

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC
Petitioners,

v.

CIPLA LTD.
Patent Owner and Licensee

Case: IPR2017-00807
U.S. Patent No. 8,168,620

**DECLARATION OF JOHN C. STAINES, JR. IN SUPPORT OF
PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE**

MARCH 6, 2018

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I. QUALIFICATIONS

1. I am a Director and Principal in the Washington, DC office of Navigant Economics LLC (“Navigant Economics”), a subsidiary of Navigant Consulting, Inc., an international consulting firm. Navigant Economics provides expertise primarily in economics, finance, public policy, and business strategy. I am knowledgeable in the fields of microeconomics, industrial organization, financial economics, and statistics, and have particular expertise in applying the tools of these disciplines to legal disputes arising in the pharmaceutical and related industries.

2. My educational background includes a B.A. in Economics and M.P.M. in Public Policy from the University of Maryland and an M.B.A. in Business Economics and Finance from the University of Chicago. Since 1984, I have worked as a consultant on economic, financial, statistical, and general business issues arising in commercial litigation disputes. My work primarily has involved analyzing competitive issues and estimating commercial damages associated with various types of legal and regulatory matters, most often relating to the pharmaceutical industry. I have been accepted as an expert witness in Federal Court to opine on economic issues arising in pharmaceutical-related patent and antitrust litigation. A copy of my curriculum vitae is included as Appendix A to this report.

3. Navigant Economics is being compensated for the work I perform in connection with this case at my standard hourly rate of \$535. Part of the work underlying this report was performed by staff of Navigant Economics working under my direction. Payment of fees to Navigant Economics associated with work performed on this matter is not contingent upon or in any way affected by the nature of my opinions or the outcome of this litigation.

II. OBJECTIVES

4. I have been retained by the Petitioners in this matter, Argentum Pharmaceuticals LLC. (“Argentum”) to render independent expert opinions concerning the existence and sources of any commercial success that may be associated with the allergic rhinitis (“AR”) treatments, Dymista[®] and Duonase (and certain Duonase “imitator” products), as they may relate to the obviousness of the technology claimed by U.S. Patent Number 8,168,620 (the “’620 patent”), entitled “Combination of Azelastine and Steroids.”¹ Dymista[®] was marketed in the United States as an AR treatment by Meda AB (“Meda”),² and currently is marketed by Mylan, Inc.

¹ Exhibit 1001.

² Exhibit 2068, p. 2.

(“Mylan”).³ Duonase is marketed in India by Cipla Ltd. (“Cipla” and “Patent Owner”).⁴ The ’620 patent was issued to Cipla on May 1, 2012,⁵ and is exclusively licensed in the United States to Mylan.⁶ On February 2, 2017, Argentum petitioned the Patent Trial and Appeal Board (“PTAB”) to institute an *inter partes* review of

³ Exhibit 2149, ¶17. Meda was acquired by Mylan in 2016. (Exhibit 2100.)

⁴ Exhibits 2072, 2087, 2088, 2126.

⁵ Exhibit 1001.

⁶ Exhibit 2049. Cipla exclusively licensed intellectual property covering azelastine/fluticasone combination nasal spray in the United States and certain other territories to MedPointe Healthcare, Inc. on November 13, 2006. (Exhibit 2019). This license was transferred to Meda AB upon Meda’s acquisition of MedPointe in 2007 (Exhibit 1057; Exhibit 2050), and subsequently to Mylan upon Mylan’s acquisition of Meda in 2016 (Exhibit 2100).

the validity of claims 1, 4-6, 24-26, 29, and 42-44 of the '620 patent,⁷ which the PTAB did institute on October 21, 2017.⁸

5. I understand that the commercial success of a product allegedly containing technology claimed by an asserted patent may in some cases represent a secondary *indicium* that the patented technology was nonobvious.⁹ In this context, counsel for Argentum has asked me to evaluate the opinions and supporting evidence expressed in the Declaration of John C. Jarosz,¹⁰ in which Mr. Jarosz con-

⁷ Argentum Pharmaceuticals LLC v. Cipla, Ltd., U.S. Patent and Trademark Office, Patent Trial and Appeals Board, IPR2017-00807, Petition for *Inter Partes* Review, filed on February 2, 2017 (“Petition”), p. 2.

⁸ Argentum Pharmaceuticals LLC v. Cipla, Ltd., U.S. Patent and Trademark Office, Patent Trial and Appeals Board, IPR2017-00807, Paper No. 12, Decision, Institution of *Inter Parties* Review, entered on October 21, 2017, pp. 26-27.

⁹ *Graham v. John Deere, Co.*, 383 U.S. 1, 17–18 (1966).

¹⁰ Second Declaration of John C. Jarosz, filed on November 20, 2017 as Exhibit 2149 (“Jarosz Declaration”).

cluded that Dymista[®] and Duonase (in combination with its “imitator” products in India) represent “marketplace successes” due, in large part, to features claimed by the ’620 patent.¹¹ My evaluation involves assessing: (1) whether there is sufficient evidence to conclude that Dymista[®] and Duonase/imitators have achieved a level and type of commercial success that would have motivated others to have developed a combination azelastine/fluticasone treatment as described by the challenged claims of the ’620 patent had that technology been obvious; and (2) whether any such commercial success that may exist has a causal nexus to the challenged claims of the ’620 patent.

III. SUMMARY OF FINDINGS

6. This evaluation, and specifically my review of the Jarosz Declaration, leads me to the opinion that there is insufficient evidence to conclude that Dymista[®] or Duonase have achieved commercial success for the following reasons.

¹¹ *Id.*, at ¶¶4, 114.

- Mr. Jarosz' analysis of Dymista®'s "Absolute Success," based solely on Cumulative Average Growth Rates in dollar sales and prescriptions, does not support his commercial success conclusion.
 - Cumulative Average Growth Rates by themselves do not address the significance and commercial success of Dymista®'s sales.
 - The average revenue growth rate is overstated because it is based on Dymista®'s \$92 million to \$157 million nominal gross revenues rather than its \$63 million to \$84 million actual net revenues, which reflects deduction of insurer rebates and other discounts.
 - Use of cumulative average growth rates masks the prompt flattening and then downward trend in Dymista® sales over time.
- Mr. Jarosz' analysis of Dymista®'s "Relative Success" compared to other antihistamine and corticosteroid nasal sprays used to treat AR does not support his commercial success conclusion.
 - Comparison only to other brand product sales is not meaningful because sales of most brands have been significantly eroded by competition from generic equivalents prior to and continuing after Dymista®'s launch.
 - Dymista®'s sales revenues are not significant when appropriately compared to sales revenues achieved by comparable brand AR nasal sprays before the entry of their generic versions.

- Dymista[®]'s share of combined brand and generic sales revenues is not meaningful because of distortion by: 1) the large number of generic alternatives that compete on price rather than on marketing; and 2) Mr. Jarosz' calculation being based on nominal gross revenues rather than actual net revenues.
- Dymista[®]'s share of combined brand and generic nasal spray prescription quantities, ranging from 1.2% to 1.8%, does not support a conclusion that Dymista[®]'s has been a "relative success."
- Even Dymista[®]'s <2% prescription share overstates the significance of its sales because it excludes OTC versions of these products, oral antihistamines, and other AR treatments.
- Other factors Mr. Jarosz did not consider indicate that Dymista[®] sales have not been significant, and thus, are not a commercial success.
 - Dymista[®] gross revenues of \$92 million to \$157 million are not large relative to brand pharmaceutical products generally, which typically require large sales revenues to recover significant past R&D investment and to fund current marketing activities.
 - Dymista[®]'s actual 2013 to 2015 net revenue of \$63 million to \$84 million are not significant compared to Meda's pre-launch net revenue forecast of \$155 million to \$544 million.
 - The estimated \$52 million present value of operating profits generated from Dymista[®] sales over 2012 to 2017 is insufficient to

recover its conservatively-estimated \$98 million in R&D investment.

- Mr. Jarosz’s analysis of sales made in India by Cipla’s Duonase and its “imitators” does not support a finding of commercial success.
 - Duonase does not contain edetate disodium, as required by claims 42 to 44 of the ’620 patent, and therefore, Mr. Jarosz’ conclusions regarding Duonase’s purported commercial success as an *indicium* of nonobviousness do not apply to these claims.
 - A useful invention in India is not necessarily a useful invention in the United States because developing the ’620 patent technology for marketing approval is far more rigorous and costly in the United States than it is in India.
 - The 23% average annual growth rate and 24% to 26% shares for combined sales of Duonase and 6 “imitator” products are inapplicable because another developer would not have been motivated to develop the ’620 patent technology by imitator product sales the developer could not appropriate. The average growth rate was only 15% and sales shares only 12% for Duonase alone.
 - The 15% cumulate average growth rate in Duonase sales from 2004 to 2017 does not demonstrate the significance of those sales or whether the product has achieved absolute success.

- Duonase’s sales revenues have averaged just \$1.6 million per year since 2004, which reflects that it competes as a generic product. These sales are not significant compared to either U.S. Dymista[®] sales of \$92 million to \$157 million, or U.S. Dymista[®] royalty revenue received by Cipla, estimated to be \$12.6 million in 2014.
- Mr. Jarosz does not consider whether Duonase sales are significant relative to operating costs and R&D investment, or to prelaunch forecasts/expectations.
- Duonase’s 12% sales share is overstated because it excludes other AR nasal spray products (other than azelastine, fluticasone, and mometasone), prescription oral antihistamines, OTC products, and other AR treatments from the marketplace denominator.
- Mr. Jarosz incorrectly infers that the commitment of resources by Apotex and the Duonase imitators to launch versions of Dymista[®] and Duonase is indicative of commercial success because these generic competitors bear much less significant cost, time, and risk than would be borne by an alternative developer of the ’620 patent technology.

7. My analysis leads me to the further conclusion that those commercial sales Dymista[®] and Duonase have generated do not have a causal nexus to the ’620 patent claims for the following reasons.

- If others would have been blocked from developing the azelastine/fluticasone combination drug by the “Hettche” and/or “Phillipps”

patents, relating to azelastine and fluticasone, respectively, Dymista®'s commercial performance has no nexus to the challenged claims of the '620 patent.

- Dymista® is not significantly differentiated from existing AR treatments, including concurrent use of uncombined antihistamines and corticosteroids, as reflected in insurers' resistance to reimburse it.
- Meda substantially reduced Dymista®'s effective price by providing large rebates to insurers and extensive copayment subsidies to patients.
- Dymista® benefited from an increasingly high share of voice in marketing to physicians, as generic entry and OTC conversion reduced marketing by other prescription brands, and as Meda's salesforce shifted promotion from Astepro® to Dymista®.
- Meda's marketing support for Dymista® did not claim any clinical superiority over concurrent use of uncombined azelastine and fluticasone products.
- Duonase is effectively supplied as a generic product that competes primarily on price rather than on any differentiated product features attributable to the '620 patent. Its prices are similar to the "imitator" and numerous other AR nasal spray products supplied by numerous "branded generic" competitors in India.

- In contrast to the U.S. marketplace, there is no standalone azelastine nasal spray in the Indian market, according to Mr. Jarosz' data, which suggests that some unknown portion of Duonase purchases could be made by those who are interested only in the azelastine component of the drug.
- The sales penetration by 10 non-imitator combination azelastine/fluticasone products in the Indian market suggests that some or all of Duonase's sales have not been driven by features unique to the '620 patent.
- Meda's licensing of the '620 patent from Cipla does not indicate a nexus to commercial success because Mr. Jarosz has not shown that the \$1.5 million fee was significant, that it represents the patent's value, or that it represents actual, rather than predicted, commercial success.

8. The opinions I express herein are based upon my personal knowledge, experience, and expertise, as well as upon evidence filed in this proceeding and my independent research in this case. This evidence consists of publicly-available information and documents collected by me and by my staff, as well as information I have requested and that has been provided to me by Petitioner's attorneys, which includes case filings, deposition transcripts and exhibits, and documents and data filed by the parties in this proceeding. Specifically, I have considered the exhibits identified throughout this Declaration,

including the Jarosz Declaration (Exhibit 2149) and documents referenced therein. The documents and data I cite in this Declaration are the types that economists consider to be reliable and upon which economists typically rely.

9. I reserve the right to amend or supplement my opinions based on further information I may receive after the date of this report, including, without limitation, documents and data filed by the parties, deposition transcripts and exhibits, legal submissions, affidavits/declarations, and expert declarations.

10. In the remaining sections of this Declaration I provide a detailed evaluation of Mr. Jarosz' conclusions and supporting analysis regarding the commercial success of products allegedly practicing the challenged claims of the '620 patent as an *indicium* that the claimed technology was nonobvious. I begin by describing the subject products, Dymista® and Duonase, and the products with which they compete. I then analyze the validity of Mr. Jarosz' opinion that the commercial sales performance of Dymista® in the United States, as well as Duonase and its imitators in India, represent a "commercial success" in the context of this obviousness inquiry. I also assess the commercial success significance Mr. Jarosz attributes to Apotex's development of a generic version of Dymista® in the United States, and the market launch of imitator Duonase products in India. Finally, I

examine Mr. Jarosz' analysis supporting his opinion of a nexus between the commercial performance of Dymista® and Duonase, and the challenged claims of the '620 patent, as well as the validity of Mr. Jarosz' inference of nexus from Meda's willingness to license the '620 patent from Cipla to allow it to develop Dymista®.

IV. PRODUCT BACKGROUND

11. The U.S. Food and Drug Administration ("FDA") granted Meda approval to market Dymista® for the treatment of seasonal AR on May 1, 2012.¹² Dymista® is a combination of two pre-existing nasal spray products separately approved for treating AR:¹³ 1) the antihistamine, azelastine hydrochloride, which is also marketed by Meda under the brand names Astelin® and Astepro® (Astepro® is a "sweetened" and higher-strength follow-on to Astelin®); and 2) the corticosteroid,

¹² Exhibit 2067.

¹³ Exhibit 1058 at p. 3. Astelin® was also approved for the treatment of Vaso-motor Rhinitis. Astepro® was also approved for the treatment of Perennial AR. Flonase® was also approved for the treatment of Perennial AR and of Non-Allergic Rhinitis. (*Id.*)

fluticasone propionate, marketed by GlaxoSmithKline under the brand name Flonase[®].¹⁴ As indicated in Ex. 1,¹⁵ generic versions of both Astelin[®] and Flonase[®] were available in generic form prior to Dymista[®]'s September 24, 2012 market launch.¹⁶ Generics for Astepro[®] became available less than two years later, in mid-2014.¹⁷

12. Concurrent administration of an antihistamine and a corticosteroid as separate products has been a common practice.¹⁸ Antihistamines are more effective at treating the “early phase response” associated with AR and

¹⁴ Exhibit 1076 at p. 24; Exhibit 1058 at p. 3.

¹⁵ I have prepared various tables and graphs to assist my analysis which are attached hereto and are referenced as “Ex. ____.” The underlying information I used to prepare my exhibits is specifically cited on each exhibit.

¹⁶ Exhibit 2093 at p. 2.

¹⁷ Exhibit 2053 at p. 194.

¹⁸ Exhibit 1003 at ¶¶68; Exhibit 2053 at pp. 70-71, 73; Exhibit 2073 at p. 1; Exhibit 2082 at p. 7.

corticosteroids are more effective at treating the “late phase response”.¹⁹ Similarly, decongestant products are often used concurrently with antihistamine products due to their complementary effects: decongestants work on congestion but not on other AR symptoms, while antihistamines tend to work best on itching, sneezing, and runny nose.²⁰ In fact, decongestants and antihistamines “were often combined with great effect in products like Allegra-D[®], Claritin-D[®], and Zyrtec-D[®].”²¹

13. Development of the combination azelastine/fluticasone product that eventually was marketed as Dymista[®] appears to have been initiated by MedPointe in 2002 as a life-cycle management strategy to extend the life of Astelin[®]’s patent protected sales.²² Astelin[®] had been approved for marketing in the United States since 1996,²³ and would eventually face entry by generic equivalents

¹⁹ Exhibit 1003 at ¶¶27-28, 52-55; Exhibit 2147 at ¶134.

²⁰ Exhibit 2147 at ¶¶42, 47.

²¹ Exhibit 2147 at ¶42; Exhibit 2053 at p. 100.

²² Exhibit 2048 at p. 4; Exhibit 2054 at pp. 10-11; Exhibit 2056 at p. 11.

²³ Exhibit 1058 at p. 3; Ex. 1.

in 2010.²⁴ In November 2006, MedPointe obtained an exclusive license from Cipla to intellectual property related to a azelastine/fluticasone combination product in the United States and certain other territories, which included Cipla's application for what later would be issued as the '620 patent.²⁵ After acquiring Medpointe in 2007,²⁶ Meda continued development of Dymista[®] through its 2012 FDA approval,²⁷ and then marketed the product up to its acquisition by Mylan in 2016.²⁸

14. Dymista[®] competes with a number of other pharmaceutical products that are used to treat AR, which primarily include antihistamine-only nasal sprays/tablets and corticosteroid-only nasal sprays, as well as decongestants, cromolyn, and leukotriene.²⁹ The intranasal formulations of corticosteroid

²⁴ Exhibit 1060; Exhibit 1061.

²⁵ Exhibit 2049 at pp. 1, 28.

²⁶ Exhibit 1057.

²⁷ *See, e.g.*, Exhibit 1058 at p. 1; Exhibit 2067.

²⁸ *See, e.g.*, Exhibits 2066, 2073, 2076, 2093, 2094, 2100; and Exhibit 2149 at ¶¶16-17.

²⁹ Exhibit 1003 at ¶29; Exhibit 2053 at pp. 67-74; Exhibit 2147 at ¶¶37-44, 47.

treatments are generally used to treat AR because of side effects associated with the oral forms.³⁰ The portion of these treatments supplied by generic producers has increased significantly over time, as generic versions of several brand AR treatments became available for the first time.³¹ The generic share of just nasal spray product prescriptions is reported to have increased from 40% in 2007/2008 to 70% in 2012, 80% in mid-2014,³² and further to 96% as of early 2017.³³

15. Ex. 1 shows that this shift corresponded to first-time generic launches for several brand nasal sprays, which include Flonase[®] in 2006, Nasarel[®] in 2007, Nasacort AQ[®] in 2011, Astelin[®] in 2010, Astepro[®], Patanase[®], and Rhinocort Aqua[®] in 2014, and Nasonex[®] in 2016.³⁴ In more recent years, some prescription nasal sprays have converted to OTC status,³⁵ including Nasacort AQ[®]

³⁰ Exhibit 2147 at ¶¶44, 138.

³¹ See, e.g., Exhibit 2079 at p. 14; Exhibit 2149 at ¶¶23-25 and Ex. 1.

³² Exhibit 2074 at p. 14, Exhibit 2075 at p. 2.

³³ Exhibit 2149 at Tab 1.

³⁴ Exhibit 2149 at Tab 1; Ex. 1.

³⁵ Ex. 1. See also, Ex. 2076 at p. 3.

in 2014, Flonase[®] in 2015, Rhinocort[®] Aqua and Nasonex[®] in 2016 and Veramyst[®] in 2017. Ex. 1 shows that as a result of these generic and OTC shifts, 6 of the 8 prescription nasal spray treatments (unique active ingredients) marketed in 2006 experienced first-time generic entry and/or OTC conversion over the next 10 years, leaving only 2 treatments, beclomethasone (Beconase AQ[®] / Qnasl[®])³⁶ and ciclesonide (Omnaris[®]/Zetonna[®]), marketing prescription nasal spray brands without bioequivalent generic competition by the end of 2016. As a result of Dymista[®]'s launch in 2012, the total number of prescription brand nasal sprays without generic competition in 2016 is now 3 (beclomethasone, ciclesonide, and azelastine/fluticasone).³⁷

16. Ex. 1 also shows that the non-sedating (“second-generation”) oral antihistamines used to treat AR, which include the “blockbusters,” Claritin[®]

³⁶ Beconase AQ[®] is a very small-selling old product that does not have patent protection, but no suppliers have elected to market a generic version of the product. (See Ex. 1 and Exhibit 1123.)

³⁷ Ex. 1 indicates that the antihistamine nasal spray, Patanase[®], launched after 2006 (in 2008) but experienced generic entry in 2014.

(loratadine), Clarinex[®] (desloratadine), Zyrtec[®] (cetirizine), Allegra[®] (fexofenadine),³⁸ and Xyzal[®] (levocetirizine), all experienced generic entry prior to 2011, at which time Claritin[®] and Zyrtec[®] were immediately converted to OTC status. Allegra[®] converted to OTC in early 2011 and Xyzal[®] very recently converted in early 2017, while Clarinex[®] still remains available only by prescription. The numerous first generation (sedating) antihistamines, such as Benadryl[®] (diphenhydramine) and Chlor-Trimeton[®] (chlorpheniramine), underwent generic entry and OTC conversion long before the non-sedating antihistamines.³⁹

17. Duonase is another combination azelastine/fluticasone nasal spray treatment for AR that purportedly also incorporates the '620 patent technology.⁴⁰ Patent Owner, Cipla, launched Duonase in India in April 2004.⁴¹ Since that time, 16 other combination/fluticasone nasal spray products have entered the Indian market,

³⁸ Exhibit 2147 at ¶¶38; Exhibit 2053 at p. 100.

³⁹ Exhibit 2147 at ¶¶38-39.

⁴⁰ Exhibit 2149 at ¶¶19, 55.

⁴¹ Exhibit 2072; Exhibit 2149 at ¶19.

of which 6 “imitator” products reportedly embody the challenged claims of the ’620 patent, leaving 10 which do not.⁴²

V. COMMERCIAL SUCCESS ANALYSIS

18. I understand that the commercial success of a product practicing features of a patented invention can represent a secondary *indiciu*m of that invention’s nonobviousness in the context of determining the patent’s legal validity.⁴³ The underlying rationale is that the product’s actual commercial success suggests others would have been motivated previously to have developed and marketed such a product before the Patent Owner, had the invention been obvious.⁴⁴ I further understand that a Patent Owner’s claim of the subject product’s actual “commercial success [is] usually shown by significant sales in a relevant market.”⁴⁵

⁴² Exhibit 2072; Exhibit 2123 at p. 23, 26; Exhibit 2124 at p. 5; and Exhibit 2149 at ¶20.

⁴³ *Graham v. John Deere, Co.*, 383 U.S. 1, 17–18 (1966).

⁴⁴ *See, e.g.*, Exhibit 1065 at pp. 10-11; Exhibit 1124 at p. 2.

⁴⁵ *J.T. Eaton & Co. Inc. v. Alt. Paste & Glue Co.*, 106 F.3d at 1563, 1571 (Fed. Cir. 1997).

Below I analyze whether the evidence presented by Patent Owner's expert in this case, Mr. Jarosz, is sufficient to support his opinions that U.S. sales of Dymista[®] and Indian sales of Duonase and its imitators have been significant and represent evidence of commercial success as a secondary *indicium* of nonobviousness.

19. Mr. Jarosz analyzes commercial success for Dymista[®] in the United States and Duonase in India in terms of "Absolute Success" and in terms of "Relative Success."⁴⁶ Based on this analysis, he concludes that Dymista[®] and Duonase (in combination with its "imitator" products) each represent a "marketplace success,"⁴⁷ which presumably equates to the "commercial success" he has been tasked to analyze. In the sections below, I evaluate Mr. Jarosz' conclusions supporting his analysis regarding Dymista[®]'s and then Duonase's alleged absolute and relative success.

⁴⁶ Exhibit 2149 at ¶¶37-39, 50-54 ("Absolute Success"). 40-49, 55-56 ("Relative Success").

⁴⁷ Exhibit 2149 at ¶¶4, 35, 114.

A. Mr. Jarosz Has Not Shown Dymista® to be an “Absolute Success”

20. The evidence Mr. Jarosz presents to support his opinion that Dymista®’s sales represent an “absolute success” consists exclusively of his calculations showing that Dymista® prescriptions grew at an average annual rate of 14.5%, from 641,212 in 2013 to 963,299 in 2016, and that its reported sales revenue grew at an average annual rate of 30.9%, from \$92 million in 2013 to \$157 million in 2015.⁴⁸ In my opinion, this analysis is insufficient to support that Dymista® is an absolute success for the reasons discussed below.

1. Average Growth Rates Alone Do Not Demonstrate Absolute Success

21. Mr. Jarosz’ calculation of the average annual growth rates in Dymista®’s sales revenue and prescriptions to assess whether those sales levels are an absolute success begs the question of how he has determined that these growth

⁴⁸ Exhibit 2149 at ¶¶38-39. Mr. Jarosz presents full-year prescription data for the years 2012 through 2016 (and the first 4 months of 2017), but full-year revenue data for 2012 to only 2015 (and the first 4 months of 2016). (Exhibit 2149 at Tabs 1 and 2.) He does not explain why he has not included full-year 2016 for analysis of sales revenue, even though has done so for prescriptions.

rates are indicative of absolute success. Any new product is bound to have positive average growth rates at the beginning of its lifecycle when measured from a small initial sales base, and Mr. Jarosz provides no basis to consider 14.5% and 30.9% to be an absolute success or an absolute failure for the first years of sales.

22. Moreover, these growth rate averages mask the more informative trend in the individual year-to-year growth rates that underlie the averages. Specifically, Ex. 2 shows that the 14.5% average annual growth in Dymista[®] prescriptions reflects a 38.8% increase in 2014, a 9.3% increase in 2015, and a decline of -1.0% in 2016. Mr. Jarosz' data for the first 4 months of 2017 indicate another -12.1% annualized decline in prescriptions, which if applicable to all of 2017, would reduce Mr. Jarosz' 14.5% average for 2013 to 2016 to a 7.2% average for 2013 to 2017. Ex. 2 also shows that Dymista[®]'s 30.9% average growth rate in sales revenue from 2013 to 2015 reflects an increase of 41.8% in 2014 that declines to 20.9% in 2015.⁴⁹ (These sales revenue growth rates are significantly overstated for reasons discussed in Section V.A.2., below.)

⁴⁹ Mr. Jarosz' 30.9% average revenue growth rate exceeds his 14.5% average prescription growth rate based at least in part because the 30.9% revenue rate is based on 2 years of growth (2013 to 2015) while the 14.5% prescription

... (Continued)

23. More fundamentally, however, the average growth rates Mr. Jarosz reports do not address the relevant question of whether the observed sales are sufficiently significant to have motivated others to have developed such a product based on the '620 patent technology. The relevant sales metric that addresses the motivation of others to invest in development is the sales *levels* resulting from those growth rates, not the growth rates themselves. Especially for relatively new products, cumulative average growth rates are generally uninformative as a measure of sales significance because they are highly sensitive to arbitrary selection of the initial base value from which, and the time period over which, they are calculated.

24. Consequently, whether an observed growth rate is significant depends on whether the sales levels associated with the growth rate are significant, which is circular. For example, Mr. Jarosz' determination that a 30.9% revenue

... (Continued)

rate is based on 3 years of growth (2013 to for 2016). Because growth rates generally decline over time, adding a 3rd year of growth (i.e., 2016) to the revenue average would likely reduce it to below 30.9%. This likelihood is further supported by the fact that prescriptions grew at slower rate (they actually declined) in the 3rd year (2016) than in the first 2 years (see Ex. 2).

growth rate by itself represents an absolute success would unreasonably indicate that a drug registering a sales increase from \$92 *thousand* in 2013 to \$180 *thousand* in 2015 is more successful than Dymista[®], with its sales increase from \$92 million to \$157 million over those years, because the former represents a 40.0% average annual rate of growth,⁵⁰ while Dymista[®] achieved only 30.9% average annual growth. Conversely, Mr. Jarosz' methodology would imply a drug with sales increasing from \$918 million in 2013 to \$1.3 *billion* in 2015 would be less successful than Dymista[®]'s corresponding \$92 million to \$157 million increase because the former growth rate is only 19%.⁵¹

25. For these reasons it is my opinion that the average growth rates Mr. Jarosz has calculated provide no basis for distinguishing significant from insignificant sales, and specifically for determining whether Dymista[®]'s annual prescriptions annual dollar sales represent an "absolute success."

⁵⁰ $(\$180,000 / \$91,850)^{(1/2)} - 1.$

⁵¹ $(\$1,300,000,000 / \$918,495,800)^{(1/2)} - 1.$

2. Actual Net Revenue Levels & Growth Lower than Jarosz Gross Revenues

26. The \$92 million to \$157 million increase in sales revenue Mr. Jarosz analyzes to assess Dymista[®]'s absolute success does not represent the revenue actually generated from Dymista[®] sales. In particular, these dollar sales data were obtained from the healthcare data firm, IMS Health,⁵² which do not reflect deduction of most manufacturer discounts provided to insurers, pharmacies, and patients,⁵³ such as rebates, cash discounts, patient copayment assistance, product returns, and other customer sales allowances.⁵⁴ Thus, the IMS dollar sales Mr.

⁵² Exhibit 2149 at ¶13, Tab 2.

⁵³ The sales data provided by IMS represent trade-level pharmacy purchases either from a wholesaler or directly from a drug manufacturer. The dollars associated with these sales to retail pharmacies is generally at or close to list price for brand drugs like Dymista[®] that do not have generic equivalents. In particular, price allowances not reflected on wholesale purchase invoices, such as insurer rebates and patient copayment assistance) are not deducted in the calculation of IMS sales dollars. *See, e.g.*, Exhibit 1069 at pp. 11, 14-15, 17, 20-21; Exhibit 1088 at pp. 40-41, 70.

⁵⁴ *See, e.g.*, Exhibit 1069 at pp. 11, 21; Exhibit 1088 at pp. 41, 70, 72.

Jarosz analyzes represent something close or identical to gross revenue, which overstates the net revenue Meda actually received on Dymista[®] product sales. It is net revenue that is relevant to another developer's motivation to have developed the '620 patent technology, and thus, net revenue is the relevant measure for assessing Dymista[®] commercial success.⁵⁵

27. Accordingly, Ex. 3 indicates that after reflecting all Meda discounts, Dymista[®]'s actual net sales revenue has risen only from \$63 million in 2013 to \$84 million in 2015, significantly less than the \$92 million to \$157 million in IMS-reported gross revenues Mr. Jarosz analyzed based on Dymista[®] list prices. Moreover, the annual growth rates of 28.9% and 3.1% in net revenue for 2014 and 2015, respectively, are substantially below the corresponding 41.8% and 20.9% growth rates underlying the gross revenue data Mr. Jarosz analyzed. In fact, Ex. 3 shows that the nearly flat (3.1%) growth in 2015 net revenue (the most recent year of revenue data) is consistent with the nearly flat growth (-1.0% decline) in 2015

⁵⁵ Meda's recognition that net revenue is the relevant measure for assessing a product's commercial performance is indicated by the fact that its revenues are generally reported in its annual reports on a "net" basis. (See, e.g., Exhibit 1066 generally, and at pp. 6, 24, 28, 66, 88, 98, 101, 104, 106, 121, 138.)

prescriptions displayed in Ex. 2. The sharply contrasting 20.9% growth in Dymista[®]'s 2015 gross revenues reflects the significant overstatement in Dymista[®] sales growth that underlies Mr. Jarosz's absolute success opinion.

28. Mr. Jarosz's failure to consider Dymista[®]'s actual net revenue levels, which are 31% to 47% lower than the gross revenue levels he analyzed,⁵⁶ and his failure to consider Dymista[®]'s actual 15.2% average net revenue growth rate, which is half of the 30.9% average he calculated based on gross revenue data,⁵⁷ render his absolute success opinion regarding Dymista[®] invalid.

B. Mr. Jarosz Has Not Shown Dymista[®] to be a "Relative Success"

29. Mr. Jarosz evaluates Dymista[®]'s "relative success" by comparing Dymista[®]'s gross sales revenue and prescriptions to 1) other *brand* AR nasal spray products,⁵⁸ and 2) combined *brand plus generic* AR nasal spray products.⁵⁹ As discussed below, I find that the portion of Mr. Jarosz' relative success analysis

⁵⁶ Ex. 2a.

⁵⁷ Ex. 3.

⁵⁸ Exhibit 2149 at ¶¶44-46.

⁵⁹ Exhibit 2149 at ¶¶47-49.

based only on comparisons to other brand products is not meaningful for purposes of assessing Dymista[®]'s commercial success. I also find that Mr. Jarosz' calculation of Dymista[®] shares of combined brand plus generic sales revenue is not meaningful for evaluating Dymista[®]'s commercial success.

30. I conclude that the only conceptually valid relative success analysis Mr. Jarosz has presented is his calculation of Dymista[®]'s share of combined brand plus generic prescription quantities, which he finds only to have ranged from 1.2 to 1.8% from 2013 to 2016.⁶⁰ And even this insignificant share is overstated because Mr. Jarosz excluded large categories of competitive products that substitute to and from the prescription antihistamine and corticosteroid nasal sprays he used as the base for calculating this share. Consequently, it is my opinion that Mr. Jarosz' analysis does not demonstrate that Dymista[®] is a relative success, as discussed in greater detail below.

1. Comparisons to Generic-Eroded Sales of Other Brands is Not Meaningful

31. One of the findings Mr. Jarosz provides in support of his relative success finding is that Dymista[®] became the 2nd highest brand nasal spray in both

⁶⁰ Exhibit 2149 at ¶47 and Tab 1.

prescriptions and sales revenue by 2014, and the 1st largest prescribed brand at the beginning of 2017.⁶¹ However, Dymista[®]'s nominally high ranking among brand AR nasal spray suppliers is unremarkable considering that the bulk of sales for 9 of the 13 brand AR products that reported dollar sales since 2012 have shifted to generic or OTC supply between 2006 to 2016.⁶² Mr. Jarosz himself acknowledges this large-scale shift to generics and OTC,⁶³ and the GlobalData study that Mr. Jarosz cites frequently in his Declaration⁶⁴ observes that “over the past decade, almost all the key drugs for the treatment of AR symptoms have lost patent protection As a result, AR, which was once a blockbuster-status area, is now highly saturated and genericized, with companies seeing large declines in the sales of their respiratory portfolios due to generic erosion.”⁶⁵

32. More specifically, Ex. 1 indicates that by the time of Dymista[®]'s 2012 market launch, sales for 3 of the 11 nasal spray brands identified in Mr. Jarosz'

⁶¹ Exhibit 2149 at ¶¶45-46.

⁶² See Ex. 1 and Exhibit 2149 at Tab 1.

⁶³ Exhibit 2149 at ¶¶24-30.

⁶⁴ Exhibit 2149 at ¶¶22 (fn. 9), 31-32, 72-74, 86, 91-92.

⁶⁵ Exhibit 2053 at p. 178.

tables (Flonase[®], Nasacort AQ[®], and Astelin[®]) had been shifted to suppliers of generic bioequivalents,⁶⁶ which Tab 1 in Mr. Jarosz' Declaration shows to have significantly reduced total brand nasal spray prescriptions to 13.3 million in that year (versus 37.7 million generic prescriptions for the 3 genericized drugs). After Dymista[®]'s launch, Ex. 1 indicates that brand sales continued to be eroded by first-time generic entry for 4 additional brands in 2014 and 2016 (Astepro[®], Rhinocort Aqua[®], Patanase[®], and Nasonex[®]), with a 5th brand (Veramyst[®]) converted to OTC sale in anticipation of generic entry. This further reduction in brands without generic/OTC conversion from 8 to 3 between 2012 to 2016 caused total brand

⁶⁶ I excluded from this evaluation 7 discontinued brands (identified by blue italics in Ex. 1) Mr. Jarosz listed in his Tabs 2 and 4 that had no dollar sales in those tables (Beconase[®], Nasacort[®], Nasalide[®], Nasarel[®], Ticanase[®], and Vancenase[®]/Vancenase AQ[®]). I also excluded Beconase AQ[®], which reported minimal sales in Mr. Jarosz' Tabs 2 and 4, is an old product first approved in 1987, has no patent exclusivity, had competed against another brand nasal spray based on the same active ingredient and same concentration (Vancenase AQ[®]), and was believed possibly to slow growth in pediatric patients. (*See* Ex. 1, Exhibit 2053 at p. 114; Exhibit 1070; Exhibit 1123.)

prescriptions to fall further, from 13.3 million in 2012 to 3.5 million in 2016, such that brand prescriptions represented only 6.7% of combined brand and generic nasal spray prescriptions in that year.⁶⁷ Prescription sales of such brands that have largely been eroded by generic/OTC conversion do not provide meaningful benchmarks for assessing the relative success of a brand such as Dymista[®] that has not yet been required to share sales with generic bioequivalents.

33. In Ex. 4 I present a more meaningful comparison of Dymista[®]'s \$157 million peak-year gross revenue to the revenue of other AR nasal spray brands prior to generic entry (or OTC conversion). The Ex. 4 graph shows that Flonase[®] and Nasonex[®] each generated revenue exceeding \$1 billion prior to generic entry, while Nasacort AQ[®] and Rhinocort Aqua[®] each achieved sales of approximately \$300 million, and Meda's Astelin[®] reached \$233 million prior to generic entry. These 5 brands generated sales revenue that exceeded those of Dymista[®] by between 48% and 629%.⁶⁸

⁶⁷ Exhibit 2149 at Tab 1. The brand prescription percentage fell further to just 3.9% for the first 4 months of 2017.

⁶⁸ $48\% = \$233 \text{ million (Astelin}^{\text{®}}) / \$157 \text{ million (Dymista}^{\text{®}}) - 1$; $629\% = \$1,145 \text{ million (Nasonex}^{\text{®}}) / \$157 \text{ million (Dymista}^{\text{®}}) - 1$. (See Ex. 4.)

34. Of the 6 remaining products with sales that roughly match or fall below Dymista[®]'s sales revenue, 4 are minimally differentiated follow-on products that launched shortly before or sometime after their predecessor brands experienced generic entry (Veramyst[®], Astepro[®], Qnasl[®], and Zetonna[®]).⁶⁹ Sales for two of these (Veramyst[®] and Astepro[®]), were likely limited by competition from the generic versions of their larger selling predecessors (Flonase[®] and Astelin[®]).⁷⁰ Sales for the 2 other follow-ons (Qnasl[®] and Zetonna[®]) that are “dry mist” versions of their predecessors were considered to be disappointing and do not appear to represent commercially successful products.⁷¹ Likewise the 2 remaining brands based on new molecules (Patanase[®] and Omnaris[®]) are also considered to be disappointing and limited in potential, and thus, also appear to be commercially unsuccessful.⁷²

35. In my opinion, Mr. Jarosz' comparison of Dymista[®]'s sales to the generically-eroded sales of other brands is not meaningful for evaluating Dymista[®]'s

⁶⁹ Exhibit 2048 at pp. 4, 106-107, 115-116.

⁷⁰ Exhibit 2048 at pp. 4, 106-107, 131-132; Exhibit 2149 at Tab 1; Ex. 1.

⁷¹ Exhibit 2149 at Tab 2; Exhibit 2053 at pp. 154, 192.

⁷² Exhibit 2048 at pp. 119, 139; Exhibit 2053 at pp. 187-188.

“relative success.” This more appropriate comparison to the pre-generic sales of other brands does not suggest Dymista® to be indicative of relative success.

2. Share of Only Brand Sales is Not Meaningful in a Genericized Market

36. Mr. Jarosz concludes from the brand-only portion of his relative success analysis that Dymista® “has been very successful,”⁷³ based on his calculation that it is the only brand that increased its share of brand nasal spray prescriptions in every year, from 5.3% in 2013 to 27.3% in 2016 to 40% through April 2017, and that it more than doubled its share of brand dollar sales from 5.6% in 2013 to 11.9% in 2015, to 15.6% for January to April 2016.⁷⁴

37. However, by excluding the dominant and increasing volume of generic sales from the marketplace denominator, these brand-only market shares dramatically overstate Dymista®’s relative importance in the market for AR treatments, and thus, are not meaningful as indicators of Dymista®’s relative success.

⁷³ Exhibit 2149 at ¶46.

⁷⁴ Exhibit 2149 at ¶¶44, 46.

38. The continued generic erosion of brand AR nasal spray prescriptions from 13.3 million in 2013 to 6.8 million by 2015 and 3.5 million in 2016 is the primary contributor to Dymista[®]'s increasing brand share of prescriptions,⁷⁵ which would have increased even if Dymista[®]'s actual sales levels had not (and they did not in 2016). It measures Dymista[®]'s increasing share of a vanishing portion of the market, concealing the bulk of the market Dymista[®] has been unsuccessful in penetrating that is served by generic suppliers of the same products offered by the brands. Although brand and generic suppliers generally employ different competitive strategies (generally marketing/differentiation versus primarily price), they nonetheless can compete with each other using these different strategies to attract sales from the same customers for the same uses.⁷⁶ Accordingly, Meda documents generally indicate that it considered brand and generic nasal sprays to be in the same market.⁷⁷

⁷⁵ Exhibit 2149 at Tab 1.

⁷⁶ *See, e.g.*, Exhibit 1092 at pp. 9-11, 32-39, 46-47.

⁷⁷ *See, e.g.*, Exhibit 2074 at pp. 11-14, 19, Exhibit 2080 at pp. 9, 20, Exhibit 2079 at p. 36.

39. Considering that the generic share of total AR nasal spray prescriptions had already grown to 74% in 2012, before increasing further to 83% in 2014 and 93% in 2016,⁷⁸ Mr. Jarosz' exclusion of the portion of the market served by these generic suppliers in his brand-only market shares inappropriately overstates the significance of Dymista[®]'s sales and renders them meaningless as an indicator of Dymista[®]'s relative success. An appropriate share calculation must include in its denominator the generic nasal sprays that readily substitute for Dymista[®].

3. Share of Brand+Generic Dollar Sales Not Meaningful in a Genericized Market

40. In the “brand plus generic” portion of his relative success analysis, Mr. Jarosz asserts that Dymista[®] “has a significant share of revenues,” citing its 8.8% revenue share in 2015, and its over 10% revenue share in January to April 2016, which coincides with the entry of a generic for Nasonex[®].⁷⁹ He does not provide a basis for concluding that these shares are “significant” or that they

⁷⁸ Exhibit 2149 at Tab 1.

⁷⁹ Exhibit 2149 at ¶48.

indicate commercial success, except to note that they ranked 3rd in revenue share, behind Nasonex[®] and generic Flonase[®].⁸⁰

41. However, assessing the significance of a brand product's sales from its revenue share of combined brand and generic products is distorted by the fact that these revenue shares reflect differences in how brand and generic products compete, in addition to measuring how successful products are in penetrating the market. As discussed above, brand suppliers typically compete based on marketing activities and differentiation, which entails pricing higher than generic suppliers who compete primarily on price.⁸¹ Consequently, revenue shares for the higher priced brand products like Dymista[®] are inherently inflated relative to generics simply because of this difference in how they compete for sales. Thus, brand product revenue shares of combined brand and generic sales revenue overstate the brand's actual success in penetrating the market.⁸² The degree of this overstatement is increased the larger is the share of total sales quantity comprised of generics,

⁸⁰ Exhibit 2149 at ¶48.

⁸¹ Exhibit 1092 at pp. 9-11, 32-39, 46-47, 50; Exhibit 1130 at p. 31; Exhibit 2064 at pp. 18-19; Exhibit 2075 at p. 2.

⁸² *See also*, Exhibit 1124 at p. 3.

which as discussed above, is very large in the case of AR nasal sprays (74% to 93%).⁸³

42. Thus, it is my opinion that the revenue shares of the “brand plus generic” marketplace that Mr. Jarosz calculated for Dymista[®] in 2015 and 2016 significantly overstate the commercial significance of Dymista[®]’s sales, such that they are not meaningful for purposes of assessing Dymista[®]’s “relative success.”⁸⁴ Likewise, Mr. Jarosz’ determination that Dymista[®]’s 2015 and 2016 dollar shares ranked 3rd largest of all products is unremarkable considering that 8 of the other 11 brands had converted to low price generic (or OTC) supply by 2016.⁸⁵

4. 1.8% Share of Brand+Generic Prescriptions is Not Significant

43. Also as part of his “brand plus generic” analysis of relative success, Mr. Jarosz calculates Dymista[®]’s share of combined brand and generic

⁸³ Exhibit 2149 at Tab 1.

⁸⁴ The revenue shares are also distorted because they are based on nominal gross sales revenue rather than actual net sales revenue. (See §V.A.2., above.)

⁸⁵ See Ex. 1.

prescriptions, which he finds “has been less than 2%.”⁸⁶ He further notes that “Dymista[®] was virtually the only branded prescription nasal spray whose share of prescriptions in this larger marketplace increased every year through 2016,”⁸⁷ and also reports, without elaboration, that generic Flonase[®] prescriptions increased from 65.9% in 2012 to 77.9% in January to April 2017.⁸⁸

44. While Dymista[®]’s share technically did increase from 2012 to 2016, the magnitude of this increase was barely perceptible. As an initial matter, the 2012 to 2013 increase from 0.1% to 1.2% is meaningless because Dymista[®] only launched in late 2012, and therefore, the 2012 share reflects only 1 quarter of prescriptions calculated on a full-year prescription base.⁸⁹ The subsequent share increases to 1.5% in 2014 and 1.8% in 2015 are minimal,⁹⁰ while the 1.78% to 1.84% increase in 2016 requires expansion of Mr. Jarosz’ Tab 1 reported shares to 2

⁸⁶ Exhibit 2149 at ¶47.

⁸⁷ Exhibit 2149 at ¶47.

⁸⁸ Exhibit 2149 at ¶47.

⁸⁹ Exhibit 2149 at Tab 1.

⁹⁰ Exhibit 2149 at Tab 1.

decimal places to detect.⁹¹ However, Dymista[®]'s prescription share through April of 2017 decreased to 1.6%, which Mr. Jarosz appropriately excludes from his 2012 to 2016 range of claimed increases.⁹²

45. But apart from the *de minimis* magnitude of this share “increase,” the fact that Dymista[®] prescriptions would grow from 2012 to 2016 is unremarkable considering that the product only launched in the last quarter of 2012. New products nearly always ramp-up share in their first few years of launch, given that they are starting from zero, regardless of whether they ultimately achieve commercial success. On the other hand, Mr. Jarosz's reference to the increase in generic Flonase[®] prescriptions from 65.9% to 77.9% indicates why the other established brands,⁹³ such as brand Flonase[®], would not be expected to record

⁹¹ 1.78% = 972,960 / 54,540,256 in 2015; 1.84% = 963,299 / 52,389,875 in 2016. (Exhibit 2149 at Tab 1.) These calculations reveal that the absolute number of Dymista[®] prescriptions actually decreased 1.0% in 2016, but the total number of prescriptions for all products fell more significantly, by 3.9%, which likely reflects the impact of the recent OTC conversions.

⁹² Exhibit 2149 at Tab 1.

⁹³ Exhibit 2149 at ¶47.

continual share increases over this time: they were losing share to their generic equivalents and to their OTC versions.

46. Given the trivial magnitude and ultimate irrelevance of the 2012 to 2016 share increases Mr. Jarosz references, the only salient finding from his analysis of “brand plus generic” prescriptions is that Dymista[®] only obtained a peak 1.8% prescription share in 2015 and 2016, which by the 1st 4 months of 2017 was already exhibiting a decline to 1.6%.⁹⁴ While Mr. Jarosz provides no discussion of how his “less than 2%” share finding affects his opinion regarding Dymista[®]’s commercial success,⁹⁵ in my opinion, such a low share is not significant and not indicative of relative success.

⁹⁴ In contrast to Mr. Jarosz’ analysis of Dymista[®]’s brand plus generic revenue sales, this calculation of Dymista[®]’s prescription share is not inappropriately inflated by differences in how brand and generic suppliers use price to compete for sales. (See §V.B.3., above.)

⁹⁵ Exhibit 2149 at ¶¶47, 49.

5. Sales Shares Overstated by Failure to Include Competing OTC Products

47. Even Mr. Jarosz' 1.8% brand plus generic prescription share calculation represents an overstatement of Dymista®'s actual marketplace penetration because it does not reflect competition from OTC antihistamines and corticosteroids that are used to treat AR. Including these OTC products in the total marketplace would increase the denominator in the share calculation, and consequently, reduce Dymista®'s peak share to below 1.8%.

48. In particular, Mr. Jarosz justifies excluding AR treatments sold as OTC products from his analysis because "physicians focus on prescription treatments, rather than medications that can be obtained over-the-counter," and because "prescription treatments are consistent with the competitors against whom Meda compares Dymista® in its ordinary course of business."⁹⁶ I disagree that these assertions justify excluding OTC products from the Dymista® market share calculations for a number of reasons.

49. First, the single Meda presentation slide Mr. Jarosz cites in support of his assertion that physicians focus on prescription treatments rather than OTC drugs actually reports that the first combination therapy a physician prescribes to a

⁹⁶ Exhibit 2149 at ¶42.

patient is an intranasal corticosteroid to be used in addition to an “OTC” (*i.e.*, OTC oral antihistamine) “and/or Xyzal,”⁹⁷ which was a prescription oral antihistamine.⁹⁸ Thus, Mr. Jarosz’ citation actually indicates that physicians view OTC and prescription antihistamines as substitutes for one another in those Dymista®-targeted, moderate to severe and persistent AR patients, who are candidates for combination corticosteroid and antihistamine treatment.^{99, 100}

⁹⁷ Exhibit 2064 at p. 5 (“First Rx: Patient goes to Dr. and receives INS (in addition to their OTC) and/or Xyzal replaces their OTC”). As discussed in §IV, above, corticosteroids are generally not used to treat AR because of adverse side effects. (Exhibit 2147 at ¶¶44, 138.)

⁹⁸ See Ex. 1.

⁹⁹ Exhibit 2053 at pp. 73, 110; Exhibit 2073 at p. 1; Exhibit 2079 at p. 6; Exhibit 2093 at p. 7.

¹⁰⁰ Mr. Jarosz also suggests that oral antihistamines were often deemed inadequate for AR symptoms that are severe or not adequately controlled. (Exhibit 2149 at ¶22.) However, the reference he cites in support of this claim goes on to indicate in the next paragraph that the combination of an antihistamine (oral or intranasal) and an intranasal corticosteroid is the second line treat-

... (Continued)

50. Second, physicians consider oral antihistamines, which are primarily OTC products,¹⁰¹ and intranasal antihistamines, which are only available by prescription,¹⁰² to be substitutable.¹⁰³ Medical treatment guidelines recommended that physicians treat moderate to severe and persistent AR symptoms with a combination of an intranasal corticosteroid and either an oral or intranasal antihistamine.¹⁰⁴ While intranasal antihistamines have the advantage of localized delivery, oral antihistamines have the advantage of addressing other AR symptoms (*i.e.*, sneezing, rhinorrhea, itchiness, eye watering/redness),¹⁰⁵ and are preferred by

... (Continued)

ment for symptoms not adequately controlled by an antihistamine or corticosteroid alone, and is the first line treatment for “moderate/severe, persistent AR.” (Exhibit 2053 at pp. 70-71, 73.)

¹⁰¹ Exhibit 2053 at pp. 99-100, 104-106; and Ex. 1.

¹⁰² Exhibit 2053 at pp. 104-106; 113; Ex 1.

¹⁰³ Exhibit 2053 at pp. 70, 73.

¹⁰⁴ Exhibit 1003 at ¶¶68, 71-72; Exhibit 2053 at pp. 70-71, 73, 95, 110, 133; Exhibit 1071 at p. 5; Exhibit 1072 at p. 6.

¹⁰⁵ Exhibit 2053 at p. 111.

patients based on their ease of administration and their avoidance of adverse side effects and negative sensory attributes of intranasal antihistamines.¹⁰⁶

51. Third, Mr. Jarosz' conclusion that Meda only compares Dymista[®] to other prescription drugs in its ordinary course of business is based on 4 slides from various Meda marketing and strategic presentations that graph brand and generic prescriptions of AR nasal spray products over time,¹⁰⁷ 1 slide comparing list prices of brand nasal sprays,¹⁰⁸ and 1 slide comparing sales revenues of brand nasal sprays.¹⁰⁹ However, more careful consideration indicates that the omission of OTC oral antihistamines from these slides does not indicate that Meda did not view OTC products as competitors for Dymista[®] sales.

¹⁰⁶ Exhibit 2053 at pp. 70, 111, 151-153; Exhibit 2147 at ¶79.

¹⁰⁷ Exhibit 2149 at ¶42, citing Exhibit 2074 at p. 15, Exhibit 2075 at p. 3; Exhibit 2079 at p. 36; Exhibit 2080 at p. 20.

¹⁰⁸ Exhibit 2149 at ¶42, citing Exhibit 2080 at p. 12.

¹⁰⁹ Exhibit 2149 at ¶42, citing Exhibit 2080 at p. 13.

52. In the case of the 4 prescription trend graphs,¹¹⁰ the absence of oral antihistamine comparators likely reflects the unavailability of comparable data for these mostly OTC products since physicians usually do not write actual prescriptions for OTC products they recommend to their patients. Thus, sales of competing oral antihistamines sold OTC will generally not be represented in the prescription count data provided by vendors of such data, such as IMS Health.¹¹¹

53. In addition to the issue of data availability, the selection of appropriate comparator products depends on the analytical purpose of the comparison. In the comparisons cited by Mr. Jarosz, it is apparent that this purpose was to inform the development of various components of Dymista®'s competitive strategy based on comparison to products that competed with similar strategies. For example, 1 of the referenced slides compared list prices of various brand nasal spray

¹¹⁰ Exhibit 2074 at p. 15, Exhibit 2075 at p. 3; Exhibit 2079 at p. 36; Exhibit 2080 at p. 20.

¹¹¹ See, e.g., Exhibit 2048 at p. 39. It appears that OTC products are sometimes covered by insurance plans and occasionally may even be “prescribed” by physicians, in which case they would be included the prescription product data. (See Exhibit 2048 at p. 38; Exhibit 2149 at Tab 1.)

products,¹¹² while another compared sales revenue for the purpose of assessing how physician salesforce size and marketing “share of voice” impact sales revenues.¹¹³ Another slide graphs the trend in monthly prescriptions for Dymista[®] and other recently-launched prescription brands, based on the number of months since each product’s market launch, apparently for the purpose of assessing the impact of physician salesforce marketing and insurance access on new brand sales.¹¹⁴ Because OTC antihistamines are predominately generic, are not marketed to physicians, and usually are not reimbursed by insurance, including OTC products in these comparisons would not be meaningful, even though these OTC products compete with Dymista[®] for sales.

54. In fact, other Meda slides in the marketing/strategy documents cited by Mr. Jarosz indicate that Meda considered OTC products to be Dymista[®] competitors. For example, 1 set of slides lists “OTC’s,” along with Nasonex[®], Qnasl[®], and Patanase[®] as Dymista[®]’s “main competitors” and later as one of its

¹¹² Exhibit 2080 at p. 12.

¹¹³ Exhibit 2080 at p. 13.

¹¹⁴ Exhibit 2075 at p. 3.

“Most Relevant Competitors.”¹¹⁵ Yet another slide regarding “Dymista Marketing Strategy” notes, “Expand Share: Nasal vs. Oral.”¹¹⁶ Yet another slide displays a graph comparing total prescriptions of intranasal corticosteroids and nasal antihistamines, together along with oral antihistamines.¹¹⁷

55. Finally, as noted above, all of the top-selling corticosteroid nasal sprays for AR had also converted to OTC status between 2011 and 2016.¹¹⁸ Thus,

¹¹⁵ Exhibit 2074 at p. 21-26. *See also*, Exhibit 2079 at p. 21 (“main competitors are OTC and generics”).

¹¹⁶ Exhibit 2079 at p. 10.

¹¹⁷ Exhibit 2079 at p. 8. These oral antihistamine “prescriptions” presumably are for the oral antihistamines that were still available only as prescription products for the time periods covered by the data, since prescriptions generally are not written for OTC products a physician specifies for a patient. This slide indicates the data extend to September 2011. Ex. 1 indicates that the large-selling oral antihistamine, Allegra[®], converted to OTC status in 2011. The oral antihistamines Xyzal[®] and Clarinex[®] (and their generics) were still available only by prescription through the end of 2016.

¹¹⁸ *See* Ex. 1.

physicians were increasingly forced to consider OTC alternatives to prescription products for both corticosteroids and antihistamines, given the increasingly limited choice of the products that, like Dymista[®], are still sold by prescription.

C. Dymista Commercial Success Criteria Mr. Jarosz Did Not Consider

56. As discussed, the only meaningful finding Mr. Jarosz derived from his evaluation of Dymista[®]'s commercial success is that Dymista[®] obtained only a peak 1.8% share of AR nasal spray prescriptions based on an overly narrow marketplace definition.¹¹⁹ But in addition to this insignificant sales share, certain other factors Mr. Jarosz did not consider likewise indicate that Dymista[®]'s sales are insignificant, and not representative of commercial success. I discuss 3 of these below.

1. Significance Threshold for Brand Pharmaceutical Sales is Comparatively High

57. In assessing the significance of Dymista[®]'s sales, it is necessary to consider them in the economic context under which they were generated. In this case, a distinguishing feature of ethical pharmaceutical economics is that brand

¹¹⁹ Exhibit 2149 at ¶47 and Tab 1.

drugs (prior to bioequivalent generic competition) typically command high prices and, as a result, often generate larger sales revenues than might be expected from products in most other industries.¹²⁰ A major reason for these higher prices and revenues is that brand pharmaceuticals are generally protected for a time by significant barriers to entry that restrict competition. These barriers include stringent legal/regulatory requirements to obtain and maintain marketing approval, data exclusivity, widespread patent protection, and, in most cases, substantial and risky R&D investments that must largely be sunk long before products can be marketed.¹²¹

58. At the same time, demand for brand pharmaceuticals is less sensitive to price than products in most other markets, in large part, because of the division of purchasing responsibility between physicians who decide which product to purchase, insurers who generally pay for the product purchased, and patients who

¹²⁰ See, e.g., Exhibit 1087 at pp. 2-3; Exhibit 1088 at pp. 18-19; Exhibit 1092 at pp. 46, 50; Exhibit 1124 at p. 2.

¹²¹ *Id.*, Exhibit 1092 at pp. 9-10, 33-34, 50.

benefit from the product purchased.¹²² As a result, brand pharmaceutical competition is generally based on perceived product differentiation,¹²³ with demand being sensitive to manufacturers' marketing/promotional efforts in support of the product.¹²⁴ The combination of restricted entry and price-insensitive demand is conducive to setting prices that are high relative to marginal costs.¹²⁵

59. These economic features of brand pharmaceutical competition indicate that what constitutes significant sales revenue for a prescription brand pharmaceutical product is, as a general matter, considerably higher than what would be considered significant in many other industries. As a rough indication of the range of annual brand drug product sales revenues, Ex. 5 presents a listing of the top

¹²² See, e.g., Exhibit 1087 at p. 2; Exhibit 1092 p. 33; Exhibit 1091 at p. 22; Exhibit 1082 at pp 9-13.

¹²³ See, e.g., Exhibit 1087 at p. 2; Exhibit 1088 at pp. 11, 37; Exhibit 2064 at pp. 18-19; Exhibit 2075 at p. 2.

¹²⁴ See, e.g., Exhibit 1091 at pp. 22-23; Exhibit 1082 at pp. 11-13; Exhibit 1092 at pp. 46, 50.

¹²⁵ See, e.g., Exhibit 1087 at p. 2.

200 brand pharmaceutical products by gross revenue generated from sales made through retail pharmacies in 2010, the last year for which this list was publicly available. The list shows that the top 30 brand drugs on this list generated annual sales of between \$1.0 billion (Provigil®) and \$5.2 billion (Nexium®), while the 50th (Flovent HFA®) recorded \$705 million and the 100th (Ortho Tri-Cyclen Lo®) registered \$332 million. The 150th ranked drug (Hyzaar®) still garnered \$207 million in sales, while the 200th (Humulin N®) registered \$150 million. Dymista®'s peak year gross sales of \$157.5 million in 2015 would rank it at 191 on this 2010 listing.

60. But even this comparison overstates the significance of Dymista®'s sales for a number of reasons. First, the top 200 drug sales levels would undoubtedly be larger if converted to 2015 dollars for direct comparison to Dymista®'s peak-year gross sales, considering healthcare price inflation that has occurred since 2010. Thus, Dymista®'s ranking actually would be even lower than 191.

61. Second, the drugs included in the top 200 list represent a cross-section of brands at various points in their product lifecycles, including not only brands at the peak of their sales-generating potential, but also newly-introduced

drugs that are still growing (some of which reflect less than a full year of sales), as well as older brands that have had their sales eroded over time by competition or other factors. Thus, Dymista[®]'s peak-level revenues would be much less significant if compared to the peak-level annual revenues of the drugs listed in Ex. 5 in whatever year their peaks were reached, rather than to the revenues these drugs happened to generate in 2010.

62. Third, the comparison does not consider that many of these drugs have generated these high sales levels over a number of years. For example, Mr. Jarosz' data indicates that the \$886 million in sales Ex. 5 reports for Nasonex[®] in 2010 had increased to approximately \$1 billion in each year from 2012 to 2016.¹²⁶ In contrast, the Dymista[®] prescription and net sales patterns displayed in Ex. 2 and Ex. 3 suggest a very short product lifecycle, with gross sales appearing already to have peaked at \$157 million in just its 3rd full year on the market.

63. Fourth, the Ex. 5 sales comparisons to Dymista[®] are based on gross revenues at list price, rather than the more relevant net revenue actually generated after deducting discounts and other sales allowances. Ex. 3 showed that Dymista[®]'s

¹²⁶ Exhibit 2149 at Tabs 2 and 4.

nominal gross revenue peak of \$157 million actually amounted to only \$84 million net of discounts. This 47% discount is atypically large for innovative brand pharmaceuticals that have no bioequivalent generic competitors.¹²⁷ To the extent the marketers of the top 200 brand drugs in Ex. 5 provided less significant discounts, Dymista® would rank still lower.

64. Finally, another relevant characteristic of the brand pharmaceutical industry is that a large proportion of marketed brand drugs ultimately prove to be unprofitable considering their pre-launch development costs.¹²⁸ Brand firms typically rely on a relatively small number of commercially successful drugs to make up for the losses incurred on the many unprofitable products and failed development projects.¹²⁹ Thus, many of the products ranked toward the bottom of the Ex. 5 Top 200 list may well represent long-run commercial failures, in that their post-launch operating profits have turned out to be insufficient to recover the prelaunch R&D and other investments that were incurred to generate them. The

¹²⁷ See, e.g., Exhibit 1085.

¹²⁸ See, e.g., Exhibit 1075 at pp. 12-13; Exhibit 1119 at pp. 4-5.

¹²⁹ See, e.g., Exhibit 1075 at pp. 12-13.

actual commercial performance of such negative return products would not be sufficient to have motivated others to have developed those products.

65. Consequently, in the context of brand pharmaceutical economics, it cannot be presumed that Dymista®'s nominal gross sales revenues, which appear to have peaked at \$157 million, constitute significant sales. The product's much lower actual net revenue peak of \$84 million net of discounts, reinforces this opinion.

2. Dymista® Sales Not Significant Relative to Prelaunch Forecasts

66. Prelaunch forecasts of product sales can represent a benchmark for the level of sales that would be sufficiently significant to have motivated development of a patented technology had it been obvious.¹³⁰ Such forecasts are not yet influenced by actual sales experience that, if disappointing, could reduce post-launch forecasts to levels that would have been insufficient to have motivated investment in the product's development that, by the time of market launch, had become sunk, irrecoverable cost.

67. A Meda slide presentation, which appears to have been prepared in mid-2011, approximately 1 year before Dymista®'s market launch, presents a

¹³⁰ Exhibit 1124 at p. 2.

“Place Holder/Forecast Requested by Sweden,” that includes Upside, Base, and Downside forecasts of Dymista® annual net sales revenue from 2012 to 2020.¹³¹ The Base forecast shows Dymista® net revenues climbing to approximately \$800 million by 2018, while the Upside forecast reaches \$1 billion and the Downside forecast still reaches approximately \$650 million in 2018.

68. Ex. 6a graphs these mid-2011 forecast scenarios for 2013 to 2016, along with the actual net revenues Dymista® generated for 2013 to 2015, the last year available. The graph shows that Dymista®’s actual sales performance of \$63 million, \$81 million, and \$84 million in 2013, 2014, and 2015, respectively, has fallen far below the \$155 million, \$323 million, and \$545 million that Meda expected in mid-2011 to be generated in those years, and has even fallen well below the corresponding \$129 million, \$269 million, \$454 million Downside forecast.

¹³¹ Exhibit 2080 at p. 11.

Cumulatively over 2013 to 2015, Dymista®'s actual net sales revenues only represent 18% of Meda' Upside forecast,¹³² and 27% of its Downside forecast.¹³³

69. Ex 6a also graphs a forecast presented in Meda's "2012 DYMISTA Strategic Plan," dated October 28, 2011, which presents a 2-year net revenue forecast that projects Dymista® sales rising from \$33 million in 2012 to \$200 million in 2013.¹³⁴ The \$200 million estimate for 2013 in this later forecast is about the same as the \$194 million estimated for 2013 in the Upside scenario of the earlier mid-2011 forecast.

70. The three scenarios of the mid-2011 forecast reflect alternative projections of Dymista®'s list price at launch (\$100, \$120, and \$150) that are

¹³² 18% = (\$63 million + \$81 million + \$84 million actual net revenue) ÷ (\$194 million + \$404 million + \$681 million Upside forecast net revenue), per Ex. 6a.

¹³³ 27% = (\$63 million + \$81 million + \$84 million actual net revenue) ÷ (\$129 million + \$269 million + \$454 million Downside forecast net revenue), per Ex. 6a.

¹³⁴ Exhibit 2079 at p. 38.

applied to a single forecast of the number of prescriptions Dymista® would generate each year. Ex. 6b indicates that the forecast estimates that Dymista® prescriptions would increase from 1.726 million in 2013 to 3.423 million in 2014, 5.496 million in 2015, and 6.595 million in 2016. However, the graph also shows that Dymista®'s actual annual prescriptions only increased from 0.641 million to 0.890 million, to 0.973 million, before falling to 0.963 million from 2013 to 2016, respectively. The actual Dymista® prescriptions cumulatively represent just 20%, of the forecast prescriptions from 2013 to 2016.¹³⁵

71. Ex. 6b also graphs prescriptions forecast in Meda's 2012 DYMISTA Strategic Plan, which estimates 2013 prescriptions of 2.578 million,¹³⁶ which is higher than the 1.726 million projected by the Mid-2011 forecast, and 2.80 million in 2014,¹³⁷ somewhat below the 3.423 million the Mid-2011 forecast

¹³⁵ 20% = (0.641 million + 0.890 million + 0.973 million + 0.963 million actual prescriptions) ÷ (1.726 million + 3.423 million + 5.496 million + 6.595 million forecast prescriptions), per Ex. 6b.

¹³⁶ Exhibit 2079 at p. 38.

¹³⁷ Exhibit 2079 at pp. 4, 12.

expected. Meda's 2012 Strategic Plan also included a Downside forecast based on a delay in adding sales representatives to market Dymista® to physicians, which projected prescriptions increasing to 2.10 million in 2013 and 2.30 million in 2014.¹³⁸ The prescriptions expected in this later forecast are also dramatically higher than the actual prescriptions dispensed for Dymista® in these years, which still represent only 28% to 35% of forecast prescriptions.¹³⁹

72. Finally, Ex. 6b shows that the Dymista® prescription shares projected in the Mid-2011 forecast of 4.5%, 8.5%, 13% and 15% for 2013 to 2016, respectively, far exceed the corresponding 1.2%, 1.5%, 1.8% and 1.8% shares Dymista® actually obtained in each of those years. These share differences largely reflect the differences between the forecast and actual prescription levels discussed above.

¹³⁸ Exhibit 2079 at pp. 23, 24, 40.

¹³⁹ $28\% = (0.641 \text{ million} + 0.890 \text{ million actual prescriptions}) \div (2.578 \text{ million} + 2.800 \text{ million forecast prescriptions})$; $35\% = (0.641 \text{ million} + 0.890 \text{ million actual prescriptions}) \div (2.100 \text{ million} + 2.300 \text{ million forecast prescriptions})$.
(See Ex. 6b.).

73. It is apparent from these forecasts that Dymista[®]'s actual sales revenue and prescription quantity through 2015/2016 have fallen dramatically short of Meda's prelaunch expectations. The significance of this shortfall is further indicated by a Meda memo prepared after Dymista[®]'s market launch, entitled "Dymista briefing document," which concluded that:

*Dymista sales are clearly behind expectations in the US.*¹⁴⁰

*Dymista was reserved for late in the treatment algorithm. This positioning turned out to be overly restricted and, in turn adversely affected patient access through managed care payers. As stated by investors: "the cost/benefit profile of Dymista versus cheap generic standard-of-care (fluticasone) is simply **not good enough for a commercial success** and that lack of payer support will continue to hamper the uptake".*¹⁴¹ [emphasis added]

*Dymista has to be the growth driver for the next 5 years [and] must reach approx. 1 billion US\$ net sales in the US Dymista must become a blockbuster product.*¹⁴²

¹⁴⁰ Exhibit 2073 at p. 2.

¹⁴¹ Exhibit 2073 at p. 1.

¹⁴² Exhibit 2073 at pp. 1-2.

74. The failure of Dymista[®] sales to approach anywhere near the levels expected prior to its market launch suggests that its sales are not sufficiently significant to have motivated others to have developed such a product if the '620 patent technology had been obvious, and consequently, that its sales are not indicative of commercial success.

3. Dymista[®] Sales Not Significant Relative to Costs and Investment

75. As an economic matter, the level of sales necessary to have motivated others to develop a product based on a particular technology would normally have to be sufficient to cover the post-launch operating costs of those sales, as well as to recover the development and other investments that were necessary to bring the drug to market, inclusive of capital costs and compensation for risk.¹⁴³ In this section, I assess the extent to which Dymista[®] sales have been sufficient to cover its operating costs and recover its development investment. Although I am not aware that Patent Owner or its experts have provided any comprehensive sources of Dymista[®]'s actual revenue, costs, and development

¹⁴³ See, e.g., Exhibit 1075 at pp. 2-3; Exhibit 1124 at p. 3; Exhibit 1088 at p. 18.

expenses over time, I am able to develop conservative estimates of these amounts from various documents that have been provided.

76. Ex. 7 derives this estimate in terms of Dymista[®]'s net present value starting with the product's actual net sales revenue from 2012 to 2015 (*see* Ex. 2a), which I have projected to 2016 and 2017 by applying the actual percentage changes in the number of Dymista[®] prescriptions in each of those years (*see* Ex. 2a). Actual 2012 to 2014 and budgeted 2015 expenses for Dymista[®] salesforce detailing, as well as for advertising and promotion expenses estimated for 2016, are reported in Meda's "Dymista[®] Brand Marketing Plan 2015" and "2016 Dymista[®] Brand Plan." In Ex. 7 I assume the Meda budgeted expenses for salesforce in 2015 extended at the same level into 2016 and 2017, and that Meda's estimated expenses for advertising and promotion in 2016 extended at the same level into 2017. The costs of procuring the product itself from Cipla ("Cost of Goods Sold") are derived by

multiplying the number of prescriptions by a cost per unit reported in Meda's "2012 DYMISTA Strategic Plan."¹⁴⁴

77. Although I have seen no information on the actual amount of prelaunch investment committed to Dymista[®]'s development, an October 2002 Medpointe document does estimate that the development of an "Astelin/Steroid Combination" product would likely require an investment of between \$75 million and \$100 million.¹⁴⁵ In fact, Meda reported 10 years later in its 2012 Annual Report that in support of Dymista[®]'s FDA approval in that year, "Dymista[®]'s efficacy and safety were documented in several studies with more than 4,600 patients, including a long-term safety study of more than 600 patients."¹⁴⁶ A recent economic study reported that the mean cost of just Phase III clinical trials for a brand (new

¹⁴⁴ Meda actually paid Cipla an amount equal to at least 15% of Dymista[®]'s net sales revenue, per terms of the first amendment to the parties' license agreement 2011. (Exhibit 2050 at p. 3; Exhibit 2149 at ¶105.)

¹⁴⁵ Exhibit 2056 at p. 11. *See also*, Exhibit 2054 at p. 11.

¹⁴⁶ Exhibit 1076 at p. 15; Exhibit 2053 at p. 126.

molecular entity) drug to be \$255 million, and a median cost to be \$200 million.¹⁴⁷ Meda submitted the results of 5 Phase III clinical trial studies it had conducted to the FDA in support of Dymista[®]'s approval. These studies incorporated the more stringent requirements the FDA specifically added for approval of Dymista[®]'s combination product formulation.¹⁴⁸ Consequently, Meda's actual prelaunch R&D expenditures for Dymista[®] may have significantly exceeded this early \$75 million to \$100 million estimate. Nonetheless, I conservatively assume in Ex. 7 that Meda (and Medpointe and Cipla) invested a total of \$75 million in Dymista[®]'s development, which I further assume was allocated evenly in four \$18.5 million increments over 2008 to 2011.¹⁴⁹

¹⁴⁷ Exhibit 1077 at p. 5.

¹⁴⁸ Exhibit 1058 at pp. 4-5, 8; Exhibit 2147 at ¶¶142-147; Exhibit 2164; Exhibit 2165.

¹⁴⁹ This assumption that Dymista[®]'s R&D investment was equally distributed over time is also conservative for purposes of calculating net present value because the investment was likely to be front-loaded to the early years, con-

... (Continued)

78. The 2012 present value of Dymista[®]'s net sales revenues through 2017, less contemporaneous operating costs (salesforce, advertising, promotion, and product costs) associated with those sales, are shown in Ex. 7 to sum to \$52.8 million. Ex. 7 also shows the 2012 present value of the \$75 million R&D investment incurred to generate these operation profits to be \$98.0 million. This implies a negative net present value of \$45.2 million, which further implies that nearly half (46%) of the conservatively-estimated \$98 million prelaunch investment remains unrecovered by Dymista[®] sales.

79. Finally, a decision to invest in the development of a new technology requires that product sales be sufficiently large to compensate for the risk the product fails to show acceptable safety and efficacy in clinical trials, or otherwise fails to obtain marketing approval and reach market launch.¹⁵⁰ A recent economic study has estimated that the average probability of a brand (new molecular entity) drug candidate entering Phase I clinical trials successfully

... (Continued)

sidering that the 5 clinical trials submitted in support of Dymista[®]'s approval were conducted from 2007 to 2009. (Exhibit 1058 at p. 8.)

¹⁵⁰ Exhibit 1077 at pp. 4-5.

obtaining FDA marketing approval is 12%, while the average probability a drug candidate entering Phase III clinical trials obtains FDA approval is 56%.¹⁵¹

80. While these probabilities apply to new molecular entities, Medpointe believed Dymista[®]'s "likelihood of success" to be "low" in 2002.¹⁵² In addition, as discussed above, the FDA had concerns about approving Dymista[®] as a combination product, which led it to develop more stringent Phase III clinical requirements for granting approval.¹⁵³ Thus, conservatively assuming that Dymista[®] only bore the 44% risk of failing Phase III clinical trials and/or failing to obtain FDA marketing approval,¹⁵⁴ Ex. 7 shows that the Dymista[®]'s net present value loss increases to \$68.4 million through 2017, on an "expected" risk-adjusted

¹⁵¹ Exhibit 1077 at p. 4. $56\% = 62\%$ probability of successful results in Phase III clinicals x 90% probability of then obtaining FDA marketing approval.

¹⁵² Exhibit 2056 at p. 11.

¹⁵³ Exhibit 2147 at ¶¶142-147; Exhibit 1058 at p. 4.

¹⁵⁴ $44\% = 1 - 56\%$ probability that a drug entering Phase III clinicals ultimately obtains FDA approval. (Exhibit 1077 at p. 4.)

basis. This loss implies that 70% of Dymista[®]'s risk-adjusted development investment remains unrecovered by Dymista[®] sales.

81. In addition to the conservative assumptions discussed above that I have adopted in generating these estimates of Dymista[®]'s revenues compared to its costs, it is likely that Meda (Cipla and Medpointe) incurred additional costs I have not identified and included in this analysis that renders these estimates even more conservative. For example, as a condition of its FDA marketing approval, Meda was required to perform post-launch ("Phase IV") pediatric clinical trials that would add to the R&D expenses required to obtain FDA marketing approval.¹⁵⁵ In addition, there are likely other operating expenses besides salesforce, advertising, and promotion that have been incurred to support Dymista[®] sales. Also, I have not included any payments Meda made to Cipla associated with the parties' license agreement, such as the 15% of net revenue payment for Cipla's supply of product.¹⁵⁶

82. Nonetheless, despite these several sources of conservatism, it appears that Dymista[®] sales have not come close to covering its operating and

¹⁵⁵ Exhibit 1083 at pp. 2-3.

¹⁵⁶ Exhibit 2050 at p. 3; Exhibit 2149 at ¶105.

prelaunch investment costs, such that they are not sufficiently significant to have motivated others to have developed such a product had the '620 patent technology been obvious.

D. Duonase & “Imitators” Sales Do Not Evidence Commercial Success

83. Mr. Jarosz finds that sales of Duonase, which he claims to embody the challenged claims of the '620 patent,¹⁵⁷ have achieved “absolute success” based on his observation that: 1) Duonase prescriptions and revenues have increased in every year since its launch in FY 2005 at a cumulative average annual rate of 15%;¹⁵⁸ and 2) combined sales of Duonase and 6 separate “imitator” products in India, which he claims also to embody the challenged claims of the '620 patent,¹⁵⁹

¹⁵⁷ Exhibit 2149 at ¶¶20, 67. Mr. Jarosz reports that the fiscal years he uses end in February of the year indicated – e.g., FY 2005 covers March 2004 to February 2005. (Exhibit 2149 at Tab 9.)

¹⁵⁸ Exhibit 2149 at ¶¶50-51.

¹⁵⁹ Exhibit 2149 at ¶20.

have increased generally consistently at a 23% average annual rate since the first imitator launched in 2006.¹⁶⁰

84. Mr. Jarosz also assesses the “relative success” of all products allegedly embodying the ‘620 patent technology combined (*i.e.*, Duonase and its 6 imitators collectively), based on his belief that “such a comparison provides insights into the extent to which the use of the patented technology is associated with notable performance among comparable products sold in the same marketplace.”¹⁶¹ He concludes from this analysis that, as a whole, Duonase/imitator sales have been “remarkable and consistent since 2005” based on maintaining a 24% to 26% share of prescription nasal spray unit and dollar sales in India.¹⁶²

85. I disagree that Duonase and its imitator sales demonstrate commercial success that is indicative of the ‘620 patent’s nonobviousness for the reasons discussed below.

¹⁶⁰ Exhibit 2149 at ¶¶53-54.

¹⁶¹ Exhibit 2149 at ¶55.

¹⁶² Exhibit 2149 at ¶56.

1. Duonase Does Not Practice Challenged Claims 42-44 of the '620 Patent

86. Mr. Jarosz concludes that the commercial performance of Duonase and its imitator products in India has a nexus to the '620 patent based on his understanding that “those products embody the entirety of the challenged claims.”¹⁶³ However, Cipla acknowledges that Duonase does not meet the limitations of claims 42 to 44 of the '620 patent,¹⁶⁴ claims that the Petitioner has challenged in this matter.¹⁶⁵ Consequently, even if Mr. Jarosz' conclusions regarding Duonase's commercial success were valid, such success would not represent an *indicium* that the challenged claims of the '620 patent were nonobvious because Duonase does not practice all of the challenged claims.

¹⁶³ Exhibit 2149 at ¶¶36, 55, 67.

¹⁶⁴ Argentum Pharmaceuticals LLC v. Cipla, Ltd., U.S. Patent and Trademark Office, Patent Trial and Appeals Board, IPR2017-00807, Patent Owner Response, filed on November 20, 2017 (“Patent Owner Response”) at pp. 55-56.

¹⁶⁵ Exhibit 1003 at p.14; Petition at p. 2; Exhibit 2149 at ¶2.

2. Useful Invention in India Not Necessarily a Useful Invention in the U.S.

87. I understand that a basic requirement for an invention's patentability is that the invention be novel, nonobvious, and useful.¹⁶⁶ For a pharmaceutical invention to be "useful," it must be capable of being developed into a product that can be demonstrated to be safe and efficacious, such that it can obtain regulatory approval to be marketed and used. Economically, it must be possible to develop the invention into a product that can generate sales sufficient to recover the investment cost, time, and risks required to make it useful. If this is not possible, the technology will not be developed, and therefore will not be useful because the value of its use is exceeded by the cost of its use. This usefulness criterion is analogous to the commercial success criterion discussed in Section V.C.3., above – *i.e.*, that a commercially successful level of sales should be at least sufficient to recover the product's past development costs.¹⁶⁷

88. Thus, even if Duonase did practice all of the challenged claims of the '620 patent, the applicability of any Duonase commercial success found in India

¹⁶⁶ 35 U.S. Code §§101-103; Exhibit 1125 at p. 2.

¹⁶⁷ §§V.C.1. and V.C.3.

to the nonobviousness of its technology in the United States, requires that this technology also be novel, nonobvious, and useful in the United States. In particular, the Duonase sales levels that would be sufficient to recover the development investment required to make the technology useful in India must also be sufficient to recover the development investment that would be required to make the technology useful in the United States. However, this equivalence is highly unlikely, as the costs of developing the '620 patent technology into a useful product capable of obtaining FDA marketing approval in the United States is likely much higher than Cipla was required to invest in developing Duonase for marketing approval in India, as discussed below.

89. The U.S. FDA has among the most stringent criteria in the world for granting approval to market a brand prescription pharmaceutical, which it strictly enforces.¹⁶⁸ Accordingly, very large investment cost, time, and risk are typically required to demonstrate a candidate brand drug based on a particular technology is sufficiently safe and efficacious to obtain FDA marketing approval – *i.e.*, for the

¹⁶⁸ See, *e.g.*, Exhibit 1127 at p. 2.

technology to be “useful.”¹⁶⁹ As discussed in Section V.C.3., above, Medpointe originally (and likely conservatively) anticipated that Dymista[®]’s development for marketing in the United States would require a \$75 million to \$100 million high-risk investment made over 6 or more years.

90. In contrast, considerably less investment, time, and risk likely was required to develop the same technology into a useful product that could be marketed in India, where approval standards are less stringent.¹⁷⁰ For example, investment in clinical trials that would be required for marketing approval in the United States could in many cases be avoided completely in India.¹⁷¹ Even when

¹⁶⁹ See, e.g., Exhibit 1077 at pp. 6-7.

¹⁷⁰ Lax enforcement, generous provision of exceptions, skewed staff priorities, critical resource constraints, jurisdictional ambiguity, and numerous other factors have been cited as contributed to the lenient prescription drug approval process in India. (See, e.g., Exhibit 1107 at pp. 1-2; Exhibit 1118 at pp. 12, 16, 19, 25-26, 36-37.)

¹⁷¹ See, e.g., Exhibit 1107 at pp. 1-2; Exhibit 1118 at pp. 24-26. Cipla specifically has been identified a company that obtained Indian drug approvals without

... (Continued)

required, clinical trials can be performed at far less cost in India.¹⁷² Indian approval criteria are specifically noted for being lax for new fixed-dose combinations of existing drugs, like Duonase,¹⁷³ which has resulted in the country being recognized for having by far the largest percentage (50%) of prescription drug products comprised of fixed-dose drug combinations.¹⁷⁴

91. I have not been able to identify information that reports or would allow me estimate the cost, time, or risks Cipla incurred specifically to develop what purportedly became the '620 patent technology for its 2004 launch in India as Duonase. However, given the very lenient requirements for approval of fixed-dose

... (Continued)

performing required Phase III clinical trials. (Exhibit 1107 at p. 2; Exhibit 1118 at pp. 24-26.)

¹⁷² See, e.g., Exhibit 1126 at p. 16.

¹⁷³ See, e.g., Exhibit 1107 at p. 2; Exhibit 1117 at pp. 2, 5-6, 10, 12; Exhibit 1118 generally, and especially at pp. 36-37, 53.

¹⁷⁴ The 2nd highest fixed-dose drug percentage was 33% in Brazil, while the fixed-dose product percentage in the United States was only 14%. (Exhibit 1117 at pp. 5, 10. See also, Exhibit 1119 at pp. 2, 5.)

combination products in India, along with the very low levels of Duonase sales (averaging \$1.6 million per year) and the large number of undifferentiated competitor products offered at similarly low prices (*see* Section V.D.3., below), it is my opinion that the investment required for the '620 patent technology to be made useful in India was considerably less than required for that technology to be made useful in the United States. Consequently, even if Duonase (and its imitators) could be shown to represent a commercial success in India, such a showing could not be used to infer that the challenged claims of the '620 patent in the United States were nonobvious because of the larger development investment required for the '620 patent technology to represent a useful invention in the United States.

3. Imitator Sales Irrelevant to Nonobviousness of '620 Patent Claims

92. Even if Duonase sales in India were relevant to the obviousness of all the challenged claims of the '620 patent in the United States, it is not appropriate to consider the combined sales of Duonase and its imitators to analyze commercial success as an *indicium* of nonobviousness. The relevant issue in the obviousness inquiry is whether a product's commercial success is sufficient to have motivated others already to have developed and marketed a product embodying the challenged

claims of the '620 patent technology had they been obvious.¹⁷⁵ This essentially puts another hypothetical developer in Cipla's place, deciding whether such development would be profitable given the sales levels that actually have been generated by the product of this development, Duonase.

93. Like Cipla in the case of Duonase, this other developer would only obtain a return on the revenues generated by sales from the developer's own product. The sales/profits of imitator firms marketing similar products could not be appropriated, and thus, would not be a factor in motivating the developer to invest in a Duonase-like product if it had been obvious. Thus, the 23% average sales growth rates and 24% to 26% market shares Mr. Jarosz calculated for Duonase and its imitators as measures of absolute success and relative success, respectively,¹⁷⁶ are irrelevant for purposes of assessing Cipla's commercial success in India as an *indicium* of the '620 patent's nonobviousness.

¹⁷⁵ See, e.g., Exhibit 1065, at 10-11; Exhibit 1124 at p. 2.

¹⁷⁶ Exhibit 2149 at ¶¶54, 56.

94. As discussed above, Mr. Jarosz has calculated that sales for Duonase itself have only increased at a 15% average annual rate.¹⁷⁷ Although he has not considered it in his opinion, Mr. Jarosz' data indicate that Duonase has only achieved a 12% share of the nasal spray product prescriptions he has identified as the marketplace for India.¹⁷⁸

4. Annual Sales of \$0.5 million to \$2.6 million Are Not Significant

95. Like his absolute success analysis for Dymista®,¹⁷⁹ Mr. Jarosz does not provide any basis for why he concludes that Duonase's FY 2005 to FY 2017 average annual growth rate of 15% in sales revenue, from 21 million to 174 million Indian rupees, and 15% in sales quantity, from 154,573 to 819,338 prescriptions, represent "absolute success."¹⁸⁰ As discussed above, the cumulative

¹⁷⁷ Exhibit 2149 at ¶¶50-51, Tabs 9 and 10.

¹⁷⁸ Exhibit 2149 at Tabs 6 and 7.

¹⁷⁹ See Section V.A.1., above.

¹⁸⁰ Exhibit 2149 at ¶¶50-51.

average growth rate in sales is a relative measure that by itself does not provide a means of determining whether sales are significant or commercially successful.¹⁸¹

96. What is relevant from Mr. Jarosz' data is that the increase from 21 million rupees of Duonase sales in FY 2005 to 174 million rupees of sales in FY 2017 equates to an increase from just \$0.5 million to \$2.6 million in U.S. dollars, respectively.¹⁸² Over these 13 years, Duonase's sales sum to only \$20.4 million,¹⁸³ averaging just \$1.6 million per year.¹⁸⁴ Mr. Jarosz has not provided any analysis of whether this level of sales revenue (apart from his uninformative growth rate calculations) constitutes an absolute success. Certainly, it would not be nearly sufficient to motivate others to have developed a product capable of obtaining U.S. approval, given the high investment required (at least \$75 million to \$100 million in the case of Dymista®).¹⁸⁵ And it is not even significant in comparison to the \$12.6

¹⁸¹ See Section V.A.1., above.

¹⁸² Exhibit 2149 at Tab 9.

¹⁸³ FY 2005 to FY 2017 sum from Exhibit 2149 at Tab 9.

¹⁸⁴ \$20.4 million / 13 years.

¹⁸⁵ See Section V.C.3., above.

million-plus royalty revenue Cipla obtained in 2015 from Meda's sales of Dymista® in the United States.¹⁸⁶ Moreover, as discussed in Section VI.D., below, Duonase actually is a "branded generic" product that competes primarily on low price, with minimal product differentiation and development investment. It does not compete based on innovative product attributes sufficient to command a premium price, which is reflected in the minimal level of sales revenue it has generated.

5. Duonase Prescription Shares Are Overstated

97. As discussed above, the share of prescriptions relevant for assessing commercial success is the 12% share Mr. Jarosz calculated for Duonase itself, exclusive of the "imitator" products that reportedly also practice the challenged claims of the '620 patent. However, even this 12% share is likely overstated because the Indian marketplace of AR nasal spray treatments Mr. Jarosz has defined includes products that are based on only 3 nasal spray molecules:

¹⁸⁶ \$12.6 million = \$83.7 million Dymista® 2015 net revenue (Ex. 2A) x 15%+ trade product charge (Exhibit 2050 at pp. 3, 5; Exhibit 2079 at p. 29, Exhibit 2149 at ¶105).

fluticasone, the azelastine/fluticasone combination, and mometasone.¹⁸⁷ In contrast, Mr. Jarosz includes AR nasal spray products based on 8 different active ingredient molecules in the United States for his analysis of Dymista[®] sales.¹⁸⁸ The fact that sales in his total Indian nasal spray market amount to between \$19 million and \$25 million annually from 2012 to 2015,¹⁸⁹ or just 1% of the U.S. nasal spray market of \$1.8 billion to \$2.2 billion annually over those years,¹⁹⁰ suggests that other drug products are being used as substitutes to treat AR in India besides those nasal spray products reported in the Indian sales data he analyzed.

98. For example, a Cipla marketing presentation on Duonase in India that presents prescription shares for AR corticosteroid nasal sprays includes 2 other corticosteroid molecules Mr. Jarosz did not include in his Indian market analysis: budesonide and beclomethasone.¹⁹¹ Both of these products are, however, included

¹⁸⁷ Exhibit 2149 at Tabs 6 and 7.

¹⁸⁸ Exhibit 2149 at Tabs 1 and 2. *See also*, Ex. 1.

¹⁸⁹ Exhibit 2149 at Tab 6

¹⁹⁰ Exhibit 2149 at Tab 2.

¹⁹¹ Exhibit 2087 at p. 17; Exhibit 2149 at Tabs 6 and 7.

in his U.S. analysis of Dymista[®] sales (brand names Rhinocort Aqua[®] and Beconase AQ[®]/Qnasl[®], respectively).¹⁹²

99. In addition, the data source from which Mr. Jarosz extracted the Indian nasal spray product sales used in his share calculations defines the “Total AR Market” to include prescription oral antihistamines, which include Allegra[®] and its fexofenadine “imitators,” as well as a Xyzal[®]/Singulair[®] combination product and its imitators,¹⁹³ none of which Mr. Jarosz considered.¹⁹⁴ Recognizing that these oral AR prescription drugs represent over 90% of the total AR sales units (and over 80% of the total AR revenue value) reported in this data source,¹⁹⁵ Mr. Jarosz’ exclusion of these prescription drugs from his Indian market sales base leads him to significantly overstate the Duonase (and Duonase plus imitator) sales shares. Further, Mr. Jarosz provides no indication of whether he considered the extent to

¹⁹² Exhibit 2149 at Tab 2.

¹⁹³ Exhibit 2123 and Exhibit 2124.

¹⁹⁴ Exhibit 2149 at Tabs 6 and 7.

¹⁹⁵ Exhibit 2123 and Exhibit 2124.

which OTC treatments for AR, including non-prescription oral antihistamines, substitute for AR nasal sprays specifically in the Indian market.

100. Because of the likelihood that Mr. Jarosz' 12% Duonase market share is based on an Indian marketplace denominator that excludes a significant volume of sales for other AR treatments that substitute for Duonase in India, I conclude that this share is overstated.

E. Attempted Entry of Apotex Generic and Duonase Imitators Do Not Evidence Commercial Success

101. Mr. Jarosz concludes that the commitment of resources by Apotex in the United States, and by the Duonase imitators in India, to develop competing versions of these products represents a "revealed preference" that suggests they view these products as sufficiently successful that the marketplace can economically support more versions of the same formulation.¹⁹⁶ Otherwise, it would make little economic sense to attempt to launch these generic/imitator versions.¹⁹⁷

¹⁹⁶ Exhibit 2149 at ¶¶99-102.

¹⁹⁷ Exhibit 2149 at ¶102.

102. I disagree with this inference. As discussed above, the economics of generic competition differs significantly from that of brand competition. A critical factor affecting generic entry in the United States is that generics can obtain FDA marketing approval simply by demonstrating bioequivalence with the corresponding reference brand drug.¹⁹⁸ This demonstration requires far less commitment of funds, time, and risk than does the development, and specifically the demonstration of safety and efficacy, required of a new brand drug.¹⁹⁹ In contrast to the minimum \$75 to \$100 million over 5 or more years with considerable risk of failure associated with bringing Dymista® to market,²⁰⁰ the launch of a generic version of a currently marketed brand typically involves comparatively minimal, short-term, safe investment of perhaps a few million dollars.²⁰¹ Generic competitors also do not bear the significant investment and costs of salesforce detailing,

¹⁹⁸ Exhibit 1088 at pp. 19, 43-44, 59-61.

¹⁹⁹ Exhibit 1088 at pp. 19-20, 43-44, 59-61; Exhibit 1092 at p. 50; Exhibit 1077 at pp. 5-6.

²⁰⁰ See §V.C.3., above.

²⁰¹ Exhibit 1088 at pp. 43-44; 59-61; Exhibit 1130 at p. 125; Exhibit 1128 at p. 1.

advertising, and promotion that brands undertake to stimulate demand.²⁰² Generics compete on price primarily with the reference brand and with each other for a claim of existing sales that were exclusively made by the brand prior to generic entry.²⁰³

103. Thus, the low-cost entry of generic versions has no bearing on the question of whether Dymista[®]'s sales are significant enough to have motivated others to have developed an original brand product based on the '620 patent technology had it been obvious. Brand sales that are significant enough to attract low-cost generic entry that diverts existing sales from the incumbent brand may be far too insignificant to have motivated others to have developed such a product anew because of the much higher time, costs, and risks, of such development.

104. Moreover, generic competitors also compete based on carrying broad product lines,²⁰⁴ which may entail investing in a generic product that by itself is not profitable, but when combined with the supplier's entire generic product portfolio increases overall competitiveness, sales, and profits of all the supplier's

²⁰² See, e.g., Exhibit 1092 at pp. 38, 47.

²⁰³ See, e.g., Exhibit 1092 at pp. 10-11, 38.

²⁰⁴ See, e.g., Exhibit 1130 at p. 31; Exhibit 1132 at pp. 12, 19, 21, 51.

profits sufficient to offset the product-specific loss. Generic competitors tend also to find it profitable to develop product lines in specific therapeutic areas and types of treatments.²⁰⁵ In this case, it is apparent that Apotex is one of the only consistent marketers of generic versions for most of the AR nasal spray brands.²⁰⁶

105. Likewise, Duonase imitators are effectively generic products that, as “imitators,” presumably incur minimal development costs to achieve entry as compared to what would be required of a developer of an original brand product based on the ’620 patent technology.²⁰⁷ As discussed above, Mr. Jarosz has not addressed the extent of the activities and investment Cipla was required to undertake to obtain marketing approval for Duonase in India. The product’s pricing and revenue levels suggest either that the investment was not substantial (which implies the technology is not particularly innovative), or that the investment has not been

²⁰⁵ See, e.g., Exhibit 1129 at pp. 3, 5, 20-21, 28; Exhibit 1132 at pp. 10, 12; Exhibit 1137 at p. 9.

²⁰⁶ Exhibit 1131; Exhibit 1113; Exhibit 1114; Exhibit 1108; Exhibit 1115; Exhibit 1116; Exhibit 2065.

²⁰⁷ See §V.D.3., above.

recovered by Duonase sales. But in any event, the entry of other low-cost Indian “imitators” does not demonstrate that sales are significant enough to have motivated others to have developed an original product incorporating the ’620 patent technology that meets the standards required for a useful invention in the United States.

VI. NEXUS ANALYSIS

106. I understand that the commercial success of a product must be attributable to the allegedly novel features of the claimed invention to represent a secondary *indicium* of a patent’s nonobviousness.²⁰⁸ I understand this requirement to mean that any alleged commercial success must be driven primarily by the claimed invention, and not by other factors unrelated to the features of the claimed invention. In other words, there must be a causal correlation, or “nexus,” between the purported merits of the claimed invention and the success of the product.

107. Based on my analysis of the evidence relating to Dymista® and to Duonase, it is my opinion that the sales of both products are primarily driven by factors unrelated to the allegedly novel features of the claims of the ’620 patent.

²⁰⁸ *J.T. Eaton*, 106 F.3d at 1571–72.

Below I evaluate the extent to which Dymista[®] and Duonase sales are due to the features claimed by the '620 patent claims versus other unpatented factors. I also assess the evidence and reasoning Mr. Jarosz advances in support of his nexus opinion.

A. Other Developers Blocked by Previously-Issued Patents

108. I understand that that there were two previously-issued patents that respectively cover the two active ingredients that comprise Dymista[®].²⁰⁹ U.S. Patent No. 4,335,121, entitled “Androstane Carbothioates” (“Phillipps patent”) relates to the fluticasone component of the Dymista[®] combination,²¹⁰ and U.S. Patent No. 5,164,194, entitled “Azelastine Containing Medicaments” (“Hettche patent”), relates to the azelastine component.²¹¹ Patent Owner reports that these patents expired in May 2004 and May 2012, respectively,²¹² and Petitioner contends that they would have blocked others from previously developing a combination

²⁰⁹ Exhibit 1004 at ¶¶21-39.

²¹⁰ Exhibit 1009; and Exhibit 1004 at ¶¶32-39.

²¹¹ Exhibit 1007; and Exhibit 1004 at ¶¶21-31;

²¹² Patent Owner Response at p. 66.

azelastine/fluticasone nasal spray product that practices the challenged claims of the '620 patent, at least until those patents expired.²¹³ To the extent that potential competitors were blocked from developing such a product by these patents, rather than by the '620 patent, the failure of a competing product to emerge earlier cannot be regarded as evidence of non-obviousness. In fact, Dymista® did not launch until September 2012, shortly after expiration of the Hettche patent and more than 10 years after the 2002 filing date of the '620 patent.

B. Dymista® Has Minimal Incremental Benefit Over Concurrent Use of Individual Antihistamine and Corticosteroid Products

109. Brand drug marketers often employ “lifecycle management” strategies to preserve a brand product’s sales in the face of generic entry often by developing a follow-on brand version of the drug that incorporates an incremental change that can qualify for a new patent or other form of marketing exclusivity.²¹⁴ The strategy involves mounting a coordinated effort to shift patients from the predecessor brand to the new brand prior to the entry of predecessor product

²¹³ Petition at pp. 57-58.

²¹⁴ See, e.g., Exhibit 1081 at pp. 6-7; Exhibit 1082 at p. 2; Exhibit 1084 at p. 6.

generics by transferring marketing and promotional efforts from the predecessor brand to the new brand.²¹⁵ After generic entry, prescriptions written by physicians for the predecessor brand are generally filled at the pharmacy with their bioequivalent generic products, but these generics cannot be substituted for prescriptions shifted to the new brand.²¹⁶ The new brand versions typically represent reformulations of the predecessor brand's active ingredient, but incorporating, for example, a different dose strength, conversion from tablet to capsule (or vice versa), removal of the inactive isomer, or combination with a pre-existing complementary drug.²¹⁷

²¹⁵ See, e.g., Exhibit 1082 at pp. 5-7, 44-46, 51-56; Exhibit 1084 at pp. 6, 11-13; Exhibit 2048 at p. 106.

²¹⁶ See, e.g., Exhibit 1082 at pp. 5-7, 17. This strategy has aroused concern that it can be employed anticompetitively, in which context it is referenced more pejoratively as “evergreening” or “product hopping.” (See, e.g., Exhibit 1084 at p. 6.)

²¹⁷ Exhibit 1082 at pp. 3, 24-26; Exhibit 1084 at p. 7; Exhibit 1081 at p. 7-9.

110. Documents considered by Mr. Jarosz indicate that in the fall of 2002, Medpointe was developing a lifecycle management strategy for its Astelin[®] (azelastine) nasal spray that identified possible Astelin[®] reformulations, including a version with improved dosing (once per day) and taste (through the possible addition of “sweeteners”), as well as a version that combined Astelin[®] with a corticosteroid in a single nasal spray product.²¹⁸ Meda went on to implement this lifecycle strategy, beginning with its launch of Astepro[®] in early 2009, a version of Astelin[®] with sweeteners added to hide azelastine’s bitter taste.²¹⁹ This product was shortly followed up with Astepro[®] 0.15% in October 2009, a higher dose version that required only once (rather than twice) per day administration.²²⁰ This 2009

²¹⁸ Exhibit 2120 at p. 3; Exhibit 2054 at pp. 10-11, 13-15; Exhibit 2055 at pp. 1, 3; Exhibit 2056 at pp. 11, 13. *See also*, Exhibit 2048 at p. 4.

²¹⁹ Exhibit 2048 at pp. 131-132; Exhibit 2053 at p. 194; Exhibit 1078 at p. 3; Exhibit 1079 at pp. 15, 39, 56, Exhibit 1067 at p. 33.

²²⁰ Exhibit 2048 at pp. 131-132; Exhibit 2053 at p. 194; Exhibit 1079, pp. 15, 39, 56.

introduction allowed Meda to shift a significant portion of Astelin[®] patients to Astepro[®] prior to the launch of generic Astelin products in mid-2010.²²¹

111. Dymista[®] represents the “Astelin[®]/corticosteroid combination” stage of the Medpointe 2002 lifecycle management strategy.²²² By combining Meda’s azelastine to generic fluticasone corticosteroid, Dymista[®] provided Meda a means to continue selling azelastine under patent protection from direct generic competition after Astepro[®] succumbed to bioequivalent generic substitution in 2014.²²³ Accordingly, Astepro[®] prescriptions increased from 955,880 in 2010 to 1,102,104 in 2012, but then fell to 785,544 in 2013,²²⁴ following Dymista[®]’s 2012 market approval (but still prior to generic Astepro[®] entry in 2014).²²⁵

112. More specifically, Ex. 8 shows that, on a monthly basis, Astepro[®]’s prescriptions fell from approximately 100,000 in the months preceding Dymista[®]’s

²²¹ Exhibit 2053 at pp. 131-132; Exhibit 1122 at p. 3.

²²² Exhibit 2048 at p. 4; Exhibit 2079 at p. 16; Exhibit 1079 at p. 39.

²²³ Ex. 1; Exhibit 2149 at Tab 1;

²²⁴ Exhibit 1122 at p. 3; Exhibit 1068 at p. 61; Exhibit 2149 at Tab 1.

²²⁵ Ex. 1; Exhibit 1067 at p. 67; Exhibit 2053 at p. 194; Exhibit 2076 at p. 3.

May 2012 FDA approval, to approximately 55,000 in the months preceding the May 2014 launch of generic Astepro[®]. Meanwhile, Dymista[®] prescriptions grew to approximately 65,000 per month in early 2014, and then to about 75,000 by the time of generic Astepro[®]'s mid-2014 launch. The graph suggests that a substantial portion of Dymista[®]'s sales were due to cannibalization of Meda's existing Astepro[®] sales, encouraged by Meda's lifecycle management efforts. Notably, Ex. 8 shows that Dymista[®] prescriptions have not increased since the mid-2014 launch of Astepro[®] generics, and have exhibited a declining trend over the second half of 2016.

113. Due to the unique nature of pharmaceutical economics, the commercial effectiveness of this lifecycle management strategy does not require that the reformulated (*e.g.*, combination) product offer any significant incremental patient advantages over the predecessor product(s).²²⁶ Specifically with respect to Dymista[®], Dr. Schleimer finds no evidence that the combination of azelastine and fluticasone in a single product provides any incremental efficacy over concurrent

²²⁶ See, *e.g.*, Exhibit 1082 at pp. 2, 5-6, 17-18, 78; Exhibit 1084 at pp. 11, 16.

use of the azelastine and fluticasone uncombined.²²⁷ The GlobalData report cited by Mr. Jarosz indicates a competitive weakness to be that the clinical trials supporting Dymista[®]'s FDA approval compared the Dymista[®] combination to each of the uncombined Astelin[®] and fluticasone components used alone as monotherapy, rather than used together concurrently.²²⁸ Concurrent use of an antihistamine (oral or nasal spray) and a corticosteroid drug (nasal spray) is common.²²⁹ The GlobalData report also found that even in comparison with the uncombined component drugs used as monotherapy, Dymista[®]'s benefits were "small and might not be clinically relevant enough to warrant the higher price associated with the FDC [fixed-dose combination] treatment."²³⁰

114. These concerns regarding Dymista[®]'s lack of therapeutic differentiation are reflected in what Mr. Jarosz characterizes as the "not particularly favorable formulary status" to which Dymista[®] has been relegated by insurers for

²²⁷ Exhibit 1003 at ¶¶106-111.

²²⁸ Exhibit 2053 at ¶¶133.

²²⁹ Exhibit 1003 at ¶¶52, 68-72, 85-91, 99-100, 109;

²³⁰ Exhibit 2053 at ¶¶133.

reimbursement.²³¹ In fact, data presented by Mr. Jarosz show that insurers representing only 21% of covered lives reimbursed Dymista[®] at the lowest (“preferred”) patient copayment tier available for a brand product, while 18% were covered at the high brand copayment tier (usually reserved for a brand that has a generic bioequivalent available).²³² The remaining 61% were either restricted by step edits (try and fail on another treatment(s) first) or by requiring prior authorization from the insurer (36%), or were not included on the formulary for insurance reimbursement at all (26%).²³³ The “Dymista[®] Brand Marketing 2015” Meda presentation slides Mr. Jarosz referenced show that in 2014 Dymista[®]’s preferred tier percentage was even lower, approximately 8%, while in contrast, the preferred percentage for Astepro[®] was 60%.²³⁴ Mr. Jarosz further notes that even Meda’s offer to cut Dymista[®]’s price by more than half (58%) could not persuade

²³¹ Exhibit 2149 at ¶83.

²³² Exhibit 2149 at ¶83, Tab 13.

²³³ Exhibit 2149 at ¶83, Tab 13.

²³⁴ Exhibit 2149 at ¶¶84-85, Figure 12; Exhibit 2074 at p. 17.

one of the largest insurers, CVS Caremark,²³⁵ to provide any insurance reimbursement for Dymista® the applicable portion (60%) of its insured lives.²³⁶

115. As “customers” who pay the bulk of Dymista®’s price, insurers’ general unwillingness to provide favorable, or any, reimbursement coverage for Dymista® is an indication that the product does not provide incremental benefits sufficient to be a significant driver of sales. Accordingly, a Meda “Dymista briefing document” found that:

Several payers did not grant Dymista unrestricted access (Tier 2 and Tier 3) arguing that the premium price is not justified (approx. 2.5 times higher than the lose [sic] combination generic equivalent). Experts consider [sic] to use the lose [sic] combination of Fluticasone propionate and Azelastine nasal spray which are commercially available, claiming the superiority of

²³⁵ CVS Caremark actually is a Pharmacy Benefit Management firm. PBMs manage drug reimbursements for most insurers. (See e.g., Exhibit 2095 at p. 1; Exhibit 1088 at p. 17; Exhibit 1089 at p. 1; Exhibit 1092 at pp. 14-19; Exhibit 1069 at pp. 10, 19, 25.)

²³⁶ Exhibit 2149 at ¶87; Exhibit 2095 at p. 1.

Dymista does not offset the additional hassle a higher price and less favorable formulary status implies".²³⁷

116. Finally, the market penetration of combination azelastine/fluticasone products in India that reportedly do not practice the challenged claims of the '620 patent, suggests that even to the extent some of Dymista®'s sales in the United States may have been driven by its combination of azelastine and fluticasone into one product, some or all of this subset of sales are not driven by the specific claims of the '620 patent. Sales of these non-“imitator” combination products in India demonstrate that combination azelastine/fluticasone products can achieve sales without practicing the '620 patent claims.

117. The evidence discussed above suggests that the marketplace does not attribute significant commercial value to the unique attributes of Dymista® that cannot be obtained from alternative treatments, such as concurrent use of uncombined antihistamine and corticosteroid products, or specifically azelastine and fluticasone. Consequently, they also suggest that Dymista®'s sales are not

²³⁷ Exhibit 2073 at p. 1.

significantly driven by any unique features, and thus, that its commercial performance does not have a nexus to the challenged claims of the '620 patent.

C. Mr. Jarosz Has Incorrectly Eliminated Non-Patented Features as Primary Drivers of Dymista®'s Sales

118. Based on my review of the evidence, it is my opinion that two non-patent factors have been primary drivers of Dymista®'s commercial sales: 1) the low effective prices charged to insurers, through the extensive provision of rebates to obtain more favorable reimbursement for Dymista®, and directly to patients, through extensive subsidization of the uninsured (*i.e.*, copayment) component of Dymista®'s total price; and 2) the high “Share of Voice” Dymista® enjoyed in brand marketing/promotion due to the extensive generic conversion of competitive brand products. I discuss the basis for these conclusions below.

1. Dymista®'s Low Effective Price to Insurers and Patients

119. The impact of a prescription pharmaceutical's price on its volume of sales is complicated by the division of payment for the drug's cost between patients and insurers, and by the delegation of the purchase decision primarily to

physicians, though being influenced by patients and insurers.²³⁸ Because the large majority of patients are insured for their prescription drug purchases, the “price” they effectively consider is the unreimbursed portion of the total drug price, which for privately-insured patients usually is in the form of a fixed insurance copayment.²³⁹ The copayment represents a portion of the drug’s total price, with the insurer responsible for paying the remaining portion.²⁴⁰ Physicians usually are ignorant of the drug’s full price,²⁴¹ though they often do consider the patient’s out-of-pocket obligation in their prescribing decisions.²⁴² This demand structure suggests that a brand drug’s sales quantity can be more sensitive to differences in the patient copayment than it is to differences in the total price, and that a manufacturer’s policies to reduce specifically the patients’ copayments can be a

²³⁸ Exhibit 1092 at p. 33; Exhibit 1093 at p. 1; Exhibit 1091 at p. 22.

²³⁹ Exhibit 1092 at pp. 33, 38; Exhibit 1089 at p. 1; Exhibit 1091 at p. 22.

²⁴⁰ *See, e.g.*, Exhibit 1088 at pp. 21-22; Exhibit 1069 at p. 25.

²⁴¹ *See, e.g.*, Exhibit 1092 p. 46; Exhibit 1100 at pp. 6-7.

²⁴² *See, e.g.*, Exhibit 1101 at pp. 4-5.

more profitable means of increasing demand than reducing the drug's overall price.²⁴³

120. On the other hand, insurers employ tools to prevent overutilization of expensive, minimally differentiated brand drugs, which include placing such drugs on higher patient copayment “tiers,” requiring physicians to contact the insurer to justify the need for the drug prior to prescribing it (“prior authorization”), requiring that the patient first try and fail on a less expensive alternative treatment (“step edits” or “step therapy”), limiting the amount of product that can be prescribed for a given period of time (“quantity limits”), and refusing to reimburse the drug at all.²⁴⁴ Brand drug suppliers may attempt to persuade insurers to grant more favorable reimbursement treatment of a minimally differentiated drug by offering substantial rebates that lower the insurer's effective price for a patient using the drug.

²⁴³ See, e.g., Exhibit 1088 at pp. 25-26; Exhibit 1102.

²⁴⁴ Exhibit 1089 at p. 3; Exhibit 1090 at pp. 1-3 (explaining prior authorization, step therapy and quantity management).

121. In this regard, Meda offered rebates of more than 50% to insurers to ease reimbursement restrictions and reduce patient copayment requirements for Dymista®.²⁴⁵ In some cases, as the one Mr. Jarosz described, insurers found even these generous rebate offers to be insufficient to justify more favorable formulary placement for Dymista® because the product still would not be cost-effective relative to alternative treatments.²⁴⁶ Mr. Jarosz mistakenly interpreted this particular rebate rejection as showing “Meda’s rebates provided very little, if any, competitive advantage.”²⁴⁷ (Exhibit 2149 at ¶87.) In fact, it addresses why Dymista® failed to achieve commercial success, as this insufficient rebate offer left the 60% of lives at the 2nd largest U.S. PBM, CVS Caremark, blocked from reimbursement.²⁴⁸ It does address the relevant nexus issue of the Dymista® sales that were made due to the

²⁴⁵ Exhibit 2095 at p. 1.

²⁴⁶ Exhibit 2149 at ¶87; Exhibit 2095 at p. 1.

²⁴⁷ Exhibit 2149 at ¶87.

²⁴⁸ Exhibit 2095 at p. 1. *See also*, Exhibit 2073 at p. 1 (¶4) discussing the negative impact of unfavorable insurer reimbursement status on Dymista®’s commercial success more generally.

large rebates Meda had to pay to those insurers that did agree to provide more favorable formulary treatment in return.

122. In particular, Meda reported that it provided the largest PBM, Express Scripts/Medco, a 59% rebate to provide unrestricted, preferred (low copayment) reimbursement for Dymista® in 2014, and also provided rebates of 25% to 59% to a number of smaller PBMs and insurers for unrestricted preferred/tier 2 status.²⁴⁹

123. In addition to providing rebates to achieve unrestricted reimbursement access and lower patient copayment tiers for Dymista®, Meda also implemented a “copayment card” program to reduce directly patients’ copayment requirement.²⁵⁰ Under this program, Meda offered to subsidize up to \$100 of commercially-insured patients’ copayment obligation for Dymista®, down to the point that the patient would only be required to pay a generic-like copayment of \$14 per prescription.²⁵¹ The copayment subsidy allowed Meda to circumvent the

²⁴⁹ Exhibit 2094 at p. 13.

²⁵⁰ Exhibit 2064 at p. 30; Exhibit 2076 at pp. 45-47, 51; Exhibit 2093 at p. 59.

²⁵¹ Exhibit 2076 at pp. 45-46, 51; Exhibit 1089 at p. 2.

Dymista[®] usage deterrents erected by those insurers that could not be persuaded to provide more favorable reimbursement placement by offers of higher rebates.²⁵² It is also a more profitable form of price reduction because it does not require any reduction in the portion of the price paid by the insurer. As discussed, patients and prescribing physicians are more sensitive to the patient's copayment requirement than to a drug's total price.

124. The net effect of Meda's extensive rebate and copayment subsidy concessions to generate Dymista[®] sales is reflected in the difference between the product's gross revenue and net revenue, graphed in Ex. 3. Ex. 2a calculates that Dymista[®]'s average discount from list price increased from 31% in 2013 to 38% in 2014, to 47% in 2015. Unfortunately, data are not available to calculate the discounts in 2016 and 2017. The discounts through 2015, however, are comparatively large for brand drugs.²⁵³ Highly differentiated drugs generally have

²⁵² Exhibit 1133 at pp. 26-27.

²⁵³ *See, e.g.*, Exhibit 1085.

small discounts, while relatively undifferentiated drugs typically have larger discounts, reflecting the greater importance of price in generating sales.²⁵⁴

125. For these reasons, it is my opinion that Dymista[®]'s low net prices, effected by Meda's copayment subsidization program and the substantial rebates Meda provided to insurers for more favorable reimbursement treatment, have been a primary driver of Dymista[®]'s sales.

2. Dymista[®]'s Increasingly High Marketing "Share of Voice"

126. A major component of brand drug marketing is the deployment of sales representatives to physicians' offices to provide targeted physicians "details" regarding the drug or drugs being promoted, for the purpose of persuading them to prescribe the manufacturer's particular brand to their patients.²⁵⁵ As discussed in Section V.C.3. above, Meda reportedly spent \$40 million in 2013 and \$30 million in

²⁵⁴ Exhibit 1085; Exhibit 1069 at p. 20.

²⁵⁵ See, e.g., Exhibit 1093 at p. 2.

2014 on a 200 or more-representative salesforce to detail Dymista[®] and to provide free samples to relevant physician specialists.²⁵⁶

127. Mr. Jarosz cites certain documents, including the 2015 GlobalData study, as indicating Dymista[®]'s sales may have been constrained by the lack of a large salesforce able to detail the vast number of primary care physicians ("PCPs") that prescribe AR treatments.²⁵⁷ However, the allergy and asthma specialists Meda did detail are more likely to be treating the moderate to severe and persistent AR patients to whom Meda was targeting Dymista[®]. Accordingly, the 2015 GlobalData study, cited by Mr. Jarosz, listed as one of Meda's strengths its "strong presence in the respiratory market, with good marketing connections to allergists and asthma specialists."²⁵⁸

128. Moreover, discussed in Section V.C.2. above, Meda's prelaunch forecasts projected comparatively large Dymista[®] net sales revenues and prescriptions, notwithstanding the assumption that its salesforce would be restricted

²⁵⁶ Exhibit 2075 at p. 5; Exhibit 2079 at pp. 4, 12, 22-23, 27-28, 40; Exhibit 2080 at p. 9.

²⁵⁷ Exhibit 2149 at ¶¶91-92.

²⁵⁸ Exhibit 2053 at p. 133.

to between 200 and 375 reps marketing to the relevant specialists. As the purpose of the nexus analysis is to evaluate the drivers of the sales actually made, rather than sales that might have been made but were not, Mr. Jarosz' discussion of the absence of PCP marketing is irrelevant to the issue of nexus. It is merely one possible explanation of why Dymista[®]'s actual sales have failed to achieve commercial success.

129. Meda estimated its initial 200-rep Dymista[®] salesforce was in about the middle of the 5 currently-marketed brands (excluding Nasonex[®]) at the time of the 4Q 2012 market launch, with salesforces ranging from 110 (Zetonna[®]) to 360 (Omnaris[®]).²⁵⁹ However, it noted that while the other 4 products were being co-marketed by those sales reps with 2 or 3 other products, the Meda sales reps would be marketing Dymista[®] alone.²⁶⁰ Meda attributed Veramyst[®]'s more successful launch (in 2007) compared to the subsequent launches of Dymista[®] and 5 other products (including Astepro[®] 0.15%) to its larger number of supporting sales reps

²⁵⁹ Exhibit 2075 at p. 5.

²⁶⁰ Exhibit 2075 at p. 5. Nasonex[®] was reported to be marketed along with 6 other products by a 1,000-rep salesforce.

along with favorable insurance formulary access.²⁶¹ At Dymista®'s September 2012 market launch, Meda estimated that its approximately 190,000 rate of sales calls exceeded other competitors, including Veramyst®, with less than 150,000, but excluding Nasonex®.²⁶²

130. Also at the time of Dymista®'s 2012 launch, 3 major AR nasal spray brands (including Astelin®) had already experienced generic entry,²⁶³ which generally entails suspension of salesforce (and other promotional) support.²⁶⁴ After Dymista®'s launch, other major AR brands experienced generic entry and/or OTC conversion, and presumably also withdrew salesforce detailing of physicians.²⁶⁵ Consequently, Dymista® has benefited from a high and increasing “share of voice”

²⁶¹ Exhibit 2075 at p. 3. However, the launch of Veramyst®, a follow-on version of Flonase®, was considered to be a commercial disappointment because it failed to launch before the entrance of Flonase® generics. (Exhibit 2048 at p. 106.)

²⁶² Exhibit 2075 at p. 4.

²⁶³ The other 2 were Flonase® and Nasacort AQ®. (See Ex. 1.)

²⁶⁴ See, e.g., Exhibit 1082 at p. 15.

²⁶⁵ See Ex. 1.

in marketing Dymista[®] to physicians, due to the large established brands losing salesforce support. A brand drug's share of salesforce expenditures on physician detailing in a drug class (*i.e.*, "share of voice") has been found to have a significant impact on the market share it obtains.²⁶⁶ Meda marketing documents indicate the importance it attributed to share of voice, as well as its expectation that Dymista[®] sales would benefit as the product's share of voice increased with the withdrawal of salesforce support for other products with progressive generic entry.²⁶⁷

131. Importantly, the effectiveness of physician detailing can in large part depend on factors unrelated to a drug's attributes, and specifically, it is often determined by the ability of the sales representatives to build personalized relationships with the physicians and their staffs over repeated encounters.²⁶⁸ Such reliance on personal relationships can make a physician's agreement to prescribe the

²⁶⁶ See, *e.g.*, Exhibit 1095 at p. 16; Exhibit 1096 at p. 3.

²⁶⁷ Exhibit 2079 at 21; Exhibit 2080 at 13 Exhibit 2093 at pp. 28, 38.

²⁶⁸ See, *e.g.*, Exhibit 1097 at pp. 3-4; Exhibit 1098 at pp. 2-3; Exhibit 1099 at p. 3.

sales rep's drug more an issue of doing a friend a favor than one of being objectively persuaded by the product's unique attributes.²⁶⁹

132. Mr. Jarosz also cites economics literature suggesting that marketing for undifferentiated products is primarily persuasive (which he identifies as "spurious product differentiation") as opposed to informative.²⁷⁰ Given Dymista®'s limited degree of differentiation discussed in Section VI.B. above, Mr. Jarosz' observation suggests that the sales impact of Meda's salesforce is primarily through persuasion rather than based on product attributes through the provision of information on any unique Dymista® product attributes.

133. In addition, I understand that the absence of head-to-head clinical trial evidence of Dymista®'s superiority over concurrent use of uncombined azelastine and fluticasone products together (as discussed in Section VI.B. above) would preclude Meda sales representatives from making any marketing claims of

²⁶⁹ See e.g., Exhibit 1098 at p. 1.

²⁷⁰ Exhibit 2149 at ¶88.

Dymista[®]'s superiority over this alternative treatment option.²⁷¹ Accordingly, the Dymista[®] marketing materials Mr. Jarosz referenced in support of his claim that "Meda advertisements and promotional aids similarly highlighted features of Dymista[®] that relate to the patented technology,"²⁷² make no claims that Dymista[®] is superior to concurrent use of uncombined antihistamines and corticosteroid products.²⁷³ In fact, one of the cited presentation slides relating to marketing strategy explicitly reports as one of the "Dymista Challenges" the "lack of supportive data for INS+INAH combo vs. oral antihistamines vs. single entities used in combination."²⁷⁴

134. Finally, it appears that a significant portion of Dymista[®]'s sales are attributable to Meda's withdrawal of marketing and promotional support from

²⁷¹ See, e.g., Exhibit 1092 at pp. 34-35; Exhibit 2053 at p. 133; Exhibit 2079 at p. 9.

²⁷² Exhibit 2149 at ¶¶66, 93.

²⁷³ See Exhibit 2064 at pp. 9, 11; Exhibit 2074 at p. 35; Exhibit 2083, Exhibit 2084; Exhibit 2085; Exhibit 2086.

²⁷⁴ Exhibit 2064 at p. 9.

Astepro[®] and the corresponding initiation of marketing and promotional support for Dymista[®] in early 2012, including a shift in sales detailing to Dymista[®] by the same Meda sales reps.²⁷⁵ This lifecycle management strategy, discussed in Section VI.B. above, is designed to enhance the follow-on drug's (*i.e.*, Dymista[®]'s) sales by cannibalizing the predecessor product's (*i.e.*, Astepro[®]'s) sales prior to the launch of generic versions of Astepro[®]. Ex. 8 indicates this strategy was effective.

135. For these reasons, I conclude that the Meda salesforce's marketing to physicians is a primary driver of Dymista[®] sales, independent of any unique product features attributable to the challenged claims of the '620 patent.

D. Duonase Sales Driven by Factors Unrelated to the '620 Patent

136. Mr. Jarosz' analysis of the existence of a nexus between Duonase's commercial performance and the challenged claims of the '620 patent is largely restricted to ruling out Cipla's reputational brand strength in India and its 2010 reformulation of Duonase as significant drivers of Duonase's purported commercial success.²⁷⁶ He provides no analysis of the intensity of Cipla's marketing support for

²⁷⁵ Exhibit 2064 at ¶21.

²⁷⁶ Exhibit 2149 at ¶¶94-98.

Duonase, limiting his analysis to the presentation of 2 Cipla slides that list Duonase's "key features."²⁷⁷ Notably, he does not consider at all the extent to which pricing was a significant driver of Duonase's sales. This omission contrasts with the 14 paragraphs he devoted in his Declaration to the consideration of marketing support and price in his analysis of nexus with respect to Dymista[®] sales in the United States.²⁷⁸ I disagree with Mr. Jarosz' conclusion of a nexus between Duonase's sales and the challenged claims of the '620 patent for the following reasons.

1. Duonase is a "Branded Generic" with Sales Driven by Price

137. The trivial \$0.5 million to \$2.6 million magnitude of Duonase sales revenues reflects that the domestic pharmaceutical market in India actually is a market of generic products, in which large numbers of suppliers offer drugs with similar or identical formulations, but under different brand names (*i.e.*, "branded

²⁷⁷ Exhibit 2149 at ¶¶68-69.

²⁷⁸ Exhibit 2149 at ¶¶63, 81-93.

generics”).²⁷⁹ Such branded generic products represent 80% to 90% of the Indian prescription drug market.²⁸⁰ Indian suppliers attempt to create some degree of differentiation by developing variations of existing drugs that require little investment to be recouped, with the most popular variation being fixed-dose combinations of existing drugs.²⁸¹ India is recognized for the ubiquity of fixed-dose combination drugs, like Duonase, which reportedly comprise 50% of all branded prescription drugs in India, far more than in any other country.²⁸²

138. This market structure is largely attributable to the availability of patent protection for manufacturing processes but not for product formulations in India prior to 2005,²⁸³ and to the lenient regulatory approval requirements that facilitated relatively easy, low-cost market entry.²⁸⁴ It also reflects the low incomes

²⁷⁹ Exhibit 1137 at p. 4; Exhibit 1135 at p. 19; Exhibit 1134 at p. 50; Exhibit 1121; Exhibit 1120 at pp. 2-3.

²⁸⁰ Exhibit 1121; Exhibit 1135 at p. 19; Exhibit 1134 at p. 50.

²⁸¹ *See, e.g.*, Exhibit 1119 at p. 5; Exhibit 1117.

²⁸² *See, e.g.*, Exhibit 1117 at p. 10. *See also*, Exhibit 1119; Exhibit 1120.

²⁸³ Exhibit 1119 at pp. 4-5; Exhibit 1120 at p. 2.

²⁸⁴ *See* §V.D.1., above.

and general absence of insurance coverage for the large majority of patients in India.²⁸⁵

139. Consequently, these branded generic suppliers generate sales primarily by competing with low prices against minimally and un-differentiated rival products,²⁸⁶ while using brand names to create some degree of brand loyalty and signal the suppliers' reputability²⁸⁷ (what Mr. Jarosz appears to reference as "spurious product differentiation"²⁸⁸). Originator brand drugs that require premium prices for recovery of large development investments are generally unable to compete in India because weak patent protection permits the relatively quick entry of branded generic imitators.²⁸⁹ Rather, originator brand drugs are usually developed and marketed in other countries that can support the higher prices

²⁸⁵ Exhibit 1120 at pp. 1-3; Exhibit 1136 at p. 25; Exhibit 1135 at pp. 11-12.

²⁸⁶ See, e.g., Exhibit 1135 at p. 23; Exhibit 1136 at pp. 9, 11, 25; Exhibit 1134 at p. 50.

²⁸⁷ See, e.g., Exhibit 1135 at p. 19; Exhibit 1120 at p. 3.

²⁸⁸ Exhibit 2149 at ¶88.

²⁸⁹ Exhibit 1135 at pp. 26; Exhibit 1120 at p. 3; Exhibit 1137 at p. 4.

necessary for investment recovery, and are only later introduced into India at lower prices to compete with local branded generic versions already available there.²⁹⁰

140. Duonase typifies the fixed-dose branded generics that pervade the Indian market. The AR nasal spray marketplace Mr. Jarosz has defined for Duonase is comprised of 64 separate products based on only 3 distinct active ingredient molecular entities – 17 azelastine/fluticasone fixed-dose combination products (including Duonase, its 6 “imitators,” and 10 other non-imitator products), 32 fluticasone-only products, and 15 mometasone products.²⁹¹ Notwithstanding the assignment of distinct brand names, the large number of products based on the same

²⁹⁰ See, e.g., Exhibit 1136 at p. 17; Exhibit 1138 at pp. 6, 8-10. For example, Mr. Jarosz’ data indicate that Nasonex[®], the original brand version of mometasone, was not introduced in India until 2011, (Exhibit 2149 Tabs 6 and 7.) This was 14 years after its 1997 launch in the United States (Ex. 1), and followed 6 branded generic versions of mometasone that had already been on the market in India prior to 2011 (Exhibit 2149 Tabs 6 and 7).

²⁹¹ Exhibit 2149 at Tab 6.

active ingredient(s) suggests that price competition is the primary driver of sales for these products.

141. Ex. 9 provides confirmatory evidence of this conclusion, by showing that the average CY 2010 to FY 2017 prices per prescription for each of the 64 Indian nasal spray products are similar, ranging between approximately \$2.50 and \$3.50 per unit, and averaging \$3.18.²⁹² This similarity is apparent not only within each of the 3 active ingredient/formulation groups, but also across them, with combination azelastine/fluticasone products averaging \$3.22 from CY 2010 to FY 2017, mometasone products averaging \$3.05, and fluticasone products averaging \$3.15. At \$3.13 per prescription, the Duonase price lies right at the overall nasal spray product average. However, considering that Duonase and the 16 other imitator and non-imitator products combine the corticosteroid fluticasone with the antihistamine azelastine, it is notable that these combination products (including Duonase) nonetheless do not command a price premium over the fluticasone-only

²⁹² Ex. 9 is derived by dividing the dollar sales for each of the drugs in each year from Exhibit 2149 at Tab 6 by the number of prescriptions for the corresponding drugs and year in Exhibit 2149 Tab 7.

products (nor over the mometasone-only products), which do not include an antihistamine component.

142. The Ex. 9a graph of these prices indicates that Duonase is priced in approximately the middle of the pack of the 64 nasal spray drugs, while there are 3 high-price outlier products, one in each of the 3 active ingredient groups: Nasonex[®] (mometasone) averaging \$5.54, Flixonase[®] (fluticasone) averaging \$5.50, and Furamist AZ (azelastine/fluticasone) averaging \$4.31.²⁹³ Nasonex[®] is the true originator mometasone product marketed by Merck, and Flixonase[®] is the true originator fluticasone product marketed by GlaxoSmithKline (which uses the brand name Flonase[®] in the United States).²⁹⁴ Furamist AZ is an azelastine/fluticasone combination drug like Duonase, but reportedly does not embody the challenged

²⁹³ Exhibit 9 provides the reports these CY 2010 to FY 2017 average prices.

²⁹⁴ Exhibit 2048 at pp. 104-105. True originator brands first launched by multi-national companies in more lucrative countries and subsequently introduced in India can still obtain some degree of price premium in India relative to local the branded generic versions despite launching after the local products. (Exhibit 1135 at pp. 22-23; Exhibit 1136 at p. 15.)

claims of the '620 patent.²⁹⁵ Interestingly, Furamist AZ is also marketed by Cipla,²⁹⁶ but at a considerably higher price (\$4.31) than the \$3.15 at which Cipla sells Duonase.

143. Ex. 9b shows that just among the 16 combination azelastine/fluticasone combination products, Cipla's Duonase is still priced in roughly the middle of the pack, while Cipla's non-imitator Furamist AZ is priced considerably above all of the other combination products. Importantly, all of these Indian AR nasal spray prices are a small fraction of the \$146 list price and \$82 net price at which Meda sold the purportedly American version of Duonase, Dymista[®], in 2014.²⁹⁷

144. The foregoing analysis indicates that Duonase sales have been driven primarily by low-price competition among relatively undifferentiated branded generic nasal spray products rather than by any unique attributes of derived from the challenged claims of the '620 patent.

²⁹⁵ Exhibit 2149 at ¶20 and Tabs 6-8.

²⁹⁶ Exhibit 2123 at p. 23; Exhibit 2124 at p. 5.

²⁹⁷ Exhibit 2093 at p. 47.

2. Duonase Sales Reflect Demand for Azelastine Alone

145. The azelastine-based products included in Mr. Jarosz' Indian marketplace are all included in combinations with fluticasone. There are no products comprised of azelastine alone, comparable to Astelin[®] and Astepro[®] (and their generic versions) in the United States. Thus, any customers (physicians/patients/insurers) in India who would prefer to purchase azelastine alone, or purchase azelastine and fluticasone separately for uncombined concurrent use, are unable to do so. They are forced to purchase an azelastine/fluticasone combination product, such as Duonase, if they want to be treated with azelastine. The significant volume of Astelin[®], Astepro[®] and generic azelastine in the United States (together representing 4.7 million prescriptions in 2016), despite the availability of the Dymista[®] combination product (that obtained only 963,299 prescriptions in 2016), suggests that a large percentage of Duonase sales in India are to customers who would be satisfied purchasing azelastine alone, and therefore, whom were not motivated to purchase Duonase by features associated with the challenged claims of the '620 patent.

3. 10 Non-Imitator Products Indicate Sales Are Not Driven by '620 Patent

146. In addition to Duonase and its 6 imitators, there are 10 generally newer azelastine/fluticasone combination products that have penetrated the Indian market that reportedly do not practice the claims of the '620 patent.²⁹⁸ As discussed above, one of these products is marketed by Cipla itself, but at a higher price than it charges for Duonase.²⁹⁹ The increasing sales of these newer azelastine/fluticasone combination products suggest that even to the extent some of Duonase's sales could have been driven by its combination of azelastine and fluticasone into one product, some or all of this subset of sales are not driven by the specific claims of the '620 patent. The larger market share Duonase and its imitators currently maintain versus the non-imitator products may reflect the outcome of price competition among them as well as the former's first-mover advantage over the non-imitators,³⁰⁰ rather than

²⁹⁸ Exhibit 2149 at ¶20, Tabs 6 and 7.

²⁹⁹ See §VI.D.2 above.

³⁰⁰ Brand drug competition has been found to be susceptible to significant first mover advantages, such that a first or early entrant enjoys higher market share and possibly can maintain higher prices than subsequent or later entrants.

(See, e.g., Exhibit 1094 at pp. 14-15; Exhibit 1087 at p. 2; Exhibit 1135 at p.

... (Continued)

any market preference for combination products that practice the challenged claims of the '620 patent.

4. Marketing Does Not Claim Combination Superiority Over Separate Use

147. As was the case with Dymista[®], the 2 Duonase marketing materials Mr. Jarosz referenced in support of his claim that Duonase “highlighted key features of Duonase that correspond to benefits provided by the '620 patent,³⁰¹ make no claims that Dymista[®] is superior to concurrent use of uncombined antihistamines and corticosteroid products.³⁰²

E. Meda-Cipla License Agreement Does Not Demonstrate Nexus

148. Mr. Jarosz contends that the financial commitments Medpointe/Meda extended to Cipla for a 2006 license to what became Cipla's '620

... (Continued)

23.) In this case, the first non-imitator product, Nezalast, is reported to have launched 1½ years after Duonase and 1 month after the 1st imitator product for Duonase. (See Exhibit 2072.)

³⁰¹ Exhibit 2149 at ¶¶68-69.

³⁰² See Exhibit 2149 at Figure 10 and Figure 11.

patent supports his “opinion that Cipla’s licensed technology is quite valuable” and is a “useful indicator of nexus.”³⁰³ This financial commitment consisted of a possible \$1.5 million payment, comprised of a \$750,000 upfront fee paid in 2006, and a potential total of another \$750,000 in future fees contingent upon attainment of certain development milestones.³⁰⁴ In 2011, Meda also agreed in a license amendment to pay 15% of Dymista®’s net revenues for its purchases of azelastine/fluticasone product supply from Cipla.³⁰⁵

149. However, Mr. Jarosz provides no basis for concluding that the \$750,000 to \$1.5 million license fee Medpointe agreed to pay should be considered as “quite valuable.” In fact, the fee appears to be insignificant in comparison to the \$75 million to \$100 million Medpointe conservatively expected to have to invest to develop the product for FDA marketing approval.³⁰⁶ Moreover, the 15% purchase “royalty” Meda subsequently agreed to pay Cipla for product purchases represented

³⁰³ Exhibit 2149 at ¶¶103-105.

³⁰⁴ Exhibit 2049 at p. 7; Exhibit 2149 at ¶104.

³⁰⁵ Exhibit 2050 at pp. 3-4; Exhibit 2149 at ¶105.

³⁰⁶ Exhibit 2056 at p. 11.

a minimal financial commitment since the payment automatically adjusts to reflect the product's actual commercial performance. Further, the small financial commitment required to obtain the license more likely reflects Medpointe's belief that it is generally "cheaper to take licenses than to defend infringements suits,"³⁰⁷ rather than reflecting the value of the underlying patent. Consequently, in my opinion, the Medpointe/Meda license fee and royalty does not support Mr. Jarosz' opinion that the '620 patent technology is "quite valuable" or an "indicator of nexus."

150. But even apart from the small magnitude of the Medpointe/Meda financial commitment, the value implied by the license agreement only reflects the parties' contemporaneous beliefs regarding the future levels of commercial sales that might be attained, before the product's market launch and before any actual commercial success was realized or assured. However, such prelaunch commitment to patent licensing (or R&D investment generally), based on prelaunch predictions

³⁰⁷ Exhibit 1065 at p. 11.

of possible commercial sales levels, does not constitute a nexus to actual commercial success, which is the relevant metric of this inquiry.

VII. CONCLUSION

151. My review of Dymista[®]'s commercial success as an *indicium* of the '620 patent's nonobviousness leads me to the opinion that Mr. Jarosz has failed to demonstrate that either Dymista[®] or Duonase has achieved such commercial success, or that the sales of either have a causal nexus to any unique associated with the challenged claims of the '620 patent. In particular, I find that Dymista[®] sales have not been significant relative to 1) brand pharmaceutical prescription products generally; 2) pre-generic sales of other AR nasal spray brands specifically; 3) Meda's pre-launch sales expectations; or 4) the investments and operating costs required to market Dymista[®]. Likewise, I conclude that sales of Duonase in India are not relevant for indicating the nonobviousness of a useful invention associated with the challenged claims of the '620 patent, and in any event, are not significant.

152. I also find that what sales Dymista[®] has generated are not primarily due to product differentiation based on the challenged claims of the '620 patent, but instead are primarily driven by factors unrelated to the '620 patent, which include its high share of voice in marketing/promotion and its low effective price to insurers

and patients as a result of extensive rebating and copayment subsidization. I also conclude that Duonase sales have been largely driven by undifferentiated price competition and by the unavailability of any non-combination azelastine products in India.

153. Overall, I conclude that neither Dymista®'s nor Duonase's commercial performance represent a secondary *indiciu*m that the challenged claims of the '620 patent were nonobvious.

Date: MARCH 6, 2018



John C. Staines, Jr.

Ex. 1 Summary Information on Alternative Treatments for Seasonal Allergic Rhinitis

[A]	[B]	[C]	[D]	[E]	[F]	[G]
Brand Name	Active Ingredient(s)	Marketer	Original Launch or Approval	Generic Entry	OTC Conversion	Pre-Generic Annual \$ Sales
						\$000s/Year Year Source
Intranasal Corticosteroids						
Nasonex®	Mometasone	Schering/Merck	1997	2016	2016	\$1,145,345 2014 Exhibit 2149 Tab 2
Flonase®	Fluticasone (propionate)	GlaxoSmithKline	1995	2006	2015	\$1,044,160 2005 Exhibit 1074
* Ticanase®	Fluticasone (propionate)	Apotex/PureTek	2016	Generic Product - ANDA-077538; NDC-59088-392		
Veramyst®	Fluticasone (fuorate)	GlaxoSmithKline	2007	2017	2017	\$171,000 2009 Exhibit 2048 p 119
** Nasacort®	Triamcinolone Acetonide	Sanofi	1991	Discontinued		
Nasacort AQ®	Triamcinolone Acetonide AQ	Sanofi	2004	2011	2014	\$311,467 2005 Exhibit 1074
Rhinocort Aqua®	Budesonide	AstraZeneca	1994	2014	2016	\$296,463 2005 Exhibit 1074
Omnaris®	Ciclesonide AQ	Sunovion	2008			\$65,000 2011 Exhibit 2053 p 187
Zetonna®	Ciclesonide (Dry)	Sunovion	2012			\$24,880 2013 Exhibit 2149 Tab 2
** Beconase®	Beclomethasone	GlaxoSmithKline	1976	Discontinued		
Beconase AQ®	Beclomethasone AQ	GlaxoSmithKline	1987	Unknown		
Qnasl® (& Child)	Beclomethasone (Dry)	Teva	2012			\$75,157 2015 Exhibit 2149 Tab 2
** Vancenase®	Beclomethasone	Schering/Merck	1981	Discontinued		
** Vancenase AQ®	Beclomethasone AQ	Schering/Merck	1987	Discontinued		
** Nasalide®	Flunisolide	Roche	1981	2002	Discontinued	
** Nasarel®	Flunisolide AQ	Roche	1995	2007	Discontinued	
Intranasal Antihistamines						
Astelin®	Azelastine	Meda	1997	2010		\$233,000 2009 Exhibit 2048 p 139
Astepro® 0.10%,0.15%	Azelastine (Sweetened, 1/day)	Meda	2009	2014		\$116,300 2012 Exhibit 2149 Tab 2
Dymista®	Azelastine/Fluticasone (propionate)	Meda	2012			\$157,477 2015 Exhibit 2149 Tab 2
Patanase®	Olopatadine	Alcon	2008	2014		\$101,816 2014 Exhibit 2149 Tab 2
Oral Antihistamines (Non-Sedating)						
Allegra®	Fexofenadine	Sanofi	1996	2005	2011	\$957,152 2005 Exhibit 1074
Allegra-D®	Fexofenadine/Pseudoephedrine	Sanofi	2000	2009	2011	\$479,000 2007 Exhibit 2048 p 70
Claritin®	Loratadine	Schering/Merck	1988		2002	\$2,000,000 2001 Exhibit 2138 p. 98
Claritin-D®	Loratadine/Pseudoephedrine	Schering/Merck	1994		2002	\$800,000 2001 Exhibit 2138 p. 95
Clarinex®	Desloratadine	Schering/Merck	2002	2010		\$353,325 2005 Exhibit 1074
Clarinex-D®	Desloratadine/Pseudoephedrine	Schering/Merck	2005	2011		\$36,000 2009 Exhibit 2048 p 89
Zyrtec®	Cetirizine	UCB/Pfizer	1995	2007	2008	\$1,700,000 2007 Exhibit 2048 p 78
Zyrtec-D®	Cetirizine/Pseudoephedrine	UCB/Pfizer	2001	2008	2008	\$163,573 2005 Exhibit 1074
Xyzal®	Levocetirizine	UCB/Sanofi	2007	2010		\$160,237 2010 Exhibit 1074
Leukotriene Receptor Antagonists						
Singulair®	Montelukast	Merck	1998	2012		\$810,133 2009 Exhibit 2048 p 150

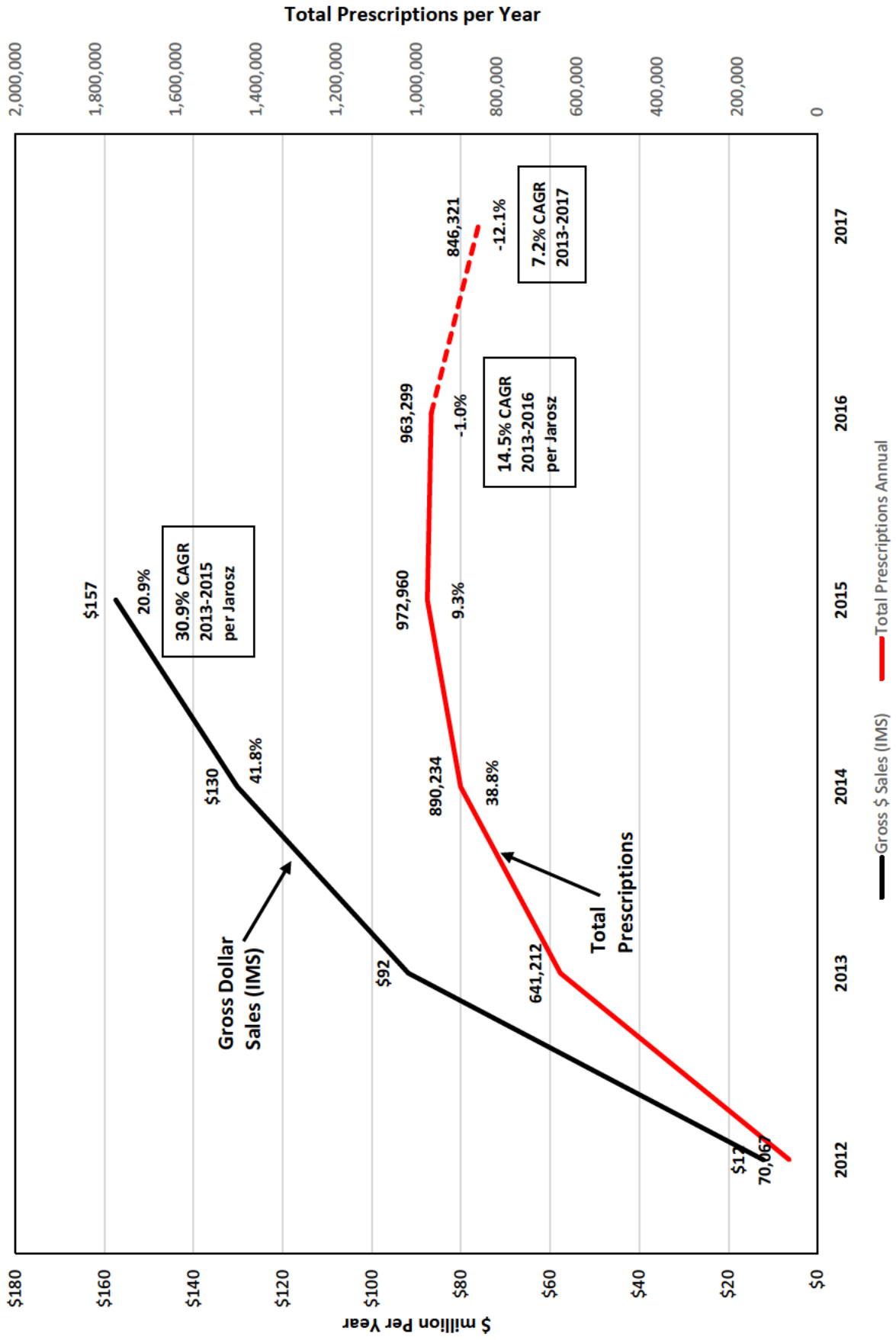
Ex. 1
Summary Information on Alternative Treatments for Seasonal Allergic Rhinitis

Sources:

- [A] Intranasal Corticosteroids: Exhibit 2149 at Tab 2; Oral Antihistamines and Leukotriene Receptor Antagonists: Exhibit 2053 at pp. 98, 100, 104-106
- [B] Exhibit 1058; Exhibit 1070; Exhibit 1105; Exhibit 1108, Exhibit 2048 pp. 66, 68; Exhibit 2053 at pp. 100, 104-106, 113, 115-116, 119, 120, 138, 180, 186, 187, 189, 191-195; Exhibit 2169
- [C] Exhibit 1070; Exhibit 1105; Exhibit 2048 p. 68; Exhibit 2053 at pp. 85, 98, 100, 104-106, 113, 115, 116, 119, 120, 138, 180, 184, 186, 187, 189, 191-194
- [D] Exhibit 1061; Exhibit 1064; Exhibit 1070; Exhibit 1105; Exhibit 1108; Exhibit 1109; Exhibit 1110; Exhibit 1113
- [E] Exhibit 2048 at pp. 66-68, 76-77, 80, 85-87, 95, 99, 104-105, 112-113, 118-119, 129-130, 138, 146; Exhibit 2053 at pp. 98, 105, 115, 116, 153, 186-187, 190-192, 194
- [F] Exhibit 1059; Exhibit 1061; Exhibit 1064; Exhibit 1104; Exhibit 1103; Exhibit 1106; Exhibit 1108
- [F] Exhibit 2048 at pp. 69-70, 75, 78-79 ; Exhibit 2053 at pp. 139, 180, 186, 189, 191, 194; Exhibit 2076 at p. 3; Exhibit 2130.
- [F] Exhibit 1059; Exhibit 1109; Exhibit 2048 at pp. 41, 75, 79, 85; Exhibit 2053 at pp. 186, 189-190; Exhibit 2076 at p. 3; Exhibit 2078; Exhibit 2081

* Ticonase® is a generic for Flonase produced under a generic ANDA approved for Apotex in 2007 and marketed by Pure Tek under the brand name, Ticonase® (see Exhibit 1112, Exhibit 1113)
** Product has been discontinued (no longer approved for marketing). Ssee Exhibit 1070; Exhibit 1108; Exhibit 1111

Ex. 2
Dymista® Gross Dollar Sales (IMS) Compared to Total Prescription Growth



Sources: Exhibit 2149 at Tab 1 and Tab 2;
Exhibit 2332; Ex. 2a.

Ex. 2a
Dymista® Prescription, Gross Revenue, and Net Revenue Levels and Growth Rates

	Oct-Dec 2012	2013	2014	2015	2016	2017
[1] Total Prescriptions Annual	70,067	641,212	890,234	972,960	963,299	846,321
[2] Annual Growth Rate			38.8%	9.3%	-1.0%	-12.1%
[3] 2013 to 2016 Average Annual Growth Rate					14.5%	7.2%
[4] Sales Dollars	\$12,155,211	\$91,849,580	\$130,225,088	\$157,477,385		
[5] Annual Growth Rate			41.8%	20.9%		
[6] 2013 to 2015 Average Annual Growth Rate				30.9%		
[7] Net Revenue (SEK million)		410	556	706		
[8] Avg Annual \$US/SEK Rate		\$6.5096	\$6.8487	\$8.4303		
[9] Net Revenue Derived		\$62,983,901	\$81,183,053	\$83,745,934		
[10] Net Revenue Reported	\$9,405,000	\$63,094,000	\$81,211,000			
[11] Net Revenue	\$9,405,000	\$63,094,000	\$81,211,000	\$83,745,934		
[12] Annual Growth Rate			28.7%	3.1%		
[13] 2013 to 2015 Average Annual Growth Rate				15.2%		
[14] Net Revenue Discount %	23%	31%	38%	47%		

Sources/Notes:

- [1] 2012-2016: Exhibit 2149 at Tab 1
2017:
Jan-Apr 2017 TRx = 286,335 Exhibit 2149 at Tab 1
÷ Jan-Apr 2016 TRx / Total 2016 TRx = 33.8% Ex. 2b col [G]₂₀₁₆, based on Exhibit 2132
- Projected 2017 Annual TRx 846,321
- [2] $([1]_t / [1]_{t-1}) - 1$
[3] $([1]_t / [1]_{2013})^{1/(t-2013)} - 1$
[4] Exhibit 2149 at Tab 2
[5] $([4]_t / [4]_{t-1}) - 1$
[6] $([4]_t / [4]_{2013})^{1/(t-2013)} - 1$
[7] Exhibit 1068 p. 56; Exhibit 1067 p. 63; Exhibit 1066 p. 65
[8] Exhibit 1068 p. 78; Exhibit 1067 p. 90; Exhibit 1066 p. 94
[9] $1,000,000 \times [7] / [8]$
[10] Exhibit 2093 at p. 75; Exhibit 2076 at p. 50
[11] Maximum of ([9], [10])
[12] $([11]_t / [11]_{t-1}) - 1$
[13] $([11]_t / [11]_{2013})^{1/(t-2013)} - 1$
[14] $1 - [11] / [4]$

Ex. 2b
Dymista® January to April and Annual
Total Prescriptions

	[A]	[B]	[C]	[D]	[E]	[F]	[G]
	January	February	March	Apr	Jan-Apr	Annual	Jan-Apr % Of Annual
2013	33,223	35,565	44,857	53,410	167,055	641,212	26.1%
2014	59,965	56,956	69,595	77,871	264,387	890,234	29.7%
2015	75,076	70,806	84,657	87,655	318,194	972,960	32.7%
2016	73,819	75,945	89,747	86,401	325,912	963,299	33.8%
2017	68,246	64,990	80,924	72,175	286,335		

Sources:

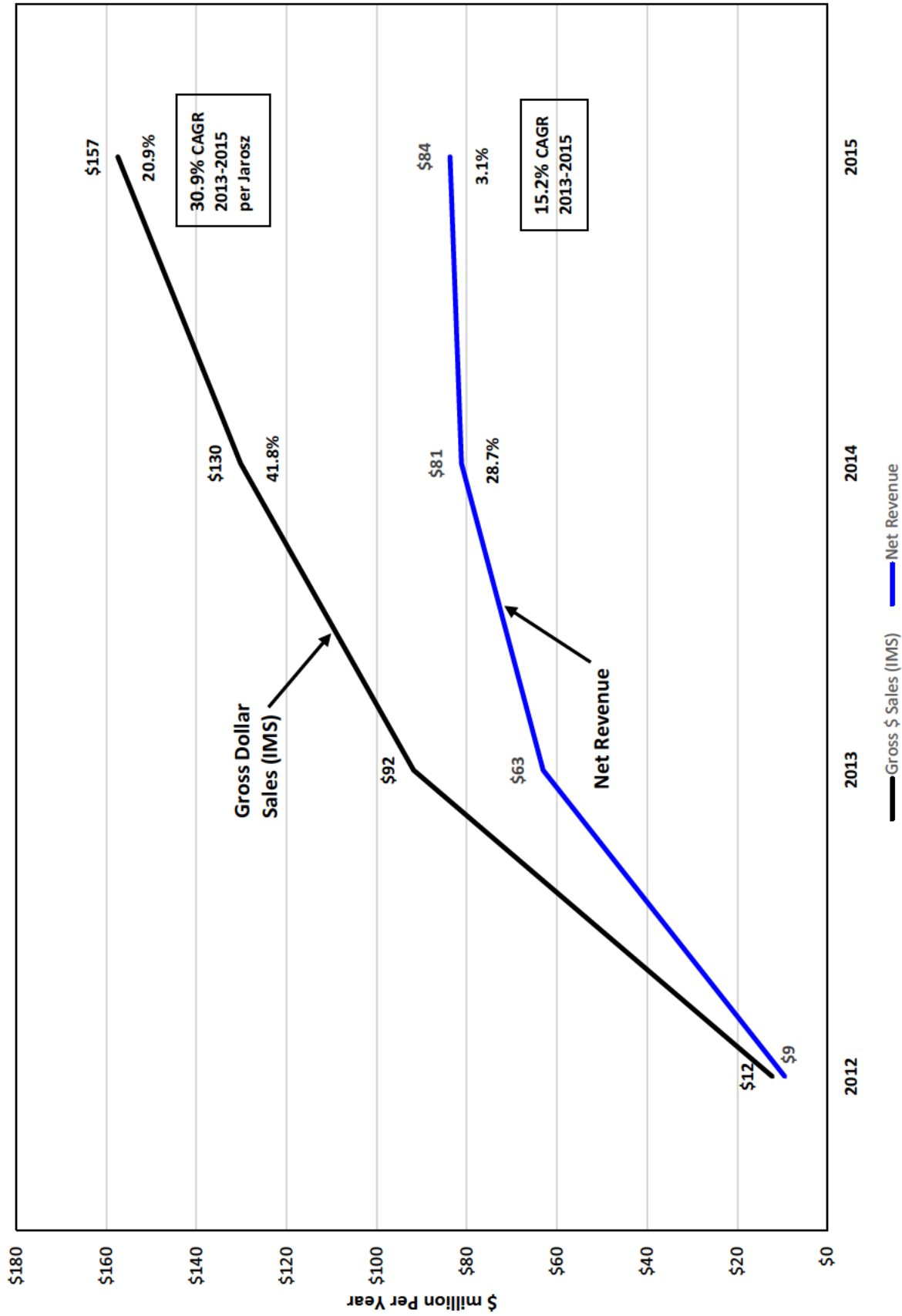
[A] to [D] Exhibit 2132

[E] Sum([A] to [D])

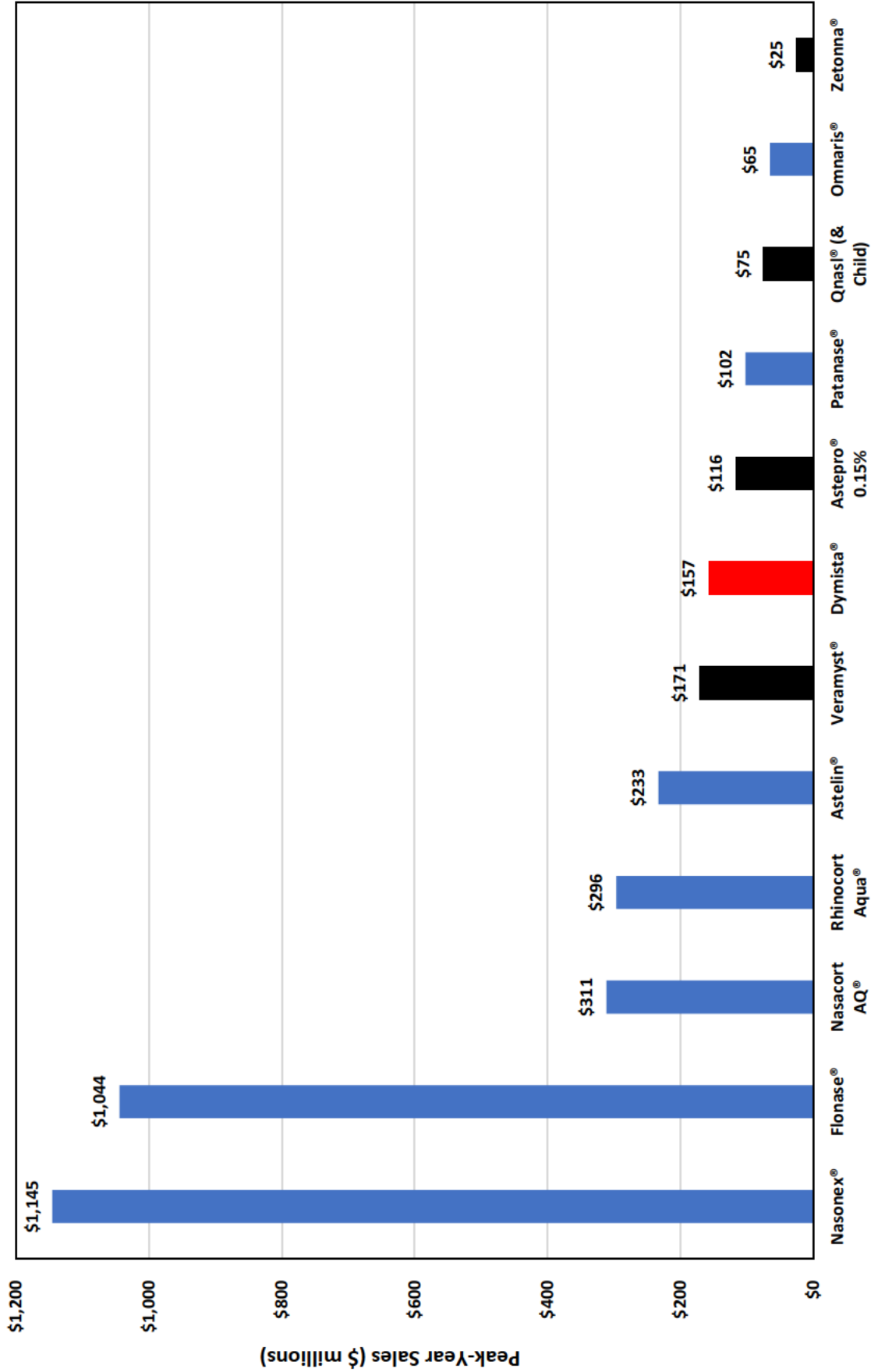
[F] Exhibit 2149 at Tab 1.

[G] [E] / [F]

Ex. 3
Dymista® Gross Dollar Sales (IMS) Compared to Net Revenue Growth



Ex. 4
Peak-Year Gross Sales Dollars for SAR Nasal Spray Treatments



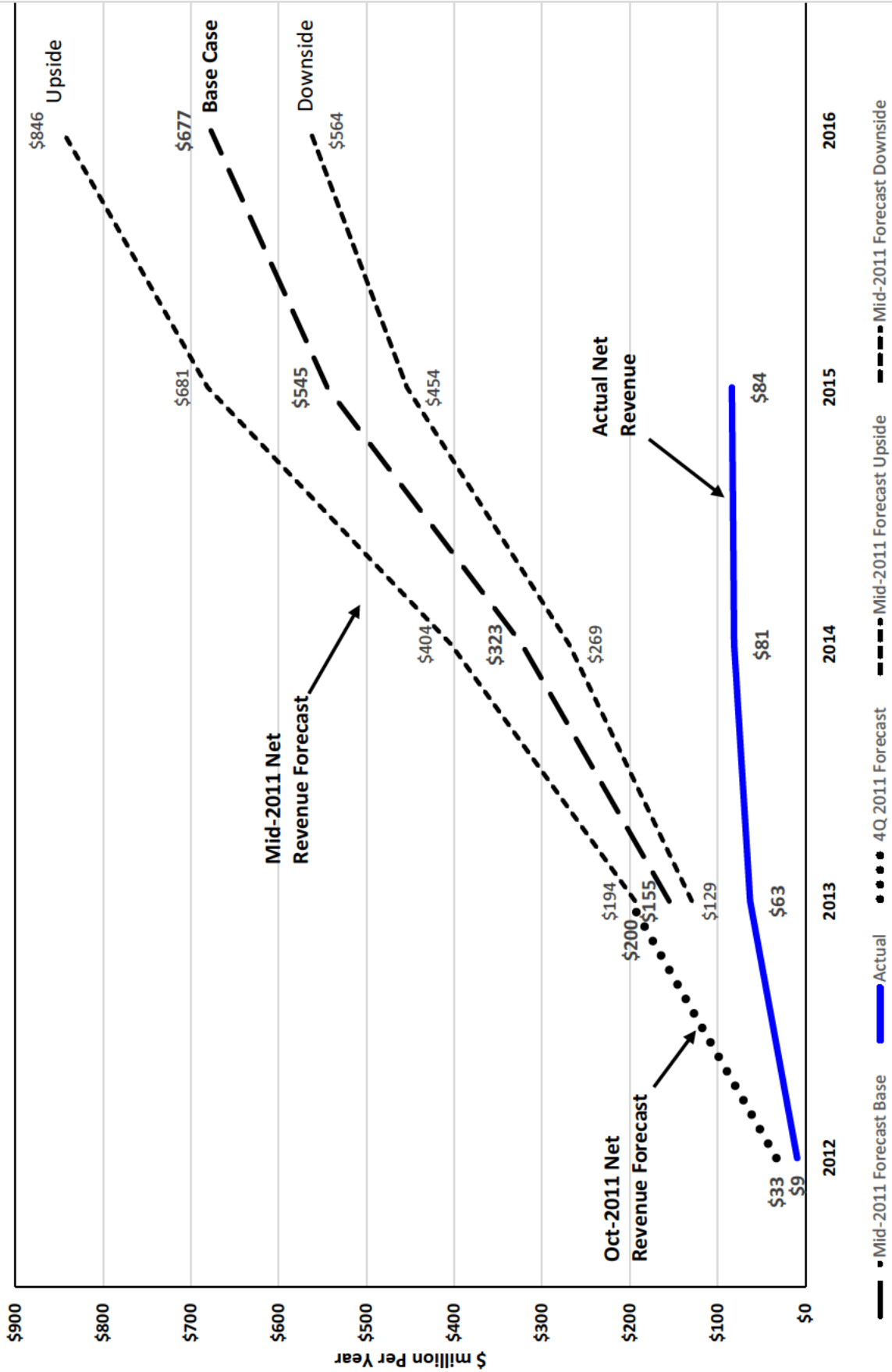
Black Bars Indicate Follow-up Products to Previously-Marketed Brands

Ex. 5
Top 200 Brand Drugs by U.S. Retail Channel Sales \$ in 2010
(\$ millions)

Rank	Drug	\$ Sales	Rank	Drug	\$ Sales	Rank	Drug	\$ Sales	Rank	Drug	\$ Sales	Rank	Drug	\$ Sales
1	Nexium	\$5,276	41	Lovenox	\$867	81	Avodart	\$441	121	Caduet	\$267	161	Nasacort AQ	\$192
2	Lipitor	\$5,273	42	Adderall XR	\$837	82	Vesicare	\$441	122	Actonel 150	\$265	162	Proventil HFA	\$192
3	Plavix	\$4,675	43	ProAir HFA	\$819	83	Trilipix	\$429	123	Risperdal Consta	\$262	163	Advair HFA	\$191
4	Advair Diskus	\$3,655	44	Truvada	\$814	84	Copaxone	\$422	124	Prograf	\$261	164	Valcyte	\$191
5	OxyContin	\$3,555	45	Niaspan	\$794	85	Focalin XR	\$416	125	Ciprodex otic	\$255	165	Wellbutrin XL	\$189
6	Abilify	\$3,514	46	Humalog	\$783	86	Reyataz	\$412	126	Vigamox	\$253	166	Oracea	\$187
7	Singulair	\$3,325	47	Cialis	\$757	87	Pristiq	\$412	127	Kadian	\$252	167	Vivelle-DOT	\$186
8	Seroquel	\$3,222	48	Namenda	\$744	88	Arimidex	\$404	128	Coreg CR	\$251	168	Uroxatral	\$186
9	Crestor	\$2,923	49	Symbicort	\$707	89	Chantix	\$395	129	Levitra	\$242	169	Zovirax topical	\$184
10	Cymbalta	\$2,639	50	Flovent HFA	\$705	90	Sensipar	\$382	130	Maxalt	\$242	170	Epipen	\$183
11	Actos	\$2,632	51	Seroquel XR	\$696	91	Avapro	\$370	131	Keppra	\$242	171	Creon	\$181
12	Lexapro	\$2,483	52	Combivent	\$693	92	Opana ER	\$366	132	Prevacid	\$241	172	Azor	\$180
13	Zyprexa	\$2,036	53	Lovaza	\$682	93	Yaz	\$362	133	Micardis	\$238	173	Pentasa	\$178
14	Spiriva	\$1,594	54	Solodyn	\$673	94	Doryx	\$362	134	Bystolic	\$231	174	Procrit	\$175
15	Lantus	\$1,526	55	Detrol LA	\$620	95	Actoplus Met	\$360	135	Prezista	\$230	175	Pataday	\$174
16	Aricept	\$1,523	56	AndroGel	\$594	96	Humira	\$358	136	Exelon Patch	\$230	176	Differin	\$171
17	Lyrica	\$1,478	57	Benicar	\$568	97	Avelox	\$353	137	Nuvigil	\$224	177	Premarin vaginal	\$171
18	Diovan	\$1,444	58	Levemir	\$567	98	NuvaRing	\$349	138	Zyvox	\$223	178	Zyprexa Zydis	\$170
19	Effexor XR	\$1,431	59	Enbrel	\$547	99	Renvela	\$334	139	Lialda	\$222	179	Tussionex	\$170
20	Concerta	\$1,408	60	Valtrex	\$534	100	Ortho Tri-Cyclen Lo	\$332	140	Epzicom	\$221	180	Victoza	\$169
21	Levaquin	\$1,355	61	Benicar HCT	\$526	101	Lamictal	\$326	141	Enablex	\$220	181	Humalog KwikPen	\$168
22	Celebrex	\$1,350	62	Gleevec	\$518	102	Availide	\$325	142	Forteo	\$219	182	Arixtra	\$166
23	Diovan HCT	\$1,315	63	Humira Pen	\$515	103	Xopenex	\$316	143	Viread	\$216	183	Qvar	\$164
24	Januvia	\$1,294	64	Synthroid	\$507	104	Actonel	\$314	144	Kaletra	\$213	184	Combivir	\$163
25	Suboxone	\$1,165	65	Xalatan	\$502	105	Dexilant/Kapidex	\$313	145	Micardis HCT	\$212	185	Testim	\$163
26	NovoLog	\$1,101	66	Premarin tabs	\$498	106	Lotrel	\$306	146	Maxalt MLT	\$211	186	Tarceva	\$161
27	Viagra	\$1,029	67	Strattera	\$497	107	Invega	\$304	147	Humalog Mix 75/25	\$211	187	Xyzal	\$160
28	Atripla	\$1,029	68	Ventolin HFA	\$497	108	Welchol	\$303	148	Xeloda	\$209	188	Elmiron	\$158
29	Tricor	\$1,016	69	Flomax	\$486	109	Avonex	\$303	149	Asmanex	\$209	189	Propecia	\$158
30	Provigil	\$1,000	70	Loestrin 24 Fe	\$484	110	Topamax	\$287	150	Hyzaar	\$207	190	CellCept	\$158
31	Zetia	\$986	71	Protonix	\$481	111	Norvir	\$287	151	Fentora	\$207	191	Skelaxin	\$156
32	Geodon oral	\$959	72	Boniva	\$480	112	Entocort EC	\$283	152	Pulmicort Respules	\$205	192	Betaseron	\$156
33	Vytroin	\$954	73	Restasis	\$480	113	Aggrenox	\$277	153	Ranexa	\$201	193	Temodar	\$154
34	Ambien CR	\$951	74	Femara	\$477	114	Travatan Z	\$274	154	RenaGel	\$199	194	Flector	\$154
35	Lunesta	\$949	75	Enbrel Sureclick	\$475	115	Isentress	\$272	155	Prempro	\$198	195	Pegasisys	\$153
36	Lidoderm	\$934	76	NovoLog Mix 70/30	\$471	116	Avandia	\$269	156	Relpax	\$197	196	Prandin	\$152
37	Lantus SoloSTAR	\$934	77	Evista	\$469	117	Prevacid SoluTab	\$268	157	Patanol	\$197	197	Veramyst	\$151
38	Vyvanse	\$931	78	Byetta	\$459	118	Exforge	\$268	158	Amnitiza	\$195	198	Intuniv	\$150
39	Aciphex	\$916	79	Janumet	\$459	119	Cozaar	\$267	159	Duragesic	\$195	199	Clobex	\$150
40	Nasonex	\$886	80	Asacol	\$451	120	Lumigan	\$267	160	Vancocin HCl	\$192	200	Humulin N	\$150

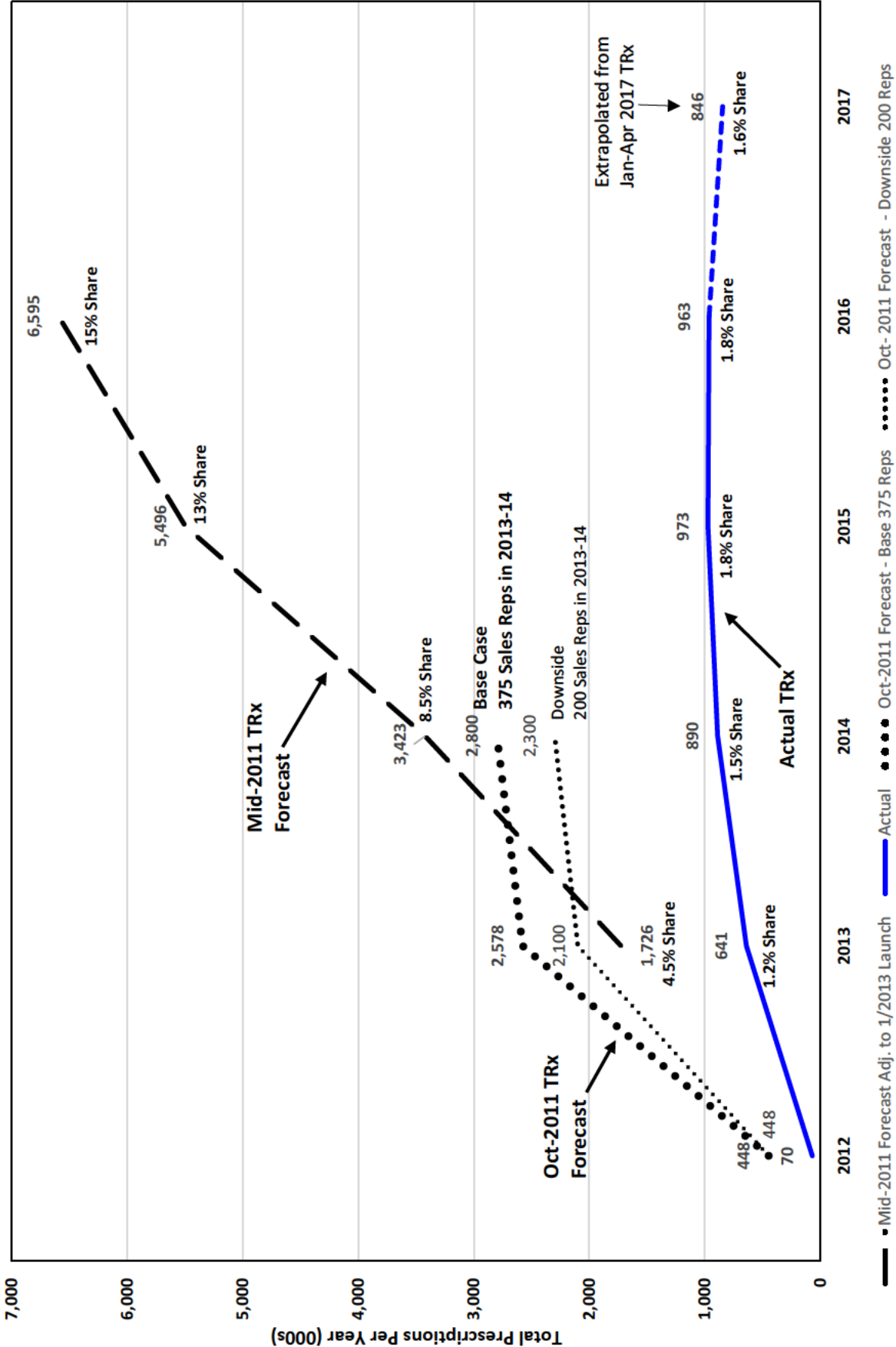
Source: Exhibit 1073

Ex. 6a
Actual Dymista® Actual Net Revenues Compared to Prelaunch Forecasts



Sources: Ex. 2a;
Exhibit 2079 at p. 38;
Exhibit 2080 at pp. 9-11.

Ex. 6b
Actual Dymista® Total Prescriptions Compared to Prelaunch Forecasts



Sources: Exhibit 2079 at pp. 12, 38, 40;
Exhibit 2080 at p. 10;
Exhibit 2149 at Tab 2; Ex. 2a.

Ex. 7
Comparison of Dymista® Sales Revenues to Operating Costs and R&D Investment
(000s, except where otherwise indicated)

	2008	2009	2010	2011	2012	2013	2014	2015	Estimated 2016	2017
[1] Prescriptions					70	641	890	973	963	846
[2] Annual % Change						815.1%	38.8%	9.3%	-1.0%	-12.1%
<u>Revenue</u>										
[3] Gross Sales \$ (IMS)					\$12,155	\$91,850	\$130,225	\$157,477		
[4] Net Revenue					\$9,405	\$63,094	\$81,211	\$83,746	\$82,914	\$72,846
<u>Operating Costs</u>										
[5] Sale Force (Cost)					\$7,600	\$40,200	\$29,800	\$27,400	\$27,400	\$27,400
[6] Advertising, Promotion & Samples					\$10,675	\$26,319	\$22,879	\$25,750	\$27,000	\$27,000
[7] COGS					\$228	\$2,084	\$2,893	\$3,162	\$3,131	\$2,751
[8] Operating Costs					\$18,503	\$68,603	\$55,572	\$56,312	\$57,531	\$57,151
<u>Operating Profit</u>										
[9] Current Operating Profit					(\$9,098)	(\$5,509)	\$25,639	\$27,434	\$25,384	\$15,695
[10] Present Value as of 2012					(\$9,098)	(\$4,963)	\$20,809	\$20,059	\$16,721	\$9,314
[11] Cumulative Present Value										\$52,843
[12] Expected Cumulative Present Value										\$29,577
<u>Prelaunch Investment</u>										
[13] R&D Expenses	\$18,750	\$18,750	\$18,750	\$18,750	\$18,750					
[14] Present Value as of 2012	\$28,464	\$25,643	\$23,102	\$20,813						
[15] Cumulative Present Value										\$98,021
[16] Net Present Value as of 2012										(\$45,178)
[17] Expected Net Present Value										(\$68,444)

Ex. 7

Comparison of Dymista® Sales Revenues to Operating Costs and R&D Investment

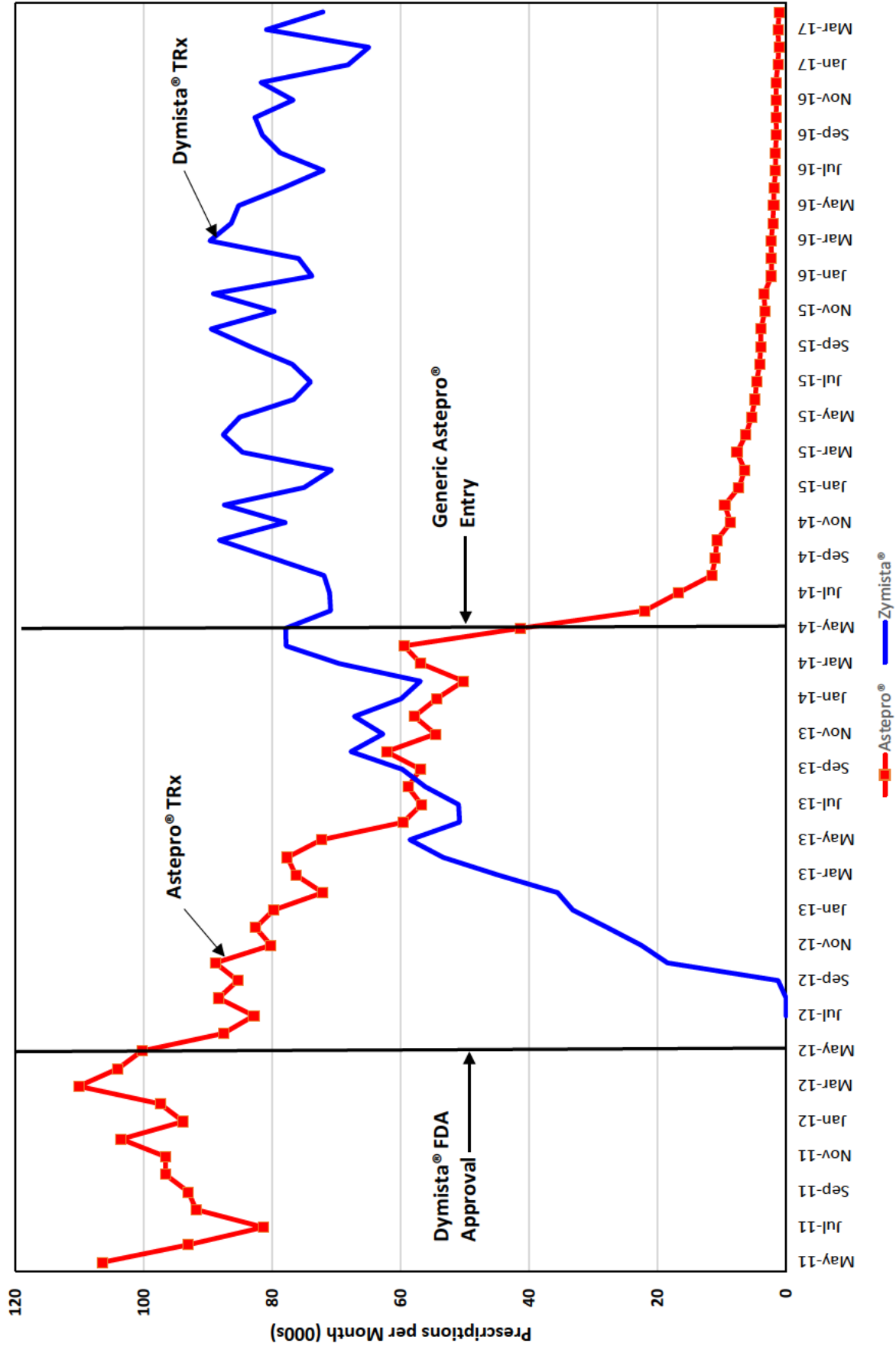
(000s, except where otherwise indicated)

Sources/Notes:

- [1] Ex. 2a, based on Exhibit 2149 at Tab 1 and Exhibit 2132
- [2] $[1] / [1]_{\text{Year-1}} - 1$
- [3] 2149 Tab 2
- [4] 2012-2015: Tab 2a row [11]
2016-2017: $[4]_{\text{Year-1}} \times (1 + [2])$
- [5] 2012-2015: Exhibit 2093 at p 75
2016-2017: $[5]_{\text{Year-1}}$
- [6] 2012-2016: Exhibit 2076 at p 50; Exhibit 2093 at p 75
2017: $[6]_{\text{Year-1}}$
- [7] $[1] \times \text{Cost/Unit}$, where Cost/Unit = \$3.25 per Exhibit 2079 at p 29
- [8] Sum([5] to [7])
- [9] [4] - [8]
- [10] $[9] \times (1 + \text{Discount Rate})^{(2012-\text{Year})}$, where Discount Rate = 11% per Exhibit 1077 at p. 5; Exhibit 1075 at p. 3
- [11] Sum([10]₂₀₀₈ to [10]₂₀₁₇)
- [12] [11] x Probability of Phase III Clinical Success & FDA approval =

	Phase III Probability	61.95% per Exhibit 1077 at p. 4
x	FDA approval probability	90.35% per Exhibit 1077 at p. 4
	Phase III & Approval	55.97%
- [13] Total R&D Expense / 4 years assumed to commence in 2008, where R&D expense = \$75,000 per Exhibit 2056 at p 11
- [14] $[9] \times (1 + \text{Discount Rate})^{(2012-\text{Year})}$, where Discount Rate = 11% per Exhibit 1077 at p. 5; Exhibit 1075 at p. 3
- [15] Sum([14]₂₀₀₈ to [14]_{Year})
- [16] [11] - [15]
- [17] [12] - [15]

Ex. 8
Astepro® & Dymista® Total Prescriptions per Month



Ex. 9

INDIA
ALLERGIC RHINITIS NASAL SPRAYS
IMS TSA DATA
UNIT PRICE (USD)
2010 - 2017

	Year Ending December 31			Year Ending March 31			Average Across All Years
	2010	2011	2012	2013	2014	2015	
	\$	\$	\$	\$	\$	\$	\$
Azelastine + Fluticasone							
Imitator Products							
Duonase	\$3.29	\$3.52	\$3.37	\$3.00	\$2.87	\$2.97	\$3.18
Azefto	\$3.06	\$3.19	\$3.06	\$2.69	\$2.57	\$2.61	\$2.72
Combinase-AQ	\$3.20	\$3.33	\$3.17	\$2.78	\$3.02	\$3.20	\$3.16
Nazomac-AF	\$3.21	\$3.33	\$3.17	\$2.78	\$2.56	\$2.88	\$2.86
Floresp-AZ			\$4.12	\$3.59	\$3.18	\$3.14	\$2.88
Ericas-AZ	\$3.24	\$3.38	\$3.36	\$2.94	\$2.70	\$2.96	\$2.99
Nasocom-AZ	\$3.21	\$3.38	\$3.42	\$3.06	\$2.79	\$3.01	\$3.09
							\$3.13
Other Azelastine + Fluticasone							
Furamist-AZ	\$5.01	\$5.21	\$4.96	\$4.36	\$3.44	\$3.71	\$3.95
Nezlast	\$3.24	\$3.37	\$3.35	\$2.94	\$2.73	\$2.87	\$2.73
Flublock-AZ					\$2.90	\$2.94	\$2.88
Azenate	\$3.25	\$3.42	\$3.29	\$2.92	\$2.66	\$2.62	\$2.59
Flutirest-AZ					\$3.71	\$3.54	\$3.18
Flutlair-AZ			\$3.30	\$2.90	\$2.61	\$2.58	\$2.35
Fivasa-AZ	\$4.30	\$4.45	\$4.21	\$3.77	\$3.44	\$3.40	\$3.10
Duospray		\$3.58	\$3.39	\$2.97	\$2.67		\$3.17
Samase	\$3.07	\$3.18					\$3.12
Combinase-Ft						\$3.54	\$3.43
Average (Excluding Duonase)	\$3.48	\$3.62	\$3.57	\$3.14	\$2.93	\$3.03	\$3.00
Mometasone							
Nasonex		\$6.68	\$6.35	\$5.57	\$5.02	\$4.96	\$5.24
Metaspray	\$2.79	\$2.89	\$2.92	\$2.62	\$2.51	\$2.77	\$2.81
Moneflo	\$2.73	\$2.85	\$2.73	\$2.40	\$2.29	\$2.34	\$2.38
Metatop	\$2.93	\$3.04	\$2.90	\$2.55	\$2.85	\$2.80	\$2.95
Aquamet	\$3.43	\$3.59	\$3.48	\$3.05	\$2.77	\$2.91	\$2.85
Nazomac-M		\$2.73	\$2.69	\$2.39	\$2.17	\$2.49	\$2.46
Esynos					\$2.33	\$2.40	\$2.24
Momenta	\$3.12	\$3.44	\$3.33	\$2.92	\$2.63	\$2.92	\$3.17
Rhine-M					\$2.41	\$2.42	\$2.34
Eziwin			\$3.83	\$3.36	\$3.03	\$2.91	\$2.57
M-Spray	\$2.61	\$2.71	\$2.67	\$2.30	\$2.06		
Sensonase	\$3.33						\$2.55
Respizen							\$3.35
Ezispray						\$3.44	\$3.39
Vioson						\$2.16	\$2.16
Average	\$2.99	\$3.49	\$3.43	\$3.02	\$2.73	\$2.89	\$2.95
							\$3.05

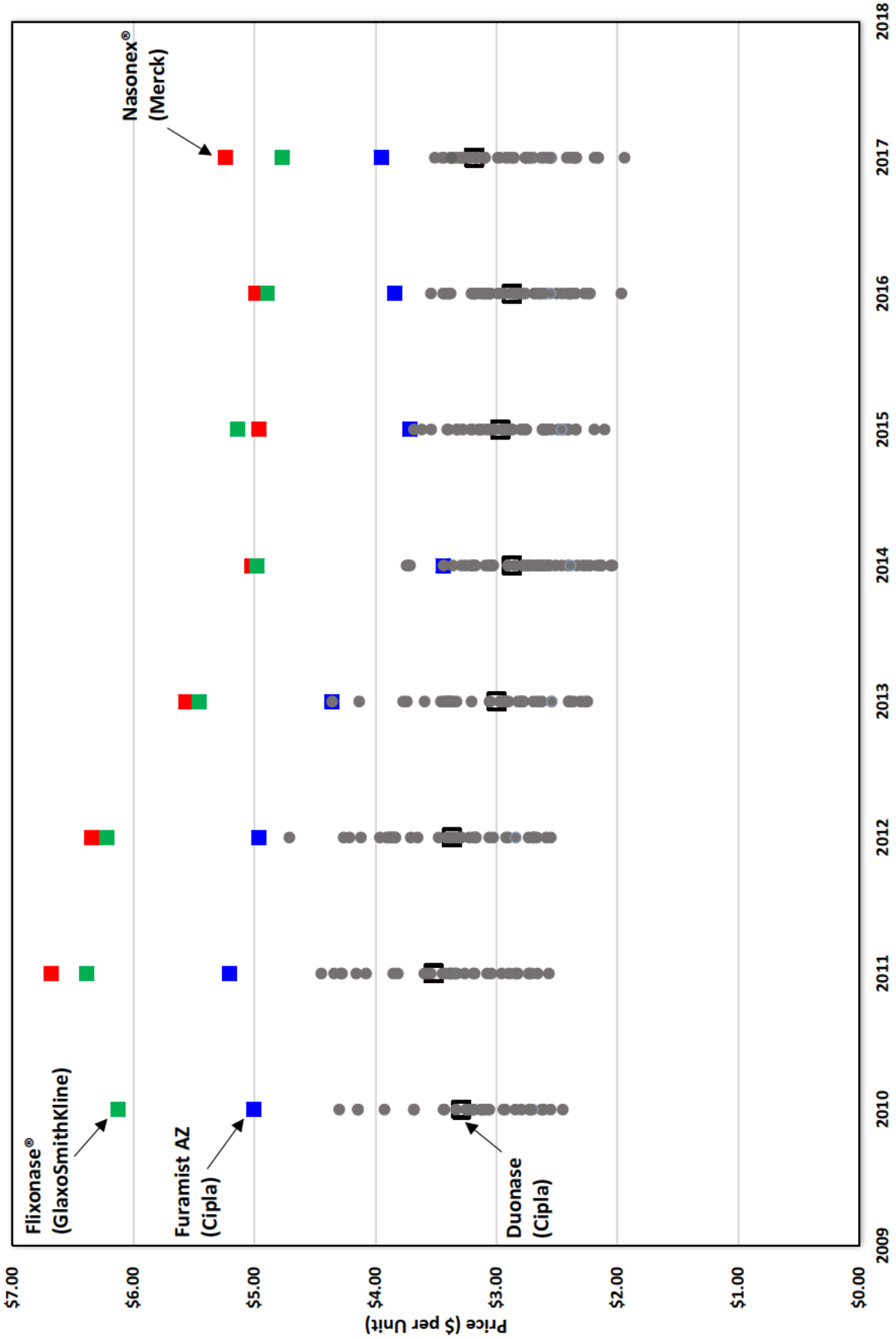
Ex. 9

INDIA
ALLERGIC RHINITIS NASAL SPRAYS
IMS TSA DATA
UNIT PRICE (USD)
2010 - 2017

	Year Ending December 31			Year Ending March 31			Average Across All Years	
	2010	2011	2012	2013	2014	2015	2016	2017
	\$	\$	\$	\$	\$	\$	\$	\$
Fluticasone								
Flomist	\$2.62	\$2.73	\$2.69	\$2.40	\$2.26	\$2.45	\$2.50	\$2.61
Fluticone-Ft	\$3.68	\$3.85	\$3.89	\$3.41	\$3.29	\$3.41	\$3.39	\$3.38
Avamys				\$4.36	\$3.74	\$3.62	\$3.38	\$3.45
Flixonase	\$6.13	\$6.38	\$6.22	\$5.46	\$4.98	\$5.14	\$4.89	\$4.77
Flutiflo	\$2.55	\$2.66	\$2.55	\$2.25	\$2.14	\$2.19	\$2.23	\$2.35
Furamist	\$3.92	\$4.08	\$3.86	\$3.39	\$3.21	\$3.33	\$3.41	\$3.51
Fluticone	\$3.10	\$3.54	\$3.65	\$3.20	\$2.90	\$2.88	\$2.85	\$2.97
Ennhale		\$4.34	\$3.84	\$3.36	\$3.03	\$3.14	\$3.20	\$3.28
Floresp			\$4.71	\$4.13	\$3.73	\$3.68	\$3.44	\$3.37
Alerflo			\$4.26	\$3.74	\$3.17	\$3.13	\$3.10	\$3.21
Flublock			\$3.91	\$3.43	\$3.09	\$3.07	\$3.14	\$3.30
Nazomac-F	\$2.45	\$2.57	\$2.59	\$2.27	\$2.04	\$2.34	\$2.27	\$2.36
Efnase	\$3.18	\$3.34	\$3.19	\$2.80	\$2.73	\$2.93	\$2.76	\$2.69
Mezaflo	\$2.94	\$3.08	\$3.03	\$2.66	\$2.46	\$2.54	\$2.39	\$2.39
Nezaflo					\$2.75	\$2.59	\$2.39	\$2.42
Freeair						\$3.28	\$3.08	\$3.17
Nasocom	\$2.70	\$2.82	\$2.84	\$2.54	\$2.39	\$2.46	\$2.55	\$2.55
Ezicas	\$3.12	\$3.26	\$3.22	\$2.82	\$2.63	\$2.75	\$2.66	\$2.76
Ezicas-F	\$4.14	\$4.28	\$3.88	\$3.40	\$3.05	\$3.11	\$3.07	\$3.11
Flutirest					\$3.25	\$3.21	\$3.17	\$3.33
Rhinofit	\$2.72	\$2.82	\$2.69	\$2.36	\$2.13	\$2.10	\$1.97	\$1.94
Furaspray	\$4.14	\$4.28	\$3.86	\$3.39	\$3.06	\$3.05	\$2.99	\$2.75
Otrivin-C	\$3.44	\$3.56	\$3.38	\$2.97	\$2.59	\$2.62		
Fivasa	\$3.68	\$3.82	\$3.71	\$3.33	\$3.05	\$3.02	\$2.82	\$2.75
Flutispray		\$4.16	\$3.96	\$3.46	\$3.20			
Nasicure					\$2.23			
Flutiflo-Ft	\$2.84	\$2.96			\$3.36	\$3.32	\$3.10	\$3.26
Odnase								\$3.37
Nazobic							\$3.40	\$3.30
Flocare							\$2.62	\$2.56
FFNS								\$3.37
Flutivio								\$2.16
Average	\$3.44	\$3.64	\$3.53	\$3.10	\$2.86	\$2.90	\$2.87	\$2.89
Average of All Products	\$3.33	\$3.59	\$3.56	\$3.16	\$2.89	\$2.99	\$2.96	\$2.97

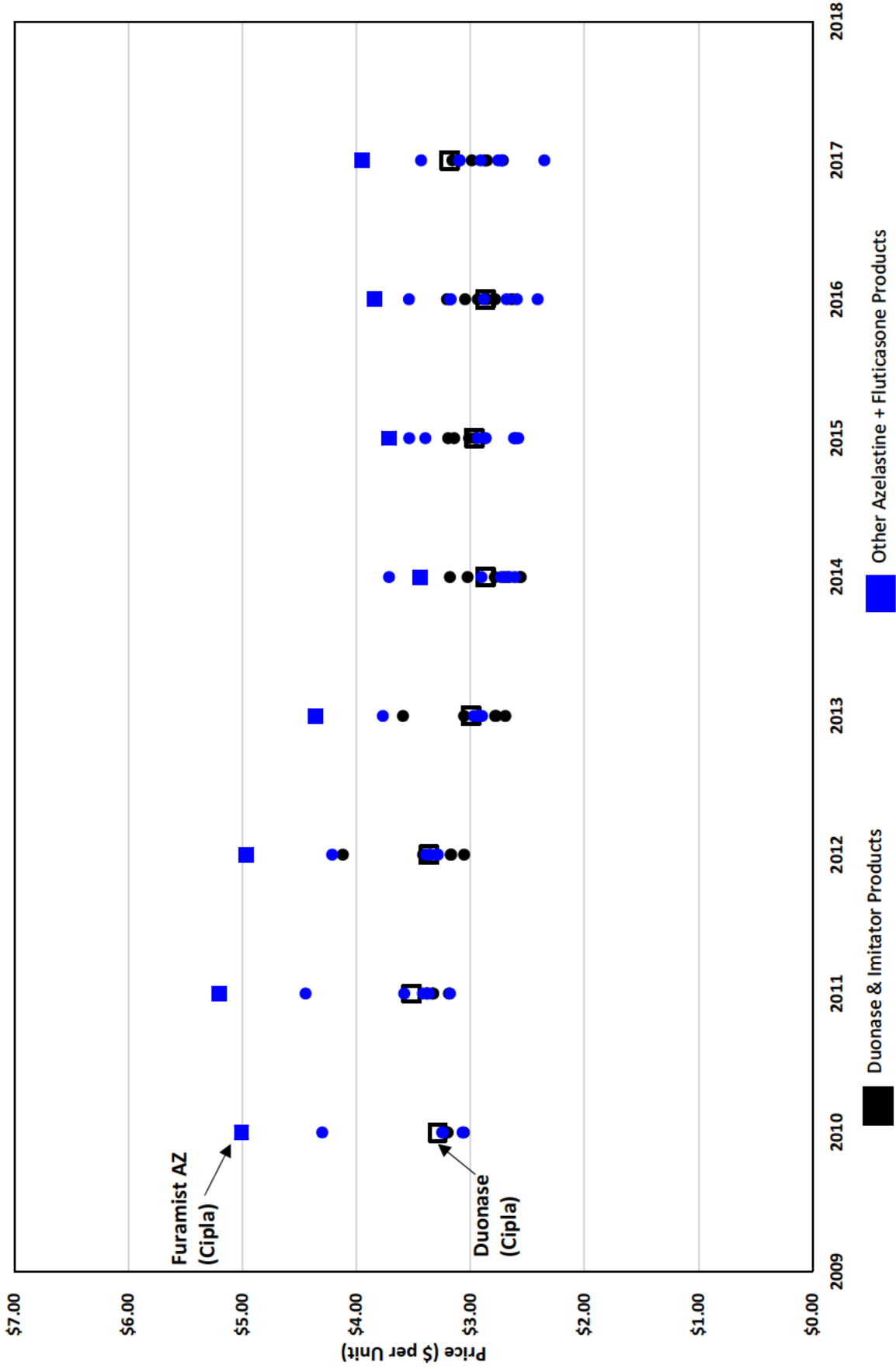
Sources: Exhibit 2149 at Tab 6 and Tab 7, based on Exhibit 2123 and Exhibit 2124

Ex. 9a
Sales \$ / Unit for Prescription AR Nasal Spray Products In India



Sources: Ex. 9; Exhibit 2149 at Tabs 6 & 7,
based on Exhibit 2123 & Exhibit 2124

Ex. 9b
Sales \$ / Unit for Combination Azelastine/Fluticasone Nasal Spray Products In India



Sources: Ex. 9; Exhibit 2149 at Tabs 6 & 7,
based on Exhibit 2123 & Exhibit 2124

Appendix A



John C. Staines, Jr.
Director & Principal

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Washington, DC 20036

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Fax: 202-973-2401
Email: john.staines@naviganteconomics.com

EDUCATION

- 1990 M.B.A., Business Economics and Finance, University of Chicago
- 1984 M.P.M., Public Policies Toward Business, University of Maryland
- 1982 B.A., Economics, University of Maryland

PROFESSIONAL POSITIONS

- 2010-Present Director & Principal, Navigant Economics Manage and conduct economic, financial and quantitative analyses related to commercial litigation and regulation.
- 2000-2010 Principal, LECG, LLC Managed and conducted economic, financial and quantitative analyses related to commercial litigation and regulation.
- 1996-2000 Principal, Putnam, Hayes & Bartlett, Inc. Managed and conducted economic, financial and quantitative analyses related to commercial litigation and regulation.
- 1990-1995 Associate, Putnam, Hayes & Bartlett, Inc. Conducted economic, financial and quantitative analyses related to commercial litigation and regulation.
- 1985-1988 Associate, Heiden Associates, Inc. Performed economic impact studies of proposed environmental and health regulations, economic analyses of antitrust issues, and statistical analyses of product safety risk.
- 1984 Analyst, U.S. Environmental Protection Agency, Office of Policy Analysis. Performed economic and risk studies of proposed environmental regulation of hazardous wastes.

RECENT EXPERT TESTIMONY

- *Acrux DDS PTY Ltd. & Acrux Ltd v. Kaken Pharmaceuticals Co., Ltd., and Valeant Pharmaceuticals International, Inc.*, U.S. Patent and Trademark Office, Patent Trial and Appeal Board, Case IPR2017-00190, U.S. Patent No. 7,214,506, 2017. (Expert Witness Report and Deposition Testimony.)
- *Hospira, Inc. v. Sylvia Mathews Burwell, Secretary, U.S. Department of Health and Human Services; Dr. Margaret Hamburg, Commissioner, U.S. Food and Drug Administration; Par Sterile Products, LLC (Intervenor-Defendant)*, U.S., District Court for the District of Maryland, Case No. 8:14-cv-02662-GJH, 2014. (Expert Witness Affidavits.)
- *SmithKline Beecham Corp., et al., v. Mylan Laboratories, Inc., et al.*, U.S., District Court for the District of New Jersey, Civ. Action No. 07-2939 (JAP), 2007. (Expert Witness Declaration.)
- *J.E. Pierce Apothecary, Inc., et al., v. Harvard Pilgrim Healthcare, et al.*, U.S., District Court for the District of Massachusetts, Civ. Action No. 98-CV-12636-RCL, 2003. (Expert Witness Declaration and Deposition Testimony.)

CONSULTING ACTIVITIES

- Experienced in applying microeconomic, financial, and other quantitative tools and theories in the areas of commercial litigation and public policy. Specific areas of experience include the economic analysis of markets and competitive effects of various business practices, as well as valuation of economic damages in intellectual property, antitrust, and other types of commercial litigation, as well as the impact of dumped and subsidized imports in international trade cases and economic impact and risk assessment in the context of product liability litigation and regulatory rulemakings.
- Work has typically included designing and directing data and other economic analyses, drafting expert reports, and evaluating analyses submitted by other experts.
- A large proportion of these consulting assignments has involved economic issues arising in the Pharmaceutical industry. Other industries studied include: Computers and Peripherals, Software Operating Systems, Applications Software, Enterprise Resource Planning Systems, Telecommunications, Steel, Coastal Oil Shipping, Oil Refining Equipment, Gasoline wholesaling and retailing, Chemicals, Plastics Additives, Wood-Panel Products, Uranium Mining and Enrichment, Crushed Stone, Athletic Footwear, Automobiles, Paint Manufacture, and Third Class Mail Delivery.

Pharmaceutical Industry Cases

Analyzed economic, statistical, and financial issues associated with pharmaceutical-related cases involving allegations of patent infringement, antitrust violations, proposed regulations, and various other commercial claims, as well as regulatory compliance. Specific projects include the following:

Pharmaceutical Patent Infringement

- Estimated lost profit and reasonable royalty damages associated with alleged sales of infringing drugs.
 - Zegerid® (omeprazole) – Ulcers and Gastroesophageal Reflux Disease (“PPI”)
 - Epivir® (lamivudine) – AIDS treatment
 - Nitro-Dur® (nitroglycerin patch) – Angina
 - Humulin® (proinsulin) – Type II Diabetes
 - Humatrope® (somatropin) – Human Growth Hormone
- Analyzed the extent and economic sources of “commercial success” for brand name drugs as possible secondary indicia of “nonobviousness” in several Hatch-Waxman patent infringement litigations brought against prospective generic entrants and *Inter Partes* reviews sought by prospective generic entrants before the Patent Trial and Appeal Board of the U.S. Patent & Trademark Office.
 - Jublia® (efinaconazole) – Toenail Onychomycosis
 - Omidria® (ketorolac/phenylephrine) – Cataract Surgery Dilation and Pain Reliever
 - Minivelle® (estradiol transdermal patch) – Menopause “Hot Flashes”
 - Colcrys® (colchicine) – Gout
 - Megace® ES (megestrol) – Appetite Stimulant for AIDS Patients
 - Trilipix® (choline fenofibrate) – Low HDL Cholesterol / High Triglycerides
 - Yaz® (drospirenone / ethinyl estradiol) – Oral Contraceptive
 - Aplenzin® (bupropion HBr) – Depression & Anxiety Disorder (“SSRI”)
 - Ritalin LA® (methylphenidate) – Attention Deficit & Hyperactive Disorder (“ADHD”)
 - Xyzal® (levocetirizine) – Non-Sedating Antihistamine for Allergic Rhinitis
 - Prevacid® (lansoprazole) – Ulcers & Gastroesophageal Reflux Disease (“PPI”)
- Analyzed economic issues and survey data to determine whether a generic entrant’s non-infringing use would be “insubstantial” in the context of a Hatch-Waxman “Section 8 Carve-Out”: Actos® (pioglitazone) type II diabetes.
- Analyzed possible irreparable harm, balance of hardships, and economic impact on the public interest of proposed Temporary Restraining Orders and/or Preliminary Injunctions on allegedly infringing product sales.
 - Precedex® (dexmedetomidine) – Sedative for Intubation and Surgery
 - Nuvigil® (armodafinil) – Excessive Sleepiness
 - Seasonique® (levonorgestrel / ethinyl estradiol) – Oral Contraceptive

- Ritalin LA® (methylphenidate) – Attention Deficit & Hyperactive Disorder (“ADHD”)
- Glucophage® (metformin) – Type II Diabetes
- Tessalon® (benzonatate) – Cough Suppressant
- Various Unapproved (“DESI”) – Topical Pharmaceutical Treatments
- Paxil CR® (paroxetine) – Depression & Anxiety Disorder
- Ethyol® (amifostine) – Ovarian/Neck/Head Cancer Chemo/Radiation side effects

Pharmaceutical Antitrust/Competition

- Alleged anticompetitive “reverse-payment” patent settlement: Lidoderm® (lidocaine patch) pain medication
- Antitrust counterclaim alleging price bundling and exclusive dealing: Epogen®/Aranesp®, Neupogen®/Neulasta® anemia and neutropenia treatments
- Alleged predation involving brand firm’s launch of an “authorized generic”: Macrobid® (nitrofurantoin monohydrate macrocrystals) urinary tract infections
- Potential antitrust counterclaims associated with brand firm’s actions to forestall generic competition: Paxil CR® (paroxetine) depression & anxiety disorder
- Competitive effects and potential antitrust implications of the proposed terms of a bulk API supply contract in the market for generic Augmentin® (amoxicillin/clavulanic acid).
- Market definition and competitive impacts of a proposed merger under FTC review in the relevant pharmaceutical markets for Enbrel® (etanercept) and Kineret® (anakinra), biological treatments for rheumatoid arthritis.
- Adequacy of competition and prospective effects of entry in various pharmaceutical controlled substance markets as part of five Drug Enforcement Administration hearings on the proposed registration of new bulk manufacturers and/or importers of:
 - opium / concentrate of poppy straw (oxycodone, hydrocodone, morphine, codeine)
 - cocaine for use as a local anesthetic
 - methylphenidate for treatment of attention deficit disorder.

Pharmaceutical Commercial Damages

- Generic lost profits from delayed FDA approval and generic exclusivity forfeiture due to flaws in a contract research organization’s bioequivalence studies: Zoloft® (sertraline) depression & anxiety disorder; Zofran ODT® (ondansetron) cancer-related nausea; Avelox® (moxifloxacin) antibiotic.
- Financial valuation of a refractory chronic gout drug in relation to a proposed temporary restraining order to delay a proposed financial transaction and motion to put owner into receivership.

- Overcharges to private insurers and State governments associated with alleged over-reimbursement of drug costs due to inflated Average Wholesale Prices (“AWPs”): Epogen®/Aranesp®, Neupogen®/Neulasta® anemia and neutropenia treatments.
- Lost profit and shareholder diminution damages due to a U.S. generic firm’s alleged failure to purchase various finished dose products from a Jordanian pharmaceutical company per terms of the parties’ agreement: Various generic drugs.
- Impact of generic entry on an acquired brand company’s financial valuation: Ifex®/Mesnex® (ifosfamide/mesna) testicular cancer.
- Overcharge damages due to a PBM’s alleged price-fixing of insurance reimbursement rates for drug prescriptions applied to a class of independent pharmacies.
- Stock market event study of the financial impact of an FTC investigation of drug products marketed by a pharmaceutical acquisition target. Skelaxin® (metaxalone) muscle relaxant.
- Shareholder value damages allegedly associated with overpayment for a generic biopharmaceutical firm acquisition.
- Variety of analyses and research activities associated with a license dispute involving U.S. sales of Epogen® and Procrit® (epoetin alfa) anemia.
 - Methodologies to track licensor/licensee sales by therapeutic indication;
 - Methods to reimburse profits on cross-indication sales;
 - Lost profits due to allegedly delayed FDA approval;
 - Financial valuation of market segments.
 - Detailed analysis of Medicare reimbursement claims data
 - Estimation of price erosion due to competition from licensee.
- Bankruptcy damages of a large pharmaceutical wholesaler (FoxMeyer Drug) allegedly caused by the flawed implementation of a new management information system.
- Lost profit/value damages associated with foregone development opportunities for drugs to treat obesity, anxiety, depression, insomnia, Alzheimer’s, and benign prostate hypertrophy, due to massive product liability claims allegedly caused by the Defendant.
- Financial analyses to support a fairness opinion for settlement of class action claims associated with adverse side effects. Redux® (dexfenfluramine) diet drug.
- Valuation analyses to support a fairness opinion for settlement of a shareholder lawsuit: ReoPro® (abciximab) treatment for patients undergoing percutaneous transluminal coronary angioplasty (PCTA) to treat coronary artery disease.
- Lost royalty damages for a prospective HIV/AIDS and hepatitis B drug that Defendant allegedly failed to develop.
- Lost royalty damages for a prospective monoclonal antibody-based drug to treat asthma and allergic rhinitis that Defendant allegedly had not timely developed. Xolair® (omalizumab).

- Lost royalty damages in the U.S., Europe, and East Asia due to the alleged failure of the licensee to obtain regulatory approval for a Hepatitis B vaccine and a cancer drug.
- Lost profit and royalty damages due to the licensee's alleged failed to supply bulk product and maintain patents for a synthetic hepatitis B and C drug in East Asia.

Pharmaceutical Consulting

- Assisted in a pharmacoeconomic analysis used to formulate a client's future marketing strategy for promoting new uses of current and prospective pacemaker technologies.
- Developed mathematical programming model to generate profit-maximizing production strategies for a pharmaceutical company's jointly-produced plasma fractions products.

Economic/Competition Analysis – Other Industries

Developed economic and supporting quantitative analyses of the level, nature, and conditions of industry competition in a variety of markets in antitrust and other legal/regulatory contexts. Evaluated the likely economic impact of proposed government regulation of industry in terms of prices, demand, investment, entry and exit, industry structure, employment, etc. Specific projects include the following:

- Analyzed competition issues raised in an antitrust counterclaim involving Standardbred Harness Horseracing.
- Performed various analyses of company financial data, operations data, and survey results to analyze pyramid scheme allegations regarding the U.S. Operations of a Multi-Level Marketing firm manufacturing and selling health foods.
- Analyzed ARCO franchisee claims of unfair competition associated with British Petroleum's pricing of wholesale gasoline supply.
- Conducted economic analyses related to proposed class certifications in litigations involving price-fixing and monopolization allegations associated with the sale of:
 - plastics additives used in the manufacture of products incorporating poly-vinyl chloride ("PVC") and certain engineering resins
 - organic peroxides used in the manufacture of various types of plastic products
 - computer operating and applications software
- Assessed the validity of potential antitrust claims against the dominant supplier of personal computer operating systems, internet browser software, and applications software arising from the company's alleged attempts to impede the adoption of a competitor's internet-based "middleware" platform software that threatened the incumbent's monopoly power.
- Analyzed price pass-through of alleged monopoly surcharges associated with certification of a class of indirect purchasers claiming damages from the purchase of

the defendant's computer operating system, word processing and spreadsheet software.

- As part of a price discrimination case, analyzed the economics of manufacturer-retail agency relationships in the cellular telephone industry, including determination of the attributes of effective retail agents and the impact of product life-cycles on the optimal retail channel.
- Performed statistical analyses of product differentiation and market delineation in the luxury automobile market in support of a price discrimination case involving the "gray market" for Mercedes Benz automobile parts.
- Performed economic analyses of the competitive, price, and financial impacts of proposed environmental and health regulations affecting manufacturers and customers various products.
 - Formaldehyde
 - Methylenedianiline
 - Audio/video/computer Magnetic Tapes & Disks
 - Crushed Stone Aggregate
- Performed analyses in support of a theoretical and empirical study of the natural monopoly rational for prohibiting the private delivery of third-class addressed mail.
- Performed industry analyses of the economic incentive effects in the Paint Industry of imposing a waste-end tax on the land disposal of hazardous wastes as a supplemental source of financing for the U.S. EPA's "Superfund" program.

Damages Analysis – Other Industries

Supervised calculation of damages based on analysis of product supply and demand, product life-cycles, prices, market share, entry and exit, first-mover effects, costs of capital, internal rates of return, opportunities for mitigation, stock price changes, and other economic factors. Specific work experience includes the following:

- Analyzed lost profit and direct cost damages sustained due to installation of allegedly defective refractory lining material in regenerator and third stage separator equipment at the FCC units of various oil refineries.
- Estimated lost repair profit damages associated with alleged infringement of design and utility patents for portable data terminals used by delivery firms and the US Postal Service to scan and store package delivery information.
- Estimated damages incurred by the owner of certain FCC wireless licenses in California that resulted from an accounting firm's alleged misrepresentation of a licensee's financial condition.
- Performed valuation of a wireless telecommunications company in Venezuela to estimate damages associated with the alleged failure of a U.S. telecommunications company to purchase shares in compliance with a put option agreement.

- Estimated the appropriate compensation due to a U.S. coastal shipping company associated with the alleged U.S. Government “taking” of the company’s oil tank barges and other capital assets that resulted from the double-hull provisions of the 1990 Oil Pollution Act.
- Calculated damages generated by alleged breaches associated with the provision of consulting services to upgrade a management information system in the computer distribution industry.
- Calculated lost profit damages associated with a telecommunications company’s alleged breach of a marketing contract with a wireless telecommunications company.
- Calculated damages to royalty owners of a CO₂ gas field resulting from alleged underpricing of well-head CO₂ and alleged tariff overcharges for pipeline transportation to enhanced oil recovery fields.
- Calculated lost profit and lost investment damages in a European breach-of-contract case associated with a patent for a new running shoe technology.
- Evaluated the theoretical framework for estimating damages in multiple breach-of-contract cases in the electric utility industry.
- Drafted report on a theoretical framework appropriate for estimating damages as part of defendant’s submission to a European Tribunal, and evaluated plaintiff’s damages estimates in a breach-of-contract case involving wood panel presses.
- Analyzed costs and estimated lost profit margins in support of expert testimony involving alleged infringement of patents related to X-Y pen plotters.

International Trade

Estimated the magnitude of import dumping margins and the resulting injury of dumped and subsidized imports to the domestic industry. Met with Department of Commerce staff to argue for modifications in margin estimates. Analyzed International Trade Commission questionnaire responses. Prepared exhibits for hearings. Evaluated and developed economic models of domestic industry impacts of unfairly traded imports.

- Developed economic arguments to support briefs and expert economic testimony in a dumping and subsidy case involving U.S. imports of seamless steel pipe from Argentina, Brazil, Germany, and Italy. Evaluated the applicability of ITC’s computer model measuring injury to the domestic industry. Identified conceptual flaws in opposing experts’ use of an oligopoly model to estimate price effects of imports.
- Performed a variety of economic, financial, and statistical analyses in a dumping investigation of U.S. imports of natural and enriched uranium from the former Soviet Union. Estimated less-than-fair-value margins based on construction of average costs. Developed market model of world uranium trade to estimate injury to the domestic industry and to simulate price impacts of alternative import restriction mechanisms proposed in Suspension Agreement negotiations.
- Analyzed and identified statistical flaws in ITC’s econometric model of the domestic price and quantity impact of unfairly traded potato imports from Canada.

Product Liability/Risk Assessment

- Developed a statistical model used by industry to assess the risk of injury and death associated with All Terrain Vehicles (ATVs). Performed risk and cost-benefit analyses of various regulatory proposals considered by the U.S. Consumer Product Safety Commission. Evaluated risk of injury and death to specific plaintiffs in support of expert testimony in ATV product liability litigation.
- Performed statistical analyses of the risk of injury and death associated with chain saws and radial arm saws in support of expert testimony in regulatory hearings and product liability litigation.
- Assisted in estimating reduction in health risks associated with proposed regulations limiting airborne emissions from industrial boilers.

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