Filed on behalf of Novartis AG

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TORRENT PHARMACEUTICALS LIMITED,

and

APOTEX, INC. and MYLAN PHARMACEUTICALS INC.,

Petitioners

v.

NOVARTIS AG and MITSUBISHI PHARMA CORP.,

Patent Owners

Case IPR2014-00784
Case IPR2015-00518
Patent 8,324,283 B2

REBUTTAL DECLARATION OF DAVID BLACKBURN, PH.D.

TABLE OF CONTENTS

I, David Blackburn, Ph.D., declare and state as follows:

I. Introduction

1. I previously submitted a declaration on behalf of Novartis on April 3, 2015 (Blackburn Declaration, or my initial declaration).[1] That declaration demonstrated Gilenya's commercial success and that this success is connected to the invention described in U.S. Patent No. 8,324,283. Since then, I have reviewed the June 5, 2015 Declaration of Professor Joel W. Hay, Ph.D. (Hay Declaration).[2]

2. While my opinion remains that Gilenya's commercial success is directly linked to the invention of the U.S. Patent No. 8,324,283, I have been asked to respond to Professor Hay and address the commercial success of U.S. Patent No. 8,324,283 and the claim limitations in the proposed, amended claims to U.S. Patent No. 8,324,283 (the '283 patent), which I understand are directed to and/or drive a stable and uniform oral pharmaceutical composition comprising fingolimod.

3. I also understand that Novartis contends that Professor Hay misunderstands that he has the burden to disprove the existence of commercial success. I am not a lawyer and therefore do not state an opinion on this legal issue. My opinions address the economics of commercial success in this matter.

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[1] Declaration of David Blackburn, Ph.D. (Exhibit 2045).

[2] Declaration of Professor Joel W. Hay, Ph.D. (Exhibit 1041).

II. Summary of Opinions

4. In his declaration, Professor Hay provides no alternative analyses of Gilenya's sales and profits, nor does he provide an analysis showing that Gilenya's solid oral formulation is unconnected to its success. He instead only provides critiques of the analyses set forth in my declaration, and on that basis says that I have failed to establish the commercial success of Gilenya and its nexus to the '283 patent.

5. As I describe in more detail below, Professor Hay's approach is inappropriate. In summary:

(a) Professor Hay's analysis ignores the voluminous evidence – from Novartis and from third parties – showing Gilenya's clear success since launch. Indeed, Professor Hay does not dispute that Gilenya's sales (over a billion dollars of Net Sales in the U.S. each year since 2013) and market share have caused it to be recognized across the industry as a blockbuster drug and among the top 50 drugs in the U.S.

(b) Professor Hay speculates that some unidentified other formulation of oral fingolimod could have been substantially as successful as Gilenya. Professor Hay, however, provides no evidence that some other oral formulation besides that of the '283 patent (supposedly in the prior art or otherwise) could have achieved success anywhere near that of Gilenya.

As I describe below, there is a direct link between Gilenya's success and its oral formulation.

(c) Professor Hay assumes that a nexus must be linked explicitly to the use of a S1P receptor agonist and/or a sugar alcohol.[3] I understand that the claims of the '283 patent, which disclose an oral formulation comprised of a S1P receptor agonist and a sugar alcohol, as well as other claims (including the proposed amended claims), are what drive or actualize the oral formulation feature of Gilenya.[4] Thus, it is sufficient to establish a nexus to the oral formulation of Gilenya, which in turn establishes a nexus to the '283 patent claims because they drive a stable and uniform oral pharmaceutical composition comprising fingolimod.

(d) My analysis of Gilenya's profitability relies on data sworn to be accurate by a Novartis executive and includes all relevant costs. Professor's Hay's assertion that a return-on-investment (ROI) analysis would show that Gilenya is not a commercial success is inappropriate both because he requires an inappropriate hurdle for success and he does not account for

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[3] Hay Declaration, ¶ 104 (Exhibit 1041).

[4] Blackburn Declaration, ¶¶ 13-4; Deposition of Dr. David J.H. Blackburn, May 29, 2015 (Blackburn Deposition, or my deposition), pp. 12-3 (Exhibit 2272).

the fact that a ROI analysis of a drug that is still early in its life cycle must account for the expected future performance of the drug. Given the available evidence, when considering this appropriately, there is no reason to doubt that Gilenya has provided, and will continue to provide, a positive ROI.

(e) Professor Hay is incorrect that an "event study" or some other analysis of Novartis's stock price would be appropriate to assess commercial success and even were it so, he provides no such analysis. As I describe below, an event study is not an appropriate tool for analyzing the success of Gilenya (or any product sold over a long period of time).

(f) The IMS data on which I rely are gold-standard data in the pharmaceutical industry and, despite Professor Hay's claims, are widely used by Novartis in assessing the performance of Gilenya and other multiple sclerosis (MS) drugs. Moreover, while Professor Hay argues that prescription data are especially unreliable and I that should have instead used IMS dollar sales data, he also did not provide any analysis of these data – which are fully available from IMS Health to any researcher. As I show below, an analysis of IMS dollar sales data shows very similar trends and further supports the commercial success of the '283 patent through Gilenya.

(g) Professor Hay also claims that I have not properly defined a market, and therefore the context in which to measure commercial success. However, Professor Hay incorrectly assumes that a precise market definition, such as one used to analyze economic issues in antitrust matters, is required to determine commercial success. My analysis focuses on the products Novartis itself evaluates as competitors to Gilenya and demonstrates the economic factors probative of commercial success, which are not dependent on any particular market definition. To the extent that a market definition is required, however, Gilenya is a success in any relevant "market" expanded to include the drugs Professor Hay proposes.

(h) The timing of the FDA's approval of Gilenya – approximately two years prior to that of any other oral treatment for MS – does not negate the nexus to the '283 patent, both because there is no evidence that Gilenya's position as the first oral treatment for MS is not due to the '283 patent (Gilenya is an embodiment of the '283 patent and that embodiment was approved approximately two years prior to any other oral treatment) and because even after the launch of other oral MS treatments, Gilenya's sales, prescriptions, and market share continue to grow. Similarly, to the extent that sales of Gilenya are driven by patients switching to Gilenya

from Tysabri, or by its pricing and promotional programs, these sales also do not negate a nexus to the '283 patent.

(i) Finally, Professor Hay's declaration contains several other mischaracterizations regarding the opinions I disclosed in my initial declaration and further discussed at my deposition.

6. Accordingly, in my opinion, the sales, profits, prescriptions, and market share of Gilenya in the U.S. and the nexus from them to the '283 patent demonstrate that the '283 patent has been a commercial success through Gilenya. While Professor Hay asserts that my analyses leading to these conclusions were inappropriate, he has not undertaken alternative analyses that would demonstrate that a substantial portion of Gilenya's sales, prescriptions and profits are due exclusively to features of the drug other than those claimed in the '283 patent. Furthermore, my analyses in fact included much of the data and information that Professor Hay claims were missing, and clearly indicate a nexus from Gilenya's sales, prescriptions, profits, and market share to its solid oral formulation.

III. Professor Hay Does Not Dispute that Gilenya's Success is Recognized Widely Both Within the Pharmaceutical Industry and by Those Who Analyze the Industry

7. Professor Hay offers no evidence to contradict my statements that Gilenya has made [redacted] in net sales and treated 100,000 patients worldwide, and over 42,000 patients in the U.S.[5]

8. In my opinion, Professor Hay does not appropriately consider the evidence from important economic actors including financial analysts and patients themselves that indicate that Gilenya has been a commercially successful drug. As evidenced by these individuals' views, a substantial contributor to Gilenya's success has been its oral dosing feature. Accordingly, Professor Hay incorrectly views Gilenya as having no "economic value."

9. Professor Hay argues that the "non-scientific" financial analyst reports and patient testimonials fail to demonstrate the "economic value of Gilenya."[6] I

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[5] Blackburn Declaration, ¶¶ 18-9 (Exhibit 2045). See also Deposition of Joel W. Hay, Ph.D., June 24, 2015 (Hay Deposition), pp. 45, 49-50, 52 (Exhibit 1107).

[6] Hay Declaration, ¶ 76 (Exhibit 1041). See also Blackburn Declaration, ¶¶ 25-8, 38-40 (Exhibit 2045).

When asked at his deposition on this dismissal of the information contained in these analyst reports, Professor Hay states that his reasons for dismissing these

note that Professor Hay does not dispute the opinions and analyses presented in the analyst reports themselves. Further, in dismissing these reports, Professor Hay overlooks the fact that peer-reviewed, scientific literature has been published that shows that opinions of financial analysts and patients are important – they are able to affect significant economic outcomes in the marketplace. As such, in my opinion, Professor Hay improperly dismisses their opinions of Gilenya as having no bearing on the supposed economic value of the drug.

10. For instance, a 2011 study found that favorable analyst reports significantly influenced non-professional investors' reactions towards a target firm, and that these reactions significantly influence their investment decisions.[7] Similarly, another study from 2014 found that paid-for research, such as that

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reports is due to the fact that one has to "pay substantial money to subscribe to the reports" and that the reports "are not public information." [Hay Deposition, pp. 54-5 (Exhibit 1107).] As an economic matter, this makes little sense – that analysts sell their work at a high price creates, if anything, a *greater* incentive to be accurate.

[7] "Investor affect, investor status, and the influence of analyst reports," *Journal of Finance and Accountancy*, 2011: 1-14 at 1, 13-4 (Exhibit 2290).

provided in financial analyst reports cited in my initial declaration, provide relevant information to investors.[8]

11. This finding is similar to the findings and recommendations of a 2006 U.S. Securities and Exchange Commission (SEC) report which found that "[a] lack of independent analyst coverage has several adverse effects, both for individual companies and for capital markets as a whole."[9] As such, though these reports may be "non-scientific" by Professor Hay's definition, research by academics and government agencies recognize the importance of the information contained in these financial analyst reports, and how recommendations can impact investment decisions, company financial performance, and capital markets.

12. Moreover, these investment analysts, through their research reports, have recognized not only Gilenya's success in the marketplace since its launch, but

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[8] "Worth the Hype? The Relevance of Paid-For Analyst Research for the Buy-and-Hold Investor," *The Accounting Review*, Vol. 89(3), 2014: 903-31 (Exhibit 2291).

[9] Final Report of the Advisory Committee on Smaller Public Companies to the United States Securities and Exchange Commission, April 23, 2006, p. 73 (Exhibit 2292).

also the contribution of Gilenya's oral formulation to its success.[10] Therefore, Professor Hay – in my opinion – fails to properly address valid and important evidence entered into the record that demonstrates that: a) Gilenya's financial performance in the marketplace is recognized and is indicative of the success of the drug and, more importantly, b) the oral formulation feature of Gilenya has contributed to this success. As such, Professor Hay's conclusion that these reports fail to demonstrate the "economic value" of Gilenya is, in my opinion, incorrect.

13. Professor Hay also dismisses the opinions of patients in the marketplace as being similarly "non-scientific" and therefore not sufficient to

[10] See Blackburn Declaration, ¶¶ 25-6, 40 (Exhibit 2045). See also Deutsche Bank 2010 Analyst Report, pp. 1, 3, 5 (Exhibit 2109); Goldman Sachs 2010 Analyst Report, pp. 1-2, 5 (Exhibit 2110); Leerink Swann 2010 Analyst Report, p. 1 (Exhibit 2112); Wells Fargo Securities 2013 Analyst Report, p. 1 (Exhibit 2195); Morgan Stanley MUFG 2014 Analyst Report, p. 1 (Exhibit 2196); Leerink Swann May 2013 Analyst Report, p. 1 (Exhibit 2192); SMBC Nikko Securities Inc. 2013 Analyst Report, March 7, 2013, p. 4 (Exhibit 2189); Leerink Swann March 2013 Analyst Report, p. 1 (Exhibit 2190); Societe Generale July 2014 Analyst Report, p. 8 (Exhibit 2197); J.P. Morgan April 2013 Analyst Report, p. 1 (Exhibit 2191); J.P. Morgan July 2013 Analyst Report, p. 1 (Exhibit 2193)

demonstrate the "economic value" of Gilenya. However, and as similarly described above, academic literature has found that patient requests for specific drugs can influence physicians' prescribing decisions, therefore impacting the number of prescriptions of a drug that will be sold in the marketplace.

14. Indeed, a study from 2013 found, citing to previous research, including survey studies, that patient requests and expectations of obtaining a prescription for a certain drug influenced physicians' decisions to prescribe the drug.[11] Similarly, a review of research from 1999 found that patients with high expectations for a prescription were more likely to receive the prescription after consulting with their physicians.[12] In addition, a review of research from 2007 found that a significant portion of patients who request a specific drug receive a

[11] "Patient-centred prescribing," *Australian Prescriber*, Vol. 36(6), 2013: 199-201 at 199 (Exhibit 2293).

[12] "The Doctor-Patient Relationship and Prescribing Patterns: A View from Primary Care," *Pharmacoeconomics*, Vol. 16(6), 1999: 599-603 at 602 (Exhibit 2294).

prescription for the drug, and that when physicians do not comply with their patient requests, these patients feel less satisfied with their physician visits.[13]

15. [redacted].[14]

16. Furthermore, physicians themselves have acknowledged the importance of patient input in their decisions to prescribe MS therapies in general, and Gilenya in particular. For instance, physicians (as well as industry experts) have indicated that they needed an oral MS drug like Gilenya in order to provide patients who did not like injecting themselves with an alternative that could increase dosing schedule compliance.[15]

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[13] "The Debate on Influencing Doctors' Decisions: Are Drug Characteristics the Missing Link?," *Management Science*, Vol. 53(11), 2007: 1688-1701 at 1690 (Exhibit 2295).

[14] 2012 Gilenya Physician ATU, p. 30 (Exhibit 2266).

[15] See, *e.g.*, 2007 Decision Resources Report, pp. 5-6, 8, 10, 100, 104 (Exhibit 2130). See also "Ask the Doctor: Can Lesions Disappear?," Multiple Sclerosis Association of America, Winter/Spring 2011 (Exhibit 2146); Long-Term

17. Professor Hay similarly does not address spontaneous statements from Gilenya patients not financed by Novartis, and which suggest that patients value the oral dosing feature of Gilenya.[16] Several of these posts include, among others: "I love Gilenya! No more needles!"; "If I have to live with MS, I am glad that now there is an everyday pill! I can live with that!"; "Its [*sic*] really nice not having to give myself shots anymore;" "I did not think I would live to see the day that MS [] could be treated with a pill!"; "Today is my 1 [*sic*] year anniversary with Gilenya.

Treatment for MS, Multiple Sclerosis Association of America (Exhibit 2123); "Multiple Sclerosis Research Update," Multiple Sclerosis Association of America, Summer/Fall 2010 (Exhibit 2145); "Update on Oral Medications For Multiple Sclerosis," *MS Progress Notes*, National Multiple Sclerosis Society, Spring 2014: 1-2 at 1 (Exhibit 2147); Gilenya – Novartis, FiercePharma, October 2, 2013 (Exhibit 2016); Gilenya: What is it and How Does it Work?, National Multiple Sclerosis Society, p. 1 (Exhibit 2127); Gilenya: Information to Consider, National Multiple Sclerosis Society, p. 4 (Exhibit 2126); 2012 Gilenya Physician ATU, pp. 18, 25, 28, 74 (Exhibit 2266); Gilenya Physician ATU – Q4 2013 Final Report, pp. 25, 27, 30 (Exhibit 2267).

[16] Blackburn Declaration, ¶ 38 (Exhibit 2045). See also About "Hey MS" (Exhibit 2244).

I love the freedom from shots!"; and "After 12 years of giving myself injections I am enjoying the freedom that GILENYA gives me!" While patient testimonials such as these may be "non-scientific," they make clear that (at least some) patients value the oral formulation of Gilenya.

18. Professor Hay also does not rebut that the FDA praised the oral dosing feature of Gilenya upon the drug's approval. According to a press release at the time of Gilenya's approval, the FDA stated that it "approve[d] the first oral drug to reduce MS relapses." Additionally, the Director of the Division of Neurology Products at the FDA's Center for Drug Evaluation and Research is quoted as saying: "Gilenya is the first oral drug that can slow the progression of disability and reduce the frequency and severity of symptoms in MS, offering patients an alternative to currently available injectable therapies."[17]

19. Professor Hay also does not rebut that Gilenya's success has been recognized in industry trade press. For instance, Gilenya was the 43rd-best selling drug in the U.S. in 2013, with sales totaling over $1 billion.[18] Similarly, it was the

[17] "FDA approves first oral drug to reduce MS relapses," *FDA News Release*, September 22, 2010 (Exhibit 2164).

[18] "Top 100 Selling Drugs of 2013," *Medscape Medical News*, January 30, 2014 (Exhibit 2297).

41st-best selling drug in the 12-month period through March 2015, with sales of over $1.5 billion.[19] These rankings are consistent with Gilenya's position as a "blockbuster" drug, which I detailed in my initial declaration. Given this evidence, as well as the evidence I have cited above, Gilenya's marketplace success is clear.

20. Professor Hay's observation that Tecfidera has sold more than Gilenya is, in my opinion, not relevant for assessing the success of Gilenya because the success of one drug is not evidence of a lack of success of another.[20] For example, one would not argue that Burger King is an unsuccessful business because it has not achieved the sales revenues of McDonald's. Similarly, Tecfidera's success is not an indication of the lack of success of Gilenya, which, as I have stated above, achieved over $1 billion in U.S. sales as early as 2013. Additionally, I note that at his deposition, Professor Hay agreed that one product being commercially successful does not preclude a competing product from being a commercial success.[21]

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[19] "100 Best-Selling, Most Prescribed Branded Drugs Through March," *Medscape Medical News*, May 6, 2015 (Exhibit 2298).

[20] Hay Declaration, ¶ 111 (Exhibit 1041).

[21] Hay Deposition, p. 62 (Exhibit 1107).

IV. Professor Hay Does Not Rebut that a Nexus Exists Between Gilenya's Success and the Oral Formulation

A. The Oral Formulation Was a Substantial Factor in Gilenya's Success

21. Professor Hay claims, using an understanding from the May 27, 2014 Declaration of John S. Kent, Ph.D. (Kent Declaration), that the "oral administration of fingolimod was disclosed in the prior art and would have been obvious to a person of ordinary skill in the art (POSA)" as early as 2003.[22] Therefore, he claims that there can be no nexus between Gilenya's sales and the features of the '283 patent. In my opinion, this argument mischaracterizes the purpose of commercial success analyses.[23]

22. As described in my initial report, a determination that an invention is a commercial success provides evidence that the patented claims were non-obvious.

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[22] Hay Declaration, ¶¶ 97-8 (Exhibit 1041). See also Kent Declaration, ¶¶ 37-8, 96, 162-84 (Exhibit 1004). However, at his deposition, Professor Hay admitted that he understands Gilenya to include fingolimod and mannitol, the formulation covered by the '283 patent. [See Hay Deposition, pp. 35-6 (Exhibit 1107).]

[23] Moreover, if the patented invention is obvious – as Professor Hay asserts – then there is no need for an analysis of commercial success, which I understand to be one of several secondary indicia of obviousness.

The commercial success of the product incorporating the invention demonstrates that it is likely there would have been strong economic incentive for the invention by others in the marketplace.[24] That they did not do so suggests that the invention is non-obvious.[25] Put differently, if the invention claimed in the '283 patent was obvious, then a person of ordinary skill in the art would have strong incentive to invent sooner and bring it to market sooner, and thus earn comparable profits (over a longer period) to what Gilenya has earned.[26]

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[24] In his deposition, Professor Hay indicated that his understanding about the purpose of an analysis of commercial success related to the "social value" of an invention, as opposed to the incentives to invent something that may or may not be obvious. [Hay Deposition, pp. 89-90 (Exhibit 1107).] However, societal value does not inform the question of whether or not there was sufficient economic incentive to invent; as such, societal value is not relevant in assessing commercial success.

[25] See, *e.g.*, "The Economics of Commercial Success in Pharmaceutical Patent Litigation," *Landslide*, Vol. 1(5), 2009: 8-12 at 8 (Exhibit 2201). See also Blackburn Declaration, ¶¶ 15-6 (Exhibit 2045).

[26] Blackburn Deposition, p. 60 (Exhibit 2272).

23. This logic holds only when the product's success can be tied to the patented invention, *i.e.*, when there is a *nexus* between the success and the claimed invention(s). A nexus exists when the patented features can be shown to be a substantial factor in the product's success. The patented elements need not be the sole driver of demand, however. That is, while the patented feature need not entirely account for the product's success, the success must be due, at least in part, to demand for patented features. Indeed, the chapter in *Economic Damages in Intellectual Property, A Hands On Guide to Litigation* to which Professor Hay cites in his declaration states: "one must be able to demonstrate that whatever demand for the product exists [ ] is due, *at least in part*, to the patent, not some other features or actions of the seller" [emphasis mine].[27] That is, in the case of Gilenya, a nexus can be established if it can be shown that at least a substantial portion of its sales, profits and prescriptions can be attributed to the features of the '283 patent – namely, an oral dosing formulation of fingolimod. At his deposition, Professor Hay readily admitted that more than one aspect of a product can share a nexus with the commercial success of that product.[28]

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[27] *Economic Damages in Intellectual Property, A Hands-On Guide to Litigation*, 2006: 161 (Exhibit 1056).

[28] Hay Deposition, p. 61 (Exhibit 1107).

24. Gilenya's oral dosing feature has been highly valued in the marketplace,[29] and much evidence suggests that a significant portion of demand for Gilenya has been driven by its oral dosing feature. For instance, evidence in this case demonstrates that both patients and physicians value Gilenya's patented features.[30] Moreover, evidence demonstrates that members of the financial community, including investors, have recognized the oral formulation feature's contribution to Gilenya's success in the marketplace.[31] Finally, Novartis has recognized the importance of Gilenya's oral dosing feature, and has extensively marketed the drug through this feature.[32] Indeed, while Professor Hay claims that "Novartis does ***not*** promote [Gilenya] based on the '283 patent claims,"[33] as shown in **Figures 1** and **2** below (and as described in much detail in my initial report),

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[29] Professor Hay does not dispute this. [Hay Deposition, pp. 56-7 (Exhibit 1107).]

[30] See Blackburn Declaration, ¶¶ 30-9, Figures 5 and 6 (Exhibit 2045).

[31] Blackburn Declaration, ¶ 40 (Exhibit 2045).

[32] Blackburn Declaration, ¶¶ 42-3, Figures 8 and 9 (reproduced as Figures 1 and 2, respectively, above) (Exhibit 2045).

[33] Hay Declaration, ¶ 86 (Exhibit 1041).

Novartis has explicitly advertised the oral dosing feature of Gilenya, a benefit which I understand flows from the '283 patent.[34]

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[34] Novartis Pharmaceuticals 2014 Edison Patent Award Nomination Application (Exhibit 2017). See also Exhibit 1001 at 000001-2.

I note that Professor Hay seems to reach this conclusion by assuming that the oral formulation is not disclosed by the '283 patent and, therefore, a nexus must be linked explicitly to the use of a S1P receptor agonist and a sugar alcohol. [Hay Declaration, ¶ 104 (Exhibit 1041).] I understand that the claims of the '283 patent, which disclose an oral formulation comprised of a S1P receptor agonist and a sugar alcohol, as well as other claims, are what enable the oral formulation feature of Gilenya. [Blackburn Declaration, ¶¶ 13-4; Blackburn Deposition, pp. 12-3 (Exhibit 2272).] As such, advertisements which focus on the fact that Gilenya is an oral treatment for MS are evidence of a nexus to the '283 patent. Put differently, there is no reason to expect a company to advertise the technical features of a product that enable a feature of the product that is desirable to consumers; it is sufficient for the company to advertise the desirable feature itself.

Figure 1 - Gilenya Brand Logo.[35]

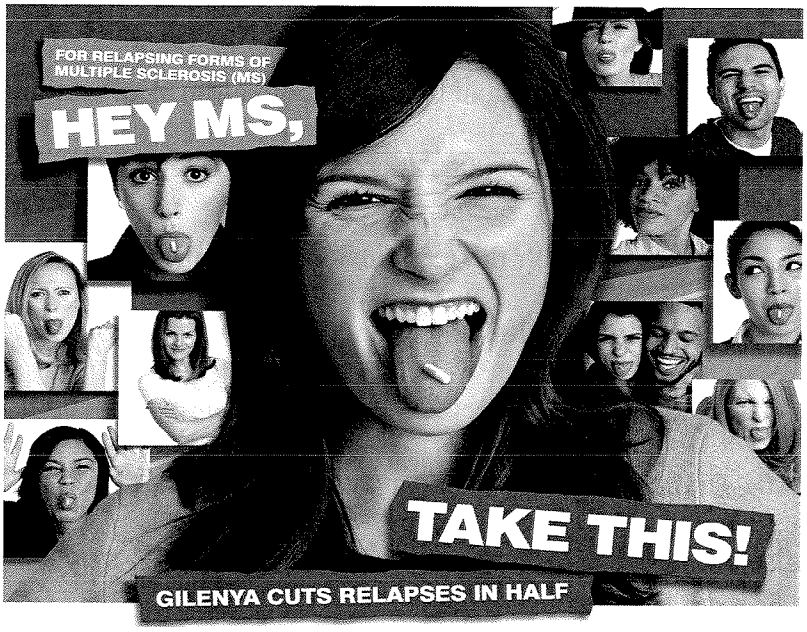

Figure 2 - Gilenya Advertisement.[36]

25. Thus, given that an oral fingolimod formulation was not introduced in the marketplace before 2010, and given the fact that the '283 patent allowed

[35] Gilenya (Exhibit 2181). See also, *e.g.*, Ask for Gilenya (Exhibit 2258); Why Choose Gilenya? (Exhibit 2260); Gilenya Brochure, April 2014 (Exhibit 2243); Gilenya Brochure, May 2014 (Exhibit 2261).

[36] Gilenya Brochure, April 2014, p. 1 (Exhibit 2243).

Gilenya to come to market as the first oral MS treatment[37] (coupled with Gilenya's strong financial performance and substantial evidence of the oral dosing feature driving demand), there is, in my opinion, sufficient evidence to establish nexus.

26. Furthermore, even assuming that Professor Hay's claim that some oral formulation for an MS drug (that does not combine a S1P receptor agonist and a sugar alcohol) existed in the prior art is correct, Professor Hay makes no attempt, nor cites to any evidence, to show that such a product could have earned similar levels of sales and profits as has Gilenya. In fact, in light of the evidence I have cited above of Gilenya's substantial sales and profits,[38] in my opinion, the only reasonable conclusion, given the long time period before Gilenya was approved for sale, is that no such alternative product would have been able to do so. If such a product could have achieved sales and profits comparable to Gilenya's, then one could reasonably assume that Novartis, Mitsubishi, or another pharmaceutical company would have launched this product long before Gilenya became commercially available. And, indeed, the other oral formulations to which

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[37] See, *e.g.*, April 3, 2015 Declaration of Madhusudhan Pudipeddi, ¶¶ 2, 9 (Exhibit 2041); April 3, 2015 Declaration of Tomoyuki Oomura, ¶ 1 (Exhibit 2043).

[38] See also Blackburn Declaration, ¶¶ 17-28 (Exhibit 2045).

Professor Hay points (Aubagio and Tecfidera) were both launched several years after Gilenya. Professor Hay provides no evidence that this prior art formulation was clinically effective, could have been approved, and would have achieved similarly substantial sales and profits like Gilenya. As such, his arguments in this respect are based on a speculative assumption that Gilenya's success could have been achieved in some other fashion; he provides no concrete evidence of how that success would have been achieved.

B. Professor Hay Provides No Analysis to Show that the Importance of Other of Gilenya's Features Negates a Nexus to the '283 Patent

27. Professor Hay seems to imply in his declaration that a nexus to the commercial success of a product can only be established if all of the product's success is tied to the patented feature, relying primarily upon a cite to a chapter within the book *Economic Damages in Intellectual Property, A Hands On Guide to Litigation*.[39] He testified otherwise in his deposition, however, acknowledging that more than one factor can contribute to a product's commercial success.[40] I agree with his deposition testimony in this regard.

28. As shown in the reference Professor Hay cites in his declaration, "one must be able to demonstrate that whatever demand for the product exists [ ] is due,

[39] Hay Declaration, ¶¶ 35-6 (Exhibit 1041).

[40] Hay Deposition, p. 61 (Exhibit 1107).

at least in part, to the patent, not some other features or actions of the seller" [emphasis mine].[41]

29. The nexus requirement is that a substantial portion (but not necessarily all) of the sales and corresponding profits of a product be tied to the patent. The available evidence makes clear that a significant portion of Gilenya's sales are due to its oral dosing feature, and not to other considerations such as its API or pricing scheme.[42] This does not necessarily imply, however, that other factors – such as, for example, the API – may not also share a nexus to Gilenya's commercial success. As described above, the nexus requirement need not be that a single, patented feature be responsible for the sales of a product.

30. Additionally, Professor Hay mischaracterizes the scope of my analysis of Gilenya's commercial success and the nexus to the '283 patent, claiming that I was retained "to find a nexus to the '283 patent and then do no further analysis."[43]

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[41] *Economic Damages in Intellectual Property, A Hands-On Guide to Litigation*, 2006: 161 (Exhibit 1056).

[42] See Blackburn Declaration, ¶¶ 44-54 (Exhibit 2045).

[43] Hay Declaration, ¶ 35 (Exhibit 1041).

Moreover, if there is a nexus to the '283 patent, no additional analysis is required. Again, I am aware of no requirement that the nexus to the '283 patent

Notwithstanding this claim, my analysis did not focus on the '283 patent to the exclusion of other factors. I considered, in great detail, other factors that could potentially be tied to Gilenya's commercial success.[44] I found that these features cannot explain substantially all of Gilenya's success by themselves. This, however, does not preclude that some of these factors could also share a nexus to Gilenya's success.

31. Similarly, although Professor Hay lists several factors that he claims drive its sales, this is insufficient to demonstrate that Gilenya's commercial success does not also have a nexus to the features of the '283 patent.[45] As I described above, in order to sufficiently do so, one must show that the '283 patent has only an insignificant effect on Gilenya's sales, profits and prescriptions. Listing other factors that are important does not provide evidence of this.

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must be the only nexus, or the strongest nexus, or any other comparison. Once a nexus to the '283 patent is shown to exist, for the purposes of this matter, no additional analysis is required. It is not necessary to prove that the commercial success is unrelated to other factors.

[44] See, *e.g.*, Blackburn Deposition, pp. 166-70 (Exhibit 2272); Blackburn Declaration, ¶¶ 44-54 (Exhibit 2045).

[45] See, *e.g.*, Hay Declaration, ¶¶ 86-95, 105-11 (Exhibit 1041).

32. For example, when one considers the sales of Apple's iPad, the fact that its slim design and light weight may be important drivers of its success does not mean that the selection of apps that can be run on it is not also an important driver of success. As described above, Professor Hay has provided no evidence that the '283 patent is not a substantial factor in Gilenya's success. That is, he provides no evidence that Gilenya's sales would not be materially affected by the presence and/or absence of the '283 patent – he simply does not attempt to conduct such an analysis. Furthermore, as the evidence in the record makes clear, in fact, without the oral formulation of fingolimod (and, possibly, without other features such as the API) Gilenya would not have been anywhere near as successful.

V. Professor Hay Critiques Several of My Analyses and Opinions without Providing Supporting Evidence or Alternative Analyses

A. IMS Data Are Appropriate and Widely Used and My Analyses Are Not Affected by Changes Professor Hay Suggests

33. Professor Hay criticizes my analysis of total prescriptions of Gilenya and its competitors as flawed because, in his view, this analysis "does not include all the key MS drugs."[46] He goes on to argue that, for this reason, my analysis of these total prescriptions as evidence of Gilenya's commercial success has "no

[46] Hay Declaration, ¶ 38 (Exhibit 1041).

proper context" and is "suspect."[47] The drugs that he argues need to have been included are, namely, Tysabri, Novantrone, Lemtrada, H.P. Acthar Gel, Campath, Ampyra, and Prednisolone.[48]

34. However, my analyses were conducted in the context of drugs that Novartis itself considers to be competitors to Gilenya. The IMS Data that Novartis relies on internally[49] show that Novartis tracks exactly the competitors used in my analyses. Given that Novartis has a clear incentive to track Gilenya's competitors accurately in order to market the drug as profitably as is possible, this set of competitors is a reasonable group to consider when examining Gilenya's success.

35. Further, with the exception of Tysabri and Lemtrada, I note that the Novartis physician ATUs do not discuss these drugs in detail, and thus, one can reasonably assume that Novartis does not consider these to be significant and/or

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[47] Hay Declaration, ¶ 38 (Exhibit 1041).

[48] Hay Declaration, ¶ 26 and footnote 6 (Exhibit 1041).

[49] April 29, 2015 Declaration of Lawrence Wai (Wai Declaration), ¶ 3 (Exhibit 2299).

relevant competitors.[50] I additionally note that Ampyra, Campath, H.P. Acthar Gel, Novantrone, and Prednisolone are not indicated for the same treatments as Gilenya and the other drugs included in my analyses.[51]

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[50] 2012 Gilenya Physician ATU (Exhibit 2266); Gilenya Physician ATU – Q4 2013 Final Report (Exhibit 2267); Gilenya Physician ATU – 3T 2014 (Exhibit 2268).

I additionally understand that data from IMS Health (IMS Data) on Tysabri are not available. Moreover, I understand that Lemtrada was approved in November 2014. Because the relevant analyses in my declaration covered up through December 2014, it is highly likely that Lemtrada had not yet begun selling, and therefore there were no total prescriptions for the drug in the IMS Data. [See "Genzyme's Lemtrada Approved by the FDA," *Genzyme Press Release*, November 14, 2014 (Exhibit 2142).]

[51] See Novantrone Highlights of Prescribing Information (Exhibit 2176); Ampyra Highlights of Prescribing Information (Exhibit 2168); Campath Highlights of Prescribing Information (Exhibit 2312); H.P. Acthar Gel Highlights of Prescribing Information (Exhibit 2313); Prednisolone Highlights of Prescribing Information (Exhibit 2314).

36. Notwithstanding that these drugs are not indicated for the same treatments as the drugs included in my analyses of the IMS Data, or are not considered to be competitors to Gilenya by Novartis, as I have described at my deposition, defining the "relevant market" in which a drug competes is not a necessary component of an analyses of commercial success.[52] The inclusion of these drugs listed above in my analyses does not change the levels of sales and profits Gilenya has been able to generate in its time on the market – they simply

[52] Blackburn Deposition, pp. 97-100 (Exhibit 2272). As I also described in my deposition, "relevant market" is a term of art in economics that has nothing to do with commercial success. I assume that Professor Hay is not using "relevant market" in its standard economic context relating to antitrust economics, in which defining a relevant market refers to a specific and detailed exercise designed to outline a market for analysis of antitrust issues. [See, *e.g.*, *Horizontal Merger Guidelines*, U.S. Department of Justice and the Federal Trade Commission (*Guidelines*), pp. 7-13 (Exhibit 2315).]

In his deposition, however, Professor Hay indicated that exactly this sort of exercise (citing the same *Guidelines*) would be an appropriate approach for defining a "relevant market" for commercial success analyses. [Hay Deposition, pp. 127-30 (Exhibit 1107).]

serve to change the denominator in any share calculations that one makes. But the ultimate focus remains on whether a product's financial success shows that a financial incentive existed to create the product earlier, regardless of market share.

37. As Professor Hay admitted at his deposition, he did not put forth an alternative definition of the relevant market, nor did he provide any alternative analyses within the context of such a relevant market.[53] Furthermore, Professor Hay admitted that the market as defined by the pharmaceutical drug company whose product is subject to an analysis of commercial success is an acceptable definition for the purposes of economic analyses.[54]

38. As noted above, Novartis's own documents make no reference to competition with the drugs Professor Hay criticizes me for leaving out, with the exception of Tysabri and Lemtrada. As I discussed in my deposition, Lemtrada was only approved at the end of 2014. That may explain why it is not included in

[53] Hay Deposition, pp. 118-9 (Exhibit 1107).

[54] Hay Deposition, pp 128-9 (Exhibit 1107). See also Wai Declaration, ¶ 3 (Exhibit 2299).

the IMS data produced to me by Novartis;[55] even were it possible to include it, it would, at most, appear in two months of data and would *not* make a difference for the conclusions I have drawn. Similarly, as I discussed previously, the data for Tysabri are simply not available.[56] The lack of available data for one drug cannot mean that an analysis of the available data is "unreliable" nor can any success of one additional drug – Tysabri – indicate a lack of success of Gilenya.

39. In addition to critiquing my analyses with IMS Data, Professor Hay criticizes the IMS Data itself in my analyses of Gilenya's commercial success, arguing that the IMS Data I have used have a "data quality problem."[57]

40. Pharmaceutical data collected by IMS Health is considered the gold standard of national prescription activity for pharmaceutical products in the U.S.[58]

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[55] "Genzyme's Lemtrada Approved by the FDA," *Genzyme Press Release*, November 14, 2014 (Exhibit 2142). See also Lemtrada Highlights of Prescribing Information (Exhibit 2175).

[56] See Blackburn Declaration, footnote 11 (Exhibit 2045). Professor Hay concedes at his deposition that this information may not be generally available, even directly from specialty pharmacies that distribute Tysabri. [See Hay Deposition, pp. 123-4 (Exhibit 1107).]

[57] Hay Declaration, ¶¶ 45, 49 (Exhibit 1041).

Moreover, in my experience, all pharmaceutical companies with which I have dealt rely on IMS Data for planning purposes with regards to their pharmaceutical offerings in order to determine, *e.g.*, their products' positions in their respective markets relative to their competitors' products, their gains and losses in market share, and for planning purposes related to entry and other changes in market conditions. Similarly, economists such as myself and other economic experts have relied on IMS Data in our own analyses, *e.g.*, of the commercial success of pharmaceutical drug products. In addition, numerous academic papers and studies have used data from IMS to conduct and support analyses, including data from the IMS National Prescription Audit (NPA), upon which I relied in my initial declaration.[59] Furthermore, I note that the IMS Data upon which I relied in my initial declaration are the same data that Novartis routinely uses to assess Gilenya's sales performance in the marketplace.[60]

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[58] About IMS Health (Exhibit 2317); HSRN DataBrief: National Prescription Audit, IMS Institute for Healthcare Informatics (Exhibit 2316).

[59] HSRN DataBrief: National Prescription Audit, IMS Institute for Healthcare Informatics (Exhibit 2316); IMS Health Bibliography (Exhibit 2318).

[60] Wai Declaration, ¶ 3 (Exhibit 2299).

41. Moreover, Professor Hay admitted at his deposition that he considers IMS Health to be a reputable source of information, and that he would rely on data provided by IMS Health in analyses of commercial success.[61] In fact, Professor Hay admitted that he indeed requested IMS Data in the preparation of his declaration.[62] However, he did not provide any alternative analyses using either IMS data or data from some other source, nor did he provide any data from the "specialty pharmacies" that he claims could have provided additional information – information which has not been produced by Novartis and is not among the information upon which Novartis relies in the normal course of business related to Gilenya.

42. Moreover, Professor Hay criticizes my analyses as comparing total prescriptions across drugs with different dosing schedules.[63] However, differences in dosing schedules – such as whether a pill is taken once per day, or twice per day – does not affect prescription data, as total prescriptions measure only how often patients go out and get (and then use) a drug. Data on total dispensed prescriptions (that I used) is, in my experience, the best way to compare how often each

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[61] Hay Deposition, pp. 47-9 (Exhibit 1107).

[62] Hay Deposition, pp. 47-8 (Exhibit 1107).

[63] Hay Declaration, ¶¶ 46-9 (Exhibit 1041).

treatment is used, and is not impacted by differences in dosing schedules because a prescription is a unit of drug usage over time. A prescription for a once-daily drug may include 30 pills, and a prescription for a twice-daily drug may include 60 pills, but each represents the same time of use of a drug, and would show up as one prescription in either case.

43. Indeed, the IMS Data I used are "particularly valuable for addressing research questions that focus on trends or estimates of prescription use or costs that do not require detailed clinical information."[64] This is exactly what I have done with my analyses.[65] Use of these data do not, in my opinion, invalidate my analyses. Indeed, using the IMS Data, I conducted reasonable and well-accepted analyses to determine the commercial success of the '283 patent through Gilenya and, again, Professor Hay provides no alternative to my use of this IMS Data.

44. In addition, as seen in the figures below, even using gross sales IMS Data for Gilenya and its competitors, as Professor Hay suggests, shows that

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[64] HSRN DataBrief: National Prescription Audit, IMS Institute for Healthcare Informatics (Exhibit 2316).

[65] See, *e.g.*, Blackburn Declaration, ¶¶ 20-4, 33-4, and Figure 2 through Figure 6 (Exhibit 2045).

Gilenya has been able to generate significant sales and capture a substantial share of the MS drug treatment space.

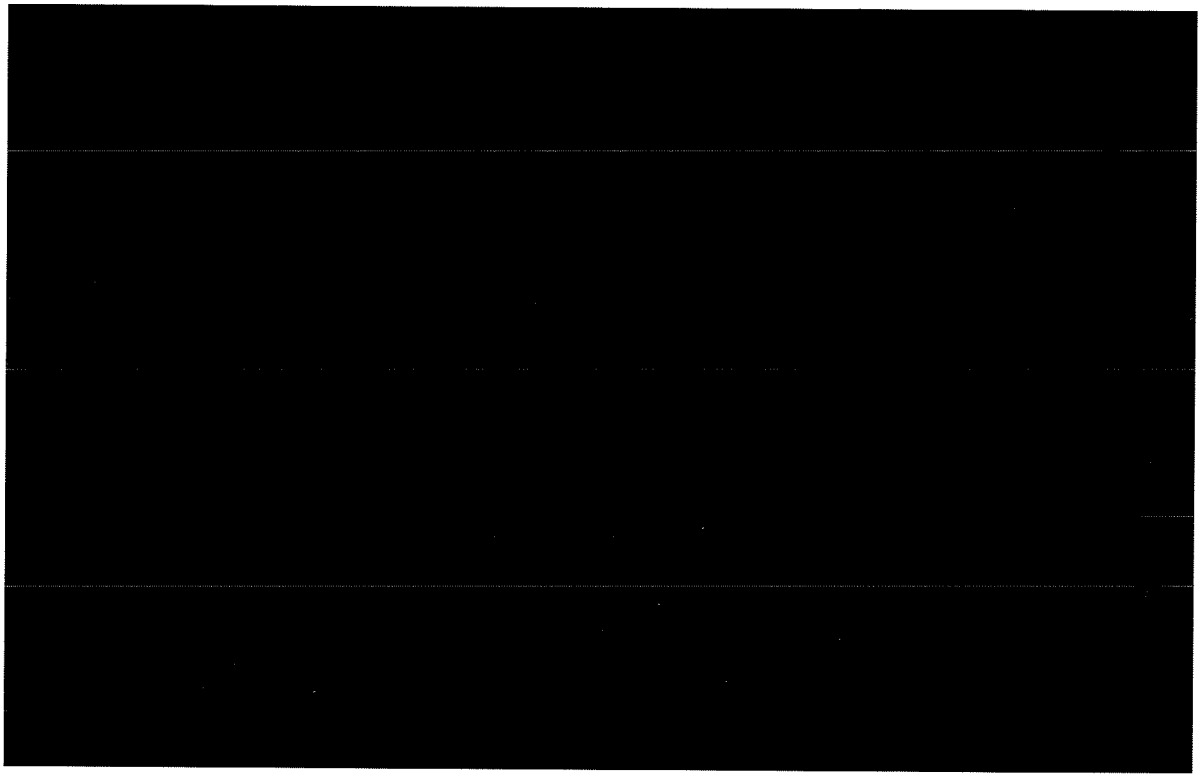

Figure 3 – Average Weekly Dollar Sales of Oral and Injectable MS Treatments by Drug, May 2010 through December 2014.

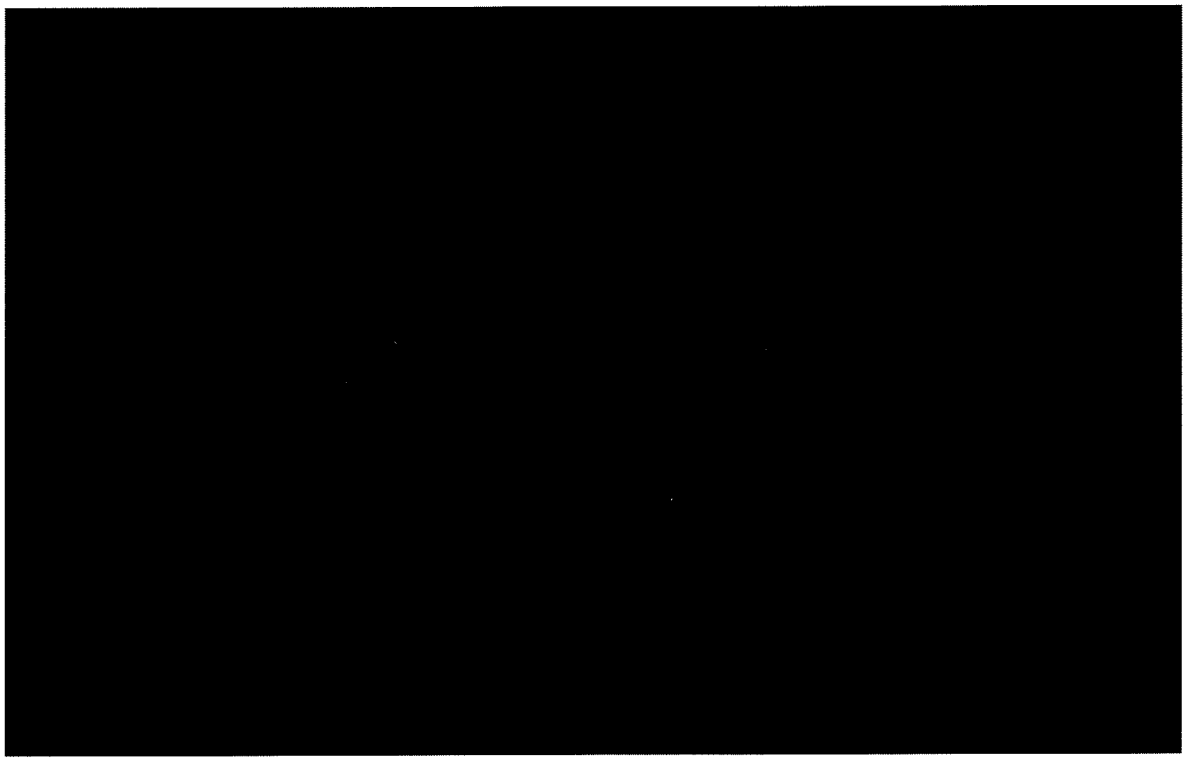

Figure 4 – Share of Average Weekly Dollar Sales of Oral and Injectable MS Treatments by Drug, May 2010 through December 2014.

Figure 5 – Change in Average Weekly Dollar Sales of Oral and Injectable MS Treatments by Drug, September 2010 through December 2014.

Thus, as shown in **Figure 3**, **Figure 4**, and **Figure 5** above, on an average weekly dollar sales basis, Gilenya has been able to generate substantial sales, capture significant share, and outpace most all of its competitors in growth in dollar sales in its time on the market (much like it has on a total prescription basis).[66]

45. Thus, Professor Hay's critiques of my analyses of Gilenya's commercial success using IMS Data as overstating Gilenya's importance and share of the MS drug treatment space are incorrect as well as contradictory. As shown above, IMS Data are well-recognized as an industry standard, and are a well-

[66] See also Blackburn Declaration, Figure 2, Figure 3, Figure 4 (Exhibit 2045).

accepted and appropriate data source to use in commercial success analyses such as this. Moreover, even adjusting for the alleged flaws in my analyses, the evidence suggests that Gilenya has been able to generate substantial dollar and prescription sales, and capture significant market share in a crowded MS treatment space, and has thus performed in a manner indicative of a commercially successful pharmaceutical product.

B. Professor Hay's Criticisms of the Gilenya Profitability Analysis Do Not Indicate a Lack of Commercial Success

46. Professor Hay mischaracterizes my analysis as a "very thin" analysis of Gilenya's profitability, and argues that I have not accurately accounted for discounts related to the promotion of Gilenya, as well as that I merely report "'accounting' profitability" in my initial declaration.[67]

47. First, I understand that the data I used to analyze Gilenya's profitability are the same data that Novartis routinely uses to assess Gilenya's financial performance and importance.[68] I note as well that, while Professor Hay seems to doubt the accuracy of these data, the Wai Declaration is sworn testimony that these data are accurate. Professor Hay provides nothing more than his own speculation to suggest that these data are inaccurate or faulty.

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[67] Hay Declaration, ¶¶ 67-9, 72, and footnote 43 (Exhibit 1041).

[68] Wai Declaration, ¶ 5 (Exhibit 2299).

48. In addition, Professor Hay's criticism that I have not sufficiently accounted for various deductions Novartis has used in promoting Gilenya is unfounded. The Gilenya financial data upon which I have relied make very clear that "Revenue Deductions" are subtracted from "Gross Sales – 3rd Party" to arrive at the "Net Sales" figures I reported in my initial report, as well as in **Figure 7** below.[69] Further, even without such explicit evidence, the definition of "Net Sales" itself is the sales a product has generated, less any returns, missing goods, and discounts and allowances.[70] I additionally note that, while Professor Hay criticizes this aspect of my analysis, he offers no alternative calculation of the sales Gilenya has generated – even though Professor Hay admitted that he regularly uses such data in his own research.[71]

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[69] Gilenya Financial Data (Exhibit 2187); Blackburn Declaration, Figure 1 (Exhibit 2045). See also Hay Declaration, footnote 43 (Exhibit 1041).

[70] Net Sales Definition, *Investopedia* (Exhibit 2319).

I note that at his deposition, Professor Hay stated that his general understanding of "Net Sales" is that they net out things such as returns, missing goods, discounts, and allowances. [Hay Deposition, pp. 43-4, (Exhibit 1107).]

[71] Hay Deposition, pp. 70-9 (Exhibit 1107).

49. Moreover, though Professor Hay claims that I have selectively reported Gilenya's "'accounting' profitability," the "Contribution Profit" I have reported in **Figure 7** below, as well as in my initial declaration, is defined as the amount of profit that a product, such as Gilenya, contributes to the overall profits of a project or enterprise, such as Novartis.[72] Furthermore, in analyses of commercial success, I, as well as numerous other economists, have routinely assessed a product's profitability using similar data when the data have been available. Accordingly, in my opinion, there is no basis (and Professor Hay provides none) to believe that this is not an accepted and reliable way in which to measure the profits generated by Gilenya.

50. Professor Hay also claims that Gilenya has maintained a high percentage of net sales as marketing expense, and that "[a]ccording to IMS, in 2011 total U.S. pharmaceutical sales were $319.9 billion and marketing and promotion averaged 2.1% of these sales."[73] Accordingly, in his experience, "it is

[72] See, *e.g.*, *Corporate Finance, 4th Edition*, p. 871 (Exhibit 2320). See also Blackburn Declaration, Figure 1 (Exhibit 2045).

[73] Hay Declaration, ¶ 70 (Exhibit 1041).

highly unusual for a drug company to be maintaining such a high percentage of net sales as marketing and selling expenses."[74]

51. To the contrary, as I stated in my deposition, the magnitude of Gilenya's marketing and selling expenses compared to the sales and profits it has been able to generate in the marketplace is indicative of commercial success.[75] Specifically, while Professor Hay relies on an industry-wide benchmark that includes, for example, sales of generic and off-patent drugs that are not marketed at all, I note that in its 2014 financial disclosure to the SEC, Novartis reported $8.2 billion in "Marketing & Sales" out of $31.8 billion in "Net sales to third parties" for its "Pharmaceuticals" segment in 2014. [redacted]

[74] Hay Declaration, ¶ 70 (Exhibit 1041).

[75] Blackburn Deposition, pp. 116-7 (Exhibit 2272).

[76] Novartis 2014 Form 20-F, p. F-26 (Exhibit 2116).

[77] While Gilenya's marketing costs have accounted for approximately 35 percent of its net sales over its entire period on the market, this is because it includes the

Accordingly, Professor Hay is incorrect to claim that Gilenya's marketing expenses are "high," and are not indicative of the commercial success of the '283 patent through Gilenya.

C. The Timing of FDA Approval Does Not Negate the Nexus to the Oral Formulation and the '283 Patent

52. Professor Hay claims that "FDA approval, in and of itself, does nothing" to show a nexus between Gilenya's commercial success and the features of the '283 patent.[78] Professor Hay further claims that "[o]nce FDA-approved, even an ineffective drug without any positive attributes may receive some exploratory sales" due to patients and physicians wanting to try new treatments.[79]

53. However, by the same logic as outlined in Professor Hay's arguments here, it is not clear that there can ever be a commercially successful FDA-approved drug product that shares a nexus with its patented features, at least in its first few years on the market. Put differently, of course the sales of a drug have a nexus to

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early years in which it was commercially available, when sales of a pharmaceutical product are generally low while marketing expenses are relatively higher.

[78] Hay Declaration, ¶ 110 (Exhibit 1041).

[79] Hay Declaration, ¶ 110 (Exhibit 1041).

its approval; *all* drugs have a nexus to approval for *all* sales. Without the approval, there would be no sales. This, however, provides no information about whether or not there is also a nexus to the '283 patent.

54. Moreover, it is not merely happenstance that Gilenya was launched as the first oral MS treatment, and was launched well before the next oral MS treatment became available.[80] Gilenya was the first oral MS treatment to seek FDA approval.[81] There is no evidence of which I am aware (and Professor Hay has provided none) that without the '283 patent, Gilenya could have been approved when it was approved as an oral MS treatment.

55. Furthermore, Professor Hay's assertion that a large portion of Gilenya's sales are "exploratory" is inconsistent with the evidence available in this case. For instance, as shown in **Figure 7** below, Gilenya's profits have grown significantly in each year since its launch, and have continued to grow following the launch of two more oral MS treatments, Tecfidera and Aubagio. Moreover, as shown **Figure 5** above and **Figure 6** (reproduced from Figure 3 in my initial declaration) below, [redacted]

[80] See, *e.g.*, Blackburn Deposition, pp. 193-202 (Exhibit 2272).

[81] See Gilenya Summary Review, p. 1 (Exhibit 2296).

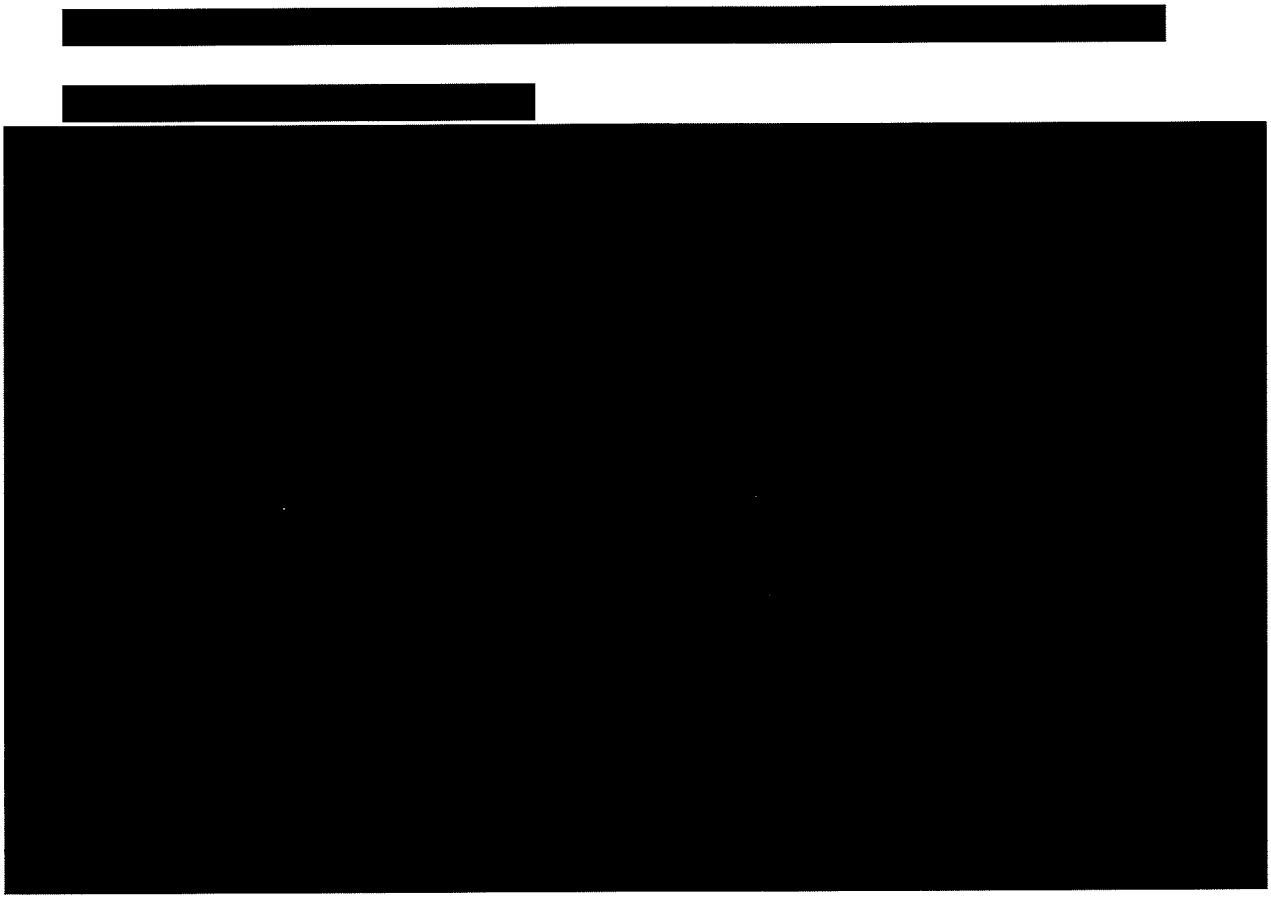

Figure 6 - Change in Total Prescriptions of MS Treatments by Drug Following Gilenya Launch, September 2010 through December 2014.

If Gilenya's sales were due, in large part, to its FDA approval as Professor Hay claims, then it follows that one would expect to see a drop in sales, prescriptions, and profits following the launches of Aubagio and Tecfidera, as physicians and patients would move from Gilenya to other newer, oral alternatives. As shown above, this has simply not occurred, and it thus follows that "exploratory" sales and Gilenya's approval as the first oral MS drugs are not the only reasons for Gilenya's success.

56. Furthermore, even to the extent that Gilenya enjoyed some benefit to being the first oral MS treatment on the market, this alone is not sufficient to negate the nexus between its success and the '283 patent. And, of course, Professor Hay provides no evidence that indicates that [redacted] in Net Sales earned by Gilenya through the end of 2014 can be fairly represented to be nothing more than "some exploratory sales." As I have shown above, without the invention claimed in the '283 patent, Gilenya simply would not have been the first oral MS treatment to launch in the marketplace.

D. Patient Switching from Tysabri to Gilenya Does Not Negate the Nexus to the Oral Formulation and the '283 Patent

57. Professor Hay claims that "Dr. Blackburn does not consider whether Gilenya's sales are due to safety warnings or restrictions on Tysabri or other MS drugs."[82] While it is true that Tysabri and other MS drugs may have safety warnings and/or other restrictions, I note that Gilenya also has a safety warning that is prominently featured on the Gilenya website.[83] Accordingly, Professor Hay has failed to demonstrate how Gilenya is differentiated from other available MS treatments in this respect, and that a perceived greater level of safety associated with Gilenya is driving its sales.

[82] Hay Declaration, ¶ 31 (Exhibit 1041).

[83] Gilenya (Exhibit 2181).

58. Furthermore, I note that none of the Novartis documents entered into the record mention that Gilenya's sales are driven by Tysabri's safety warnings.[84] In addition, even if one supposes that some of Gilenya's sales are due to patients switching to the drug from Tysabri due to Tysabri's safety warnings, Professor Hay has failed to show how this precludes a nexus between the sales of Gilenya and the features of the '283 patent. If, absent the invention claimed in the '283 patent, following these warnings, patients were to switch from Tysabri to another MS treatment instead of Gilenya, this does not preclude a nexus between the success of Gilenya and the '283 patent. Put differently, Professor Hay does not demonstrate that patients are not switching from Tysabri to Gilenya due to the features of the '283 patent in combination with the supposed effect of safety warnings.

E. Pricing and Promotional Programs for Gilenya Do Not Negate the Nexus to the Oral Formulation and the '283 Patent

59. Professor Hay criticizes my analyses of the pricing schemes of the MS treatments as incomplete.[85] First, I note that the pricing data upon which I relied

[84] See, *e.g.*, 2012 Gilenya Physician ATU (Exhibit 2266); Gilenya Physician ATU – Q4 2013 Final Report (Exhibit 2267); Gilenya Physician ATU – 3T 2014 (Exhibit 2268).

[85] Hay Declaration, ¶¶ 91-5 (Exhibit 1041).

for the analyses in my initial declaration are the same data Novartis uses to assess Gilenya's price in the marketplace relative to competitors.[86] Similarly, at his deposition, Professor Hay admitted that he did not examine rebate or pricing information for Gilenya, nor did he look at WAC or Average Wholesale Price information, and also admitted that he did not know if Gilenya's rebate and pricing schemes are materially different from its competitors.[87]

60. Moreover, while Professor Hay shows a price list for the various MS treatments at two pharmacy chains in one specific state to support his claim that Gilenya is less expensive than its competitors,[88] he does not address wider evidence in the record that indicates Gilenya has been priced at a premium to its

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[86] Wai Declaration, ¶ 4 (Exhibit 2299).

[87] Hay Deposition, pp. 76-8 (Exhibit 1107).

[88] Hay Declaration, ¶93 (Exhibit 1041). I note that, while Professor Hay's example shows Gilenya is priced lower than competing drugs at Walgreen's in Florida, it is actually priced higher than five out of the six competing drugs at Walmart, suggesting that Professor Hay's comparison does nothing to establish whether Gilenya is, overall, priced at a premium to competing drugs.

competitors for much of its time on the market. For instance, I note that several financial analyst reports note Gilenya's premium price.[89]

61. In addition, I understand that the MS treatment market is not considered very price-sensitive, and that new MS treatments are typically priced at a premium to existing therapies. For instance, a 2007 report on the MS treatment industry stated that "the lack of cost-sensitivity in the MS market has historically driven emerging agents to be priced at a premium to current therapies," and that "emerging therapies will command higher prices thanks to improvements in convenience or efficacy."[90] Additionally, like the sources cited above, these industry reports make note of Gilenya's premium price position relative to competing MS treatments available.[91] Lastly, I note that several news articles, as

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[89] See, *e.g.*, Current Research, LLC October 2010 Analyst Report, p.1 (Exhibit 2205); Goldman Sachs 2010 Analyst Report, pp. 2, 4 (Exhibit 2037).

[90] 2007 Decision Resources Report, p. 4 (Exhibit 2130). See also 2009 Decision Resources Report, p. 224 (Exhibit 2131); 2011 Decision Resources Report, p. 100 (Exhibit 2132); November 2013 Decision Resources Report, p. 233 (Exhibit 2134).

[91] See, *e.g.*, 2009 Decision Resources Report, p. 124 (Exhibit 2131); 2011 Decision Resources Report, pp. 4, 90, 100-1 (Exhibit 2132); November 2013

recently as this year, have noted that Gilenya is more expensive than many of its competitors.[92]

62. Additionally, Professor Hay argues that promotional programs for Gilenya, such as co-payment programs, coupons, rebates, and discounts, will drive sales of Gilenya, but that these sales have no nexus with the '283 patent.[93] Professor Hay's argument is off-point because he makes no showing that physicians are prescribing the drug because of these promotional programs as opposed to the oral formulation. That is, he fails to provide any evidence that these are the sole drivers of Gilenya's sales or otherwise demonstrate a lack of nexus to the '283 patent.

Decision Resources Report, p. 116 (Exhibit 2134); 2014 Decision Resources Report, p. 83 (Exhibit 2135).

[92] See, *e.g.*, "How Much Would You Pay for an Old Drug? If You Have MS, a Fortune," *BloombergBusiness*, April 24, 2015 (Exhibit 2322); "BioGen prices Tecfidera below oral MS rival Gilenya," *FiercePharma*, March 29, 2013 (Exhibit 2321).

[93] Hay Declaration, ¶ 89 (Exhibit 1041).

63. Furthermore, as shown in **Figure 7** below [redacted] I also note that many of the other MS treatments also have promotional programs such as co-payments, coupons, rebates, and discounts, similar to Gilenya's.[96] Accordingly, Professor Hay does not address how Gilenya's promotional programs differ from those of many of its competitors, and how these programs drive sales of Gilenya relative to sales of other available MS treatments.

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[94] I note that Professor Hay does not dispute this number. [See Hay Deposition, pp. 45-6 (Exhibit 1107).]

[95] See **Figure 7**. See also Gilenya Financial Data (Exhibit 2187).

[96] See, *e.g.*, Tecfidera (Exhibit 2182); Aubagio Cost (Exhibit 2323); Avonex (Exhibit 2153); Betaseron Financial Support (Exhibit 2324); Copaxone (Exhibit 2155); Plegridy (Exhibit 2239); Rebif Co-Pay (Exhibit 2325).

VI. Professor Hay's Opinions Contain Several Methodological Flaws

A. Gilenya's Short Time on the Market Makes a Return On Investment (ROI) Analysis Inapt

1. An ROI Analysis Requires Sufficient Time to Demonstrate a Sufficient Return

64. Professor Hay claims that I "presented nothing whatsoever on Gilenya's overall profitability (or overall ROI)," and further claims that an ROI would suggest that "Gilenya is far from profitable."[97]

65. While I agree that an ROI analysis can be a relevant factor in assessing the commercial success of a product, due to the required information for such an analysis, it is not an appropriate analysis here (and, I note, Professor Hay provides no such analysis of actual ROI for Gilenya). Indeed, in the chapter in *Economic Damages in Intellectual Property, A Hands On Guide to Litigation* to which Professor Hay cites extensively in his declaration, the authors provide a stylized example of an ROI analysis in which they examine the net profits of a product "[o]ver its entire life cycle."[98] Furthermore, the authors suggest that, in real-world ROI commercial success analyses, in which a product may have not yet fully realized the profits it will generate over its life on the market, one can

[97] Hay Declaration, ¶¶67, 72 (Exhibit 1041).

[98] *Economic Damages in Intellectual Property, A Hands-On Guide to Litigation*, 2006: 163 (Exhibit 1056).

examine the product's trend in profitability to determine if it will one day earn a positive return.[99]

66. Indeed, as I note in **Figure 7** (reproduced from Figure 1 in my initial declaration), Gilenya has less than five years of sales data.

[99] *Economic Damages in Intellectual Property, A Hands-On Guide to Litigation*, 2006: 165 (Exhibit 1056).

Figure 7 - Gilenya Profit and Loss Statement, 2010 through 2014.[100]

Accordingly, Gilenya has not had sufficient time on the market to demonstrate the extent to which it represents a significant and positive return. In my opinion, it is improper, as a matter of economics, to claim that, at this early stage in Gilenya's life cycle and given its growth in sales and profits over time, Gilenya has not earned a positive ROI, and is therefore not a commercial success.[101] Therefore,

[100] As noted in my deposition, **Figure 7** accounts for an additional expense,

[101] Blackburn Deposition, pp. 81-3 (Exhibit 2272).

Gilenya needs sufficient time, and certainly more than five years on the market, for an ROI analysis to determine its commercial success to be apt in this instance.

2. Available Evidence Suggests Gilenya Has – To Date – Provided a Return Indicative of Success

67. Notwithstanding the fact that Gilenya has not had sufficient time on the market to earn a positive return, the available evidence indicates that Gilenya has, and/or will, provide a return that is indicative of its commercial success. Indeed, as shown in **Figure 7** above, [redacted] Accordingly, this evidence provides no reason to believe (and Professor Hay provides no such reason or evidence[103]) that Gilenya

[102] I note that **Figure 7** is reproduced from data that Novartis routinely, and as part of its regularly conducted business activities, uses to assess Gilenya's financial performance. [See Wai Declaration, ¶ 5 (Exhibit 2299). See also Gilenya Financial Data (Exhibit 2187).]

[103] Indeed, Professor Hay claims that it is reasonable to look at trends in sales, profitability, etc., and to look at, in this case, Novartis's own data on the financial performance of Gilenya, in order to determine how a product will perform in the future in order to assess the ROI of drugs that have not yet

would not reasonably be expected to continue to earn greater and greater sales and profits in the future, thus earning a greater and greater ROI over time.

68. At his deposition, Professor Hay claimed that a forecast would have needed to be conducted in order to determine the true expected profitability of Gilenya through its lifecycle.[104] Professor Hay, however, does not make any reference to forecasts of Gilenya's future sales. For example, an analyst report from July 2014 provides a discounted cash flow analysis of Gilenya (a projection of the overall future value of Gilenya going forward), valuing the drug at at least $4 billion.[105] While it remains the case that full details on Gilenya's R&D costs are not available (which should not, in my opinion, invalidate the value of any review of Gilenya's profitability since launch), as I describe below, this projection of the value of Gilenya suggests it would earn a positive return even assuming a very high estimate for its R&D costs. Accordingly, there exists at least one recent analysis from a disinterested, third-party source that provides forecasting of

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reached the end of their lifecycles. [See Hay Deposition, pp. 110-3 (Exhibit 1107).]

[104] Hay Deposition, pp. 109-12 (Exhibit 1107).

[105] Societe Generale July 2014 Analyst Report, p. 6 (Exhibit 2197). See also USD-CHF Exchange Rate, *BloombergBusiness* (Exhibit 2328).

Gilenya's future profitability which is in conflict with Professor Hay's claim that Gilenya is not a profitable drug.

69. In addition, Professor Hay claims that "the average pharmaceutical brought to market costs $2.6 billion in R&D costs."[106] However, as I explained at my deposition, and as Professor Hay admits, this estimate includes R&D expenditures for all drugs developed (including those that are not successfully approved).[107] Because Gilenya has been successfully approved, the comparison Professor Hay makes between the profits it has earned and the costs associated with R&D for any new drug is inapt and overstated. Indeed, one study has found that only about eight percent of new drugs in development are ever successfully approved.[108] Moreover, a more recent study found that the approval rate for

[106] Hay Declaration, ¶ 72 (Exhibit 1041).

[107] Blackburn Deposition, pp. 114-5 (Exhibit 2272); Hay Declaration, ¶¶ 72-4 (Exhibit 1041).

[108] The Drug Development and Approval Process, *FDAReview.org* (Exhibit 2300). See also "The price of innovation: new estimates of drug development costs," *Journal of Health Economics*, Vol. 22 (2003): 151-85 at 158 (Exhibit 2301).

Central Nervous System (CNS) drugs, a class to which I understand Gilenya belongs, is even lower, at about six percent of all such drugs developed.[109]

70. Accordingly, it is very likely that Novartis's R&D expenditures for developing Gilenya are *significantly* lower than the $2.6 billion Professor Hay estimates, which includes the R&D costs for *all* drugs across *all* therapeutic classes, regardless of whether or not they were successfully approved for marketing in the U.S. As such, given the [redacted][110] and given that Gilenya's R&D costs are likely substantially less than the $2.6 billion that Professor Hay estimates, there is no reason to believe that Gilenya has not already provided a positive ROI or, if not yet, that it soon will. Furthermore, I note that, given the Gilenya valuation

[109] "CNS drugs take longer to develop, have lower success rates, than other drugs," *Tufts Center for the Study of Drug Development Impact Report*, Vol. 16(6), 2014 (Exhibit 2304). See also, *e.g.*, ConnectiCare Pharmacy Drug List, April 2015 (Exhibit 2302); United Healthcare 2015 Prescription Drug List (Exhibit 2303).

[110] Again, I note that Gilenya has been one of the Top 50 selling branded drugs in the U.S. in recent years.

described above, Gilenya is forecasted to earn a positive ROI, even if its R&D costs were the $2.6 billion as Professor Hay claims.

71. Nevertheless, Professor Hay asserts that the appropriate yardstick for measuring Gilenya's ROI is R&D costs of $2.6 billion, because if drugs that are brought to market don't return at least $2.6 billion on average, drug companies would be unsuccessful – "[t]he successful drugs… have to cover the costs of the unsuccessful ones and still generate an average positive return on investment capital in order to be commercially successful."[111] The idea that a drug can be considered a success only if it earns more than $2.6 billion in *profits* makes no economic sense. While it may be true that successful companies must have launched drugs that earn enough profits to pay for the R&D on the failed drug projects, *it is **not** true that successful drug companies have to cover the R&D costs for failed drugs of other companies.* For simplicity, imagine a world with two drug companies – SuccessCo. and FailCo. At SuccessCo, all drug products lead to approved and launched products, while at FailCo., all drug products fail to get approved. It cannot be that SuccessCo.'s products are only considered successful

[111] Hay Declaration, ¶ 74 (Exhibit 1041).

if they cover the costs of SuccessCo.'s products *and* the costs of FailCo.'s failed products. That makes no economic sense.[112]

72. While that is a stylized example, it highlights the flaw in using an industry average (such as the $2.6 billion) as a benchmark – if so, then the standard for success is universal and does not depend, in any way, on the specifics of the drug in question. That cannot be right. Moreover, even if one had a similar number (including the costs of failed and successful products) for a specific firm, it would be inappropriate to measure the success of a product at that firm against that number. Instead, it is only appropriate to measure the success of a product against its own costs.

73. The logic is simple – if a product earns more profits following launch than the properly measured costs associated with bringing it to launch, then the product has earned a positive return to the company. The company is *better off* as a result of having embarked on the project than it would have been if it did not.

[112] Such a view may be explained by Professor Hay's opinion that an analysis of commercial success should be done from the perspective of social welfare. In that light, it may be appropriate to look at the success of one drug against the cost of the failures of many others. However, as I describe in the following paragraphs below, this would be inappropriate when analyzing the economic incentive to develop any particular invention or product.

Put differently, the economic incentive at the time the project started (given the subsequent history) would be to develop the product. In the context of commercial success, this is precisely the correct question – was there an economic incentive to invent the invention at issue or not? There may be many drugs that earn a positive return on their own costs but would fail to earn a return sufficiently large to cover the average costs of all the failed drugs in the industry, but *all* of those drugs have helped the industry (and their companies) and, as such, should rightfully be viewed as successful.

74. Professor Hay's assertion that the appropriate benchmark is the average cost of all drugs, rather than the specific costs of a drug under examination, in my opinion, is not consistent with the economic incentives faced by inventors or the basis of a commercial success analysis. As I have described above, however, when put in the proper context, the hundreds of millions of dollars that Gilenya has earned since launch, as well as the reasonable expectation that such profits will continue in the future, suggest that Gilenya has generated, or soon will generate, a positive ROI. Indeed, Novartis's statements about Gilenya (for example, calling it a "[t]op-performing Pharmaceutical product" and a "growth" product) indicate that Novartis sees it as successful and that success is growing.[113]

[113] Novartis 2014 20-F, pp. 111-2 (Exhibit 2116).

B. Event Study Analyses Are Unsuitable for Evaluating the Commercial Success of the '283 Patent through Gilenya

75. Professor Hay argues that an event study – an analysis of Novartis's stock price following Gilenya's launch – would show that Gilenya has had little financial impact on Novartis, and is, accordingly, not a commercial success.[114] However, I note that an event study is not identified as an appropriate measure for determining the commercial success of a product.[115] For example, the U.S. Patent and Trademark Office (USPTO) does not identify event studies as determinants of commercial success.[116]

76. Furthermore, Professor Hay himself does not undertake any such analysis – he simply asserts that "if one examines the Novartis stock price from the time of the Gilenya launch… there is no evidence of an increase in Novartis stock value until September 2012," without presenting any such evidence or explaining

[114] Hay Declaration, ¶¶ 81-3 (Exhibit 1041).

[115] See, *e.g.*, *Economic Damages in Intellectual Property, A Hands-On Guide to Litigation*, 2006: 159-68 (Exhibit 1056).

[116] USPTO Manual of Patent Examining Procedure, § 716.03.(a)-(b) (Exhibit 2305). Of course, there may be valid methodologies that are not laid out by the USPTO, but as I describe in more detail above, event studies are not one of them.

how he can conclude that these trends can be isolated to Gilenya, rather than other factors.[117]

77. As I noted at my deposition, however, conducting an event study with Gilenya requires overcoming the fact that Novartis's stock price depends on many different factors and any analysis focused on Novartis's stock price would need to appropriately account for all of them. Indeed, even if Novartis were to see its stock price shoot up following Gilenya's launch, one could not reasonably conclude that this was due to Gilenya.[118] Furthermore, stock price changes occur when the market adapts to *unexpected* events.[119] Given that Gilenya's development was known years before its launch, and that its launch was covered extensively in the financial community, a change in Novartis's stock price following Gilenya's launch would therefore only indicate the extent to which the launch was better or worse than expected.[120]

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[117] Hay Declaration, ¶81 (Exhibit 1041).

[118] Blackburn Deposition, pp. 164-5 (Exhibit 2272).

[119] "How Do Stock Returns React to Special Events?," *Business Review*, 1989: 17-29 at 17 (Exhibit 2306).

[120] See, *e.g.*, "FDA approves first oral drug to reduce MS relapses," *FDA News Release*, September 22, 2010 (Exhibit 2010); 2007 Decision Resources Report,

78. The fact that Novartis's stock price did not change following Gilenya's launch may simply indicate that Gilenya's approval, launch, and success was anticipated and realized, and the success has occurred over a number of years. Accordingly, an event study is simply not appropriate in this instance, and Novartis's stock price cannot be evidence of the commercial success of the '283 patent through Gilenya. Indeed, at his deposition, Professor Hay recognized that Novartis's stock price may have been unchanged for any number of reasons.[121]

79. An event study is simply not designed to, and is not appropriate to, analyze the success of a product sold over a long period of time. Event studies, by their very nature, rely on changes in stock prices that are timed to a specific event that occurs over a short period of time. Gilenya was launched in 2010 and continues to be sold today.

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pp. 5, 8, 55, 98 (Exhibit 2130); 2009 Decision Resources Report, pp. 2, 5, 8, 100-2, 106 (Exhibit 2131); Deutsche Bank 2010 Analyst Report (Exhibit 2109); Goldman Sachs 2010 Analyst Report (Exhibit 2110); Leerink Swann 2010 Analyst Report (Exhibit 2112).

[121] Hay Deposition, p. 114 (Exhibit 1107).

80. In addition, I note that, despite Professor Hay's claim to the contrary, I am well aware of event study analyses and multivariate regression analysis, as I said in my deposition.[122]

81. Further, as I have noted immediately above and in more detail below, academic literature relating to event studies make clear that these limitations render an event study inapt in this context and Professor Hay's discussion of Novartis's stock price does not appear to address them. For instance, Gilenya's launch date may not appropriately define the period in which to conduct an event study. That is, while Gilenya may have been launched at a specific point in time, this is not necessarily the date on which the market anticipated its launch.[123] Indeed, as I have stated above, Gilenya's development was known several years prior to its launch. Accordingly, one could reasonably expect the market to have anticipated Gilenya's launch well before its actual launch, and thus did not react in a way so as to meaningfully change Novartis's stock price on the day Gilenya became commercially available.

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[122] See Blackburn Deposition, pp. 164-5 (Exhibit 2272).

[123] See, *e.g.*, "Problems and Solutions in Conducting Event Studies," *The Journal of Risk and Insurance*, Vol. 57(2), 1990: 282-306 at 284 (Exhibit 2307).

82. In this same vein, evidence indicates that a company's stock price may not change on the day of a specific event, such as, *e.g.*, the launch of a new drug. For instance, one study regarding mergers and acquisitions found that the shareholders of acquiring firms do not earn abnormal returns following the completion of an acquisition.[124] Similarly, research on event studies emphasizes the importance of selecting the proper date(s) on which to view and analyze a particular event.[125] In addition, while some research suggests that a change in stock price reflects the market's view of a firm's current and future business strategies, Dr. Hay merely cites to data on Novartis's stock price over a 10-year period, and makes no attempt to account for how Gilenya impacts Novartis's overall business strategy.[126] Indeed, as I stated at my deposition and as Professor

[124] "Risk and Return: The Case of Merging Firms," *Journal of Financial Economics*, Vol. 1, 1974: 303-35 at 29 (Exhibit 2308).

[125] "Measuring Security Price Performance," *Journal of Financial Economics*, Vol. 8, 1980: 205-58 at 49 (Exhibit 2309); "Using Daily Stock Returns: The Case of Event Studies," *Journal of Financial Economics*, Vol. 14, 1985: 3-31 at 14-5 (Exhibit 2310).

[126] "Using Capital Markets as Market Intelligence: Evidence from the Pharmaceutical Industry," *Management Science*, Vol. 51(10), 2005: 1467-80 at

Hay concurred in his, changes in Novartis's stock price could reflect market reactions to many firm-specific and market events.[127]

83. As such, an event study is not appropriate in evaluating the commercial success of a product such as Gilenya. Such a study, like the one proposed by Professor Hay, measures the change in a firm's stock price at a specific point in time, and thus does not adequately capture the sales and profits of a firm's specific product, such as Gilenya, which has continued to exhibit sales and profitability growth over a period of several years. Similarly, because changes in stock prices reflect market reactions to unexpected events, and because Gilenya's development and launch was well documented several years before it became commercially available, a change (or lack thereof) in Novartis's stock price following Gilenya's launch says nothing about Gilenya's financial impact on Novartis. Thus, because a market's reaction to a specific event, such as the launch of Gilenya, could occur prior to the event actually occurring, it is unsurprising that Novartis's stock price did not change following Gilenya's launch, as the market

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67 (Exhibit 2311). See also Hay Declaration, ¶ 81 and footnote 57 (Exhibit 1041).

[127] Blackburn Deposition, pp. 164-5 (Exhibit 2272). See also Hay Deposition, p. 114 (Exhibit 1107).

could have anticipated the launch several years prior to its occurrence. In addition, an event study such as that proposed by Professor Hay, does not account for other Novartis-specific and market factors besides the launch of Gilenya that could have affected Novartis's stock price following Gilenya's launch. Furthermore, because an analysis of commercial success requires examining the entire history of a product's financial performance,[128] and because an event study analyzes the change in a firm's stock price at a specific point in time, it is not an appropriate measure of commercial success. According, for these reasons, the change (or lack thereof) in Novartis's stock price is not an appropriate measure of the commercial success of the '283 patent through Gilenya.

VII. Professor Hay's Declaration and Testimony Provide Several Mischaracterizations of My Analyses and Opinions

84. As described in detail above, Professor Hay mischaracterizes several of the arguments made in my initial declaration and at my deposition. These mischaracterizations I have addressed above include:

- Professor Hay's claim that Novartis has not promoted and advertised Gilenya through the features of the '283 patent;

[128] See again *Economic Damages in Intellectual Property, A Hands-On Guide to Litigation*, 2006: 163 (Exhibit 1056).

- Professor Hay's dismissal of the financial analyst reports and patient testimonials that recognize Gilenya's success, and the significant contributions its oral formulation have made to that success;
- Professor Hay's claim that the oral formulation of fingolimod was disclosed in prior art, and that this therefore precludes a nexus between the '283 patent and Gilenya's commercial success;
- Professor Hay's improper claim that a nexus can only be established if it can be shown that the patented features of a product are the sole driver of the product's sales;
- Professor Hay's claim that a ROI analysis would show that Gilenya is not a commercial success;
- Professor Hay's insistence that an event study is a proper determinant of the commercial success of a product, and that such an analysis would show that Gilenya is not a commercial success;
- Professor Hay's claim that my analyses of IMS Data are flawed;
- Professor Hay's claim that a significant portion of Gilenya's sales are due to its FDA approval, and that this approval thus precludes a nexus between Gilenya's commercial success and the '283 patent;
- Professor Hay's claim that I fail to account for sales of Gilenya being due to patient switching to the drug from Tysabri;

- Professor Hay's claim that my analysis of Gilenya's pricing data is incomplete, and that sales of Gilenya due to its promotional programs have no nexus to the '283 patent; and
- Professor Hay's claim that my analysis of Gilenya's profitability is "thin" and insufficient to demonstrate the commercial success of the drug.

85. In addition, Professor Hay presents several other mischaracterizations of the evidence in the record, and of my analyses and testimony, to which I will respond in the remainder of this section.

86. Professor Hay claims that my initial declaration shows a "lack of knowledge" of how to analyze commercial success using IMS Data, and criticizes my analyses of total prescriptions of MS treatments for not controlling for the different dosing schedules of each of the drugs.[129] While I note that Professor Hay presents no alternative analyses using the IMS Data, as I have explained above, the IMS Data I have used have been widely used, and are considered to be reputable data – as Dr. Hay himself has testified – in academic research, in analyses of commercial success by other economic experts, and by pharmaceutical companies,

[129] See, *e.g.*, Hay Declaration, ¶ 48 (Exhibit 1041).

including Novartis.[130] Moreover, and as stated above, I understand the IMS Data I have used are useful when comparing prescribing trends across different drug treatments, even without any information regarding their different dosing schedules.[131]

87. Professor Hay claims that his cost effectiveness study does not support a claim that Gilenya is more costly than its competitors.[132] Specifically, he states that in this study he did not "simply consider MS drug prices, but rather the

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[130] HSRN DataBrief: National Prescription Audit, IMS Institute for Healthcare Informatics (Exhibit 2316). See also About IMS Health (Exhibit 2317); IMS Health Bibliography (Exhibit 2318); Wai Declaration, ¶ 3 (Exhibit 2299).

[131] HSRN DataBrief: National Prescription Audit, IMS Institute for Healthcare Informatics (Exhibit 2316). See also Wai Declaration, ¶ 3 (Exhibit 2299).

[132] Hay Declaration, ¶ 80 (Exhibit 1041).

However, I note that at his deposition, Professor Hay admitted that his study factored in the prices of the drugs studied. [Hay Deposition, pp. 69-1 (Exhibit 1107).] Similarly, he stated that his study was conducted from "a societal perspective" and thus included costs, such as quality of life of the patient, which would not be considered if it were conducted from the perspective of a third-party payer. [Hay Deposition, pp. 120-1 (Exhibit 1107).]

total cost of MS treatment with each drug, including hospitalizations, ambulatory care, lab tests, adverse events costs, non-adherence costs, disease progression costs, etc."[133] However, he fails to show why these additional costs refute the claim that Gilenya's commercial success is not due to it being less costly than, or being priced below, its competitors. If, for example, patients were willing to ask for, and be prescribed Gilenya despite these higher costs, then one could reasonably assume that sales of the drug are not being driven by any reduced costs in the marketplace compared to other MS treatments. Accordingly, Professor Hay fails to show how his cost effectiveness study rebuts this claim.[134]

[133] Hay Declaration, ¶ 80 (Exhibit 1041).

[134] As well, Professor Hay, in my opinion, fails to explain why cost effectiveness is a measure of a drug's commercial success (or lack thereof). Again, it may be appropriate from a clinical or social welfare point of view to measure cost effectiveness, but with respect to the economic incentive to invent – the relevant benchmark for an analysis of commercial success related to allegations of obviousness of a patented invention – Professor Hay does not describe why cost effectiveness is indicative of that incentive. Regardless of the cost effectiveness of Gilenya compared to Tecfidera and Aubagio (Professor Hay's own article finds Gilenya to be more cost effective than the injectable treatments), Gilenya has earned substantial sales, profits and prescriptions that are tied directly to the

88. Professor Hay also claims that "Dr. Blackburn concedes that oral fingolimod formulations were disclosed in the prior art and therefore his evidence of alleged commercial success is tied not to original claims of the '283 patent, but rather to disclosed prior art."[135] I note that Professor Hay provides no evidence that I have conceded this point either in my initial declaration or at my deposition (and as I have noted – I am not a technical expert and provide no expert opinion of the state of the prior art). Furthermore, as Professor Hay himself notes, he is not a technical expert.[136] Accordingly, he has no basis to make such a claim.

89. At his deposition, Professor Hay claimed that Gilenya has "rapidly" lost market share since the launches of Aubagio and Tecfidera.[137] When one considers my analyses, it is not clear how Professor Hay reaches this conclusion, and he provides no analysis of his own to support this claim. As shown in **Figure 4** above as well as in Figure 4 in my initial declaration, Gilenya has grown to an

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'283 patent and demonstrate the substantial incentive to invent. [See Hay Declaration (Exhibit 1041), Exhibit 1040, Exhibit 1054, Exhibit 1055.]

[135] Hay Declaration, ¶ 30 (Exhibit 1041).

[136] Hay Declaration, ¶ 104 (Exhibit 1041). See also Hay Deposition, pp. 16, 36 (Exhibit 1107).

[137] Hay Deposition, pp. 63, 110 (Exhibit 1107).

approximately [redacted] Professor Hay also states that I fail to consider market share and revenue growth in my analyses.[138] However, I explicitly discuss the growth in revenues, profits, and total prescriptions Gilenya has exhibited in its time on the market in my initial declaration.[139] Accordingly, my analyses simply do not show what Professor Hay claims; Gilenya has not "rapidly" lost share.

90. Professor Hay also testifies that the total prescription figures of the drugs I analyzed are not comparable with one another due to differences in the number of pills per prescription.[140] However, as I stated above, this is not true.[141] Although IMS Health does track some sales based upon the number of pills per prescription (such as, *e.g.*, through data on dispensed extended units), the number of pills in a prescription of each of the MS treatments included in my analyses would not affect the total prescription figures for these drugs. Thus, while

[138] Hay Deposition, pp. 103-4 (Exhibit 1107).

[139] See, *e.g.*, Blackburn Declaration, ¶¶ 18, 24 (Exhibit 2045).

[140] Hay Deposition, pp. 125-7 (Exhibit 1107).

[141] HSRN DataBrief: National Prescription Audit, IMS Institute for Healthcare Informatics (Exhibit 2316).

Professor Hay's criticism may be relevant to some IMS data that I did not use, it is not relevant to the IMS Data I used to conduct my analyses in my initial declaration.

91. Similarly, Professor Hay claims that there is a lack of correlation between dollar sales and total prescriptions in data provided by IMS Health, including the IMS Data I used in my initial declaration, although he provides no evidence that this is so.[142] To the contrary, as is shown in **Figure 3**, **Figure 4**, and **Figure 5** above, as well as in Figures 2 through 4 in my initial declaration, the trends in sales, market shares, and changes in sales across total prescriptions and dollar sales for each of the MS treatments are substantially similar. Accordingly, Professor Hay's criticism here is irrelevant to the facts of this case.

92. Professor Hay claims that, in analyzing the growth in prescriptions since the launch of Gilenya for various drugs, I have "cherry-picked" the end date of the analysis (December 2014) and "ignored" the fact that some months after Gilenya's launch had lower prescriptions than at the start date (August 2010).[143] This is not true. The start date was chosen to be the time of Gilenya's launch, the only natural start date; the end date was the last date of available data (December

[142] Hay Declaration, ¶ 49 (Exhibit 1041); Hay Deposition, p. 126 (Exhibit 1107).

[143] Hay Declaration, ¶ 62 (Exhibit 1041).

2014). Had the available data run until February 2015, I would have used that as the end date; had it run only until October 2014, I would have used that as the end date. No other start date or end date makes sense to use.

93. Professor Hay also claims that I have presented multiple definitions of the relevant market without identifying which definition is correct.[144] However, Professor Hay does not provide evidence to support his claim that an analysis of commercial success must have a single, unified definition of a "relevant market." Furthermore, as I have shown, changing the definition of the relevant market does nothing to alter the substantial sales and profits Gilenya has been able to generate since it became commercially available. Accordingly, and I note that Professor Hay provides no alternative definition of a relevant market through which the '283 patent should not be viewed as a commercial success, my alleged references to varied sets of competitors (and "relevant markets") do not alter the conclusions that the '283 patent (through Gilenya) has been a commercial success.

94. Professor Hay additionally claims that the concept of a relevant market is similar in analyses of anticompetitive effects antitrust matters as it is in

[144] Hay Declaration, ¶ 39 (Exhibit 1041); Hay Deposition, pp. 127-8 (Exhibit 1107).

analyses of the commercial success of patented products.[145] However, in an antitrust matter, the focus on defining a relevant market is rightly on what the anticompetitive effects of a merger will be (*i.e.* an economic outcome), as opposed to the market definition in and of itself.[146] Indeed, the merger *Guidelines* also make clear that the defining of a relevant market is not necessary to infer the competitive effects of a merger and that multiple candidate markets may be appropriate.[147]

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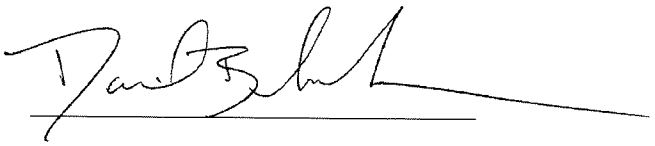
[145] Hay Deposition, pp. 128-30 (Exhibit 1107).

[146] See, *e.g.*, *Guidelines*, p. 7 (Exhibit 2315).

[147] *Guidelines*, p. 7 (Exhibit 2315): "For example, evidence that a reduction in the number of significant rivals offering a group of products causes prices for those products to rise significantly can itself establish that those products form a relevant market. Such evidence also may more directly predict the competitive effects of a merger, reducing the role of inferences from market definition and market shares. Where analysis suggests alternative and reasonably plausible candidate markets, and where the resulting market shares lead to very different inferences regarding competitive effects, it is particularly valuable to examine more direct forms of evidence concerning those effects."

95. Similarly, in my analysis of the commercial success of the '283 patent through Gilenya, I focused on the sales and profitability of Gilenya (*i.e.* its economic outcomes), both in absolute terms and relative to various competitors. Accordingly, as I have done, the focus in defining a relevant market, in either an antitrust matter or an issue of commercial success, should be on the economic outcomes that occur in the market (*e.g.*, the sales and profits Gilenya has generated in its time on the market), as opposed to the specific details of which competitors should and should not be included in the definition.

I declare under penalty of perjury that the foregoing is true and correct.



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Attachment 1

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Universidad Nacional de Tucumán, Argentina
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Written Testimony

Supplemental Rebuttal Expert Report of David Blackburn, *International Business Machines Corporation v. BGC Partners, Inc., BGC Brokers US, L.P., BGC Financial L.P., and BGC USA, L.P.*, U.S. District Court, Southern District of New York, Civil Action No. 1:10-cv-00128, May 2015. Assess IBM's supplemental claim for damages resulting from BGC's alleged breach of contract and copyright infringement.

Expert Report of David Blackburn, Ph.D., *Supernus Pharmaceuticals, Inc. v. Actavis Inc., and Actavis Laboratoties FL, Inc., Actavis Pharma, Inc., Watson Laboratories, Inc., and ANDA, Inc.*, United States District Court, District of New Jersey, Civil Action No. 13-4740 (RMB) (JS) and Civil Action No. 14-1981 (RMS)(JS), May 2015. Assess the commercial success of Oxtellar XR, a pharmaceutical product sold by Supernus.

Declaration of David Blackburn, Ph.D. in Support of SoundExchange's Motion in Limine to Exclude the Written Rebuttal Testimony of Todd Kendall, *14-CRB-0001-WR (2016-2020) Determination of Royalty Rates for Digital Performance in Sound Recordings and Ephemeral Recordings (Web IV)*, Before the United States Copyright Royalty Judges, Library of Congress, Washington, D.C., April 2015.

Declaration of David Blackburn, Ph.D., *Torrent Pharmaceuticals Limited and Apotex, Inc. and Mylan Pharmaceuticals, Inc., Petitioners v. Novartis AG and Mitsubishi Pharma Corp., Patent Owners,* Before the Patent Trial and Appeal Board, Case IPR2014-00784, Case IPR2015-00518, Patent 8,324,283 B2, April 2015. Assess the commercial success of Gilenya, a pharmaceutical product sold by Novartis.

Declaration of David Blackburn, Ph.D., *Otsuka Pharmaceutical Co., Ltd. v. Actavis Elizabeth LLC, Jubilant Life Sciences Limited, Jubilant Generics Limited and Jubilant Life Sciences (USA) Inc.*, United States District Court, District of New Jersey, Civil Action No. 14-cv-07106-JBS-KMW, March 2015. Assess potential impact of at-risk entry by Actavis and others of a generic formulation of aripiprazole.

Written Rebuttal Testimony of David Blackburn, Ph.D., On Behalf of SoundExchange, Inc., *14-CRB-0001-WR (2016-2020) Determination of Royalty Rates for Digital Performance in Sound Recordings and Ephemeral Recordings (Web IV)*, Before the United States Copyright Royalty Judges, Library of Congress, Washington, D.C., February 2015. Assess webcasting and relationship to other music distribution channels.

Expert Report of David Blackburn, Ph.D., *Endo Pharmaceuticals Inc. and Grünenthal GmbH v. Actavis Inc., Actavis South Atlantic LLC, and Watson Pharmaceuticals, Inc.*, United States District Court for the Southern District of New York, C.A. No. 13-cv-436-TPG, January 2015. Assess the commercial success of Opana ER, a long-acting opiod sold by Endo.

Expert Report of David Blackburn, Ph.D., *Takeda Pharmaceuticals Co., Ltd., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. v. TWI Pharmaceuticals, Inc.*, United States District Court for the Northern District of California, Case No. 5:13-cv-02420 LHK (PSG), December 2014. Assess the commercial success of Takeda's Dexilant pharmaceutical product.

Report of David Blackburn, Ph.D., On Behalf of SoundExchange, *14-CRB-0001-WR (2016-2020) Determination of Royalty Rates for Digital Performance in Sound Recordings and Ephemeral Recordings (Web IV)*, Before the United States Copyright Royalty Judges, Library of Congress, Washington, D.C., October 2014. Assess webcasting and relationship to other music distribution channels.

Expert Report of David Blackburn, Ph.D., *Carrier Corporation v. Goodman Global, Inc., Goodman Manufacturing Company, L.P., Goodman Global Holdings, Inc., Goodman Distribution, Inc., and Goodman Sales Company,* United States District Court, District of Delaware, C.A. No. 12-930 (SLR), February 2014. Assess commercial success of Carrier's Infinity HVAC system and related patents.

Declaration of David Blackburn, Ph.D., *Ferring B.V. v. Watson Laboratories, Inc. - Florida*, United States District Court, District of Nevada, Case Nos.: 3:11-cv-00481-RCJ-VPC, 2:12-cv-01935-RCJ-VPC, and 3:11-cv-00853-RCJ-VPC, February 2014. Asses potential impact of continued sale of Watson's generic tranexamic acid tables.

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Updated: June 29, 2015

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Federal Trade Commission, March 2005.

University of Texas-Dallas, Economics Department Seminar, February 2005.

U.S. Department of Justice, February 2005.

Wellesley College, Economics Department Seminar, February 2005.

University of Southern California, Economics Department Seminar, February 2005.

Harvard University, Industrial Organization Seminar, November 2004.

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Fellowships and Awards

Certificate for Excellence in Teaching, Harvard University, 2002-2005

Charles H. Smith Fellowship in Economics, Harvard University

Updated: June 29, 2015

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