RESPONDENTS' APPENDIX A

No. 21-1070

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellee,

v.

ACCORD HEALTHCARE INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., EMCURE PHARMACEUTICALS, HERITAGE PHARMACEUTICALS INC., GLENMARK PHARMACEUTICALS INC., USA, GLENMARK PHARMACEUTICALS LIMITED, HETERO USA INC., HETERO LABS LIMITED UNIT-V, HETERO LABS LIMITED, MYLAN PHARMACEUTICALS, INC., PRINSTON PHARMACEUTICALS INC., STRIDES GLOBAL PHARMA PRIVATE LIMITED, STRIDES PHARMA, INC., TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., ZYDUS PHARMACEUTICALS (USA) INC., CADILA HEALTHCARE LIMITED, APOTEX INC., APOTEX CORP., SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMACEUTICAL INDUSTRIES INC., SUN PHARMA GLOBAL FZE,
Defendants,

HEC PHARM CO., LTD., HEC PHARM USA INC.,
Defendants-Appellants.

Appeal from the United States District Court for the District of Delaware
Case No. 1:18-cv-01043-KAJ, Circuit Judge Kent A. Jordan

REBUTTAL DECLARATION OF
IVAN T. HOFMANN, IN SUPPORT OF DEFENDANTS-APPELLANTS' RESPONSE TO
PLAINTIFF-APPELLEE'S MOTION TO STAY THE MANDATE

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I. QUALIFICATIONS AND EXPERIENCE

1. I am a Vice President and Managing Director at Gleason IP ("Gleason"). Gleason is an economic, accounting, and financial consulting firm. I am the leader of the Intellectual Property Practice. Prior to joining Gleason, I worked for the global firm of Deloitte.

2. I graduated *magna cum laude* from the University of Notre Dame with a Bachelor of Business Administration degree and a double major in Economics and Accounting. I am a Certified Public Accountant ("CPA"). I am also Certified in Financial Forensics ("CFF"). I am a member of the Licensing Executives Society ("LES") and earned my Certified Licensing Professional ("CLP") designation, which is granted by the LES to professionals demonstrating extensive knowledge and experience in the areas of intellectual property and licensing. I am also a member of the American Economic Association. I have attended and instructed numerous continuing education seminars since the completion of my formal education and have been a speaker on numerous occasions on a variety of financial, economic, accounting, and valuation topics. I have presented to various bar associations and organizations on the issues of intellectual property, objective indicia of nonobviousness, financial damages, valuation, financial statement analysis, and other topics.

3. I have extensive knowledge and experience in the areas of economic and market analysis. My intellectual property experience includes valuation of intellectual property, analysis of objective indicia of nonobviousness, market analysis involving product performance, the determination of damages associated with patent infringement and other intellectual property (including lost profits, disgorgement, and reasonable royalties, as applicable), consideration of

irreparable harm, analysis of *Panduit* Factors, and analysis of *Georgia-Pacific* Factors. I have analyzed damages claims in trademark infringement, false advertising, and other cases involving the Lanham Act. I have experience in a broad range of industries including pharmaceutical and life sciences, manufacturing, retail, technology, healthcare, communications, construction, extractive, and other industries.

4. My work experience includes litigation support and consulting engagements with a variety of pharmaceutical and biologics companies. In my work in the pharmaceutical and life sciences industry, I have performed financial and economic analysis for hundreds of prescription pharmaceutical and biologic products, including virtually every major therapeutic class of drugs. I have been asked to study and analyze objective indicia of nonobviousness (including commercial success and nexus), consider claims of irreparable harm, the balance of equities, and public interest factors (and related issues associated with bonds therewith), determine and quantify damages, and assist with licensing and settlement discussions.

5. My work experience also includes assisting clients with product pipeline consulting. Specifically, I analyze markets and assess the impact that a launch of a product may have on a relevant market. In providing product pipeline consulting, I use my extensive experience in financial modeling for pharmaceutical and life science products that have not yet launched. More precisely, I develop assumptions for financial models in order to project market formation, market penetration, market share, and pricing on a regular basis. Global pharmaceutical and life sciences companies often retain me and my firm to perform these analyses and make decisions based on the accuracy and reliability of the financial modeling that I perform.

6. In the course of my work in providing consulting and expert services, I regularly analyze and review data for the pharmaceutical and life sciences industry, including data from IQVIA, Inc. ("IQVIA"), Symphony Health Solutions ("Symphony"), Truven Health Analytics ("Truven"), IntrinsiQ Specialty Solutions, Inc. ("IntrinsiQ"), and other service providers. I am knowledgeable regarding the role of pharmaceutical databases such as First Databank, Medispan, Gold Standard, and other information sources in the fulfillment of prescriptions. I am also knowledgeable regarding the process of prescription writing, fulfillment, and product substitution in the pharmaceutical and life sciences industry. I have analyzed data and information and testified as an expert witness numerous times in matters involving the pharmaceutical and life sciences industry and the role of brand versus generic competition. I have been qualified as an expert witness in pharmaceutical economics on numerous occasions by various federal courts and institutions.

7. I have been engaged by the United States Patent and Trademark Office ("USPTO") and Office of the Solicitor as an expert to analyze and testify on economic issues involving intellectual property in proceedings for the Honorable David Kappos, while Under Secretary of Commerce for Intellectual Property and Director of the USPTO; the Honorable Michelle Lee, while Under Secretary of Commerce for Intellectual Property and Director of the USPTO; the Honorable Joseph Matal, while performing the functions and duties of Under Secretary of Commerce for Intellectual Property and Director of the USPTO; and the Honorable Andrei Iancu, while Under Secretary of Commerce for Intellectual Property and Director of the USPTO.

8. I also have extensive experience in analyzing, calculating, and determining damages and other financial and economic issues in various dispute settings. I have been designated as a testifying expert in federal and state courts, Chancery Court, the United States International Trade Commission, the Patent Trial and Appeal Board ("PTAB"), and on matters before various domestic and international arbitration panels. I have analyzed damages involving intellectual property disputes, breach of contract claims, shareholder disputes, insurance recovery, class actions, and others. I also have experience assessing claims of irreparable harm, the balance of equities, and public interest factors in connection with temporary restraining order hearings, preliminary injunction hearings, and other injunctive relief and determining whether financial damages are calculable, including issues associated with related bonds.

II. PRIOR TESTIMONY AND FEES

9. Gleason is being compensated for the work performed on this engagement based on the time incurred by me at a rate of $535 per hour. Our compensation is not affected by the outcome of this case. Attached as **Exhibit 1** is a copy of my curriculum vitae and a list of the cases in which I have provided expert testimony, either through deposition or at trial, during the last four years.

III. OBJECTIVE OF THE ENGAGEMENT

10. I have been retained by Skiermont Derby LLP on behalf of HEC Pharm Co., Ltd. and HEC Pharm USA, Inc. (collectively, "HEC") to review and respond to various economic issues raised in the Confidential Declaration of Christopher Vellturo, Ph.D., In Support of Plaintiff-Appellee's Motion to Stay the Mandate, dated September 23, 2022 (the "Vellturo Declaration").

Specifically, I have been asked to respond to whether Novartis Pharmaceuticals Corporation ("Novartis" or the "Plaintiff") will experience irreparable harm as a result of the Court of Appeals for the Federal Circuit ("CAFC") mandate issuing and the subsequent launch of generic fingolimod hydrochloride ("fingolimod") capsules by HEC and/or other generic manufacturers; economic factors influencing the balance of equities between the Plaintiff and HEC; and economic considerations impacting the public interest factor.

11. I previously prepared and issued the Rebuttal Expert Declaration of Ivan T. Hofmann, dated April 9, 2019 (the "Original Hofmann Declaration") in response to the Declaration of Christopher A. Vellturo, Ph.D. In Support of Novartis's Motion for a Preliminary Injunction, dated February 19, 2019 (the "Original Vellturo Declaration") and the Declaration of Arvashni Seeripat In Support of Novartis's Motion for a Preliminary Injunction, dated February 19, 2019 in the District Court litigation.[1]

12. This declaration is based on information known to me as of the date I signed this declaration, and I reserve the right to amend or supplement this declaration in view of any additional discovery, documents, information, reports, and/or testimony that I receive after issuance of this declaration. The work on this engagement was performed by me and others at Gleason working under my direct supervision. I also reserve the right to rebut opinions and testimony offered by witnesses for the Plaintiff.

[1] Various defined terms within this declaration were previously defined in the Original Hofmann Declaration. See the Original Hofmann Declaration for such defined terms (D. Ct. Dkt. 471 (redacted) or 459 (unredacted)).

IV. MATERIALS REVIEWED

13. The bases for my opinions herein and any testimony that I may be called upon to provide are: (i) the materials and independent research identified throughout this declaration; (ii) my knowledge, education, and experience; and (iii) the materials listed in **Appendix 3** of the Original Hofmann Declaration.[2] The foregoing are among the types of information reasonably relied upon by experts in my field for the purposes of forming opinions or inferences on the matters that are the subject of my work in this case. Throughout this declaration, I cite portions of these documents. These citations are intended only as examples, however, and I reserve the right to rely on all portions of these documents in addition to those cited in this declaration. Additionally, I may use these materials to assist me in preparing demonstratives such as graphics and animations for any testimony I may be asked to provide.

V. SUMMARY OF OPINIONS

[redacted] Based upon my analysis, the potential harms to Novartis claimed in the Vellturo Declaration purportedly resulting from the issuance of the mandate and potential subsequent launch of generic fingolimod products by HEC and/or other generic manufacturers are speculative and not irreparable. The claimed harms contained in the Vellturo Declaration are quantifiable and are regularly calculated by financial and economic experts, including Dr. Vellturo and myself. [redacted]

[2] Throughout this declaration I reference Bates stamped documents and information that were used in the Original Hofmann Declaration (D. Ct. Dkt. 471 (redacted) or 459 (unredacted)). I understand that there has been limited additional documents and information produced recently in this matter that would be available to update my analysis within this declaration. However, if additional documents are provided, I reserve the right to update such analyses included within this declaration.

[redacted]

15. Furthermore, from an economic perspective, the balance of equities factor and the public interest factor both weigh in favor of allowing the mandate to issue.

VI. BACKGROUND

16. In the Original Hofmann Declaration, I provided background on the litigation and the market for fingolimod, which is marketed as Gilenya®.[3] At the time of the Original Hofmann Declaration, there were multiple ANDA filers involved in the litigation. [redacted]

[3] I incorporate by reference the Case Background and Background of Multiple Sclerosis sections of the Original Hofmann Declaration (D. Ct. Dkt. 459).

[redacted] and that HEC is the only remaining ANDA filer challenging the '405 Patent.

VII. THE CLAIMED HARMS IN THE VELLTURO DECLARATION ARE NOT IRREPARABLE

17. The potential harms to Novartis claimed in the Vellturo Declaration purportedly resulting from the issuance of the mandate and subsequent potential launch by HEC and/or other manufacturers of generic fingolimod products are not irreparable. [redacted] In any event, the potential damages resulting from HEC's potential launch of generic fingolimod products are quantifiable for this limited period of time.

[4] For example, see the Declaration of Robert W. Trenchard In Support of Novartis's Motion for a Preliminary Injunction (the "Trenchard Declaration"), Exhibit 130 – D. Ct. Dkt. 366-3, pg. 2; Novartis Fourth Quarter 2018 Earnings Call Slides, slide 19 (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 58), see https://seekingalpha.com/article/4236603-novartis-ag-2018-q4-results-earnings-call-slides?part=single, accessed October 3, 2022.

A. Novartis Will Not Suffer Irreparable Harm

18. The Vellturo Declaration claims various forms of alleged irreparable harm to Novartis related to the issuance of the mandate and subsequent potential launch of generic fingolimod, but focuses on three "primary elements."[5] The three claimed primary elements are "1) Price erosion in the marketplace for RRMS therapies; 2) The impact of generic launch on the availability of FDO; and 3) Harm to Novartis's goodwill."[6] I disagree that these purported claims would result in irreparable harm to Novartis. Even assuming that Novartis experiences price erosion on sales of Gilenya® due to the launch of generic fingolimod, any such harm that results would be quantifiable and/or is the result of business decisions by Novartis. Furthermore, the claimed impacts allegedly caused by the potential launch of generic manufacturers other than HEC and the [redacted] would also be the result of business decisions made by Novartis. Finally, the Vellturo Declaration's claims regarding a loss to Novartis's goodwill and relationships are flawed and unreliable.

1. <u>The Claimed Harms Related to Purported Price Erosion in the Vellturo Declaration Are Speculative and Not Irreparable</u>

19. The Vellturo Declaration claims that a form of irreparable harm is the potential price erosion effects of Gilenya® on Novartis.[7] I disagree. Price erosion (if any) is a potential form of harm that is calculable, and Novartis can claim these potential damages if Novartis prevails and is entitled to price erosion damages. Furthermore, if it is determined that sales of HEC's

[5] Vellturo Declaration, pars. 7-9 and 32.
[6] Vellturo Declaration, par. 32.
[7] Vellturo Declaration, pars. 33-40.

fingolimod products (and other generic manufacturers) should cease, and if Novartis actually reduces its price of Gilenya® as a result of generic competition, Novartis can increase the price of Gilenya® to pre-generic levels (I discuss examples where markets have recovered below).

20. [redacted] Furthermore, it is speculative for the Vellturo Declaration to assume that Novartis will [redacted] In my experience, such a strategy is common in the pharmaceutical industry and would not cause price erosion on Novartis's sales of Gilenya®. Furthermore, to the extent that Novartis is confident that it will prevail in its appeal, Novartis may similarly decide to maintain its pricing, collect potential damages (assuming liability is found), and continue selling

[8] Trenchard Declaration, Exhibit 129 – D. Ct. Dkt. 366-3, slide 39. As previously discussed, Novartis has not produced updated presentations or data to analyze updated pricing trends.
[9] Trenchard Declaration, Exhibit 130 – D. Ct. Dkt. 366-3, slide 12.
[10] Trenchard Declaration, Exhibit 130 – D. Ct. Dkt. 366-3, slide 12.
[11] Indeed, the Vellturo Declaration acknowledges [redacted]

its branded product without generic fingolimod competition if such competition ceases further sales.

[redacted]

22. It is economically irrational for payers or patients to be unwilling to pay for, or prescribers to be unwilling to prescribe, Gilenya® at a price consistent with the price of Gilenya® prior to generic competition once generic fingolimod sales cease. If Gilenya® was previously the RRMS product of choice at a certain price for a formulary prior to the launch of generic fingolimod, it would be logical that at some point in the future (even if the modification is that generic fingolimod products were available for a period of time, prices changed, generic fingolimod sales ceased, and the fingolimod market went back to the prior state) that the same formulary would list Gilenya® at the same price. There is no reason to believe that payers, physicians, or patients would choose an alternative RRMS product when they had previously chosen Gilenya®, when this decision is made a second time under similar conditions as the first.

[redacted]

24. Furthermore, even if Novartis [redacted] claimed harms described in the Vellturo Declaration are not irreparable and Novartis would be able to recover its market share and price if it is determined that generic fingolimod products are to cease further sales. Indeed, any claimed lost market volume for Gilenya® would rebound, the price of Gilenya® would be restored, and [redacted]

[redacted]

[12] Vellturo Declaration Exhibit 1, at slide 2.

[redacted]

26. Based upon my analysis, the potential impact on Novartis claimed in the Vellturo Declaration is not irreparable and Novartis can be compensated by monetary damages, if appropriate.

[redacted]

[13] Vellturo Declaration, par. 30.
[14] Vellturo Declaration, par. 20.

[redacted]

30. Furthermore, the Vellturo Declaration fails to address that various products have faced generic competition and have recovered subsequent to the generic products ceasing further sales. These brand products faced generic competition and more than recovered from any temporary lost sales. Therefore, if the generic fingolimod products cease further sales, evidence based on actual experience involving other prescription pharmaceutical products suggests that Novartis would be able to recover sales to previous levels.

31. Plavix® (clopidogrel bisulfate) is an example of a product that experienced generic competition and then was able to significantly recover market share once Apotex ceased further sales of the generic products.

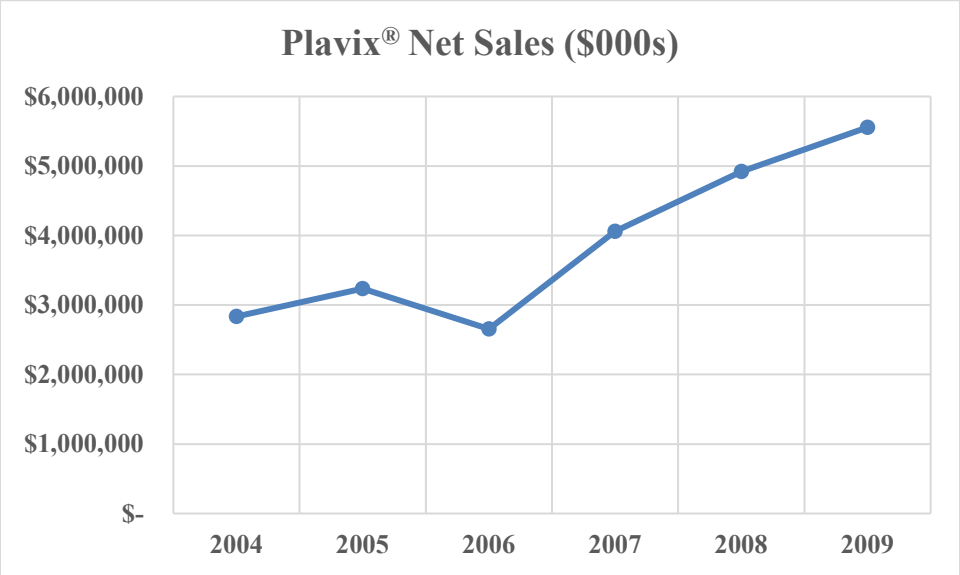
32. Plavix® was marketed in the U.S. by Bristol-Myers Squibb Company ("BMS"). Apotex launched a generic version of Plavix® in 2006.[15] Although Apotex was only on the market for three weeks, I understand that Apotex sold approximately six months of supply during this limited time frame.[16] Indeed, according to a BMS public filing, the launch by Apotex of a generic version of Plavix® in 2006 had a negative effect on 2006 and 2007 sales and earnings.[17] Apotex

[15] "Apotex Launches At-Risk Generic Plavix," Law360, dated August 8, 2006, (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 66) (available at https://www.law360.com/articles/8328/apotex-launches-at-risk-generic-plavix, accessed October 3, 2022).

[16] See Wendy K. Bodine, "Generic Plavix Hits the Shelves, Temporarily?" Pharmacy Times (September 2006) (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 67) (available at https://www.pharmacytimes.com/view/2006-09-5846, accessed October 3, 2022).

[17] Bristol-Myers Squibb Company Form 10-K for the year ended December 31, 2007, pg. 3, see https://www.sec.gov/Archives/edgar/data/14272/000119312508035566/d10k.htm, accessed October 3, 2022.

was later enjoined from further sales of generic clopidogrel bisulfate.[18] When Apotex ceased sales of its generic product, Plavix® was able to recover to pre-generic sales levels (and even further increase sales). The graph below shows how BMS recovered (and surpassed) the historic pre-generic net sales of Plavix®:[19]



33. Plavix® is an example of a brand product that experienced generic competition and the brand market was able to recover to historic pre-generic net sales levels.[20] This provides

[18] "Sanofi, Sun Settlement Ends Plavix Patent Case," Law360, dated December 22, 2011, (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 69) (available at https://www.law360.com/articles/295745/sanofi-sun-settlement-ends-plavix-patent-case-, accessed October 3, 2022).

[19] Bristol-Myers Squibb Company Form 10-K for the year ended December 31, 2004, pg. 45, see https://www.sec.gov/Archives/edgar/data/14272/000119312505041808/d10k.htm, accessed October 3, 2022; Bristol-Myers Squibb Company Form 10-K for the year ended December 31, 2007, pgs. 52-53, see https://www.sec.gov/Archives/edgar/data/14272/000119312508035566/d10k.htm, accessed October 3, 2022; and Bristol-Myers Squibb Company Form 10-K for the year ended December 31, 2009, pg. 44 (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 70).

[20] In addition to Plavix®, I understand that there are several other examples of branded products that were able to recover to pre-generic sales levels following the launch and subsequent cessation of sales of a generic equivalent to the brand product. These examples include Tarka®, Pulmicort Respules®, Ortho Tri-Cyclen Lo®, and Eloxatin® (an injection). See, Blackburn and Jorgenson, "Economics in Life Sciences: Does Temporary Generic Competition Have a Lasting Impact on Branded Drug Sales?" NERA Economic Consulting (March 18, 2021) **(Exhibit 2)**.

support that brand products can experience generic competition, the generic products can cease further sales, and the brand market can recover.

[redacted]

3. [redacted] Would be the Result of Novartis's Business Decisions

[redacted]

[21] Vellturo Declaration, pars. 44-45 and 48.

[redacted]

[redacted] The Vellturo Declaration claims a ruling by the Supreme Court would likely not issue until mid-2023.[23] However, [redacted]

[redacted]

37. [redacted]

[redacted]

[22] Vellturo Declaration, par. 46.
[23] Vellturo Declaration, par. 29.
[24] Vellturo Declaration, par. 41.
[25] Vellturo Declaration, par. 18.
[26] Trenchard Declaration, Exhibit 140 – D. Ct. Dkt. 367-2, slides 18, 25, and 45.

[redacted]

[redacted]

[redacted]

[redacted]

38. [redacted]

[redacted]

[27] Trenchard Declaration, Exhibit 140 – D. Ct. Dkt. 367-2, slide 9.
[28] Trenchard Declaration, Exhibit 140 – D. Ct. Dkt. 367-2, slide 29 (*emphasis added*).

[redacted]

[redacted] The claimed irreparable harm in the Vellturo Declaration [redacted] is flawed and misleading. Furthermore, to the extent that Novartis believes that it will be successful on appeal, [redacted]

4. The Claimed Harms in the Vellturo Declaration Related to Purported Loss of Goodwill and Relationships are Flawed and Unreliable

40. The Vellturo Declaration fails to adequately support the claim that Novartis will suffer a loss of goodwill and relationships and simply speculates as to the purported loss of goodwill and relationships.[29] Brand pharmaceutical products routinely face generic competition in the normal course of business and Novartis itself has lost patent protection on its leading products multiple times in the past, and yet continues to develop new products that obtain formulary coverage.

[29] Vellturo Declaration, pars. 49-52.

41. Novartis is a large multi-national company that has gone through changes in the past and specifically has lost patent protection on many leading products. Indeed, Novartis AG's annual Form 20-F filing states "[p]harmaceutical companies routinely face generic competition when their products lose patent or other intellectual property protection, and Novartis is no exception."[30] Furthermore, a [redacted] Specifically, Novartis lost patent protection on a prior leading product, Gleevec®/Glivec® in 2016 and stated in the 2017 Form 20-F annual filing "[o]ur results underscore the breadth and strength of our product portfolio and highlight our success at steering through the patent expiration of one of our biggest-selling drugs."[32] Novartis also stated:

> *Novartis delivered solid results in 2016, countering much of the effects of the loss of US patent protection during the year for our pioneering leukemia drug, Gleevec. This underscores the strength of our pipeline and our ability in recent years to renew our product portfolio and control costs to manage through important patent expirations.*[33]

42. In 2017, after experiencing the impact of a full year of generic competition for Gleevec®, Novartis total global net sales to third parties increased from 2016.[34] The loss of patent protection for Gleevec® does not appear to have harmed the goodwill and relationships at Novartis.

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[30] Novartis AG Form 20-F for the year ended December 31, 2017 (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 88), pg. 152.
[31] NPCFINGO006576325-76 (Original Hofmann Declaration – D. Ct. Dkt. 459, Exhibit 89), at 35.
[32] Novartis AG Form 20-F for the year ended December 31, 2017 (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 88), pg. 108.
[33] Novartis AG Form 20-F for the year ended December 31, 2017 (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 88), pg. 122.
[34] Novartis AG Form 20-F for the year ended December 31, 2017 (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 88), pg. 110.

To claim that such harm will occur for Gilenya® (which Novartis has been informing the public of the potential loss of exclusivity for years) is flawed and unsupported.

The Vellturo Declaration claims that purported harm to Novartis's goodwill and relationships is irreparable because Novartis will need to first decrease and then raise prices for Gilenya® if generic fingolimod products cease further sales.[35]

The Vellturo Declaration further speculates that

[35] Vellturo Declaration, par. 51.
[36] Vellturo Declaration, par. 50.

[redacted]

B. Novartis Has Been Preparing for the LOE of Gilenya®

45. Novartis has been aware of the risk of potential generic competition for Gilenya® for years. [redacted]

[37] Vellturo Declaration, par. 46 and Vellturo Declaration Exhibit 1, at slide 2.
[38] NPCFINGO006576506-41 (Original Hofmann Declaration – D. Ct. Dkt. 459, Exhibit 61), at 07; NPCFINGO006576325-76 (Original Hofmann Declaration – D. Ct. Dkt. 459, Exhibit 89), at 25 and 28.
[39] Trenchard Declaration, Exhibit 130 – D. Ct. Dkt. 366-3, slide 2; Novartis Fourth Quarter 2018 Earnings Call Slides (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 58), slide 19, see https://seekingalpha.com/article/4236603-novartis-ag-2018-q4-results-earnings-call-slides?part=single, accessed October 3, 2022; Novartis AG Form 20-F for the fiscal year ended December 31, 2018 (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 65), pg. 106.
[40] NPCFINGO006574920-81 (Original Hofmann Declaration – D. Ct. Dkt. 459, Exhibit 93), at 56.

Indeed, Novartis provided margin guidance on its fourth quarter 2019 earnings call and stated that it "would expect to achieve these margins independent of when potential Gilenya LOE occurs."[41]

46. [redacted] Furthermore, Novartis has plans to [redacted] other Novartis products used for the treatment of relapsing forms of MS.[44] Indeed, in the Novartis second quarter 2022 earnings call transcript, Harry Kirsch, Novartis Chief Financial Officer, stated that "[i]t is worth noting that U.S. Gilenya sales have been steadily declining due to competitive pressures and, of course, our key focus [ph] being on Kesimpta."[45] Additionally, when answering a question related to the status of the Gilenya® litigation and entry of generic fingolimod on the sales of Gilenya® and impact to Novartis, Vasant Narasimhan, Novartis Chief Executive Officer, stated that "from a midterm growth standpoint, this is not having a significant bearing."[46] [redacted]

[41] Novartis Fourth Quarter 2019 Earnings Call Transcript, pg. 7, see https://seekingalpha.com/article/4319978-novartis-ag-nvs-ceo-vasant-narasimhan-on-q4-2019-results-earnings-call-transcript, accessed October 3, 2022 **(Exhibit 3)**.
[42] Vellturo Declaration Exhibit 1, at slide 2.
[43] Vellturo Declaration Exhibit 1, at slides 20 and 39.
[44] Kesimpta® FDA Label, at https://www.novartis.com/us-en/sites/novartis_us/files/kesimpta.pdf, accessed October 1, 2022 and Mayzent® FDA Label, at https://www.novartis.com/us-en/sites/novartis_us/files/mayzent.pdf, accessed October 1, 2022.
[45] Novartis Second Quarter 2022 Earnings Call Transcript, pg. 11, see https://seekingalpha.com/article/4524269-novartis-ag-nvs-ceo-vas-narasimhan-on-q2-2022-results-earnings-call-transcript, accessed October 3, 2022 **(Exhibit 4)**.
[46] Novartis Second Quarter 2022 Earnings Call Transcript, pg. 37, see https://seekingalpha.com/article/4524269-novartis-ag-nvs-ceo-vas-narasimhan-on-q2-2022-results-earnings-call-transcript, accessed October 3, 2022 **(Exhibit 4)**.

[redacted]

47. Gilenya® is part of the Novartis Innovative Medicines operating division.[47] Listed below are the 2017, 2018, 2019, 2020, and 2021 global net sales for Novartis compared to the U.S. net sales of Gilenya® and the global net sales for the Innovative Medicines segment compared to the U.S. net sales of Gilenya®:[48]

	Gilenya® U.S. Net Sales (in millions)	Novartis Global Net Sales (in millions)	Gilenya® Percent of Novartis Global Net Sales
2017	$ 1,709	$ 49,109	3.5%
2018	$ 1,765	$ 51,900	3.4%
2019	$ 1,736	$ 47,498	3.7%
2020	$ 1,562	$ 48,659	3.2%
2021	$ 1,427	$ 51,626	2.8%

	Gilenya® U.S. Net Sales (in millions)	Innovative Medicines Net Sales (in millions)	Gilenya® Percent of Innovative Medicines Net Sales
2017	$ 1,709	$ 32,278	5.3%
2018	$ 1,765	$ 34,892	5.1%
2019	$ 1,736	$ 37,714	4.6%
2020	$ 1,562	$ 39,013	4.0%
2021	$ 1,427	$ 41,995	3.4%

[47] Novartis AG 2021 Annual Report, pg. 57, see https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2021.pdf, accessed October 3, 2022.
[48] Novartis AG Form 20-F for the fiscal year ended December 31, 2018 (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 65), pgs. 81-83, and 93 and Novartis AG 2021 Annual Report, pgs. F-1, F-25, F-26, and F-27, see https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2021.pdf, accessed October 3, 2022.

As shown above, Gilenya® U.S. net sales accounted for a small single digit percentage of global Novartis net sales and also a small single digit percentage of global Novartis Innovative Medicines net sales. Furthermore, since 2018, Novartis's net sales for Gilenya® have been declining annually, as confirmed recently in Novartis's second quarter 2022 earnings call transcript, due to competition, including from Novartis's own drugs, Kesimpta® and Mayzent®.[49]

C. Potential Damages Are Quantifiable

48. In any event, if the mandate issues and there are subsequent launches of generic fingolimod by HEC (and/or other potential generic manufacturers), the potential harm to Novartis due to HEC's launch is quantifiable. The Vellturo Declaration claims that such claimed irreparable harm will be difficult to quantify.[50] I disagree. Furthermore, although the Vellturo Declaration claims it may be "difficult," this demonstrates that damages are still able to be quantified. If the '405 Patent is ultimately determined to be valid, the amount of potential damages to Novartis would be determined by analyzing the market dynamics and actual market results. The pharmaceutical market (brand and generic) has been analyzed numerous times by developing financial models and then using such financial models for the calculation of potential damages. The purported challenges claimed in the Vellturo Declaration are issues routinely addressed by financial and economic experts when quantifying damages. These calculations of damages have been accepted by courts for years. Once generic pharmaceutical companies launch, and pricing, market share, units, and sales are identified (as well as other relevant information), damages will

[49] Novartis Second Quarter 2022 Earnings Call Transcript, pg. 11, see https://seekingalpha.com/article/4524269-novartis-ag-nvs-ceo-vas-narasimhan-on-q2-2022-results-earnings-call-transcript, accessed October 3, 2022 **(Exhibit 4)**.
[50] Vellturo Declaration, pars. 40, 45, and 51.

be quantifiable, [redacted]

49. While there may be some uncertainty as to the exact actions that will be taken by various parties, the impact on the market, and the related financial impact, the passage of time will allow damages to be quantified and assessed with a reasonable degree of certainty once the number of generics that launch and other changes in the market are known. Indeed, financial and economic experts (including Dr. Vellturo and myself) are regularly called upon to perform such analysis and testify as to their opinions on such issues.[51] Therefore, the claimed harms in the Vellturo Declaration are quantifiable and are not irreparable.

50. [redacted] The Vellturo Declaration claims that a ruling by the Supreme Court would likely not issue until mid-2023 (assuming the Supreme Court first grants certiorari).[52] In contrast, HEC's Supreme Court counsel have informed me that they believe a ruling by the Supreme Court would more likely issue in late-2023 or 2024 (again, assuming the Supreme Court first grants certiorari). Whatever the case may be, [redacted]

[51] Vellturo Deposition 2018 (Original Hofmann Declaration – D. Ct. Dkt. 459, Exhibit 59), pg. 13:10-19.
[52] Vellturo Declaration, par. 29.

[redacted] The Vellturo Declaration fails to appropriately address this limited period where damages would be quantifiable (assuming Novartis is successful on appeal to the Supreme Court).

VIII. THE BALANCE OF EQUITIES WEIGHS IN FAVOR OF HEC

[redacted] From an economic perspective, the balance of equities weighs in favor of HEC regarding the issuance of the mandate and subsequent potential launches of generic fingolimod products by HEC and/or other generic manufacturers. The Vellturo Declaration overstates and mischaracterizes the potential harms to Novartis from generic competition for Gilenya®. The launch of generic fingolimod products may reduce Novartis's net sales and profits for a period of time. [redacted]

52. If HEC and/or other generic manufacturers launch generic fingolimod products, and it is later determined that the mandate should not have issued and HEC and/or other generic manufacturers should not have launched generic fingolimod products because the '405 Patent is valid and infringed, Novartis can be compensated with monetary damages, as applicable.

[53] Vellturo Declaration Exhibits 1 and 2.

53. Furthermore, Novartis has already enjoyed patent protection and exclusivities on Gilenya® for over a decade. Indeed, Gilenya® launched in 2010, and through 2021 Novartis generated more than $14 billion in U.S. net sales for Gilenya®. The historical U.S. net sales of Gilenya® from 2010 through 2021 are shown below:[54]

Gilenya® U.S. Net Sales (in millions)		
2010	$	12.8
2011		382.9
2012		727.4
2013		1,022.9
2014		1,190.0
2015		1,496.8
2016		1,682.8
2017		1,709.1
2018		1,765.0
2019		1,736.0
2020		1,562.0
2021		1,427.0
Total Through 2021	$	14,714.7

54. If the mandate does not issue and HEC is enjoined from launching its generic fingolimod product and is later permitted to launch, HEC would be deprived of earnings sales and profits on generic fingolimod products during the period of time HEC is held off the market. HEC may be able to recover lost sales and profits from Novartis if HEC is improperly enjoined (assuming that a sufficient bond is posted by Novartis). However, since Gilenya® is priced higher

[54] Trenchard Declaration, Exhibit 138 – D. Ct. Dkt. 367-1 and Novartis AG 2021 Annual Report, pgs. F-25, F-26, and F-27, see https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2021.pdf, accessed October 3, 2022.

than what HEC is likely to price its generic fingolimod product, Novartis will likely earn profits greater than it would be required to pay in damages to HEC. This would result in Novartis receiving a windfall from the sales of Gilenya® while HEC [redacted] Novartis would be able to retain excess profits even though such sales should not have occurred because generic fingolimod products should have been allowed to launch).

55. Furthermore, in my experience, the order of generic entry can have a material impact on a generic company's sales and market share. Delaying HEC's launch could impact the order of entry for generic fingolimod products, and/or limit the period of time HEC is on the market before additional potential generic competition. As a general economic issue, later entrants can sometimes face challenges relative to earlier entrants with respect to establishing market share and customers. If the mandate does not issue and HEC is unable to launch, HEC will presumably be forced to argue what its pricing would have been and what market share it would have obtained compared to other generic manufacturers in order to recover from a potential bond. Furthermore, an injunction would provide time for additional generic competitors to gain FDA approval and be prepared for launch after the injunction is lifted, compared to if the mandate issues and the injunction is not granted. This could impact the order of entry and significantly affect the market share gained by HEC.

IX. THE PUBLIC INTEREST FACTOR WEIGHS IN FAVOR OF ALLOWING THE MANDATE TO ISSUE AND GENERIC FINGOLIMOD TO LAUNCH

56. Based upon my analysis, from an economic perspective, the public interest factor also weighs in favor of allowing the mandate to issue and generic fingolimod to launch. Generic products provide a lower cost alternative to brand products for patients and the general public. Third-party payors, Medicare, and Medicaid represent the vast majority of annual payments for prescription drugs.[55] The savings from generic (and biosimilar) products is substantial to the public. For example, total cost savings for 2020 were approximately $338 billion as a result of the use of generic (and biosimilar) versions of higher priced branded products (total cost savings over the past 10 years (2011-2020) are estimated to be approximately $2.4 trillion).[56] As previously discussed, Novartis will have experienced more than a decade of exclusivity and has generated more than $14 billion in net sales related to Gilenya® as of the end of 2021.

57. If the mandate does not issue and the injunction is not lifted, preventing the launch of generic fingolimod products, the cost savings to patients, payors, and the general public (if a generic fingolimod product were available) will be lost forever (and rather realized as additional windfall profits for Novartis).

58. Based upon the above, from an economic perspective, the public interest factor weighs in favor of allowing the mandate to issue.

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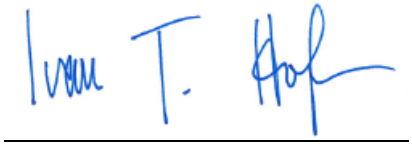
[55] United States Government Accountability Office, "Drug Pricing: Research on Savings from Generic Drug Use," (January 31, 2012) (Original Hofmann Declaration – D. Ct. Dkt. 471, Exhibit 100) (available at https://www.gao.gov/assets/gao-12-371r.pdf, accessed October 3, 2022), pgs. 5-6.

[56] Association for Accessible Medicines – 2021 U.S. Generic and Biosimilar Medicines Savings Report, pgs. 6-8 (available at https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf, accessed October 3, 2022).

* * * * * * * * *

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information and belief.

Dated: October 4, 2022



Ivan T. Hofmann

Exhibits

EXHIBIT 1

Ivan T. Hofmann, C.P.A., C.F.F., C.L.P.

Curriculum Vitae

Professional History

Gleason IP, a division of Gleason & Associates, P.C. – Vice President and Managing Director *2006 to Present*

Ivan Hofmann is a Vice President and Managing Director at Gleason IP. He has years of professional experience with a deep specialization in complex intellectual property matters. Mr. Hofmann's IP expertise includes extensive litigation support and testifying experience in quantifying financial damages related to patent infringement and other intellectual property issues, as well as breach of contract claims, class action law suits and other litigation-related matters. His experience includes using statistical, financial, and economic analysis and models related to various technical issues. He provides value-added services in all phases of litigation in various capacities, including assistance with discovery, depositions, expert opinions, and testimony during trial.

Mr. Hofmann's experience with intellectual property matters includes false advertising cases, theft of trade secrets, and trademark infringement matters. He has performed analysis of irreparable harm in preliminary injunction hearings and regularly performs analysis of commercial success in connection with secondary considerations of nonobviousness. The United States Patent and Trademark Office and the Office of the Solicitor has engaged Mr. Hofmann on several projects as an expert in economics regarding intellectual property issues involving patents. Mr. Hofmann has experience with intellectual property issues in numerous industries, including extensive experience in the pharmaceutical industry.

As a Certified Licensing Professional (CLP), Mr. Hofmann has demonstrated knowledge and experience in analyzing license agreements and royalty terms. He assists companies in licensing negotiations with economic analysis in licensing agreements. He also has performed royalty audits on behalf of universities and corporations. Mr. Hofmann's extensive knowledge of licensing is useful in his analysis of reasonable royalties in patent infringement cases.

Also, Mr. Hofmann has experience in the areas of accounting, auditing, forensic accounting, fraud investigations and due diligence work. He has been involved in matters in state and federal courts, as well as domestic and international arbitration and other forums for dispute resolution. His experience includes matters with public and private companies in a broad range of industries including pharmaceuticals, communications, health care, manufacturing, retail, oil and gas, coal, utilities, land development, hospitality, and others.

Deloitte & Touche LLP – Senior Manager *1994 -2006*

Mr. Hofmann was a senior manager with the global firm of Deloitte in the Forensic and Dispute Services and Assurance and Advisory services departments. He served numerous clients in various industries ranging in size from small, privately held companies to large, multi-national Fortune 500 companies.

Education and Certification

Bachelor of Business Administration, double major in Accounting and Economics, *Magna Cum Laude*, University of Notre Dame, 1994
Certified Public Accountant, Pennsylvania 1996
Certified in Financial Forensics, 2008
Certified Licensing Professional 2010

Professional and Business Affiliations

American Economic Association, Member
American Institute of Certified Public Accountants, Member
Licensing Executives Society, Member
Pennsylvania Institute of Certified Public Accountants, Member

Civic Affiliations

Notre Dame Club of Pittsburgh

Ivan T. Hofmann CPA/CFF, CLP
Cases in which Mr. Hofmann has testified at deposition or at trial in the past four years.

LIST OF CASES PURSUANT TO 26(a)(2)(B)

Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and Rhodes Technologies v. Accord Healthcare Inc. – United States District Court for the District of Delaware, 2022 (Trial)

Astellas US LLC, Astellas Pharma US, Inc., and Gilead Sciences, Inc. v. Mylan Pharmaceuticals Inc. – United States District Court for the Northern District of West Virginia, 2022 (Deposition)

Melinta Therapeutics, LLC, Melinta Subsidiary Corp., and Rempex Pharmaceuticals, Inc. v. Nexus Pharmaceuticals, Inc. – United States District Court for the Northern District of Illinois, 2022 (Declaration)

Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S, v. Zenara Pharma Private Ltd., Biophore India Pharmaceuticals Private, Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Company GmbH, Raks Pharma Pvt. Ltd., Prinston Pharmaceutical Inc., Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Apotex Inc., Apotex Corp., Apotex Pharmachem Inc., Signa S.A. de C.V., Optimus Pharma Pvt. Ltd., MSN Laboratories Pvt. Ltd., MSN Pharmaceuticals Inc., Zydus Pharmaceuticals (USA) Inc., Zydus Lifesciences Limited, Sandoz Inc. – United States District Court for the District of Delaware, 2022 (Deposition)

Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and Rhodes Technologies v. Accord Healthcare Inc. – United States District Court for the District of Delaware, 2022 (Deposition)

Mylan Pharmaceuticals Inc., Celltrion, Inc., and Apotex, Inc. v. Regeneron Pharmaceuticals, Inc. – United States Patent Trial and Appeal Board, 2022 (Deposition)

Bial – Portela & CA S.A., Bial – Holdings, S.A., and Sunovion Pharmaceuticals Inc. v. Alkem Laboratories Limited and S&B Pharma, Inc. – United States District Court for the District of Delaware, 2022 (Trial)

Alkermes, Inc. and Alkermes Pharma Ireland Limited v. Teva Pharmaceuticals USA, Inc. – United States District Court for the District of New Jersey, 2022 (Deposition)

Mylan Pharmaceuticals Inc., Celltrion, Inc., and Apotex, Inc. v. Regeneron Pharmaceuticals, Inc. – United States Patent Trial and Appeal Board, 2022 (Declaration)

Tris Pharma, Inc. v. Teva Pharmaceuticals USA, Inc. – United States District Court for the District of New Jersey, 2022 (Trial)

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LIST OF CASES PURSUANT TO 26(a)(2)(B)

In re Entresto (Sacubitril/Valsartan) Patent Litigation (Novartis Pharmaceuticals Corporation v. Alkem Laboratories Ltd., Aurobindo Pharma USA Inc., Aurobindo Pharma Ltd., Biocon Pharma Limited, Biocon Limited, Biocon Pharma, Inc., Crystal Pharmaceutical (Suzhous) Co., Ltd., Laurus Labs Limited, Laurus Generics Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., Lupin Pharmaceuticals, Inc., Nanjing Noratech Pharmaceutical Co., Limited, Teva Pharmaceuticals USA, Inc., Torrent Pharma Inc., Torrent Pharmaceuticals Ltd.; Novartis Pharmaceuticals Corporation v. Alembic Pharmaceuticals Limited, Alembic Pharmaceuticals Inc., Macleods Pharmaceuticals Ltd., Macleods Pharma USA, Inc.; Novartis Pharmaceuticals Corporation v. Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Hetero USA Inc., Hetero Labs Limited., Hetero Labs Limited Unit III, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, MSN Life Sciences Private Limited, Novugen Pharma (Malaysia) SDN. BHD., Zydus Pharmaceuticals (USA) Inc., Cadila Healthcare Ltd.; and Novartis Pharmaceuticals Corporation v. Mylan Pharmaceuticals, Inc. – United States District Court for the District of Delaware, 2022 (Deposition)

Hoffmann-La Roche, Inc., Chugai Pharmaceutical Co. Ltd., and Genentech, Inc. v. Fresenius Kabi USA, LLC – United States District Court for the District of Delaware, 2022 (Deposition)

Darren Clevenger and David Bloom on behalf of themselves and all others similarly situated v. Welch Foods Inc., A Cooperative, The Promotion in Motion Companies, Inc., a Delaware Corporation, and Does 1 through 25, inclusive – United States District Court for the Central District of California, 2022 (Declaration)

Gilead Sciences, Inc. v. Apotex, Inc., Lupin Limited, Laurus Labs Limited, Shilpa Medicare Limited, Sunshine Lake Pharma Co., Ltd., Natco Pharma Limited, Cipla Limited, Macleods Pharmaceuticals Ltd., Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Limited – United States District Court for the District of Delaware, 2022 (Deposition)

Tris Pharma, Inc. v. Teva Pharmaceuticals USA, Inc. – United States District Court for the District of New Jersey, 2022 (Deposition)

AstraZeneca AB and AstraZeneca Pharmaceuticals LP v. Mylan Pharmaceuticals Inc. and Kindeva Drug Delivery, LP – United States District Court for the Northern District of West Virginia, 2022 (Declaration)

Bial – Portela & CA S.A., Bial – Holding, S.A., and Sunovion Pharmaceuticals Inc. v. Alkem Laboratories Limited and S&B Pharma, Inc.; and Bial – Portela & CA S.A., Bial – Holding, S.A., and Sunovion Pharmaceuticals Inc. v. Apotex Inc. and Apotex Corp. – United States District Court for the District of Delaware, 2022 (Deposition)

Ivan T. Hofmann CPA/CFF, CLP
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LIST OF CASES PURSUANT TO 26(a)(2)(B)

Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc. v. Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and Aurobindo Pharma U.S.A., Inc.; Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc. v. Accord Healthcare Inc.; Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc. v. Natco Pharma Ltd. and Natco Pharma, Inc.; Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc. v. MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. – United States District Court for the District of Delaware, 2022 (Deposition)

Venn Therapeutics v. Corbus Pharmaceuticals Holdings, Inc. – United States District Court for the Middle District of Florida, 2022 (Declaration)

Bionpharma Inc. v. CoreRx, Inc. – United States District Court for the Southern District of New York, 2021 (Declaration)

Xodus Medical, Inc., Alessio Pigazzi, and Glenn Keilar v. Prime Medical LLC, Symmetry Surgical Inc., and G&T Industries, Inc. – United States District Court for the Eastern District of Tennessee, 2021 (Declaration)

Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc. – United States District Court for the District of Delaware, 2021 (Deposition)

Promotion in Motion, Inc. v. Haribo of America, Inc. – United States District Court for the District of New Jersey, 2021 (Deposition)

Horizon Medicines LLC and Nuvo Pharmaceuticals (Ireland) Designated Activity Company v. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd. – United States District Court for the District of New Jersey, 2021 (Deposition)

Indivior Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc. v. Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. v. Atlantic Specialty Insurance Company and Berkley Insurance Company – United States District Court for the District of New Jersey, 2021 (Deposition)

Xodus Medical, Inc., Alessio Pigazzi, and Glenn Keilar v. Prime Medical LLC, Symmetry Surgical Inc., and G&T Industries, Inc. – United States District Court for the Eastern District of Tennessee, 2021 (Deposition)

Vifor (International) AG and American Regent, Inc. v. Mylan Laboratories Ltd. and Sandoz Inc. – United States District Court for the District of New Jersey, 2021 (Trial)

Amgen Inc. v. Sandoz Inc., et al. – United States District Court for the District of New Jersey, 2021 (Trial)

Vifor (International) AG and American Regent, Inc. v. Mylan Laboratories Ltd. and Sandoz Inc. – United States District Court for the District of New Jersey, 2021 (Deposition)

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LIST OF CASES PURSUANT TO 26(a)(2)(B)

Astellas US LLC, Astellas Pharma US, Inc., and Gilead Sciences, Inc. v. Apotex Inc., et al. – United States District Court for the District of Delaware, 2021 (Deposition)

Amgen Inc. v. Amneal Pharmaceuticals LLC, et al. and Slate Run Pharmaceuticals, LLC v. Amgen Inc. – United States District Court for the District of Delaware, 2021 (Hearing)

Amgen Inc. v. Sandoz Inc., et al. – United States District Court for the District of New Jersey, 2021 (Deposition)

Amgen Inc. v. Amneal Pharmaceuticals LLC, et al. and Slate Run Pharmaceuticals, LLC v. Amgen Inc. – United States District Court for the District of Delaware, 2021 (Deposition)

Martin R. Prince, M.D., Ph.D. v. General Electric Company – JAMS Arbitration, 2021 (Hearing)

Allergan Sales, LLC and Allergan, Inc. v. Sandoz, Inc. and Alcon Laboratories, Inc. – United States District Court for the District of New Jersey, 2021 (Deposition)

Silvergate Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC – United States District Court for the District of Delaware, 2021 (Trial)

Martin R. Prince, M.D., Ph.D. v. General Electric Company – JAMS Arbitration, 2021 (Deposition)

Genzyme Corp. and The Regents of the University of Michigan v. Apotex Inc. and Apotex Corp., et al. – United States District Court for the District of Delaware, 2020 (Deposition)

Silvergate Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC – United States District Court for the District of Delaware, 2020 (Deposition)

Philips North America LLC, Philips Medical Systems Nederland B.V., Philips India Ltd., Philips Medical Systems (Cleveland), Inc., Philips Medical System Technologies Ltd., and Koninklijke Philips N.V. v. 626 Holdings, Inc. and Alexander Kalish – United States District Court for the District of Florida, 2020 (Deposition)

Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV v. Teva Pharmaceuticals USA, Inc. – United States District Court for the District of New Jersey, 2020 (Trial)

Cytonome/ST, LLC v. NanoCellect Biomedical, Inc. – United States District Court for the District of Delaware, 2020 (Deposition)

UCB, Inc., UCB Pharma GmbH, and LTS Lohmann Therapie-Systeme AG v. Actavis Laboratories UT, Inc. – United States District Court for the District of Delaware, 2020 (Trial)

Ivan T. Hofmann CPA/CFF, CLP
Cases in which Mr. Hofmann has testified at deposition or at trial in the past four years.

LIST OF CASES PURSUANT TO 26(a)(2)(B)

H. Lundbeck A/S, Takeda Pharmaceutical Company LTD., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc. v. Apotex Inc., et al. – United States District Court for the District of Delaware, 2020 (Deposition)

AstraZeneca AB and AstraZeneca Pharmaceuticals LP v. Mylan Pharmaceuticals Inc. and 3M Company – United States District Court for the Northern District of West Virginia, 2020 (Deposition)

Pharmacyclics LLC and Janssen Biotech, Inc. v. Fresenius Kabi USA, LLC, et al. – United States District Court for the District of Delaware, 2020 (Deposition)

UCB, Inc., UCB Pharma GmbH, and LTS Lohmann Therapie-Systeme AG v. Actavis Laboratories UT, Inc. – United States District Court for the District of Delaware, 2020 (Deposition)

Actelion Pharmaceuticals Ltd. v. Zydus Pharmaceuticals (USA) Inc., et al. – United States District Court for the District of New Jersey, 2020 (Deposition)

Club Champion LLC v. True Spec Golf LLC – United States Patent Trial and Appeal Board, 2020 (Declaration, Deposition)

Amgen Inc. v. Alexion Pharmaceuticals, Inc. – United States Patent Trial and Appeal Board, 2020 (Declarations, Deposition)

Pfizer Inc., PF Prism C.V., C.P. Pharmaceuticals International C.V., PBG Puerto Rico LLC, and PF Prism IMB B.V. v. Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. – United States District Court for the District of Delaware, 2020 (Deposition)

Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited v. Hikma Pharmaceuticals USA Inc., Hikma Pharmaceuticals International Limited, Dr. Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories, Ltd. – United States District Court for the District of Nevada, 2020 (Trial)

Autoliv ASP, Inc. v. Hyundai Mobis Co. Ltd. and Mobis Alabama L.L.C. – United States District Court for the Middle District of Alabama, 2019 (Deposition)

Biogen International GmbH and Biogen MA Inc. v. Sandoz Inc., Prinston Pharmaceutical Inc., MSN Laboratories Private Limited and MSN Pharmaceuticals Inc., Zydus Pharmaceuticals (USA) Inc., Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited, and Shilpa Medicare Limited – United States District Court for the District of Delaware, 2019 (Trial)

Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV v. Teva Pharmaceuticals USA, Inc. – United States District Court for the District of New Jersey, 2019 (Deposition)

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Adapt Pharma Operations Limited, Adapt Pharma Inc., Adapt Pharma Limited, and Opiant Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. – United States District Court for the District of New Jersey, 2019 (Trial)

Biogen International GmbH and Biogen MA Inc. v. Sandoz Inc., Prinston Pharmaceutical Inc., MSN Laboratories Private Limited and MSN Pharmaceuticals Inc., Zydus Pharmaceuticals (USA) Inc., Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd., Aurobindo Pharma U.S.A., Inc. and Aurobindo Pharma USA LLC, Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited, and Shilpa Medicare Limited – United States District Court for the District of Delaware, 2019 (Deposition)

Biogen International GmbH and Biogen MA Inc. v. Mylan Pharmaceuticals, Inc. – United States District Court for the District of West Virginia, 2019 (Deposition)

Adapt Pharma Operations Limited, Adapt Pharma Inc., Adapt Pharma Limited, and Opiant Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. – United States District Court for the District of New Jersey, 2019 (Deposition)

Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited v. Hikma Pharmaceuticals USA Inc., Hikma Pharmaceuticals International Limited, Dr. Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories, Ltd. – United States District Court for the District of Nevada, 2019 (Deposition)

Galderma Laboratories, L.P. Galderma, S.A., and Nestlé Skin Health S.A. v. Teva Pharmaceuticals USA, Inc. – United States District Court for the District of Delaware, 2019 (Trial)

Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. v. Actavis Elizabeth LLC, Actavis LLC, and Actavis Inc., et al. – United States District Court for the District of Delaware, 2019 (Deposition)

Novartis Pharmaceuticals Corporation v. Accord Healthcare Inc., et al. – United States District Court for the District of Delaware, 2019 (Declaration, Deposition)

True Spec Golf LLC and Club-Conex LLC v. Club Champion LLC – United States District Court for the Southern District of New York, 2019 (Declaration, Deposition)

Galderma Laboratories, L.P. Galderma, S.A., and Nestlé Skin Health S.A. v. Teva Pharmaceuticals USA, Inc. – United States District Court for the District of Delaware, 2019 (Deposition)

Astellas Pharma Inc., Astellas US LLC, Astellas Pharma US, Inc., Medivation LLC., Medivation Prostate Therapeutics LLC, and The Regents of The University of California v. Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. – United States District Court for the District of Delaware, 2019 (Deposition)

Ivan T. Hofmann CPA/CFF, CLP
Cases in which Mr. Hofmann has testified at deposition or at trial in the past four years.

LIST OF CASES PURSUANT TO 26(a)(2)(B)

Valeant Pharmaceuticals International, Inc., Salix Pharmaceuticals, Inc., Progenics Pharmaceuticals, Inc., and Wyeth LLC v. Actavis Laboratories FL, Inc. – United States District Court for the District of New Jersey, 2019 (Deposition)

Figuli Venture Holdings LLC and David J. Figuli v. Arist Education System LLC and Bertelsmann, Inc. – JAMS Arbitration, 2019 (Hearing)

Galderma Laboratories, L.P., Nestlé Skin Health S.A., and TCD Royalty Sub LLC v. Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. – United States District Court for the District of Delaware, 2018 (Trial)

Indivior Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc. v. Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. – United States District Court for the District of New Jersey, 2018 (Declaration)

BTG International Limited, Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC v. Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Mylan Pharmaceuticals Inc., Mylan, Inc., Teva Pharmaceuticals USA, Inc., West-Ward Pharmaceuticals Corp., Hikma Pharmaceuticals, LLC, Wockhardt Bio AG, Wockhardt USA LLC, Wockhardt Ltd. and Amerigen Pharmaceuticals, Inc, Amerigen Pharmaceuticals Ltd. – United States Court of Appeal for the Federal Circuit, 2018 (Declaration)

Galderma Laboratories, L.P., Nestlé Skin Health S.A., and TCD Royalty Sub LLC v. Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. – United States District Court for the District of Delaware, 2018 (Deposition)

Morphosys AG v. Janssen Biotech, Inc., Genmab US, Inc. and Genmab A/S – United States District Court for the District of Delaware, 2018 (Deposition)

Genentech, Inc., Biogen, Inc. Hoffmann-La Roche, Inc. and City of Hope v. Celltrion, Inc., Celltrion Healthcare, Co., Ltd., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals International GmbH – United States District Court for the District of New Jersey, 2018 (Declaration, Deposition)

Alcon Research Ltd. v. Watson Laboratories, Inc. – United States District Court for the District of Delaware, 2018 (Deposition)

Ivan T. Hofmann CPA/CFF, CLP
Cases in which Mr. Hofmann has testified at deposition or at trial in the past four years.

LIST OF CASES PURSUANT TO 26(a)(2)(B)

BTG International Limited, Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC v. Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Apotex Corp., Apotex Inc., Citron Pharma LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Mylan Pharmaceuticals Inc., Mylan, Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Sun Pharmaceuticals Industries, Ltd., Sun Pharmaceuticals Industries, Inc., Teva Pharmaceuticals USA, Inc., West-Ward Pharmaceuticals Corp., Hikma Pharmaceuticals, LLC, Wockhardt Bio AG, Wockhardt USA LLC, and Wockhardt Ltd. – United States District Court for the District of New Jersey, 2018 (Trial)

Indivior Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc. v. Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. – United States District Court for the District of New Jersey, 2018 (Declaration)

Hospira, Inc. v. Fresenius Kabi USA, LLC – United States District Court for the Northern District of Illinois (Eastern Division), 2018 (Deposition)

Ameranth, Inc. v. Pizza Hut, Inc., Pizza Hut of America, Inc. and QuikOrder, Inc. – United States District Court for the District of Southern California, 2018 (Deposition)

ApoPharma Inc., ApoPharma USA, Inc., and Apotex Technologies Inc. v. Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals, U.S.A., Inc. – United States District Court for the Eastern District of Texas, 2018 (Deposition)

Purdue Pharma L.P., Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc. and Grünenthal GmbH v. Alvogen Pine Brook LLC – United States District Court for the District of Delaware, 2018 (Deposition)

Bayer Intellectual Property GmbH, Bayer Pharma AG, and Janssen Pharmaceuticals, Inc. v. Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Breckenridge Pharmaceutical, Inc., Invagen Pharmaceuticals, Inc., Micro Labs Ltd., Micro Labs USA Inc., Mylan Pharmaceuticals, Inc., Prinston Pharmaceutical Inc., Sigmapharm Laboratories, LLC, Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. – United States District Court for the District of Delaware, 2018 (Trial)

Alnylam Pharmaceuticals, Inc. v. Dicerna Pharmaceuticals, Inc. – Superior Court Department, Commonwealth of Massachusetts, 2018 (Deposition)

Shire Orphan Therapies LLC and Sanofi-Aventis Deutschland GmbH v. Fresenius Kabi USA, LLC – United States District Court for the District of Delaware, 2018 (Trial)

EXHIBIT 2

NERA
ECONOMIC CONSULTING

18 March 2021

Economics in Life Sciences: Does Temporary Generic Competition Have a Lasting Impact on Branded Drug Sales?

By **Dr. David Blackburn** and **Dr. Rasmus Jørgensen**[1]

Background

The Drug Price Competition and Patent Term Restoration Act, better known as the Hatch-Waxman Act, provides generic drug companies several pathways to enter the market prior to patent expiration of the reference drug.[2] By filing a paragraph IV certification with the US Food and Drug Administration (FDA), a generic drug maker may challenge the extant patent(s) covering the branded drug.[3] In response, the branded drug company can file a patent infringement suit, which under certain conditions results in an automatic regulatory stay of 30 months, during which the FDA cannot approve the generic drug application.[4] If the patent infringement suit is still pending after 30 months—or in cases in which no such stay exists—the generic drug may launch as soon as it receives FDA approval, prior to the completion of all patent disputes.[5]

In this situation, the patent holder may file for a preliminary injunction to halt the generic launch. In order to obtain a preliminary injunction, the patent holder must establish (i) a reasonable likelihood of success on the merits of its claims, (ii) irreparable harm if the preliminary injunction is not granted, (iii) that the balance of hardships is on the branded drug, and (iv) that the injunction is in the public interest.[6]

The courts have considered many forms of irreparable harm in prior decisions, including loss of market share to therapeutic competitors, price erosion, loss of research and development (R&D) opportunities, loss of goodwill, formulary displacement, and loss of production capacity. While the ultimate determination of whether or not there is likely to be irreparable harm is a case-specific inquiry, it is commonly argued that a generic competitor is likely to permanently alter the branded drug's prospects in the marketplace. This argument typically runs along the lines that even if a generic entrant is ultimately removed from the market were the patent holder to prevail in the patent litigation, the existence of a generic alternative

is expected to lower sales and pricing for the brand and the economic loss from this generic entry may not end when the generic is withdrawn from the marketplace. This supposed lasting impact of generic entry would, it is argued, be uncompensable and, therefore, irreparable.

While the typical impact of generic entry on branded drugs has been researched extensively, the question of what happens to branded drug sales after generic entry and subsequent exit is less well-understood.[7] This is at least partly due to the fact that so-called "at-risk" launches are relatively rare. However, in this paper, we analyze the performance of branded drugs following the entry and exit of an "at-risk" generic competitor. The evidence from six pharmaceutical products demonstrate that, in the majority of instances we studied, branded drugs have been able to return to their long-term sales and prescriptions trends once exclusivity has been restored. Although this does not preclude the possibility that in some instances there is risk of irreparable harm, this finding demonstrates that one should not presume that temporary generic competition will have a lasting impact on branded drug sales.

The Competitive Impact of Generic Entry and Exit

We have identified six branded pharmaceutical products with corresponding generic versions that (i) were launched "at-risk," (ii) were subsequently withdrawn leading to a period of time in which generics were no longer available, and (iii) had data available for a sufficient period of time to identify whether or not there was a lasting impact from the temporary generic entry. Doing this allows us to analyze launches in which we can identify three distinct segments of data: a pre-launch brand-only period, a period with both a brand and generic versions, and a post-generic, brand-only period.[8]

To assess the impact of transitory generic competition on the long-term market positions of branded drugs, we rely on national estimates of prescriptions and retail sales from the IQVIA National Prescription Audit (NPA).[9] The IQVIA data we acquired ran from January 2004 to July 2016.[10] One notable feature of the IQVIA data is that it tallies prescriptions and sales when they are dispensed to patients—and not when they are shipped from manufacturers to wholesalers and retailers.

The case studies discussed in this paper cover a diverse set of pharmaceutical products in terms of therapeutic classes, the time period in which the generic products were sold in the marketplace, and the legal countermeasures used to halt further shipments of generic products. These examples provide important insights into the market responses to temporary generic entry and their potential long-term effects. While the case studies are instructive, we must caution that our findings about past launches do not automatically apply to any other launches not considered here.

In the remainder of this paper, we go through the six examples we have identified that meet our criteria: Plavix® (clopidogrel), Tarka® (trandolapril and verapamil extended release), Pulmicort Respules® (budesonide inhalation suspension), Tri-Cyclen Lo® (norgestimate, ethinyl estradiol), Amrix® (cyclobenzaprine hydrochloride extended-release capsules) and Eloxatin® (oxaliplatin).[11]

Plavix

Plavix is a blood thinner prescribed to prevent heart attacks and strokes.[12] It was approved by the FDA in November 1997 and has been one of the best-selling drugs in the world with more than $90 billion in lifetime sales.[13]

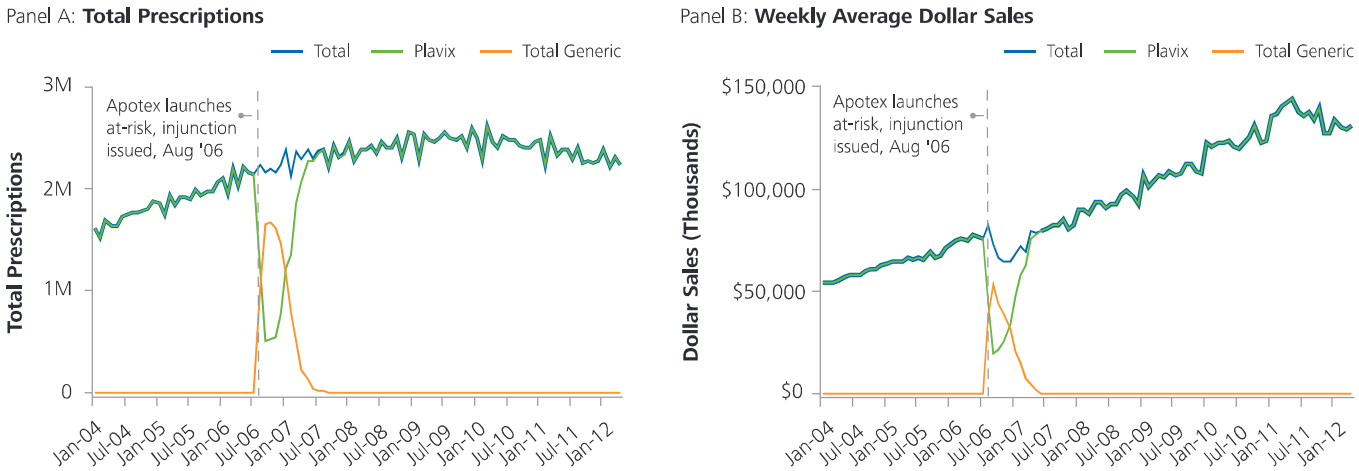
Apotex was the first company to seek FDA approval to market a generic version of Plavix in the United States.[14] In its November 2001 application, Apotex challenged the patent covering the active ingredient in Plavix (clopidogrel) using a paragraph IV certification.[15] In March 2002, the two makers of Plavix—Bristol Myers Squibb and Sanofi-Aventis—filed a patent infringement suit against Apotex, thus triggering a 30-month stay in the FDA's approval process.[16] A generic version of Plavix was approved by the FDA in January 2006 while the patent litigation was still pending.[17]

Apotex launched "at-risk" a generic version of Plavix on 8 August 2006 after a settlement between the three companies failed to receive antitrust clearance.[18] The US District Court of the Southern District of New York issued a preliminary injunction on 31 August 2006, ordering Apotex to halt further sales of generic Plavix.[19] The district court eventually upheld the validity of the patent covering Plavix and issued a permanent injunction against Apotex on 19 June 2007.[20]

Apotex sold its generic Plavix drug for a total of 24 days and shipped, in this relatively short period, several months of supply before it was ordered to cease and desist. As shown in Figure 1, the "at-risk" launch of generic Plavix led to an immediate decline in the sales and prescription volumes of its branded counterpart. In fact, branded Plavix sales dropped by 71% in September 2006 relative to the year before.

Generic Plavix continued to flow through the pharmaceutical supply chain until mid-2007, with Apotex capturing a sales share of 54%—and a prescription share of 64%—in the six-month period following its "at-risk" launch. Once the inventories of generic Plavix were depleted, the total dollar sales and prescription volumes of branded Plavix returned to trend levels comparable to those observed before generic entry.[21] This rebound was even foreshadowed by Sanofi-Aventis in their press release from 1 August 2007, stating that "Plavix recovers its position in the US, full impact expected in H2."[22] Indeed, the IQVIA data shows that Plavix was able to regain its past prescriptions and sales revenues once the "at-risk" generic drug was removed from the marketplace.

Figure 1. **Sales of Plavix and Its Generics**



Tarka

Tarka was approved by the FDA in October 1996 for the treatment of high blood pressure.[23] More than a decade later, Glenmark Pharmaceuticals submitted an application to market a generic version of Tarka—an application that was eventually approved by the FDA in May 2010.[24] In response to the regulatory approval of generic Tarka, a preliminary injunction motion was filed against Glenmark, which the district court denied.[25] Shortly thereafter, Glenmark launched its generic drug "at-risk."[26]

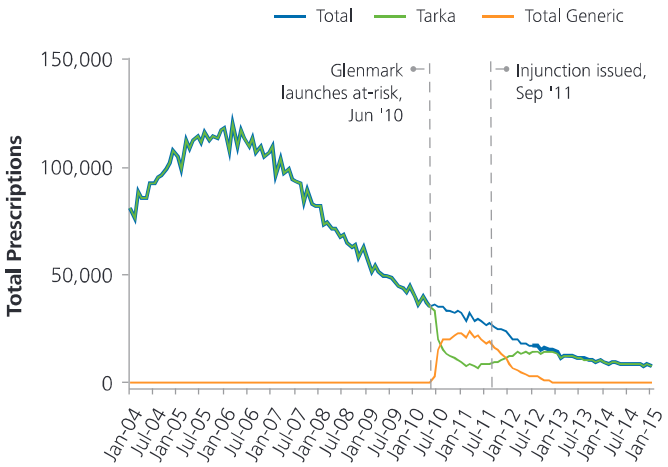
Generic Tarka was marketed for more than a year before injunctive relief was granted to the branded drug makers when the district court permanently enjoined Glenmark from manufacturing, selling, or importing generic forms of Tarka.[27]

As shown in Figure 2, the "at-risk" launch of generic Tarka led to a large drop in the total sales and prescription volumes of branded Tarka. Glenmark's initial win in the courtroom meant that generic Tarka competed head-to-head with its branded counterpart for a considerable period of time in the marketplace. In this situation, generic Tarka gained a market share of 60% of total prescriptions in the first 12 months after its launch.

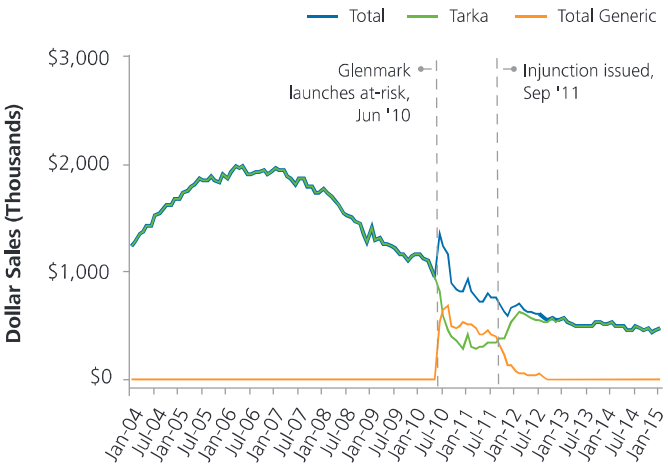
A permanent injunction was issued against Glenmark in September 2011, but product inventories were not depleted until late 2012. After the withdrawal of generic Tarka, the IQVIA data shows that branded sales and prescriptions volumes returned to their pre-generic trends—even after two-and-a-half years of generic competition.[28]

Figure 2. **Sales of Tarka and Its Generics**

Panel A: **Total Prescriptions**



Panel B: **Weekly Average Dollar Sales**



Pulmicort Respules

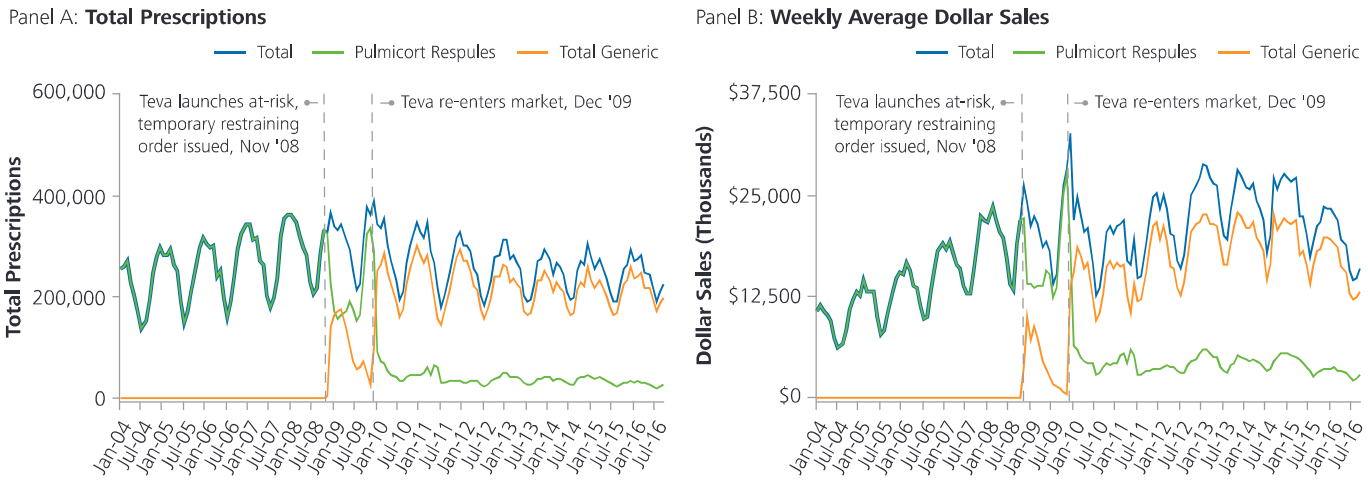
Pulmicort Respules is indicated for the control and prevention of asthma in young children.[29] Teva launched a generic version of Pulmicort Respules "at-risk" as soon as it was approved by the FDA.[30] One day after Teva's generic drug launch—on 19 November 2008—the US District Court for the District of New Jersey issued a temporary restraining order, instructing Teva to suspend its sales of generic Pulmicort Respules.[31] On the same day, AstraZeneca—the maker of Pulmicort Respules—announced an agreement with Par Pharmaceuticals to distribute an authorized generic version of its branded drug.[32] One week later, a settlement was reached that would allow Teva to sell generic Pulmicort Respules under an exclusive license from AstraZeneca beginning in December 2009.[33] The settlement with Teva meant that AstraZeneca's agreement with Par Pharmaceutical was discontinued.[34]

As shown in Figure 3, Teva sold a large volume of generic Pulmicort Respules within the 24 hours between its launch and the granting of the temporary restraining order. In fact, Teva's generic drug accounted for 40% of total prescriptions—and 32% of sales—in the six months following generic entry.

The IQVIA data shows that Teva's "at-risk" generic drug continued to generate revenue up until the licensed entry in December 2009, although by that point, the remaining generic sales were limited. Nonetheless, branded sales and prescription volumes appear to have followed a similar upward trend in late 2009, as was observed the year before, and the trends for total (brand plus generic) sales and prescriptions demonstrate that no lasting harm appears to have occurred.[35]

Even after Teva's entry, AstraZeneca retained a steady revenue stream from its branded Pulmicort Respules product. In fact, branded Pulmicort Respules sales have held on to a 20% market share since Teva's licensed entry in December 2009.

Figure 3. **Sales of Pulmicort Respules and Its Generics**



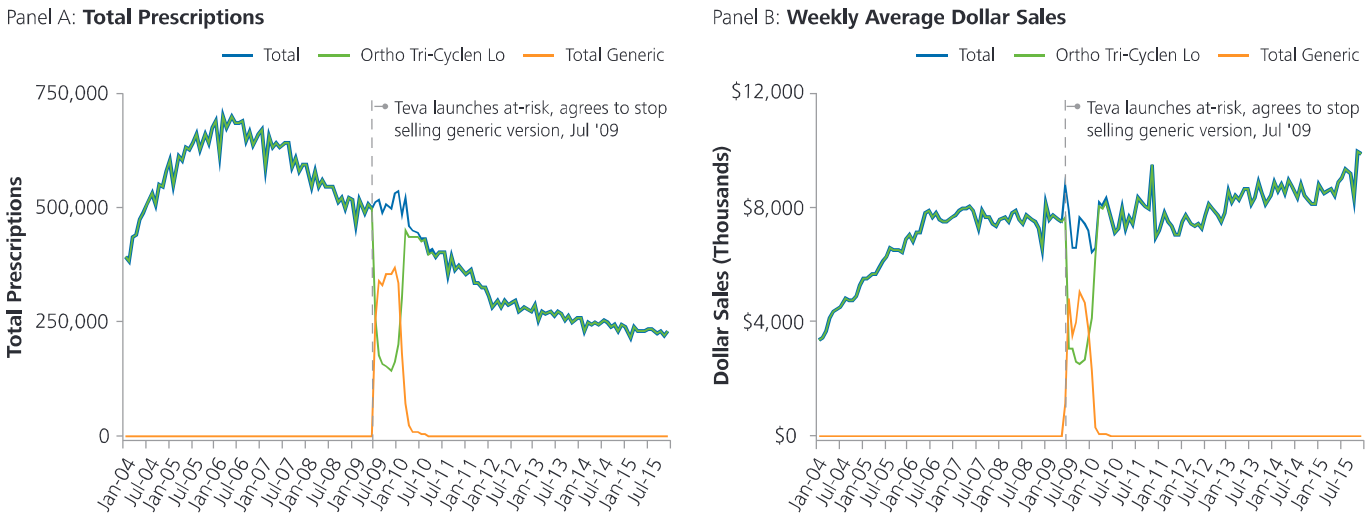
Ortho Tri-Cyclen Lo

Ortho Tri-Cyclen Lo is an oral contraceptive that was approved by the FDA in August 2002. On 1 July 2009, Teva launched a generic version of Ortho Tri-Cyclen Lo just days after receiving its drug approval from the FDA.[37] Six days later, Teva ceased shipments of its generic contraceptive, awaiting a court ruling on a preliminary injunction motion filed by Johnson & Johnson—the maker of Ortho Tri-Cyclen.[38] In mid-July, a settlement between Johnson & Johnson and Teva was announced that granted Teva a license to re-enter the market on 31 December 2015.[39]

As shown in Figure 4, Teva's generic contraceptive outperformed Ortho Tri-Cyclen Lo in terms of sales and prescription volumes in the months after generic entry. During its "at-risk" launch, Teva was able to ship several months' supply of its generic contraceptive, with Teva capturing a revenue-based market share of 60% in the six-month period after it entered the market.

In early 2010, the IQVIA data shows that the total dollar sales of branded Ortho Tri-Cyclen Lo were able to return to their pre-generic levels once Teva's generic contraceptive had exited the market.[40] In early 2010, the IQVIA data shows that the total dollar sales of branded Ortho Tri-Cyclen Lo were able to return to their pre-generic levels once Teva's generic contraceptive had exited the market.

Figure 4. **Sales of Ortho Tri-Cyclen Lo and Its Generics**



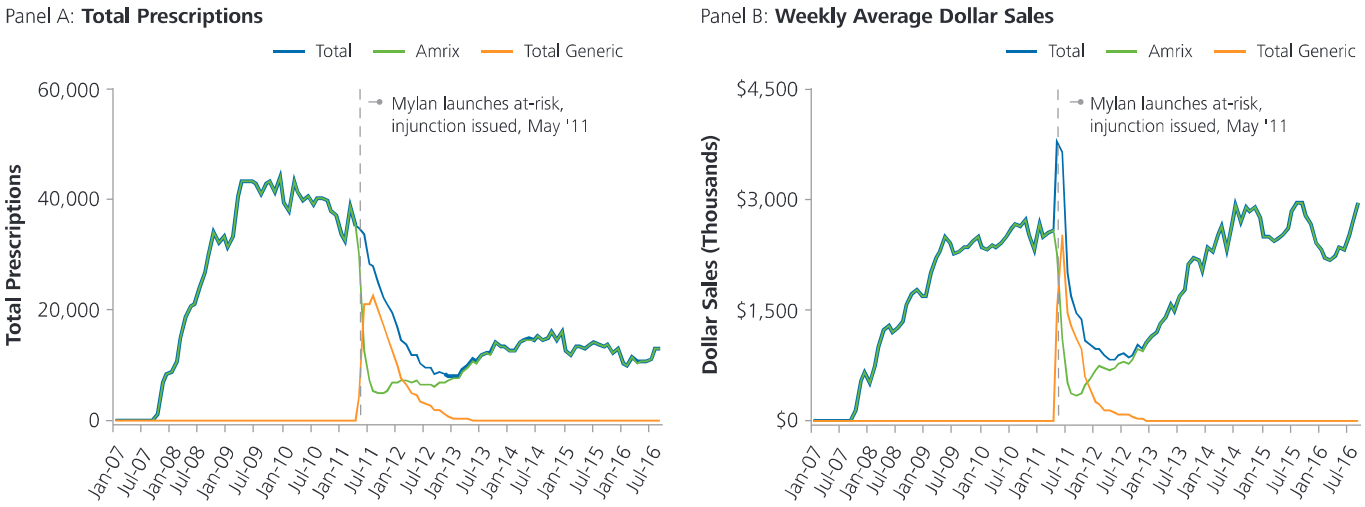
Amrix

Amrix is an extended-release muscle relaxer that was approved by the FDA in February 2007.[41] On 13 May 2011, Mylan launched a generic version "at-risk."[42] A few weeks later, the US District Court for the District of Delaware issued a preliminary injunction barring Mylan from selling its generic version of Amrix.[43]

As shown in Figure 5, total dollar sales—i.e., total brand plus generic sales—plummeted shortly after generic entry and—in contrast to the other drugs we have considered here—did not revert to its pre-generic levels shortly after the removal of Mylan's generic drug. Contrary to sales, the number of branded Amrix prescriptions remained at a lower level after the generic drug was pulled from the market.

Amrix's story, however, is more complicated than just the launch of a generic version. Teva announced plans to acquire Cephalon—the maker of Amrix—just days before the "at-risk" launch in May 2011 and closed on the transaction in October 2011.[44] Thus, any impact of Mylan's generic drug that could be seen in the IQVIA trends will be confounded with the impact of the transition from Cephalon to Teva. Therefore, it is not clear that the failure of Amrix to rebound in a manner consistent with the other drugs is a result of long-term consequences of generic entry; rather, the Amrix example highlights the importance of the fact-specific nature of establishing the likelihood of irreparable harm.

Figure 5. **Sales of Amrix and Its Generics**

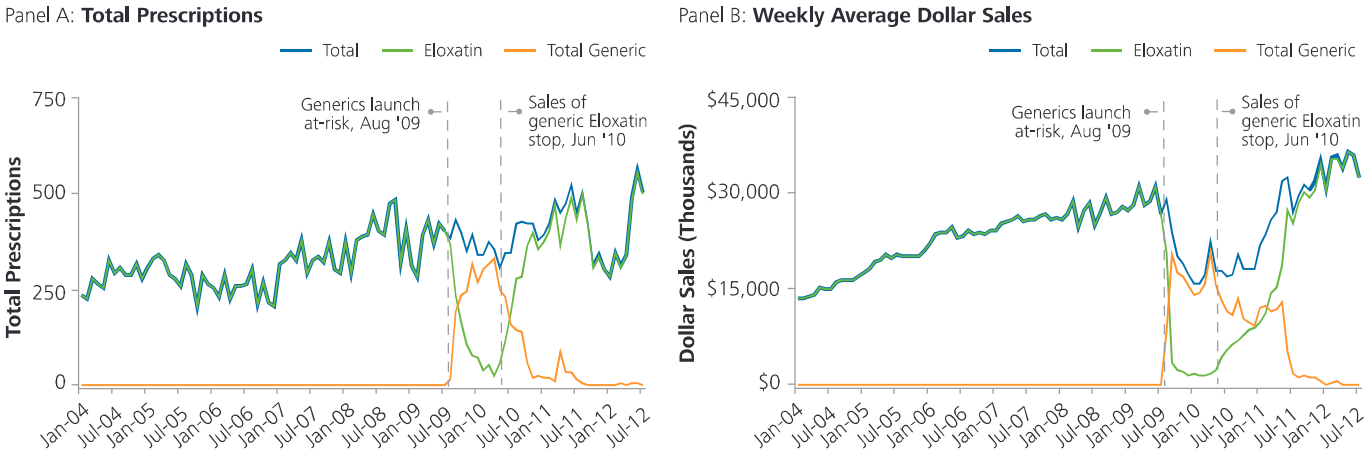


Eloxatin

Eloxatin is an anti-cancer drug that was approved by the FDA in August 2002.[45] On 7 August 2009, the FDA approved five separate applications for generic Eloxatin submitted by Fresenius Kabi, Hospira, Sandoz, Sun, and Teva.[46] Several manufacturers launched generic Eloxatin immediately after receiving regulatory approval, with the exception of Sun that launched a licensed version of generic Eloxatin in January 2010.[47] Settlement agreements between Sanofi-Aventis—the maker of branded Eloxatin—and the generic drug companies were announced in April 2010.[48] Each settlement required the generic drug makers to stop selling generic Eloxatin in June 2010 in exchange for a licensed entry in August 2012.[49]

As shown in Figure 6, generic Eloxatin gained market share immediately after the "at-risk" generics entered the market. However, the sales of branded Eloxatin increased from a very low level in early 2010 to their pre-generic levels by mid-2011 as the inventories of generic Eloxatin ran out.[50]

Figure 6. **Sales of Eloxatin and Its Generics**



Implications for Irreparable Harm

As noted at the outset, the issue of irreparable harm often arises when the owners of a patent (or patents) listed in the Orange Book seek a preliminary injunction against an "at-risk" launch of a generic competitor. Although "at-risk" launches themselves are relatively rare, the sales at risk are often large, such that the potential harm and benefit to both the branded drug, the generic drug, and consumer welfare may be substantial. Thus, the past launches can be instructive, as they shed some light on the risks to the branded drugs from temporary generic competition. In the cases we have identified, we have sought to focus on the question of whether or not—as is often asserted related to irreparable harm—generic competition, even if later withdrawn, will cause persistent harm to the branded drug's position.

The data from these cases indicate that the prescription volumes and total retail dollar sales of the branded drugs were often able to return to pre-generic trend levels once the generic products left the market. This suggests that—at least in these instances—there was no long-lasting impact of temporary generic competition on the branded drug's ability to recover.

Instead, it appears that while the branded drug's reduced prescription and retail sales may continue after the generic drug is removed from the market, these losses are limited to the continued sale of inventories of generic products. Once those inventories run dry, the branded drugs considered here have been able to re-establish their prior position.[51]

This evidence suggests that while temporary generic competition is associated with significant exchanges of market shares between the branded and generic drugs, the pre-generic market conditions have generally been restored once the branded drug's market exclusivity has been reinstated. We must be clear, however, that this finding alone does not mean that "at-risk" generic entry could never create the likelihood of irreparable harm to the branded drug company. Rather, the evidence highlights the importance of *not* assuming that temporary generic entry will be likely to cause lasting harm to the branded drug, and underscores the importance of assessing the specific factors at issue that may or may not suggest that irreparable harm is likely.

While case-specific facts are critical, it can also be relevant to consider the lessons and experiences from past "at-risk" generic drug launches. The six examples analyzed in this paper may be anecdotal, but due to the limited number of relevant comparisons, they are the few situations where it is possible to see how the retail sales and prescription volumes respond to the entry and exit of "at-risk" generic competitors. They demonstrate that branded drug sales have generally been able to recover their pre-generic sales trends after the generic drug has left the market—and that one should not presume that long-lasting harm would necessarily exist.

Notes

[1] We would like to thank Dr. Christine Meyer and Dr. Omar Robles for helpful comments and suggestions.

[2] "Abbreviated New Drug Application," US Food and Drug Administration (FDA), available at https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda, accessed on 2 September 2020.

[3] "Patent Certifications and Suitability Petitions," FDA, available at https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions, accessed on 2 September 2020.

[4] *Ibid.*

[5] Launching a generic drug prior to the resolution of all patent disputes is often referred to as an "at-risk" launch. While this term is not generally used in other industries, it is, of course, common in these other areas that defendants in patent disputes actively sell allegedly infringing products.

[6] *Amazon.com v. Barnesandnoble.com, Inc.*, United States Court of Appeals, Federal Circuit, Case No. 00-1109, 14 February 2001, 239 F.3d 1343.

[7] See, e.g., Henry G. Grabowski, et al., "Recent Trends in Brand-Name and Generic Drug Competition," *Journal of Medical Economics*, 2013, pp. 1–8; Henry G. Grabowski and John M. Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act," *Journal of Law and Economics*, Vol. 35, 1992, pp. 331–50; Henry G. Grabowski and John M. Vernon, "Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act After One Decade," *Pharmacoeconomics*, Vol. 10 No. 2, 1996, pp. 110–23; Atanu Saha, et al., "Generic Competition in the US Pharmaceutical Industry," *International Journal of the Economics of Business*, Vol. 13, No. 1, February 2006, pp. 15–38. V

[8] Some well-known cases of "at-risk" launches, such as Protonix, are excluded from our analysis, as generic products were available until the expiration of the relevant patents, with no "post-generic" period available for analysis.

[9] See, "Prescription Information," IQVIA, available at https://www.iqvia.com/locations/united-states/solutions/commercial-operations/essential-information/prescription-information, accessed on 12 November 2020.

[10] In several of the cases considered here, generic entry is also observed after the underlying patent dispute has been resolved. We exclude these episodes from our analysis as they are not relevant for assessing the impact of temporary "at-risk" generic competition.

[11] For simplicity and ease of reading, we do not use the trademark symbol throughout the rest of the paper. For simplicity and ease of reading, we do not use the trademark symbol throughout the rest of the paper.

[12] "Plavix Oral," WebMD, available at https://www.webmd.com/drugs/2/drug-5869/plavix-oral/details, accessed on 6 October 2020.

[13] "Top Global Biopharma Drugs by Lifetime Sales up to 2018," *Statista*, available at https://www.statista.com/statistics/1089322/top-drugs-by-lifetime-sales-globally/, accessed on 12 November 2020.

[14] "Approval Letter for ANDA 076274," FDA, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/076274Orig1s000ltr.pdf.

[15] "Approval Letter for ANDA 076274," FDA, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/076274Orig1s000ltr.pdf.

[16] *Ibid.*

[17] "Apotex Receives Approval for First Generic Plavix®," Apotex Corporation, available at https://web.archive.org/web/20061023224524fw_/http://www.apotexcorp.com/press/20060125-01.htm, accessed on 6 October 2020.

[18] "Apotex Launches First Generic Plavix®," Apotex Corporation, available at https://web.archive.org/web/20061023224848fw_/http://www.apotexcorp.com/press/20060808-01.htm, accessed on 6 October 2020.

[19] "Preliminary injunction ordered in PLAVIX® patent infringement case - Apotex to halt sales of unauthorized generic," Sanofi, available at http://www.news.sanofi.us/press-releases?item=118385, accessed on 12 November 2020.

[20] Christine Caulfield, "Apotex To Appeal Court's Plavix Patent Ruling," *Law360*, 19 June 2007, available at https://www.law360.com/articles/27261/apotex-to-appeal-court-s-plavix-patent-ruling.

[21] Although this paper does not attempt to estimate damages from generic entry, it is worth noting that, fundamentally, economic damages should measure the difference between the actual profits earned in the actual world and the profits that would have been earned in a but-for world in which the generic had not launched.

As is commonly the case in any assessment of economic damages, in the case of Plavix, there are several confounding events that would need to be considered. For instance, the FDA approved an additional indication for Plavix on 17 August 2006. In July 2009, Effient was approved by the FDA and it was "touted as a potential Plavix-killer." In March 2010, the Plavix label was revised to include a "black box" warning.

It is beyond the scope of this paper to implement a full econometric model that isolates the loss of sales caused by temporary generic competition, while excluding any changes in sales arising from other sources. That said, we have estimated a simple relationship between observed Plavix sales and a time polynomial using pre-generic observations. This allows us to construct counterfactual sales that can be compared to actual sales in the period after the "at-risk" generic product exited the market. We do not present the results of these analyses, but they are supportive of our discussions and conclusions for each of the six pharmaceutical products analyzed in this paper.

[22] "First half: solid results in a difficult context. Plavix® recovers its position in the US, full impact expected in H2," Sanofi, 1 August 2007, available at http://www.news.sanofi.us/press-releases?item=118334.

[23] "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," FDA, available at https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=079135#27046, accessed on 12 November 2020.

[24] "ANDA 079135," FDA, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/079135s000ltr.pdf, accessed on 12 November 2020.

[25] *Sanofi-Aventis Deutschland et al. v. Glenmark Pharmaceuticals et al.*, United States Court of Appeals, Federal Circuit, Case No. 07-CV-5855, 21 April 2014, 748 F.3d 1354.

[26] *Ibid.*

[27] "Court Enjoins Infringing Drug Seller Despite Previously Denying a Preliminary Injunction and Payments by Patent Owner to its Exclusive Licensee to Offset Harm of a Generic Drug Entering the Market," Finnegan, 27 February 2012, available at https://www.finnegan.com/en/insights/articles/court-enjoins-infringing-drug-seller-despite-previously-denying.html.

[28] As noted above for Plavix, this is confirmed with a simple time-based polynomial analysis of trends. As noted above for Plavix, this is confirmed with a simple time-based polynomial analysis of trends.

[29] "Pulmicort Respules®,"FDA, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020929s052lbl.pdf.

[30] Orange Book; "ANDA 77-519,"FDA, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2008/077519s000ltr.pdf.

[31] "AstraZeneca granted Temporary Restraining Order in PULMICORT RESPULES patent litigation," AstraZeneca, 20 November 2008, available at https://web.archive.org/web/20100102152429/http://astrazeneca.com/media/latest-press-releases/2008/4215773?itemId=4215773.

[32] "AstraZeneca Enters Agreement for Authorized Generic Pulmicort Respules," AstraZeneca, 19 November 2008, available at https://web.archive.org/web/20101031070718/http://astrazeneca.com/media/latest-press-releases/2008/4215797?itemId=4215797.

[33] "AstraZeneca Settles US Pulmicort Respules Patent Litigation with Teva," AstraZeneca, 2008, available at https://web.archive.org/web/20100102150259/http://astrazeneca.com/media/latest-press-releases/2008/4251198?itemId=4251198.

[34] *Ibid.*

[35] As noted above for Plavix, this is confirmed with a simple time-based polynomial analysis of trends.

[36] Orange Book.

[37] Teva Pharmaceutical Industries Limited Form 6-K for the month of July 2009.

[38] Lewis Krauskopf, "UPDATE 1-Teva, J&J settle oral contraceptive patent case," *Reuters*, available at https://www.reuters.com/article/teva-jj/update-1-teva-jj-settle-oral-contraceptive-patent-case-idUSN2447653020090724.

[39] *Ibid.*

[40] As noted above for Plavix, this is confirmed with a simple time-based polynomial analysis of trends.

[41] Orange Book.

[42] "Mylan Launches First Generic Version of Amrix® Capsules," Mylan, available at https://investor.mylan.com/news-releases/news-release-details/mylan-launches-first-generic-version-amrixr-capsules.

[43] *Eurand, Inc. et al., v. Impax Laboratories, Inc. et al.*, United States Court of Appeals, Federal Circuit, Case No. 09-MD-2118, 1 February 2013, 504 Fed. Appx. 900.

[44] "Teva to Acquire Cephalon in $6.8 Billion Transaction," *Businesswire*, 2 May 2011, available at https://www.businesswire.com/news/home/20110502005825/en/Teva-to-Acquire-Cephalon-in-6.8-Billion-Transaction; https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2011/Teva-Completes-Acquisition-of-Cephalon/default.aspx.

[45] "Eloxatin,"FDA, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021492s016lbl.pdf.

[46] Orange Book.

[47] *Sanofi-Aventis et al. v. Sandoz et al.*, United States Court of Appeals, Federal Circuit, Case No. 07-CV-2762, 22 December 2010, 405 Fed. Appx. 493.

[48] "UPDATE 2-Sanofi settles with Sandoz, Teva on Eloxatin patent," *Reuters*, 1 April 2010, available at https://www.reuters.com/article/sanofi-idCNLDE63002M20100401.

[49] *Ibid.*

[50] As noted above for Plavix, this is confirmed with a simple time-based polynomial analysis of trends.

[51] It is worth noting that post-trial prescriptions filled with existing inventories should not represent "future" harm in that the units have already been sold by the generic and should, therefore, be quantifiable at the time of trial.

[52] Indeed, Dr. Blackburn has submitted declarations focused on issues relating to irreparable harm in which he has relied on similar data as presented herein. See, e.g., Merck & Cie, et al., *Applicants, v. Watson Laboratories, Inc., Respondent*, Respondent's Opposition to Application to Stay Mandate, In the Supreme Court of the United States, No 16A74, 26 July 2016.

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EXHIBIT 3

Transcripts | Healthcare

Novartis AG (NVS) CEO Vasant Narasimhan on Q4 2019 Results - Earnings Call Transcript

Jan. 29, 2020 6:12 PM ET | **Novartis AG (NVS)** | 2 Likes

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Q4: 2020-01-29 Earnings Summary

Play Call | Slides

EPS of $1.32 beats by $0.01 | Revenue of $12.40B (-6.53% Y/Y) beats by $101.30M

Novartis AG (NYSE:NVS) Q4 2019 Results Earnings Conference Call January 29, 2020 8:00 AM ET

Company Participants

Samir Shah - Global Head of IR

Vasant Narasimhan - CEO

Harry Kirsch - CFO

Marie-France Tschudin - President of Novartis Pharmaceuticals

Susanne Schaffert - President of Novartis Oncology

John Tsai - Head of Global Drug Development & Chief Medical Officer

Richard Saynor - CEO of Sandoz

Shannon Klinger - Group General Counsel

Conference Call Participants

Steve Scala - Cowen

Graham Parry - Bank of America

Andrew Baum - Citi

Tim Anderson - Wolfe Research

Seamus Fernandez - Guggenheim

Matt Weston - Credit Suisse

Florent Cespedes - Societe Generale

Peter Welford - Jefferies

Stephan Schneider - Vontobel

Richard Parkes - Deutsche Bank

Keyur Parekh - Goldman Sachs

Laura Sutcliffe - UBS

Richard Vosser - JPMorgan

Eric Le Berrigaud - Bryan Garnier

Naresh Chouhan - Intron Health

Mark Purcell - Morgan Stanley

Simon Baker - Redburn

Operator

Good morning, and good afternoon. And welcome to the Novartis Q4 and Full Year 2019 Results Release Conference Call and Live Audio Webcast. Please note that during the presentation, all participants will be in listen-only mode and the conference is being recorded. [Operator Instructions] A recording of the conference call, including the Q&A session, will be available on our website shortly after the call ends. [Operator Instructions]

With that, I would now like to turn the conference over to Mr. Samir Shah, Global Head of Investor Relations. Please go ahead, sir.

CHMP positive opinion, we anticipate in Q1 of this year. With respect to Japan, we anticipate an approval in the first half of this year and I would say conversations, both in the Europe and Japan are going very well.

And then we also anticipate decisions in other markets around the world, including Switzerland, Canada, Australia, Brazil and as well as number of countries in the Middle East. These will be additional areas of potential future growth for the medicine.

So Zolgensma is delivering on the promise of bringing a transformational gene therapy to children. And we look forward to continuing to progress expanding its application in more patient populations, in more geographies in the year to come.

So moving to Slide 15. On the margins, we've guided the last time we spoke about this - Q4 of last year that we expect to have reach to mid 30s in the near term and you can see us already getting close to that with 33.5% exiting 2019, and the mid to high-30s in the medium term.

One important thing to note about our margin guidance is we would expect to achieve these margins independent of when potential Gilenya LOE occurs. And that's really driven by a combination of strong sales momentum of our growth drivers, productivity programs, which I'll talk about in a moment, as well as excellent resource allocation from our older brands to newer launches. And with that, we're able to offset generic erosions, as well as any launch investments we need for upcoming launches including the newly acquired inclisiran asset.

So moving to Slide 16. I just wanted to say a word about the transformation we're advancing in NTO and NBS. With respect to manufacturing, we're well on our way of our goal of consolidated footprint that's much more focused on high-end technologies.

We also are advancing our efforts in procurement and manufacturing are really reducing the excess inventories that we're holding and also deploying data & digital much more aggressively across the manufacturing network.

In NBS, we are on track now with respect to our movement of roles to our global service centers. We've been able to take a number of actions to consolidate our footprint, as well as consolidate our overall real estate operations. We have a new Chief Procurement Officer, who has now been enrolled for a number of months already optimizing our top 100 suppliers.

EXHIBIT 4

Transcripts | Healthcare

Novartis AG (NVS) CEO Vas Narasimhan on Q2 2022 Results - Earnings Call Transcript

Jul. 19, 2022 1:47 PM ET | **Novartis AG (NVS)**, **NVSEF**

SA Transcripts
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Q2: 2022-07-19 Earnings Summary

▶ Play Call | Slides

EPS of $1.56 beats by $0.02 | Revenue of $12.78B (-1.35% Y/Y) beats by $42.50M

Novartis AG (NYSE:NVS) Q2 2022 Results Conference Call July 19, 2022 8:00 AM ET

Company Participants

Samir Shah - Global Head, IR

Vas Narasimhan - CEO

Harry Kirsch - CFO

Conference Call Participants

Matthew Weston - Credit Suisse

Tim Anderson - Wolfe Research

Richard Vosser - JP Morgan

Emmanuel Papadakis - Deutsche Bank

Graham Parry - Bank of America

Steve Scala - Cowen

Florent Cespedes - Société Générale

Emily Field - Barclays

Simon Baker - Redburn

Kerry Holford - Berenberg

Seamus Fernandez - Guggenheim Securities

Andrew Baum - Citi

Laura Sutcliffe - UBS

Keyur Parekh - Goldman Sachs

Naresh Chouhan - Intron Health

Sarita Kapila - Morgan Stanley

Peter Welford - Jefferies

Wimal Kapadia - Bernstein

Richard Parkes - BNP Paribas

Operator

Good morning and good afternoon, and welcome to the Novartis Q2 2022 Results Release Conference Call and Live Webcast.

Please note that during the presentation, all participants will be a listen-only mode and the conference is being recorded. [Operator Instructions] A recording of the conference call, including the Q&A session, will be available on our website shortly after the call ends.

With that, I would like to hand over to Mr. Samir Shah, Global Head of Investor Relations. Please go ahead, sir.

Samir Shah

Then moving to the next slide on slide 19. We're on track largely against our key 2022 events. Just three things to note: three submission-enabling readouts coming up in the second half of this year, CANOPY A, iptacopan and PNH, and as already mentioned, Pluvicto in the pre-taxane setting. So, we'll look forward to those study readouts and updating all of you as we get that data in-house.

So, with that, I will hand it over to Harry.

Harry Kirsch

Yes. Thank you very much, Vas. Good morning and good afternoon, everybody.

I'm now going to walk you through some of the financials for the second quarter and the first half. And as always, my comments refer to growth rates in constant currencies unless otherwise noted.

So on the next slide, yes, we show our quarter two and half one financial results summary. As you can see, quarter two sales and core operating income both grew 5% in constant currencies with sales benefiting from the continued strong performance of our key growth brands and core operating income growth driven mainly by the higher sales. However, operating income and net income declined significantly in the quarter. This was mainly due to prior year divestment gains from tail end products and higher impairments and higher restructuring costs this quarter, mainly for the transformation for growth program.

Core EPS grew 1%. However, if you exclude the impact of the prior year Roche income, core EPS would have grown 10%. Overall, we delivered solid sales and core operating income growth for the quarter, resulting also in a strong operational half one performance, with sales growing 5% and core operating income 7%. Core EPS in half one grew 11%, excluding the Roche stake impact.

On the next slide, I would like to drill down a bit into the performance by division. So, for quarter two, you can see that Innovative Medicines top line grew 5% and the bottom line, 6%, resulting in an improvement in the core margin of 15 basis points to 37.2%. Sandoz net sales also grew 5% although core operating income decreased 4%, mainly due to increased M&S investments and higher other expenses. This was reflected in the core margin, which decreased to 20.4%. Overall, for the first half, we saw a strong performance for Innovative Medicines and Sandoz, Innovative Medicines sales growing 5% and core operating income 6% in half one.

Sandoz grew 6% on the top line and 10% on the bottom line in half one, driven by a very strong quarter one. And as a reminder, as we discussed in April, Sandoz benefited from a return towards normal business dynamics compared to a lower prior year base.

Our half one core margin improved by 30 basis points for Innovative Medicines, 70 basis points for Sandoz and 60 basis points for the total group.

Turning now to our guidance on slide 23. So, within the divisions, we expect Innovative Medicines sales growing mid-single digit and core operating income growing mid- to high-single digit ahead of sales. The expected IM core margin increase will be driven by expected continued good top line momentum and continuation of our productivity programs, of course, including the new organizational structure, giving us some benefits in the second half already.

For Sandoz, the performance year-to-date allows us to upgrade sales guidance to grow low single digit, which is a one-notch upgrade, and core operating income guidance is upgraded by 2 notches to now be broadly in line with the prior year. For the group, we confirm our overall full year guidance. We continue to expect both, top and bottom line to grow mid-single-digit in 2022.

The key assumption for this guidance is that we see a continuing return to normal global healthcare systems, including prescription dynamics and that no Gilenya and no Sandostatin LAR generics would enter in the U.S. in 2022.

As many of you know, in June of this year, the U.S. appeals court held the Gilenya U.S. dosing regimen patent invalid. We plan to petition the appeals court for further review to uphold validity of this patent. And as a reminder, there's no generic competition in the U.S. at this point in time for Gilenya. And in quarter two, U.S. sales were $332 million for Gilenya. It is worth noting that U.S. Gilenya sales have been steadily declining due to competitive pressures and, of course, our key focus [ph] being on Kesimpta.

Thank you. Your next question comes from the line of Richard Vosser from JP Morgan. Please go ahead. Your line is open.

Richard Vosser

Just one on the LOEs that we should expect in '23. I think Promacta is slated, but there are some formulation and use patents that might actually push that out. And maybe similarly, just anything else like Lucentis that we should be thinking about? Thanks very much.

Vas Narasimhan

Yes. Thanks, Richard. Yes, on Promacta, we're continuing to work to really support all the full range of patents we have on the medicine. I think in appropriate time, if we're successful, we'll provide an update on Promacta. But it is something we're very focused on. And then, on Lucentis, we do expect the biosimilar -- a few biosimilar entries in Europe. I think it's important to note that with the broad scale availability of Avastin for now many, many years that we believe the biosimilars market has -- in effect, already happened in Europe. So, we would expect a moderate decline on the launch of the biosimilars, but maybe not what you would see with other biologics when biosimilar entry occurs. So, that's how we're forecasting Lucentis now for the coming years. And one last question, operator?

Operator

Thank you. Your final question comes from the line of Graham Parry from Bank of America. Please go ahead. Your line is open.

Graham Parry

So just one on Gilenya. So, obviously, you've had the overturning the decision from the appeal court and you said you're going to petition. So just help us understand time frame for the petition? Does that prevent a launch happening in the intervening time frame, so your level of confidence that we won't see a launch this year, or is the guidance just a guidance assumption but that could change depending on what happens with the court? And then, just one last one, Kisqali growth was just well above prescription growth, although, obviously, we are seeing resurgence there. Is that reflective of real volume growth, or could it be just a sort of prescription retail versus other channels that we're seeing and actually the reported growth is much more in line with the real volume growth? Thank you.

Vas Narasimhan

Yes. On Gilenya, right now, no generics can enter the market. We are petitioning the court. And we would expect to get a response from the court in the coming months. If granted, then it would be another set of months before the hearing and then the hearing will take another set of months. As a reminder, we guided to generics entering in 2024. So really, what we look at here is between now and that timeline when exactly the entry might happen. So, we'll know more, I think, as the court gives us feedback once we -- we have -- yes, we are in the process of submitting the petition. The petition would then need to be reviewed. We'd either be rejected at that point or the petition would be granted and then we would then move forward from there.

So, that's kind of the scenarios right now on Gilenya. But to remind again, the longstop date was any way in '24. So from a midterm growth standpoint, this is not having a significant bearing. Also in Europe, where we were granted the patent by the European patent office, we expect that patent to be issued later this year, and we'll continue to defend Gilenya across Europe. So, a lot of things, puts and takes, I think, on Gilenya at the moment.

And I think on your question on Kisqali, I don't know the answer, so we'll just have to follow-up with you. But we'll get back to you on that to make sure you're clear on the volume price dynamics. But I would say that what we see in our numbers is a strong growth in underlying demand for Kisqali that we'd like to sustain.

So, thanks, everyone, for joining the call. Apologies we didn't get to every single question. But I really appreciate everyone taking the time, and we'll look forward to catching up soon. Bye, bye.

Operator

Thank you. This concludes today's conference call. Thanks for participating. You may now disconnect.