.8%	16.4%	14.6%	13.5%	12.9%	13.2%	12.2%	7.2%	2.2%	1.6%	1.0%	0.7%
Acular LS®	35.7%	34.8%	35.2%	36.0%	35.4%	34.5%	31.9%	16.0%	2.8%	1.9%	1.2%	0.8%
Acuvail®							0.4%	11.5%	11.3%	6.8%	5.9%	4.7%
Ketorolac Trometh							9.3%	23.3%	27.0%	28.3%	29.6%	
Nepafenac												
Nevanac®	24.1%	24.5%	25.4%	23.9%	24.1%	24.7%	25.8%	26.4%	28.5%	29.9%	28.8%	28.6%
Ilevro®												
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
Total Xibrom®/Bromday®/Prolensa®	19.6%	19.5%	20.3%	22.0%	23.1%	22.8%	24.6%	24.5%	26.2%	27.0%	28.5%	29.0%

APPENDIX 6

OPHTHALMIC NSAIDS  
 SHARE OF TOTAL PRESCRIPTIONS DISPENSED  
 EXCLUDING FLURBIPROFEN SODIUM PRODUCTS AND ACULAR PF®  
 UNITED STATES

	2011				2012				2013			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium												
Xibrom®	14.2%	3.8%	0.8%	0.5%	0.2%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Bromday®	13.7%	19.5%	22.4%	24.4%	22.6%	20.7%	19.5%	19.1%	19.1%	15.9%	6.3%	1.6%
Prolensa®										2.3%	10.8%	16.2%
Bromfenac Sodium		1.4%	3.7%	4.1%	4.3%	4.6%	4.3%	3.8%	4.3%	4.3%	4.0%	4.3%
Diclofenac Sodium												
Voltaren®	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Diclofenac Sodium	7.2%	8.4%	8.6%	8.1%	8.3%	8.4%	8.3%	8.5%	8.6%	8.9%	9.2%	9.0%
Ketorolac Trometh												
Acular®	0.6%	0.5%	0.4%	0.3%	0.2%	0.2%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%
Acular LS®	0.6%	0.6%	0.4%	0.3%	0.2%	0.2%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%
Acuvail®	3.8%	2.6%	1.9%	1.5%	1.3%	1.0%	0.8%	0.7%	0.6%	0.5%	0.4%	0.4%
Ketorolac Trometh	32.3%	37.1%	36.4%	35.2%	36.6%	38.0%	37.6%	37.2%	38.5%	40.0%	39.8%	38.5%
Nepafenac												
Nevanac®	27.4%	26.3%	25.3%	25.6%	26.3%	26.9%	29.2%	30.4%	28.6%	25.7%	21.7%	17.4%
Ilevro®									0.1%	2.1%	7.5%	12.4%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Total Xibrom®/Bromday®/Prolensa®	28.0%	23.3%	23.2%	24.8%	22.8%	20.8%	19.5%	19.1%	19.1%	18.2%	17.2%	17.8%

	2014				2015			2013 Q2 – 2015 Q3
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	
Bromfenac Sodium								
Xibrom®	0.0%	0.0%	0.0%	0.0%	0.0%			0.0%
Bromday®	0.3%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	2.3%
Prolensa®	17.4%	17.3%	17.3%	17.8%	17.8%	17.3%	17.6%	15.3%
Bromfenac Sodium	4.6%	4.4%	4.4%	4.4%	4.0%	3.6%	3.4%	4.1%
Diclofenac Sodium								
Voltaren®	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Diclofenac Sodium	9.1%	9.1%	9.3%	9.3%	9.7%	10.0%	10.2%	9.4%
Ketorolac Trometh								
Acular®	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Acular LS®	0.2%	0.1%	0.1%	0.1%	0.1%	0.0%	0.1%	0.1%
Acuvail®	0.3%	0.3%	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%
Ketorolac Trometh	38.7%	40.0%	40.0%	39.7%	40.8%	42.7%	42.5%	40.3%
Nepafenac								
Nevanac®	14.3%	11.4%	9.6%	8.3%	7.1%	5.7%	5.0%	12.4%
Ilevro®	15.0%	17.3%	18.8%	20.1%	20.3%	20.4%	21.0%	15.7%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Total Xibrom®/Bromday®/Prolensa®	17.7%	17.4%	17.4%	17.8%	17.8%	17.4%	17.6%	17.6%

Notes & Sources:  
 From IMS Data.

APPENDIX 7

OPHTHALMIC NSAIDS  
SHARE OF TOTAL PRESCRIPTIONS DISPENSED  
UNITED STATES

	2005			2006				2007			
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium											
Xibrom®	0.1%	3.2%	5.3%	7.2%	8.2%	10.0%	12.3%	13.5%	15.1%	16.9%	17.9%
Bromday®											
Prolensa®											
Bromfenac Sodium											
Diclofenac Sodium											
Voltaren®	17.4%	16.2%	12.6%	10.1%	8.8%	8.4%	7.8%	7.1%	6.1%	5.6%	5.1%
Diclofenac Sodium	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Flurbiprofen Sodium											
Ocufer®	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Flurbiprofen Sodium	3.0%	3.0%	2.9%	2.8%	2.4%	2.5%	2.4%	2.6%	2.5%	2.6%	2.6%
Ketorolac Trometh											
Acular®	45.3%	39.8%	32.1%	28.5%	28.5%	24.6%	21.3%	20.0%	20.1%	17.4%	15.7%
Acular LS®	33.6%	36.6%	32.1%	30.6%	30.4%	32.6%	33.9%	35.3%	35.0%	35.2%	34.9%
Acular PF®	0.5%	0.5%	0.4%	0.3%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Acuvail®											
Ketorolac Trometh											
Nepafenac											
Nevanac®		0.6%	14.3%	20.4%	21.4%	21.7%	21.9%	21.1%	20.9%	22.1%	23.6%
Ilevro®											
<b>Total</b>	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Total Xibrom®/Bromday®/Prolensa®	0.1%	3.2%	5.3%	7.2%	8.2%	10.0%	12.3%	13.5%	15.1%	16.9%	17.9%

	2008				2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium												
Xibrom®	19.0%	19.0%	19.7%	21.3%	22.5%	22.2%	23.8%	23.8%	25.4%	26.2%	27.6%	26.9%
Bromday®												1.2%
Prolensa®												
Bromfenac Sodium												
Diclofenac Sodium												
Voltaren®	2.5%	1.3%	0.8%	0.6%	0.4%	0.3%	0.2%	0.1%	0.1%	0.2%	0.1%	0.1%
Diclofenac Sodium	2.2%	3.3%	3.6%	3.9%	4.0%	4.3%	4.7%	4.9%	5.3%	5.5%	6.0%	6.3%
Flurbiprofen Sodium												
Ocufer®	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Flurbiprofen Sodium	2.7%	2.6%	2.7%	2.7%	2.7%	2.7%	2.9%	2.9%	3.0%	3.0%	3.1%	3.1%
Ketorolac Trometh												
Acular®	15.3%	16.0%	14.2%	13.1%	12.5%	12.9%	11.9%	7.0%	2.1%	1.6%	0.9%	0.6%
Acular LS®	34.6%	33.8%	34.2%	35.0%	34.4%	33.5%	31.0%	15.5%	2.7%	1.8%	1.2%	0.8%
Acular PF®	0.2%	0.2%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%
Acuvail®							0.4%	11.2%	11.0%	6.6%	5.7%	4.6%
Ketorolac Trometh							9.0%	22.6%	26.2%	27.4%	28.7%	
Nepafenac												
Nevanac®	23.4%	23.9%	24.7%	23.2%	23.4%	24.0%	25.0%	25.7%	27.7%	28.9%	27.9%	27.7%
Ilevro®												
<b>Total</b>	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Total Xibrom®/Bromday®/Prolensa®	19.0%	19.0%	19.7%	21.3%	22.5%	22.2%	23.8%	23.8%	25.4%	26.2%	27.6%	28.1%

APPENDIX 7

OPHTHALMIC NSAIDS  
SHARE OF TOTAL PRESCRIPTIONS DISPENSED  
UNITED STATES

	2011				2012				2013			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium												
Xibrom®	13.8%	3.7%	0.8%	0.4%	0.2%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Bromday®	13.3%	18.8%	21.6%	23.6%	21.8%	20.0%	18.8%	18.4%	18.4%	15.4%	6.1%	1.5%
Prolensa®										2.2%	10.4%	15.6%
Bromfenac Sodium		1.3%	3.6%	4.0%	4.1%	4.4%	4.1%	3.7%	4.1%	4.2%	3.9%	4.1%
Diclofenac Sodium												
Voltaren®	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Diclofenac Sodium	7.0%	8.1%	8.3%	7.9%	8.0%	8.1%	8.0%	8.2%	8.3%	8.6%	8.8%	8.6%
Flurbiprofen Sodium												
Ocufen®	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Flurbiprofen Sodium	3.2%	3.4%	3.4%	3.3%	3.3%	3.5%	3.6%	3.5%	3.5%	3.6%	3.7%	3.8%
Ketorolac Trometh												
Acular®	0.6%	0.5%	0.4%	0.3%	0.2%	0.2%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%
Acular LS®	0.6%	0.5%	0.4%	0.3%	0.2%	0.2%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%
Acular PF®	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Acuvail®	3.7%	2.5%	1.8%	1.5%	1.2%	0.9%	0.8%	0.7%	0.6%	0.5%	0.4%	0.4%
Ketorolac Trometh	31.3%	35.8%	35.1%	34.1%	35.3%	36.7%	36.3%	35.9%	37.1%	38.6%	38.4%	37.1%
Nepafenac												
Nevanac®	26.5%	25.4%	24.5%	24.7%	25.3%	25.9%	28.1%	29.3%	27.6%	24.8%	20.9%	16.8%
Ilevro®									0.1%	2.0%	7.2%	12.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
<b>Total Xibrom®/Bromday®/Prolensa®</b>	<b>27.1%</b>	<b>22.5%</b>	<b>22.4%</b>	<b>24.0%</b>	<b>22.0%</b>	<b>20.1%</b>	<b>18.8%</b>	<b>18.4%</b>	<b>18.4%</b>	<b>17.6%</b>	<b>16.5%</b>	<b>17.1%</b>

	2014				2015			2013 Q2 - 2015 Q3
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	
Bromfenac Sodium								
Xibrom®	0.0%	0.0%	0.0%	0.0%	0.0%			0.0%
Bromday®	0.3%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	2.2%
Prolensa®	16.7%	16.6%	16.7%	17.1%	17.1%	16.7%	16.9%	14.7%
Bromfenac Sodium	4.5%	4.3%	4.3%	4.2%	3.8%	3.4%	3.3%	4.0%
Diclofenac Sodium								
Voltaren®	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Diclofenac Sodium	8.7%	8.8%	8.9%	9.0%	9.3%	9.6%	9.8%	9.0%
Flurbiprofen Sodium								
Ocufen®	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Flurbiprofen Sodium	3.8%	3.6%	3.7%	3.7%	3.8%	3.9%	3.8%	3.7%
Ketorolac Trometh								
Acular®	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Acular LS®	0.2%	0.1%	0.1%	0.1%	0.1%	0.0%	0.1%	0.1%
Acular PF®						0.0%	0.0%	0.0%
Acuvail®	0.3%	0.3%	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%
Ketorolac Trometh	37.3%	38.5%	38.5%	38.2%	39.3%	41.0%	40.9%	38.8%
Nepafenac								
Nevanac®	13.8%	11.0%	9.3%	8.0%	6.8%	5.5%	4.8%	12.0%
Ilevro®	14.4%	16.6%	18.1%	19.4%	19.5%	19.6%	20.2%	15.1%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
<b>Total Xibrom®/Bromday®/Prolensa®</b>	<b>17.0%</b>	<b>16.7%</b>	<b>16.7%</b>	<b>17.1%</b>	<b>17.1%</b>	<b>16.7%</b>	<b>16.9%</b>	<b>16.9%</b>

Notes & Sources  
From IMS Data



**APPENDIX 8**  
**OPHTHALMIC NSAIDS**  
**TOTAL EXTENDED UNITS SOLD**  
**UNITED STATES**

	2005				2006				2007			
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Bromfenac Sodium Xibrom® Bromday® Prolensa® Bromfenac Sodium	38,185	89,415	140,575	180,778	204,958	225,965	274,978	297,463	359,978	386,905	406,605	
Diclofenac Sodium Voltaren® Diclofenac Sodium	506,345 448	470,050 875	384,525 260	321,603	335,530	313,553	303,413	287,753	287,040	266,910	256,543	
Flurbiprofen Sodium Ocufen® Flurbiprofen Sodium	12,195 358,848	10,798 349,358	9,685 354,200	8,865 341,703	8,348 366,905	7,905 337,963	6,965 351,520	6,525 328,618	6,785 354,398	9,170 340,875	9,865 343,090	
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail® Ketorolac Trometh	1,452,395 811,235 38,544	1,262,035 895,925 33,739	1,072,565 796,340 29,875	953,411 754,250 16,186	1,102,009 864,585 25,301	954,714 920,060 22,296	841,695 1,015,205 24,221	841,987 1,044,820 24,422	950,715 1,167,835 23,789	868,354 1,208,945 24,552	778,613 1,201,395 21,658	
Nepafenac Nevanac® Ilevro®		29,571	268,002	320,097	366,174	362,316	374,373	367,728	411,501	440,526	484,227	
<b>Total</b>	<b>3,218,194</b>	<b>3,141,765</b>	<b>3,056,227</b>	<b>2,896,891</b>	<b>3,273,809</b>	<b>3,146,771</b>	<b>3,192,469</b>	<b>3,199,315</b>	<b>3,562,040</b>	<b>3,546,237</b>	<b>3,481,995</b>	
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	2,808,608	2,747,871	2,662,467	2,530,138	2,873,256	2,778,608	2,809,763	2,839,750	3,177,069	3,171,640	3,107,383	
Total Xibrom®/Bromday®/Prolensa®	38,185	89,415	140,575	180,778	204,958	225,965	274,978	297,463	359,978	386,905	406,605	
	2008				2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium Xibrom® Bromday® Prolensa® Bromfenac Sodium	421,353	466,373	491,735	514,903	561,450	605,663	627,015	617,383	614,198	686,078	723,000	710,905 28,099
Diclofenac Sodium Voltaren® Diclofenac Sodium	136,343 175,610	88,265 188,125	53,453 202,258	38,963 190,233	32,003 229,843	28,905 257,468	14,200 296,605	8,923 305,828	7,855 394,283	7,230 341,138	5,160 382,283	4,740 387,695
Flurbiprofen Sodium Ocufen® Flurbiprofen Sodium	6,710 328,053	6,460 355,233	6,800 347,313	5,980 337,315	6,390 322,143	4,408 350,510	4,468 350,135	3,383 344,045	3,505 333,013	3,418 355,238	2,990 352,110	3,270 353,830
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail® Ketorolac Trometh	748,093 1,119,405 23,074	871,520 1,313,165 23,669	784,750 1,224,795 23,405	706,653 1,193,293 21,226	723,047 1,325,080 23,366	810,317 1,303,370 24,720	741,209 1,166,665 14,947	440,490 522,650 1,142	136,591 91,240 125	94,870 66,200 29	74,255 58,695 24	61,090 55,320 426,096
Nepafenac Nevanac® Ilevro®	459,639	538,146	551,238	488,769	525,090	584,883	589,470	618,030	611,640	698,742	665,694	699,650
<b>Total</b>	<b>3,418,278</b>	<b>3,850,955</b>	<b>3,685,725</b>	<b>3,503,338</b>	<b>3,748,411</b>	<b>3,970,240</b>	<b>3,988,266</b>	<b>3,317,322</b>	<b>4,695,997</b>	<b>4,359,188</b>	<b>4,294,216</b>	<b>4,221,084</b>
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	3,060,442	3,465,594	3,308,208	3,138,817	3,396,312	3,590,603	3,618,716	4,968,750	4,359,354	4,000,503	3,939,092	3,863,984
Total Xibrom®/Bromday®/Prolensa®	421,353	466,373	491,735	514,903	561,450	605,663	627,015	617,383	614,198	686,078	723,000	739,004



APPENDIX 9

OPHTHALMIC NSAIDS  
AVERAGE SELLING PRICE PER PRESCRIPTION  
UNITED STATES

	2005			2006				2007				
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Bromfenac Sodium Xibrom® Bromday® Prolensa® Bromfenac Sodium	\$953.02	\$96.85	\$89.08	\$104.58	\$123.68	\$111.01	\$108.33	\$105.56	\$107.26	\$104.92	\$107.51	
Diclofenac Sodium Voltaren® Diclofenac Sodium	\$69.31 \$92.33	\$70.17 \$279.09	\$70.42 \$89.53	\$77.64	\$81.65	\$79.44	\$79.91	\$92.35	\$96.35	\$94.58	\$94.38	
Flurbiprofen Sodium Ocufen® Flurbiprofen Sodium	\$118.36 \$46.95	\$129.35 \$44.94	\$140.31 \$46.59	\$168.14 \$46.84	\$192.78 \$48.20	\$207.38 \$42.88	\$211.20 \$44.65	\$187.22 \$36.26	\$226.17 \$36.26	\$217.92 \$33.16	\$240.00 \$32.62	
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail® Ketorolac Trometh	\$80.47 \$62.86 \$157.39	\$80.46 \$64.58 \$151.55	\$81.79 \$63.47 \$163.05	\$87.95 \$67.63 \$112.30	\$90.08 \$68.91 \$202.52	\$89.35 \$67.86 \$199.25	\$88.29 \$69.78 \$212.22	\$94.47 \$70.24 \$212.90	\$98.66 \$73.53 \$200.16	\$102.12 \$74.95 \$221.70	\$99.80 \$73.36 \$220.51	
Nepafenac Nevanac® Ilevro®		\$254.02	\$87.56	\$74.41	\$70.14	\$67.54	\$67.79	\$69.21	\$71.90	\$72.19	\$73.81	
<b>Total</b>	<b>\$73.26</b>	<b>\$73.81</b>	<b>\$73.04</b>	<b>\$78.12</b>	<b>\$80.69</b>	<b>\$78.08</b>	<b>\$78.37</b>	<b>\$80.69</b>	<b>\$84.09</b>	<b>\$84.45</b>	<b>\$84.00</b>	
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	\$73.57	\$74.28	\$75.49	\$78.83	\$81.13	\$78.64	\$79.07	\$81.56	\$85.05	\$85.53	\$85.11	
Total Xibrom®/Bromday®/Prolensa®	\$953.02	\$96.85	\$89.08	\$104.58	\$123.68	\$111.01	\$108.33	\$105.56	\$107.26	\$104.92	\$107.51	
	2008				2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium Xibrom® Bromday® Prolensa® Bromfenac Sodium	\$111.69	\$118.97	\$121.58	\$126.53	\$137.07	\$144.66	\$143.15	\$149.85	\$162.90	\$169.14	\$168.70	\$175.35 \$226.19
Diclofenac Sodium Voltaren® Diclofenac Sodium	\$102.73 \$46.60	\$108.71 \$28.26	\$118.89 \$24.95	\$124.34 \$20.38	\$155.07 \$21.61	\$172.67 \$19.61	\$133.87 \$20.57	\$155.62 \$18.94	\$195.30 \$23.26	\$83.99 \$16.03	\$115.22 \$14.62	\$117.84 \$13.91
Flurbiprofen Sodium Ocufen® Flurbiprofen Sodium	\$236.91 \$30.96	\$174.26 \$30.82	\$229.60 \$29.31	\$229.50 \$27.84	\$269.38 \$29.47	\$240.59 \$26.64	\$343.30 \$25.64	\$274.86 \$24.49	\$252.18 \$24.30	\$232.05 \$23.91	\$241.36 \$21.94	\$273.67 \$21.88
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail® Ketorolac Trometh	\$106.84 \$75.79 \$234.43	\$110.48 \$81.09 \$214.64	\$114.75 \$80.80 \$227.08	\$114.90 \$79.57 \$263.97	\$132.05 \$94.57 \$310.35	\$141.07 \$97.29 \$337.10	\$150.27 \$101.31 \$278.39	\$146.83 \$92.20 \$64.53	\$145.86 \$87.36 \$18.98	\$127.82 \$83.65 \$9.85	\$162.66 \$115.36 \$40.20	\$183.78 \$166.41 \$113.63 \$13.63
Nepafenac Nevanac® Ilevro®	\$76.98	\$80.73	\$80.23	\$76.46	\$86.22	\$85.58	\$91.08	\$95.39	\$103.79	\$104.15	\$105.32	\$114.44
<b>Total</b>	<b>\$86.78</b>	<b>\$90.48</b>	<b>\$90.69</b>	<b>\$90.31</b>	<b>\$102.81</b>	<b>\$105.96</b>	<b>\$110.68</b>	<b>\$109.92</b>	<b>\$100.00</b>	<b>\$92.23</b>	<b>\$91.97</b>	<b>\$94.88</b>
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	\$88.02	\$91.82	\$92.09	\$91.80	\$104.49	\$107.79	\$112.99	\$112.48	\$102.37	\$94.33	\$94.22	\$97.19
Total Xibrom®/Bromday®/Prolensa®	\$111.69	\$118.97	\$121.58	\$126.53	\$137.07	\$144.66	\$143.15	\$149.85	\$162.90	\$169.14	\$168.70	\$177.56

APPENDIX 9

OPHTHALMIC NSAIDS  
AVERAGE SELLING PRICE PER PRESCRIPTION  
UNITED STATES

	2011				2012				2013			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium												
Xibrom®	\$213.83	\$277.12	\$31.55	\$16.00	\$6.35	\$1.84	\$15.68	\$20.61				
Bromday®	\$116.31	\$114.78	\$127.11	\$147.57	\$157.05	\$171.14	\$175.88	\$178.74	\$177.72	\$169.83	\$155.61	\$18.56
Prolensa®										\$238.92	\$172.61	\$157.18
Bromfenac Sodium		\$381.98	\$145.79	\$153.50	\$153.30	\$148.78	\$143.69	\$165.77	\$169.64	\$174.37	\$162.32	\$173.39
Diclofenac Sodium												
Voltaren®	\$136.26	\$152.54	\$106.71	\$100.61	\$75.85	\$28.67	\$7.37	\$11.67				
Diclofenac Sodium	\$13.88	\$13.06	\$11.78	\$12.69	\$10.85	\$10.70	\$10.91	\$9.95	\$9.87	\$9.62	\$9.16	\$8.87
Flurbiprofen Sodium												
Ocufer®	\$186.45	\$374.72	\$354.82	\$403.55	\$861.42	\$434.89	\$468.39	\$501.94	\$580.38	\$367.55	\$397.58	\$434.34
Flurbiprofen Sodium	\$21.02	\$20.26	\$17.84	\$17.98	\$15.37	\$15.59	\$14.58	\$14.85	\$14.70	\$14.82	\$14.42	\$13.51
Ketorolac Trometh												
Acular®	\$219.90	\$211.25	\$248.59	\$267.56	\$318.09	\$343.22	\$331.03	\$321.23	\$464.68	\$477.05	\$320.99	\$578.51
Acular LS®	\$194.27	\$176.40	\$211.42	\$177.42	\$212.92	\$223.92	\$255.45	\$252.61	\$269.73	\$234.22	\$268.58	\$389.34
Acular PF®												
Acuvail®	\$114.35	\$121.89	\$149.52	\$157.70	\$163.73	\$124.29	\$139.57	\$168.52	\$196.54	\$198.96	\$223.26	\$225.01
Ketorolac Trometh	\$13.51	\$13.65	\$12.76	\$13.20	\$11.18	\$10.95	\$11.90	\$10.71	\$10.31	\$10.43	\$10.21	\$9.98
Nepafenac												
Nevanac®	\$130.98	\$130.24	\$129.57	\$132.84	\$131.00	\$132.27	\$133.50	\$137.21	\$148.73	\$149.20	\$145.80	\$145.70
Ilevro®									\$1,587.43	\$149.51	\$141.10	\$131.76
<b>Total</b>	<b>\$92.24</b>	<b>\$81.51</b>	<b>\$75.37</b>	<b>\$83.51</b>	<b>\$82.28</b>	<b>\$82.68</b>	<b>\$83.83</b>	<b>\$86.34</b>	<b>\$89.12</b>	<b>\$85.65</b>	<b>\$81.31</b>	<b>\$78.78</b>
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	\$94.61	\$83.67	\$77.37	\$85.72	\$84.72	\$85.12	\$86.41	\$88.93	\$91.80	\$88.27	\$83.87	\$81.31
Total Xibrom®/Bromday®/Prolensa®	\$165.95	\$141.49	\$123.62	\$145.16	\$155.86	\$170.70	\$173.70	\$178.62	\$177.63	\$178.43	\$166.30	\$144.84
	2014				2015			2013 Q2 - 2015 Q3				
Bromfenac Sodium												
Xibrom®												N/M*
Bromday®	\$9.73	\$10.23	\$6.76					\$50.92	\$153.00			
Prolensa®	\$172.35	\$173.88	\$171.41	\$168.10	\$189.36	\$182.32	\$184.61	\$175.87				
Bromfenac Sodium	\$202.89	\$154.40	\$129.45	\$137.38	\$128.92	\$129.01	\$113.88	\$151.33				
Diclofenac Sodium												
Voltaren®												N/M*
Diclofenac Sodium	\$8.14	\$7.55	\$6.90	\$6.77	\$6.89	\$6.37	\$8.15	\$7.79				
Flurbiprofen Sodium												
Ocufer®	\$369.97	\$568.86	\$893.07	\$436.26	\$434.89	\$477.71	\$918.42	\$400.40				
Flurbiprofen Sodium	\$13.83	\$12.95	\$12.34	\$12.41	\$13.35	\$13.01	\$12.32	\$13.27				
Ketorolac Trometh												
Acular®	\$648.04	\$567.86	\$464.25	\$503.26	\$681.94	\$491.11	\$532.29	\$542.66				
Acular LS®	\$355.69	\$409.61	\$347.71	\$393.77	\$546.89	\$569.80	\$655.00	\$385.31				
Acular PF®												N/M*
Acuvail®	\$283.98	\$281.75	\$283.87	\$278.83	\$301.63	\$313.65	\$331.73	\$258.30				
Ketorolac Trometh	\$13.37	\$13.60	\$15.24	\$16.78	\$20.14	\$19.26	\$18.15	\$14.87				
Nepafenac												
Nevanac®	\$158.06	\$159.77	\$179.56	\$191.89	\$206.89	\$235.78	\$241.99	\$166.70				
Ilevro®	\$153.72	\$154.37	\$163.21	\$172.97	\$186.04	\$200.62	\$202.83	\$172.49				
<b>Total</b>	<b>\$90.13</b>	<b>\$86.76</b>	<b>\$88.79</b>	<b>\$92.23</b>	<b>\$98.12</b>	<b>\$97.28</b>	<b>\$97.38</b>	<b>\$89.74</b>				
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	\$93.10	\$89.51	\$91.71	\$95.26	\$101.49	\$100.66	\$100.76	\$92.70				
Total Xibrom®/Bromday®/Prolensa®	\$169.48	\$172.91	\$171.11	\$168.01	\$189.31	\$182.49	\$184.60	\$172.82				

Notes & Sources

\* Value is not meaningful since sales data does not show any sales during this period.  
Calculated as Total Sales / Total Prescriptions Dispensed. From Appendix 2 and Appendix 5

**APPENDIX 10**  
**OPHTHALMIC NSAIDS**  
**AVERAGE SELLING PRICE PER MILLILITER OF DRUG**  
**UNITED STATES**

	2005			2006				2007				
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Bromfenac Sodium Xibrom® Bromday® Prolensa® Bromfenac Sodium	\$14.97	\$14.88	\$14.89	\$18.28	\$24.80	\$24.79	\$25.00	\$25.79	\$26.99	\$27.62	\$28.76	
Diclofenac Sodium Voltaren® Diclofenac Sodium	\$10.34 \$11.35	\$10.30 \$11.16	\$10.17 \$11.02	\$10.64	\$10.78	\$10.67	\$10.62	\$12.30	\$12.31	\$12.05	\$12.32	
Flurbiprofen Sodium Ocufen® Flurbiprofen Sodium	\$6.00 \$1.68	\$6.16 \$1.66	\$6.20 \$1.65	\$6.66 \$1.66	\$6.65 \$1.60	\$6.56 \$1.59	\$6.67 \$1.60	\$6.80 \$1.56	\$6.57 \$1.56	\$3.80 \$1.53	\$3.48 \$1.52	
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail® Ketorolac Trometh	\$10.90 \$11.31 \$8.81	\$10.83 \$11.28 \$8.69	\$10.75 \$11.25 \$8.69	\$11.47 \$11.99 \$9.17	\$11.72 \$12.19 \$9.63	\$11.63 \$12.16 \$9.64	\$11.53 \$12.01 \$9.61	\$12.07 \$12.74 \$9.92	\$12.48 \$13.19 \$10.44	\$12.38 \$13.17 \$10.11	\$12.29 \$12.97 \$10.40	
Nepafenac Nevanac® Ilevyo®		\$20.83	\$20.78	\$20.73	\$20.60	\$20.48	\$20.49	\$21.30	\$21.85	\$21.88	\$21.92	
<b>Total</b>	<b>\$9.89</b>	<b>\$10.03</b>	<b>\$10.79</b>	<b>\$11.78</b>	<b>\$12.40</b>	<b>\$12.55</b>	<b>\$12.69</b>	<b>\$13.54</b>	<b>\$14.14</b>	<b>\$14.39</b>	<b>\$14.69</b>	
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	\$10.97	\$11.13	\$12.04	\$13.18	\$13.82	\$15.92	\$14.12	\$14.97	\$15.58	\$15.83	\$16.21	
Total Xibrom®/Bromday®/Prolensa®	\$14.97	\$14.88	\$14.89	\$18.28	\$24.80	\$24.79	\$25.00	\$25.79	\$26.99	\$27.62	\$28.76	
	2008				2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium Xibrom® Bromday® Prolensa® Bromfenac Sodium	\$29.92	\$31.58	\$31.58	\$33.67	\$35.21	\$37.47	\$37.54	\$39.44	\$41.86	\$43.89	\$45.19	\$47.98 \$71.27
Diclofenac Sodium Voltaren® Diclofenac Sodium	\$11.24 \$3.55	\$10.54 \$3.22	\$11.11 \$2.90	\$11.39 \$2.60	\$12.44 \$2.40	\$11.91 \$2.31	\$13.10 \$2.25	\$13.06 \$2.06	\$12.58 \$1.96	\$12.46 \$1.75	\$12.41 \$1.60	\$12.36 \$1.64
Flurbiprofen Sodium Ocufen® Flurbiprofen Sodium	\$4.66 \$1.51	\$4.10 \$1.48	\$3.95 \$1.47	\$3.91 \$1.46	\$4.00 \$1.57	\$5.02 \$1.43	\$4.61 \$1.44	\$3.60 \$1.42	\$5.47 \$1.38	\$5.91 \$1.37	\$6.05 \$1.37	\$6.36 \$1.38
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail® Ketorolac Trometh	\$13.00 \$13.93 \$10.77	\$13.21 \$13.61 \$11.08	\$13.42 \$14.62 \$11.14	\$13.72 \$14.99 \$11.54	\$14.70 \$15.73 \$12.37	\$15.83 \$17.67 \$13.41	\$16.62 \$18.56 \$13.34	\$15.92 \$18.66 \$13.44	\$14.03 \$16.28 \$14.73	\$14.39 \$15.87 \$16.31	\$14.37 \$16.24 \$16.75	\$13.95 \$16.80 \$8.78 \$1.90
Nepafenac Nevanac® Ilevyo®	\$23.26	\$23.35	\$23.31	\$23.31	\$24.62	\$24.87	\$26.68	\$27.06	\$29.13	\$29.35	\$31.00	\$32.80
<b>Total</b>	<b>\$15.08</b>	<b>\$15.33</b>	<b>\$15.95</b>	<b>\$16.56</b>	<b>\$17.59</b>	<b>\$18.86</b>	<b>\$19.15</b>	<b>\$14.13</b>	<b>\$13.21</b>	<b>\$14.39</b>	<b>\$15.02</b>	<b>\$16.25</b>
Total (Excluding Flurbiprofen Sodium products and Acular PF®)	\$16.59	\$16.80	\$17.53	\$18.24	\$19.17	\$20.62	\$20.90	\$15.01	\$14.12	\$15.55	\$16.25	\$17.62
Total Xibrom®/Bromday®/Prolensa®	\$29.92	\$31.58	\$31.58	\$33.67	\$35.21	\$37.47	\$37.54	\$39.44	\$41.86	\$43.89	\$45.19	\$48.86





**APPENDIX 11**  
**OPHTHALMIC NSAIDS**  
**TOTAL PROMOTIONAL SPENDING**  
**UNITED STATES**

	2005			2006				2007			
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium Xibrom® Bromday® Prolensa® Bromfenac Sodium	\$921	\$3,748	\$2,860	\$5,070	\$5,622	\$3,524	\$3,795	\$4,090	\$4,904	\$3,735	\$4,148
Diclofenac Sodium Voltaren® Diclofenac Sodium	\$1,164	\$999	\$1,853	\$1,998	\$1,884	\$1,004	\$414	\$12	\$13		\$6 \$0
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail® Ketorolac Trometh	\$529 \$6,324 \$12	\$622 \$5,426	\$539 \$7,608 \$24	\$352 \$6,744	\$929 \$6,426	\$629 \$6,506	\$261 \$7,669	\$572 \$6,289	\$295 \$9,779	\$452 \$8,191	\$169 \$9,152
Nepafenac Nevanac® Ilevro®		\$1,481	\$6,923	\$7,774	\$7,443	\$4,307	\$4,302	\$9,306	\$4,563	\$5,275	\$3,030
<b>Total</b>	<b>\$8,950</b>	<b>\$12,276</b>	<b>\$19,807</b>	<b>\$21,938</b>	<b>\$22,304</b>	<b>\$15,970</b>	<b>\$16,441</b>	<b>\$20,269</b>	<b>\$19,554</b>	<b>\$17,653</b>	<b>\$16,507</b>
<b>Total (Excluding Acular PF®)</b>	<b>\$8,938</b>	<b>\$12,276</b>	<b>\$19,782</b>	<b>\$21,938</b>	<b>\$22,304</b>	<b>\$15,970</b>	<b>\$16,441</b>	<b>\$20,269</b>	<b>\$19,554</b>	<b>\$17,653</b>	<b>\$16,507</b>
<b>Total Xibrom®/Bromday®/Prolensa®</b>	<b>\$921</b>	<b>\$3,748</b>	<b>\$2,860</b>	<b>\$5,070</b>	<b>\$5,622</b>	<b>\$3,524</b>	<b>\$3,795</b>	<b>\$4,090</b>	<b>\$4,904</b>	<b>\$3,735</b>	<b>\$4,148</b>

	2008				2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium Xibrom® Bromday® Prolensa® Bromfenac Sodium	\$5,884	\$8,324	\$5,549	\$6,381	\$7,607	\$6,930	\$9,210	\$7,271	\$11,789	\$17,243	\$13,924	\$9,241 \$13,277
Diclofenac Sodium Voltaren® Diclofenac Sodium	\$6		\$1				\$9		\$180 \$282	\$121		\$70
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail® Ketorolac Trometh	\$120 \$7,114 \$69	\$695 \$5,653	\$92 \$10,131	\$250 \$5,704 \$7	\$288 \$7,978	\$46 \$17,451	\$633 \$6,544	\$42 \$1,221	\$886 \$442		\$113	\$230
Nepafenac Nevanac® Ilevro®	\$5,944	\$6,185	\$7,923	\$3,925	\$5,869	\$5,730	\$8,309	\$6,967	\$6,576	\$5,010	\$3,359	\$4,491
<b>Total</b>	<b>\$19,136</b>	<b>\$20,857</b>	<b>\$23,697</b>	<b>\$16,267</b>	<b>\$21,742</b>	<b>\$30,157</b>	<b>\$26,978</b>	<b>\$18,414</b>	<b>\$21,817</b>	<b>\$23,758</b>	<b>\$17,997</b>	<b>\$27,730</b>
<b>Total (Excluding Acular PF®)</b>	<b>\$19,067</b>	<b>\$20,857</b>	<b>\$23,697</b>	<b>\$16,260</b>	<b>\$21,742</b>	<b>\$30,157</b>	<b>\$26,978</b>	<b>\$18,414</b>	<b>\$21,817</b>	<b>\$23,758</b>	<b>\$17,997</b>	<b>\$27,730</b>
<b>Total Xibrom®/Bromday®/Prolensa®</b>	<b>\$5,884</b>	<b>\$8,324</b>	<b>\$5,549</b>	<b>\$6,381</b>	<b>\$7,607</b>	<b>\$6,930</b>	<b>\$9,210</b>	<b>\$7,271</b>	<b>\$11,789</b>	<b>\$17,243</b>	<b>\$13,924</b>	<b>\$22,518</b>



**APPENDIX 12**

**BRANDED OPHTHALMIC NSAIDS  
TOTAL PROMOTIONAL SPENDING AS A PERCENT OF TOTAL SALES  
UNITED STATES**

	2005			2006				2007				
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Bromfenac Sodium Xibrom® Bromday® Prolensa®	161.1%	281.6%	136.6%	153.5%	110.6%	62.9%	55.2%	53.3%	50.5%	35.0%	35.5%	
Diclofenac Sodium Voltaren®	22.2%	20.6%	47.4%	58.4%	52.1%	29.8%	12.8%	0.3%	0.4%		0.2%	
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail®	3.3%	4.6%	4.7%	3.2%	7.2%	5.7%	2.7%	5.6%	2.5%	4.2%	1.8%	
Nepafenac Nevanac® Ilevro®		240.4%	124.3%	117.2%	98.6%	58.1%	56.1%	118.8%	50.7%	54.7%	28.5%	
<b>Total</b>	<b>28.1%</b>	<b>39.0%</b>	<b>60.1%</b>	<b>64.3%</b>	<b>55.0%</b>	<b>40.4%</b>	<b>40.6%</b>	<b>46.8%</b>	<b>38.8%</b>	<b>34.6%</b>	<b>32.3%</b>	
<b>Total Xibrom®/Bromday®/Prolensa®</b>	<b>161.1%</b>	<b>281.6%</b>	<b>136.6%</b>	<b>153.5%</b>	<b>110.6%</b>	<b>62.9%</b>	<b>55.2%</b>	<b>53.3%</b>	<b>50.5%</b>	<b>35.0%</b>	<b>35.5%</b>	
	2008				2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Bromfenac Sodium Xibrom® Bromday® Prolensa®	46.7%	56.5%	35.7%	36.8%	38.5%	30.5%	39.1%	29.9%	45.9%	57.3%	42.6%	27.1% 663.0%
Diclofenac Sodium Voltaren®	0.4%						4.8%		182.6%			
Ketorolac Trometh Acular® Acular LS® Acular PF® Acuvail®	1.2%	6.0%	0.9%	2.6%	2.7%	0.4%	5.1%	0.6%	46.3%		11.8%	24.8%
Nepafenac Nevanac® Ilevro®	55.6%	49.2%	61.7%	34.5%	45.4%	39.4%	52.8%	41.7%	36.9%	24.4%	16.3%	19.6%
<b>Total</b>	<b>37.1%</b>	<b>35.3%</b>	<b>40.3%</b>	<b>28.0%</b>	<b>33.0%</b>	<b>40.3%</b>	<b>35.3%</b>	<b>24.5%</b>	<b>35.2%</b>	<b>37.9%</b>	<b>27.9%</b>	<b>40.4%</b>
<b>Total Xibrom®/Bromday®/Prolensa®</b>	<b>46.7%</b>	<b>56.5%</b>	<b>35.7%</b>	<b>36.8%</b>	<b>38.5%</b>	<b>30.5%</b>	<b>39.1%</b>	<b>29.9%</b>	<b>45.9%</b>	<b>57.3%</b>	<b>42.6%</b>	<b>62.4%</b>





APPENDIX 13

QUARTERLY PROLENSA® DATA  
UNITED STATES

	Sales	Total Prescriptions	Extended Units Sold	ASP per Prescription	ASP per Milliliter of Drug	Promotional Spending
	[A]	[B]	[C]	[D]	[E]	[F]
Q2 2013	\$4,786	20,034	76,597	\$238.92	\$62.49	\$12,282
Q3 2013	\$16,492	95,546	243,986	\$172.61	\$67.59	\$15,727
Q4 2013	\$23,023	146,478	325,001	\$157.18	\$70.84	\$11,662
Q1 2014	\$25,751	149,409	351,899	\$172.35	\$73.18	\$14,848
Q2 2014	\$28,456	163,653	395,300	\$173.88	\$71.98	\$13,880
Q3 2014	\$28,667	167,241	400,754	\$171.41	\$71.53	\$16,133
Q4 2014	\$28,473	<b>169,388</b>	398,494	\$168.10	\$71.45	\$16,070
Q1 2015	\$29,713	156,919	396,020	\$189.36	\$75.03	\$10,021
Q2 2015	\$30,360	166,337	436,649	\$182.52	\$69.53	\$11,301
Q3 2015	<b>\$31,181</b>	168,902	<b>453,386</b>	\$184.61	\$68.77	\$9,398
<b>Total</b>						
2013 Q2 – Q4	\$44,302	262,058	645,584	\$169.05	\$68.62	\$39,670
2014	\$111,347	649,691	1,546,447	\$171.38	\$72.00	\$60,931
2015 Q1 – Q3	\$91,254	492,158	1,286,055	\$185.42	\$70.96	\$30,719
<b>Grand Total</b>	<b>\$246,902</b>	<b>1,403,907</b>	<b>3,478,086</b>	<b>\$175.87</b>	<b>\$70.99</b>	<b>\$131,320</b>

Notes & Sources:

Extended units are defined as the number of milliliters of liquid sold. (Ex. 2192.)

Peak quarterly values are in bold.

[A] From Appendix 2. Values in thousands of USD.

[B] From Appendix 5.

[C] From Appendix 8.

[D] From Appendix 9.

[E] From Appendix 10.

[F] From Appendix 11. Values in thousands of USD.