UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED FOOD AND COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND and LABORERS HEALTH AND WELFARE TRUST FUND FOR NORTHERN CALIFORNIA, on behalf of themselves and others similarly situated,

Plaintiffs,

v.

NOVARTIS PHARMACEUTICALS CORP., NOVARTIS AG, and NOVARTIS CORPORATION,

Defendants.

Civil Action No. _____

CLASS ACTION COMPLAINT

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XII. DEMAND FOR RELIEF....81

1. Plaintiffs, United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund and Laborers Trust Fund for Northern California, on behalf of themselves and all others similarly situated, for their complaint against defendants Novartis Pharmaceuticals Corporation, Novartis AG, and Novartis Corporation (collectively "Defendant" or "Novartis"), alleges as follows based on (a) personal knowledge; (b) the investigation of their counsel; and (c) information and belief.

I. INTRODUCTION

2. This civil action seeks to prevent the unlawful delay of generic entry into the U.S. market for Gleevec (imatinib mesylate), an FDA-approved prescription drug that radically improves the lives of the thousands of patients suffering chronic myeloid leukemia (CML), a cancer of the blood and bone marrow.

3. Gleevec, which costs about $9,000-a-month, should go generic this July 5, 2015: the period of lawful exclusivity from the basic imatinib patent expires on July 4th, and the FDA has cleared two generic applications. But brand company Novartis has unlawfully extracted an additional seven months of exclusivity from generic maker Sun Pharma. Novartis unlawfully listed invalid follow-on patents in the FDA's Orange Book, frivolously sued (belatedly) first-in-line generic Sun for infringing one of those patents, and extracted from Sun a promise not to launch its generic for seven extra months beyond the compound patent's expiration in the guise of settling the bogus infringement lawsuit.

4. Novartis should rightly enjoy exclusivity for Gleevec through the expiry of the original compound patent in early July 2015 (having grossed over $13.5 billion in U.S. sales over the years from the drug, which now yields about $2 billion per year). But patent gamesmanship and frivolous litigation undertaken solely for the purpose of extracting settlements that delay generic entry violate basic principles of antitrust law, and should be enjoined.

5. Plaintiffs seek a permanent injunction prohibiting Novartis from taking any steps to enforce the May 2014 settlement agreement that would prevent Sun or other generics from launching generic Gleevec after the compound patent expires this July. This complaint seeks only injunctive relief, as damages will not accrue until July. Plaintiffs and the proposed class of direct purchasers and end payers who are currently paying for, and expect to continue paying for, branded Gleevec after July 4, 2015, will suffer irreparable harm in their business by having to pay for more expensive branded Gleevec instead of less expensive generic alternatives.

6. This sham litigation case presents a straightforward, simple question: Would a reasonable pharmaceutical company in Novartis's position realistically expect to win a patent infringement suit accusing Sun Pharmaceuticals of infringing the '051 patent for the mesylate salt and β-crystal form of imatinib? Given the narrow issue presented, and the possibility of preventing plaintiffs' injuries, plaintiffs seek an expedited trial as soon as practicable.

II. JURISDICTION AND VENUE

7. This action under section 2 of the Sherman Act, 15 U.S.C. § 2. Plaintiffs and the proposed class seek permanent injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

8. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 26.

9. This Court has personal jurisdiction over Novartis because Novartis transacts business within this District, and carries out interstate trade and commerce in substantial part in this District and/or has an agent or agents in this District and/or can be found in this District.

10. Venue is appropriate within this District under section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §§ 1391(b) and (c).

III. PARTIES

11. Plaintiff United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") is an employee welfare benefit plan. UFCW maintains its office, from which it pays medical benefits including benefits for prescription drugs, in Cook County, Illinois. It has paid some or all of the price of 100 mg and 400 mg Gleevec tablets on behalf of its plan participants. UFCW will pay more for Gleevec than it would have absent Novartis's unlawful scheme to prevent and delay generic entry.

12. Plaintiff Laborers Trust Fund for Northern California ("Laborers") is a trust fund administered pursuant to the Taft-Hartley Act, 29 U.S.C. § 186, by an equal number of trustees appointed by labor representatives and union representatives; Laborers is an employee welfare benefit plan maintained pursuant to Section 302(c)(5), and as defined by Sections 1002(1) and (3) of ERISA, 29 U.S.C. § 1001, et seq. Laborers maintains its office in Fairfield, California. It has paid some or all of the price of 100 mg and 400 mg Gleevec tablets on behalf of its plan participants. Laborers will pay more for Gleevec than it would have absent Novartis's unlawful scheme to prevent and delay generic entry.

13. Defendant Novartis Pharmaceuticals Corporation is corporation organized and existing under the laws of the State of Delaware. Novartis Pharmaceuticals Corporation is a subsidiary of Defendant Novartis AG and the NDA holder/applicant as well as a distributor for the prescription drug Gleevec.

14. Novartis Pharmaceuticals Corporation purports that its principal place of business is at 59 Route 10, East Hanover, New Jersey 07936. Novartis Pharmaceuticals Corporation occupies 1.2 million square feet of office and laboratory space in Cambridge, Massachusetts, with construction underway to add another 550,000 square feet along Massachusetts Avenue, and is one of the largest corporate employers in Cambridge, MA (employing over 2,000

associates). The Cambridge campus is also home to the Novartis Institutes for BioMedical Research, Novartis Vaccines and Diagnostics, and the U.S. office of the Novartis Venture Funds.

15. Defendant Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and a place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

16. Defendant Novartis Corporation is a corporation organized and existing under the laws of the State of New York, having its principal place of business at 608 Fifth Avenue, New York, New York 10020. Novartis Corporation is the assignee of the '184 patent (discussed below).

17. As used herein, "Novartis" refers to any or all defendants.

18. All of Novartis's actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Novartis's various officers, agents, employees, or other representatives while actively engaged in the management of Novartis's affairs within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Novartis.

IV. REGULATORY BACKGROUND

19. Brand drug companies can, and do, obtain valid patents that cover their new prescription drug products. Such patents encourage discovery and development of new medicines, providing protection from competition by other drug companies for a length of time set under a statute by Congress.

20. Once the lawful periods of exclusivity expire on brand products, generic companies can seek FDA approval to sell generic versions of the brand, allowing the generic companies to manufacture generic products that are just as safe and effective, but far less

expensive than the brand. The medication becomes affordable for all, and purchasers are no longer burdened by the high cost of the brand drug.

21. The American system of access to prescription drugs balances the desire to reward innovation with the desire to provide access to affordable drugs. Brand companies have a statutory period of time – generally 20 years from the time of filing the patent – to charge very high prices for medications that, in fact, cost little to manufacture. But, after that period elapses, generic companies can compete with low-cost substitutes. From this basic principle emerges a simple rule: a brand company may not assert invalid, unenforceable, or uninfringed patents in order to delay entry of less expensive, but therapeutically equivalent, generic medications.

22. This case involves a breach by one large brand drug company, Novartis, of this basic rule.

A. The Regulatory Structure for Approval of New Drugs

1. Basic Principles of Pharmaceutical Formulation

23. In developing a new drug, it is not enough to discover a chemical that has a desired effect when tested in vitro. The chemical must be developed into an acceptable pharmaceutical compound (or "active pharmaceutical ingredient") that is, among other things, stable and able to be manufactured in commercial quantities. A standard operating procedure in drug development is the selection of the salt and polymorphic form to be used for this purpose.

a. The Salt Selection

24. Active pharmaceutical ingredients in free base form often do not exhibit the range of physical properties that are suitable for development. One common method of modifying the characteristics of drug substance is to create a salt.

25. Choosing the salt form is one of the most important decisions made during the drug development process. A guideline of good pharmaceutical processes is that a salt should be selected, and that salt used for the further formulation, development, and testing processes.

26. Different salts can have different solubilities, dissolution rates, melting points, chemical stability, hygroscopicity, and mechanical properties. The benefits of using salt forms as active pharmaceutical ingredients are well known, and represent one means to increase the solubility of otherwise intractable substances, and potentially to increase bioavailability (the amount of drug that makes its way into the blood).

27. The goal of salt selection is to identify a molecule that can optimally be used in the myriad of activities needed to study, register, and manufacture a drug. Selecting a salt involves input from a number of different groups. Process chemists consider the yield, rate, and quality of the crystallization, as well as cost. Formulation chemists are concerned with hygroscopicity (*i.e.*, how readily the compound takes up or retains moisture), stability, solubility and processability of the salt form. The drug metabolism and safety assessment groups focus on the pharmacokinetic aspects and the safety (*e.g.*, toxicology effects) of a particular salt form. Given these competing interests, the final choice of salt form is often a compromise. Since at least the mid 1980s, scientific literature has discussed how such compromises should be approached, as well as the pros and cons of particular salt forms.

b. Basic Compounds are Often Formulated as Mesylate Salts

28. One consideration in choosing a salt is the basicity or acidity of the compound. Acidic compounds are often formulated as sodium salts. Basic compounds are often formulated as "acid addition salts," salts formed by adding hydrochloric, sulfuric, nitric, methanesulfonic, or other acids.

29. There are not many acid addition salts that are both environmentally safe when produced in large, commercial quantities and also safe for individual consumption. As an example: hydrochloric acid can be well tolerated in the human body but it can corrode stainless steel, cause unacceptable levels of corrosion in factory settings, and require very expensive, specialized equipment.

30. For a "basic" compound (*i.e.*, one that contains one or more atoms, like a nitrogen, capable of being protonated), routine screening for pharmaceutically acceptable addition salts is typically done by mixing the parent compounds with an acid that is "generally regarded as safe" in a suitable solvent. The list of acids typically screened is limited, but usually includes inorganic acids (hydrochloric acid, hydrobromic acid, phosphoric acid, sulphuric acid), strong organic acids (methanesulfonic acid, benzenesulfonic acid, toluenesulfonic acid) and weak organic acids (acetic acid, citric acid, maleic acid).

31. A salt of methanesulfonic acid (CH_3SO_3H) is called a "mesylate." Mesylates are a common form of acid addition salts. As far back as 1974, mesylates made up more than 2.0 % of all FDA-approved commercially marketed salts. (The 2% was a significant number, as about half of the marketed salts used hydrochloric acid (HCl), and other salts rarely topped 1%). Mesylates are commonly used in the pharmaceutical industry for enhanced water solubility as compared with the free base form of a compound, as well as for their stable crystalline forms, which may have better handling properties that are useful for large-scale production.

32. In the early 1990s, among the first salts that one skilled in the art of drug formulation would look at for a compound would be HCl and methanesulfonic acid salts – HCL salts because stomach acid already contains HCl, and methanesulfonic acid because mesylate salts were known to be well behaved and well suited for use in drugs.

c. Formulation Chemists and Engineers Prefer Non-Needle Shaped Crystal Habits

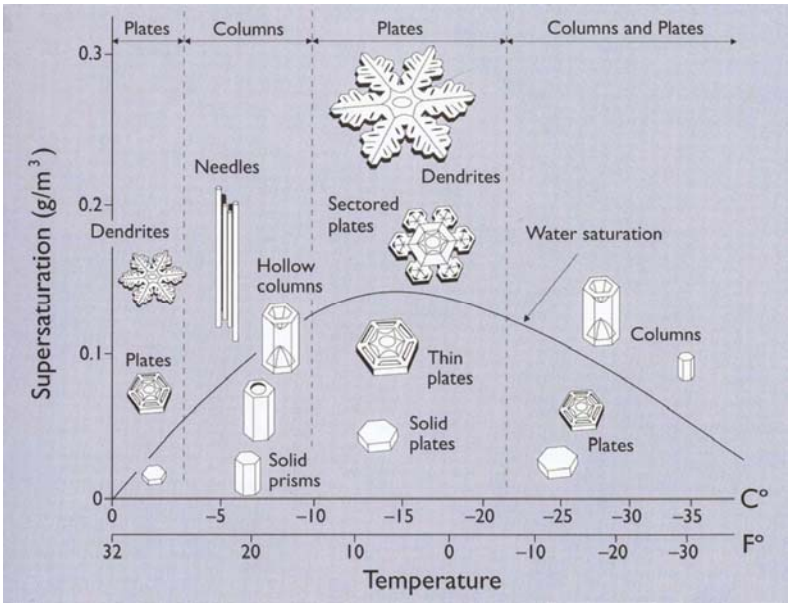
33. A separate but related decision is the choice of a suitable polymorphic form of the selected salt. Polymorphism is the ability of a solid material to exist in more than one form or crystal structure. Polymorphism is important in the development of pharmaceutical ingredients.

34. Salts can exist in amorphous or crystalline form. Salts can crystallize in a variety of shapes, depending on conditions like temperature, solvent, and degree of supersaturation, and some of the forms are preferable over others for pharmaceutical industry use.

35. Molecules can exist as crystalline solids in which a network of individual molecules form a lattice. The external shape that a crystal takes is referred to as the "crystal habit." As an example, consider when water freezes to form ice or snow. Depending on the conditions of crystallization, water can crystallize as plates, needles, columns, prisms, dendrites, or (the most common form of snow) irregular crystals that are small and clumped together.

36. Meteorologists can predict, based on atmospheric conditions, what type of snow to expect (*e.g.*, dry powder versus heavy/wet snow), as shown in Figure 1. Likewise, a chemist can often predict the expected crystal habit, or properties of a crystal habit, in the laboratory.

Figure 1: Snow crystal habit as a function of temperature and the supply of water vapor in clouds where the crystals grow (supersaturation), from Ken Libbrecht's Field Guide to Snowflakes, Voyager Press, 2006



37. In selecting a pharmaceutical form, the goal is to identify a physical form of the active pharmaceutical ingredient that handles well and performs consistently as larger and larger batches of material are prepared and stored. Criteria include room temperature stability (*i.e.*, the form will not change while being stored), hygroscopicity, friability, and dissolution rate, as well as properties relating to how well the materials can be formulated as a tablet. Other practical considerations, given the goal of large scale mass production, include flow properties (static nature), compressibility, bulk density, and particle size.

38. Forms with inherently poor properties would not be chosen for development. Instead, more appropriate forms would be selected or engineered.

39. Needle-shaped crystals, which are long and very thin as their name implies, are often the first products of supersaturation. Well before the early 1990s it was known in the industry that needle-shaped crystals are very difficult to handle both in the laboratory and in commercial production due to the slow filtration and flow problems associated with the needle

shape: needles behave like fiberglass, glass wool insulation, or cotton candy. Imagine pouring cotton candy into a hopper; one would not expect it to flow like sand.

40. Any trained pharmaceutical formulation chemist developing a new product in the 1990s would have known that a needle-shaped crystal would not be acceptable and would have chosen a non-needle form if one was observed, or sought a non-needle form by standard laboratory procedures.

41. If a non-needle form had not yet been observed, scientists convert existing needle forms by modifying the crystal habit. Chemists routinely modify crystal habits by varying temperature and degree of supersaturation, solvent, nucleation, and mechanical means. Often, needle-forms are converted to more dense plates by suspending needles in a solvent and stirring overnight.

42. Any trained pharmaceutical formulation chemist developing a new product in the 1990s would have been motivated to prepare a form of the compound that was stable, with good flow properties, and suitable for mass production.

43. A trained pharmaceutical formulation chemist developing a new product in the 1990s would have perceived a reasonable expectation of success in making a non-needle form in light of the prior art.

2. Patent Protection for New Drugs

44. There is a predictable pattern to the way brand drug companies develop their patent portfolios for blockbuster drugs. The first group of patents in the brand drug company's portfolio for the drug may reflect a genuine technological breakthrough that may later contribute to the success of the drug; these initial patents usually cover the active compound in a prescription drug or a particular pharmaceutical composition, and are correspondingly robust.

45. After filing applications for the original patents, the company continues its research and development efforts to develop a drug product that could, eventually, be approved by the FDA. As the company's research matures, the patent filings continue, often for narrow modifications relating to specific formulations (*e.g.*, for a specific salt, extended dissolution profile, or enantiomer), methods of using the drug, or processes for creating the drug product disclosed in the original patent filings. But the original patent filings are now in the "prior art" and thus limit the scope of follow-on patents that can legitimately be obtained. New patents can be obtained for features of the drug only if the brand drug company can show that the new features are non-obvious improvements over the growing body of prior art, which includes patents and printed publications, among other things. Often, methods of using the earlier invention are disclosed by the earlier compound or composition patent. To lawfully acquire one of these secondary patents, the patentee must disclose to the Patent Office all material prior art so as to assure that the application for the secondary patent is not just an effort to gain a patent for a modification that would be obvious to a person skilled in the art from reading disclosures already publicly available.

46. Patents present, at minimum, obstacles for would-be generic competitors to design around. Some patents broadly cover a drug's active ingredient and – if valid and enforceable – may prove impossible to design around while meeting the FDA's criteria forgeneric equivalence. While approved generic versions of the brand product may be able to enter the market before all patents expire, once all the valid patents covering its blockbuster drug have expired, the brand drug company has no lawful means of preventing competitors from entering the market.

47. Therefore, a typical patent portfolio for a brand drug has its most significant patent issuing first; later, secondary patents are (and should be) more difficult to obtain. Even if the secondary patent is obtained, these later-issuing patents are more vulnerable to attack as invalid for covering subject matter that is old or obvious. They may also be relatively easy to design-around, and thus not infringed.

48. In patent cases, prior art may include items that were publicly known or used or offered for sale, publications, or patents that disclose the claimed invention or elements of the claimed invention. To be prior art, the item or reference must have been published, patented, generally known, offered for sale, or publicly used either before the invention was made or before the filing date of the priority patent application.

49. A patent is obvious if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

50. When developing a new drug, often the need arises to improve or modify an aspect of the active ingredient, and a formulation chemist can look at how other prior art items that had the same need were addressed. In the pharmaceutical field, various problems and their solutions have been well documented. If the ingredient is not very soluble (and hence hard to absorb), there are well-known techniques for making it soluble: changing the associated salt of the drug, or formulating it using some carrier or vehicle. New salts and/or polymorphic forms can always be made or attempted. However, when the evidence shows that a skilled chemist at the time would simply have made an already-known pharmaceutically-acceptable salt of

whatever active ingredient with which he or she was working at the time, the "new" associated salt or form of the drug is obvious and non-patentable.

3. FDA Approval of New Drugs

51. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a branded drug manufacturer obtains FDA approval to market a drug product by filing a New Drug Application ("NDA").[1]

52. The FDA may not approve an NDA if the data and test results provided fail to show that the drug is safe or if there is a lack of substantial evidence that the drug will be effective to treat the conditions suggested in the proposed labeling. The FDA approves new drugs based on their ability to satisfy the minimum regulatory requirements, *i.e.*, show that they are safe and effective to treat a particular indication. New drug applicants are not required to, and usually do not try to, show that their new drug product is better than other similar, already approved, products.

4. Brand Companies List Patents in the FDA's "Orange Book"

53. To notify other drug manufacturers about potential proprietary intellectual property claims for newly approved drugs, a manufacturer of a new drug product must tell the FDA about patents that it believes cover its drug products. The FDA publishes a list of those patents and the corresponding drugs in the publicly-available compendium, *Approved Drug Products with Therapeutic Equivalence Evaluations,* commonly known as the "Orange Book." Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. Once patents are listed in the Orange Book, potential generic competitors are on notice regarding the patents that are claimed to relate to the brand-name drug.

[1] 21 U.S.C. §§ 301–392.

54. The brand-name drug manufacturer can list its patents in the Orange Book by filing a Form 3542 with the FDA. Under the FDA rules, the branded manufacturer is only permitted to list patents that are *reasonably enforceable*. Form 3542 expressly asks the applicant whether the drug presents a "No Relevant Patent" situation (*i.e.*, a situation where there are no patents that could be *reasonably asserted* in an infringement lawsuit). Form 3542 likewise requires the signatory to affirm, under penalty of perjury, that all the patent information submitted to the FDA on each patent that claims the drug substance, drug product, or method of use that is the subject of the approved NDA or supplement is complete and accurate.

55. The FDA relies completely on the manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's representations. The FDA performs only a ministerial act in listing the patents identified by the manufacturer in the Orange Book.

B. The Regulatory Structure for Approval of Generic Drugs

1. Congress's Effort to Get Generics to Market Sooner

56. In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments were designed to speed introduction of low-cost generic drugs to market by permitting generic manufacturers to file abbreviated new drug applications (ANDAs) relying on the scientific findings of safety and effectiveness included in the brand-name drug manufacturer's original NDA. The FDA requires only a showing that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand-name drug. The premise – codified by Congress and implemented by the FDA for the past thirty years – is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, and are absorbed into the bloodstream at a similar rate over a similar period of time, are expected to be equally safe and effective.

57. At the same time, the Hatch-Waxman Amendments sought to protect pharmaceutical companies' incentives to create new and innovative products, by, among other things, permitting a brand company to file a legitimate patent infringement lawsuit against a generic manufacturer before the generic actually brought its product to market.

58. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand-name pharmaceutical companies. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of prescriptions. By 2013, total prescription drug revenue had soared to over $329 billion, with generic drugs accounting for 84% of prescriptions filled.

2. Hatch-Waxman Encourages Generics to Challenge Questionable Patents

59. The Hatch-Waxman Amendments also created a mechanism to resolve patent disputes between brand and generic manufacturers before generic products launched, in the hopes of resolving patent challenges in advance of the generic launch (so that generic launch is not unnecessarily delayed while patent squabbles play out). The Amendments permit a brand manufacturer to sue a generic manufacturer for patent infringement even if their proposed ANDA product has not launched yet.

a. Paragraph IV Certifications

60. Once one or more patents are listed in the Orange Book for a particular drug, to obtain FDA approval of an ANDA a generic manufacturer must certify that the proposed generic drug will not infringe any of those patents. A generic manufacturer can make one of four certifications:

i. that no patent for the brand-name drug has been filed with the FDA;

ii. that the patent for the brand-name drug has expired;

iii. that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date; or

iv. that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV" certification).

61. If a generic manufacturer files a Paragraph IV certification, a brand-name manufacturer can sue the ANDA applicant for patent infringement immediately. If the brand-name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification ("Hatch-Waxman Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA cannot authorize the generic manufacturer to go to market with its product.

62. If a brand company sues a generic company for patent infringement in response to receiving a Paragraph IV certification, the generic company may defend itself by showing (i) that the asserted patent is invalid or unenforceable or (ii) that the generic product does not infringe the patent.

63. Patents are not bulletproof. To the contrary, patents are routinely invalidated, either upon reexamination by the PTO, by court decision, or by jury verdict. In the pharmaceutical and biotechnology field, for example, more than 60% of patents challenged between 1995 and 2013 have been invalidated. And, in the context of Hatch-Waxman litigation, generic companies have succeeded in about half of all ANDA litigations resulting in a judicial decision or jury verdict between 2006 and 2013.

b. Tentative Approval

64. When an ANDA otherwise meets the substantive requirements for approval, but cannot receive effective approval because of pending Hatch-Waxman litigation or some form of exclusivity (*e.g.*, a 30-month stay, an unchallenged patent, or another marketing exclusivity), the FDA may grant the application "tentative approval."[2]

65. To receive tentative approval, an ANDA must meet all of the requirements for approval generally; that is, the *only* barrier to outright approval must be the pendency of litigation or an exclusivity period.[3] Therefore, an ANDA may not receive tentative approval if, for example, bioequivalence has not been shown, or if the manufacturer's compliance with current Good Manufacturing Practices (cGMP) has not been established.

66. An ANDA that has received tentative approval may not legally be marketed until the FDA issues a final approval letter.[4]

3. Hatch-Waxman's "First-to-File" Incentive

67. Pursuant to the Hatch-Waxman Amendments, the first generic manufacturer to file an ANDA containing a Paragraph IV certification (discussed in Paragraphs below) receives 180 days of market exclusivity. This means that other generic manufacturers will not be able to launch their own generic products for at least six months after the first generic – known as the "first filer" – launches its product.[5]

68. During the exclusivity period, the first filer is the only ANDA-approved generic manufacturer permitted on the market. As recognized by the Supreme Court, it is often the case

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[2] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); 21 C.F.R. § 314.107(b)(3)(v).

[3] 21 U.S.C. § 355(j)(5)(B)(iv)(dd)(AA).

[4] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB); 21 C.F.R. §§ 314,105(d), 314.107(b)(3)(v).

[5] The "exclusivity" label is a bit of a misnomer because, while later ANDA-approved generic makers must wait six months after the first filer's market entry for FDA approval, a brand's "authorized" generic, marketed under the authority of the brand manufacturer's NDA, may enter at any time.

that most of a first filer's profits with respect to an ANDA product are earned during the exclusivity period.[6]

69. If the only versions of a drug on the market are the brand and the first filer's product, then the first filer prices its product below the brand product, but not as low as if it were facing competition from other generics. Because the branded company does not drop the brand price to match the first filer, the first filer does not face the degree of price competition it will when additional generic products are available.

4. The Hatch-Waxman Scheme is Subject to Abuse

70. The Hatch-Waxman regulatory scheme was intended to incentivize early generic entry to market. But brand and generic companiesbegan abusing this scheme through collusive agreements and other unlawful tactics. Recognizing that the Hatch-Waxman scheme imposed no penalty on a first-to-file ANDA applicant that delayed coming to market, brand-name companies would simply pay generic companies to stay off the market.

71. Generic companies holding first-to-file exclusivity would leverage their first-to-file status into a large payment from the brand company, often substantially delaying the timely appearance of generic drugs in the marketplace.

72. To prevent this abuse, Congress amended the FDCA, passing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA").[7] The MMA codified the FDA's long-standing practice of issuing tentative approval for generic drugs ensnared in litigation. And it enumerated conditions under which a first-to-file ANDA applicant may forfeit its 180 days of exclusivity. Congress added these provisions in an effort to "ensure

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[6] *See Federal Trade Comm'n v. Actavis*, 133 S. Ct. 2223, 2229 (2013).

[7] Pub. L. No. 108-173, Stat. 2066 (Dec. 8, 2003).

that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition."[8]

73. A first-to-file generic applicant forfeits its 180-day exclusivity if: (1) it fails timely to market the drug; (2) it withdraws the ANDA, or the FDA constructively withdraws it on the manufacturer's behalf because "the application does not meet the requirements for approval"; (3) it amends or withdraws its Paragraph IV certification; (4) it fails to obtain tentative approval "within 30 months after the date on which the application is filed";[9] (5) it enters into an anticompetitive agreement with another applicant; or (6) all valid patents over the brand version of the drug expire.[10]

74. As a result of the MMA, to preserve its 180-day exclusivity period, a generic applicant generally must obtain at least tentative approval within 30 months of the date the ANDA was filed. The FDA may grant exceptions to this deadline in special circumstances.

75. The brand company may file patent infringement claims more than 45 days after receiving the Paragraph IV certification, but doing so does not trigger the automatic 30-month stay of approval.

5. The Patent Information Submission

76. Because, under most circumstances, the FDA cannot authorize marketing a generic drug that would infringe a patent, the timing of an ANDA's approval depends on the scope and duration of the patents covering the brand-name drug.[11]

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[8] 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer).

[9] A narrow exception to this condition exists where "the failure [to obtain tentative approval within 30 months] is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed." 21 U.S.C. § 355(j)(5)(D)(i)(IV).

[10] 21 U.S.C. § 355(j)(5)(D)(i)(I)-(VI).

[11] *See* 21 U.S.C. § 355(j)(2)(A)(vii)-(viii).

77. The FDA does not have the resources or authority to independently ascertain a drug's relevant patents and verify their validity and preclusive scope. The FDA instead relies completely on branded drug manufacturers to submit such information.

78. Under the Hatch-Waxman Amendments, brand manufacturers can only submit to the FDA the patent number and expiration date on a patent when the patent (1) "claims the drug for which the application was submitted or which claims a method of using such drug" and (2) "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."[12] Notwithstanding the propriety of the brand's patent submission, the FDA is obliged to publish the information in the "Orange Book."[13]

79. The brand drug's patent information in the Orange Book is meant to serve as a frame of reference for ANDA applicants, who must assure the FDA that their generic drug will not infringe any patent. An ANDA applicant provides this assurance by providing one of the four certifications mentioned in paragraph 60 above. But, the Paragraph IV Certification is the only certification among the four that would enable the generic to come to market before a listed patent's expiration date.

80. When a generic certifies under Paragraph IV, the patent statute treats such a filing as itself an act of infringement, which gives the brand an immediate right to sue, citing 35 U.S.C. § 271(e)(2)(A). If the brand files suit within 45 days after receiving notice of the ANDA applicant's Paragraph IV certification, the suit triggers an automatic stay of FDA approval of the

[12] 21 U.S.C. § 355(b)(1)(G).

[13] If a patent is obtained after an NDA is approved, the NDA applicant can submit the patent information to the FDA within 30 days of the date of issuance of the patent. *See* 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53(d)(3).

ANDA for 30 months – a rough practical equivalent of an automatic preliminary injunction.[14] Furthermore, the Hatch-Waxman Amendments provide the first ANDA filer containing a Paragraph IV Certification with a coveted 180 day-exclusivity; that is, the FDA will not approve an ANDA with a later-filed Paragraph IV Certification to the same patent as an earlier-filed ANDA for at least 180 days after the first commercial marketing of the drug under the first ANDA, provided there is not a forfeiture of exclusivity as defined under the statute.

81. When a brand manufacturer's 30-month stay or a first ANDA filer's 180-day exclusivity have yet to lapse (and have not been forfeited), a subsequent ANDA filer otherwise entitled to final marketing approval from the FDA cannot enter the market and thus may only be afforded "tentative approval."

82. The statute is clear, however, that a generic's 180-day exclusivity and a brand's 30-month stay apply only vis-à-vis ANDAs containing Paragraph IV certifications. If an ANDA applicant is seeking immediate approval without having to certify under Paragraph IV, there is no 30-month stay and the FDA can approve the ANDA without regard to whether any other ANDA applicant is otherwise entitled to a 180-day exclusivity period.

83. There can thus be significant regulatory and competitive consequences that flow from a brand's listing of a patent in the Orange Book that would require an ANDA applicant to maintain a Paragraph IV certification as a condition to obtaining final marketing approval.

6. Abuse of the Hatch-Waxman Scheme is Both Illegal and Widespread

84. Brand manufacturers have enormous incentives to use patents to unlawfully forestall generic entry. Several anticompetitive practices are all too often used.

[14] 21 U.S.C. § 355(j)(5)(B)(iii).

85. For example, a brand-name manufacturer lists a patent in the Orange Book not eligible for listing (*e.g.*, because it does not actually cover the drug, because it was obtained by fraud, etc.). The brand company then files a sham lawsuit, accusing a generic company of infringing the patent that should not have been listed in the first place.

86. According to the Federal Trade Commission ("FTC"), brand-name manufacturers began exploiting this feature of the Hatch-Waxman Amendments starting in the late 1990s.[15] In its 2002 report, the FTC found that brand manufacturers inappropriately submitted patents for listing in the Orange Book when, for example, there was no reasonable basis to believe the patent could be asserted in patent litigation and withstand a challenge to its validity, enforceability, or preclusive scope.[16] Indeed, the report found that generic manufacturers prevail in Paragraph IV litigation in nearly three-quarters of all such cases involving a decision by the court, by obtaining a judgment of invalidity or non-infringement.

87. But brand manufacturers know that they need not win the patent lawsuit to obtain the desired anticompetitive result – they just need to file it. By suing the generic for infringement, the brand immediately accomplishes two things: first, it triggers the 30-month stay, and ensures that the FDA cannot approve a generic for two-and-a-half years. Second, it creates the possibility of "settling" the sham lawsuit; a settlement may or may not run afoul of the antitrust laws (discussed below), but no settlement would exist without the sham lawsuit.

88. As another example of how the Hatch-Waxman scheme can be manipulated, brand-name and first-filer generic manufacturers sometimes agree to "settle" the Paragraph IV litigation with an exclusion payment: the brand manufacturer pays the first-filer generic

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[15] *See generally* FTC, Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002) (Generic Drug Entry) (discussing manufacturers' anticompetitive behavior); *Caraco*, 132 S. Ct. at 1678 (explaining the FTC study).

[16] 21 U.S.C. § 355(b)(1)(G).

manufacturer to stay off the market, thus (a) withdrawing that competitive threat from the market, and (b) at times, "bottlenecking" approval for other would-be generic competitors. The unlawful preservation of the enormous, monopoly profits enjoyed by brand-name manufacturers provides ample revenue to permit the brand-name manufacturers to share some of their profits with the conspiring generic competitors, rather than having the total revenues available for both parties lessened by the falling prices that generic competition would engender.

C. The Competitive Effects of AB-Rated Generic Competition

89. Generic versions of brand-name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand-name counterparts. The only material difference between generic drugs and their corresponding brand-name versions is their price.

90. Because generic versions of a corresponding brand drug product are commodities that cannot be differentiated, the primary basis for generic competition is price. Typically, generics are at least 25% less expensive than their brand-name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings to all drug purchasers.

91. Since the passage of Hatch-Waxman, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic equivalent hits the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the

market within the first six months. This results in a loss of revenue for the brand drug company, but dramatic savings for the American public.

92. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85%. As a result, competition from generic drugs is viewed by brand-name drug companies, such asNovartis, as a grave threat to their bottom lines.

93. Generic competition enables purchasers to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

94. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as Novartis, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible – including illegal means.

1. The First AB-rated Generic is Priced Below the Brand

95. Experience and economic research show that the first generic manufacturer to launch prices its product below the prices of its branded counterpart. Every state either requires or permits a prescription written for the brand drug to be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the branded form of the molecule. At the same time, there is a reduction in average price paid for a prescription for the molecule.

2. Later Generics Drive Prices Down Further

96. When multiple generic competitors enter the market, competition accelerates and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.

97. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic launch results in a near-term retail price reduction of at least 10%, but that with two generic entrants near term retail price reduction is about 50%.

98. Soon after generic competition begins, the vast majority of the sales formerly enjoyed by the brand shift to generic sellers. In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the prices paid prior to generic entry. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.

V. FACTS

A. The 1950s – 1970s Facts

1. Scientists Discovered the Philadelphia Chromosome

99. Chronic myeloid leukemia (CML) is a cancer of the blood and bone marrow in which the body produces cancerous white blood cells. In 1959, the disease was universally fatal. Most patients died within six years of their diagnosis.

100. In 1959, a scientist at the University of Pennsylvania looked at a cell of a person with CML under a camera-equipped microscope – a hot commodity in the late 1950s – and

noticed that one chromosome, chromosome 22, was shorter than it should be. Stubby, even. A piece was simply missing.

101. Blood samples from six other CML patients had the same chromosomal abnormality. What now is taken for granted was, back then, a radical observation: a form of cancer was correlated with an abnormal chromosome.

102. A year later, in 1960, the scientist and a colleague published three short paragraphs – 300 words – describing their discovery of what later came to be called "the Philadelphia chromosome."

2. Swiss Drug Companies Ciba and Geigy Merged

103. In 1970, two Swiss drug companies merged to create Ciba-Geigy Ltd., a predecessor to defendant Novartis.

3. Scientists Linked Genetic Mutations, Kinases, and Cancer

104. In 1972, a scientist at the University of Chicago noticed that the missing piece of chromosome 22 had attached itself to chromosome 9. The DNA wasn't missing; it had moved. The movement was later referred to as "translocation."

105. In 1978, a post-doctoral researcher at the University of Dundee in Scotland, Nick Lydon, learned from some scientists who worked down the hall that a cancer-causing gene (not the Philadelphia chromosome) encoded a form of protein called a kinase. Kinases work by picking up one phosphate from an adenosine triphosphate ("ATP") molecule (found floating inside living cells). The addition of that phosphate turns on the protein, and it starts doing whatever it is supposed to do. Once it is done with its work, a different protein takes away the extra phosphate, and the kinase goes dormant.

B. The 1980s Facts

1. Scientists Discovered that the Philadelphia Chromosome Encodes the Bcr-Abl Kinase

106. In 1984, researchers at the University of California Los Angeles discovered that cells from a CML patient contained a tyrosine kinase, a type of protein that serves as an on/off switch for cellular processes, stuck in the "on position." Meaning, the tyrosine kinase began kept on plucking up phosphates from ATP molecules, kept growing, and never turned off.

107. Also in 1984, scientists in Holland found that the Philadelphia chromosome translocation creates a fused gene that encodes a tyrosine kinase, Bcr-Abl.

108. So by 1984, it was known that the Philadelphia chromosome brought Bcr and Abl together, this fusion gene created a fusion protein, the fusion protein got stuck in a loop, and the continuous loop continuously triggered the excessive production of white blood cells. There was no proof that the always-on kinase caused CML, but a number of cancer researchers were thinking it might.

2. Ciba-Geigy Starts Studying Kinases

109. In the summer of 1984, Nick Lydon, then at Schering, read about the new research relating to tyrosine kinases. Right around the same time, a former colleague of Lydon's – now at Ciba-Geigy – called to offer Lydon a chance to work with him on a new kinase inhibitor program.

110. Though Ciba-Geigy had shut down its cancer research programs in the early 1980s (executives had concluded that the returns did not justify the required investment), the company agreed to fund a new kinase inhibition program and a specific laboratory to study tyrosine kinases. The proposal approved by Ciba-Geigy was likely the first effort to design a drug to treat a specific target (a process sometimes known as "rational drug design," as it begins

with the hypothesis that modulation or modification of a specific biological target may have therapeutic value).

111. At the time, cancers were treated with chemotherapy drugs that "carpet bombed the body in the hopes of hitting cancer cells." In contrast, the Ciba-Geigy scientists, helmed by Lydon, set out to design a compound to shut down the specific overfiring kinase. The goal was to create a medication that would grab on to the misfunctioning kinase – in effect, covering it – and prevent it from picking up phosphates from ATP molecules (thereby preventing it from sparking the overproduction of white blood cells). The key was to design a drug that perfectly interlocked with all the nooks and crannies of the kinase.

112. By late 1985, the project included a group of chemists and a group of biologists (overseen by Lydon) working together to study anti-kinase activity.

C. The 1990 Facts

113. Chemist Jurg Zimmermann began working on making kinase inhibitors at Ciba-Geigy in 1990. At that point, the biologists (including Elisabeth Buchdunger) tested Zimmerman's candidates. When the chemists managed to create a compound that was both selective (targeting one form of kinase only) and sufficiently potent, they gave it to the biologists. The biologists then tested the candidate to see if it could cause the death of cancer cells. To be considered a drug candidate, a compound had to be selective, potent, and active.

114. Also in 1990, a scientist in a lab in Baltimore conducted experiments in mice that proved the Philadelphia chromosome was the sole cause of CML. This discovery made CML a perfect test case for rational drug design: if a patient took a Bcr-Abl kinase inhibitor and his cancer stopped progressing, the scientists would know that the drug was responsible for the improvement because there were no other confounding variables.

115. Brian Druker, an oncologist working at the Dana Farber Cancer Clinic in Boston had been following the Ciba-Geigy team's work on CML and the signaling pathway triggered by the Bcr-Abl kinase through his friendship with Nick Lydon. Druker and Lydon shared a keen interest in the Bcr-Abl kinase and its role in CML.

116. But in 1990, Dana Farber entered into an agreement with then Ciba-Geigy rival Sandoz that forbid Druker from reaching out to or otherwise collaborating with Lydon.

D. The 1992 Facts

1. Ciba-Geigy Developed CGP 57148, a Bcr-Abl Kinase Inhibitor

117. In or around 1992, Zimmermann and the other Ciba-Geigy cancer scientists developed a compound that seemed to inhibit the activity of the Bcr-Abl kinase.

118. When biologist Buchdunger observed the activity of the compound, she saw that it had strong activity against Abl.

119. The Ciba-Geigy chemists started with an already existing chemical called 2-phenylaminopyrimidine, a compound with anti-inflammatory effects. When tested against protein kinase C ("PKC") (one of the three kinases the company was originally targeting), the biologists observed that the protein was blocked but the effect was weak; it would have required massive doses that were impractical. So the chemists added a 3'-pyridyl molecule, and the biologists observed that it blocked the kinase more effectively. Next, the chemists added a benzamide group, and the biologists saw that the molecule was even more active against multiple kinases – including Abl, part of the kinase involved in CML. Finally, the chemists added a flag methyl, a portion of a methyl group, in the middle of the compound's "backbone." They named the resulting compound "imatinib," and referred to it by its code name: "CGP 57148."

120. The Ciba-Geigy team synthesized a number of different salt forms of the CGP 57148 compound, including the methane sulfonate acid addition salt. They referred to this as

"imatinib mesylate" and/or "CGP 57148B." The final molecular formula for the mesylate salt form was 4-[(4-methyl-1-piperazinyl) methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl] amino]-phenyl]benzamide methanesulfonate.

121. In or around this time, the Ciba-Geigy team also determined a polymorphic form to be used for imatinib mesylate.

2. Ciba-Geigy Developed the Mesylate Salt Form, Called CGP 57148B

122. As described above, pharmaceutical companies employ salt forms of chemical substances to modify important characteristics such as aqueous solubility, dissolution rate, solution pH, crystal form, hygroscopicity, chemical stability, melting point, and even mechanical properties. The benefits of using salt forms as active pharmaceutical ingredients are well known to increase the solubility of otherwise intractable substances, and hopefully to increase bioavailability.

123. According to Ciba-Geigy, under some conditions the methanesulfonic acid addition salt of imatinib forms as needle-shaped crystals. As described above, a needle-shaped form is not optimal for drug development as the needles often make it quite difficult to perform various formulation and manufacturing steps due to difficulties of slow filtration and flow. (It is not known what the Ciba-Geigy chemists called the needle-shaped form of methanesulfonic acid addition salt of imatinib at that time; in a much later patent application they would refer to it as the "α-crystal" form).

124. Addressing an undesired polymorphism is a not uncommon step in pharmaceutical development, and in the 1990s known techniques were available to obtain a different, more desirable crystal shape. The handling problems of "needle" forms of crystalline materials would have made searching for and choosing a non-needle form of a crystal obvious to any person skilled in the art in the early 1990s. And there was nothing about the structure or

composition of methanesulfonic acid addition salt of imatinib that would have dissuaded a person skilled in the art not to seek to use known techniques to obtain a more desired crystal form.

125. The Ciba-Geigy chemists developed a non-needle shaped crystal form methanesulfonic acid addition salt of imatinib. Apparently they used at least one of two known techniques. In one, a crystal or amorphous form of the methanesulfonic acid addition salt of imatinib is digested with a suitable polar solvent (usually methanol) in a suspension. In the other, a crystal or amorphous form of the methanesulfonic acid addition salt of imatinib is dissolved in a polar solvent (usually methanol) at a suitable heated temperature up to the reflux temperature of the reaction mixture, and then initiating crystallization by adding a small amount of the non-needle form as seed crystal to the supersaturated solution.

126. The development of the non-needle form of the methanesulfonic acid addition salt of imatinib involved routine steps, employed with a known goal, and arrived at an expected result of achieving a non-needle shaped form. There was no unusual skill or undue degree of experimentation required to discover the non-needle form of the methanesulfonic acid addition salt of the compound. The resultant characteristics of a non-needle shape (better flow, less hygroscopic, and potentially more stable) were the desired and expected features of such a polymorphic form.

127. After development of the non-needle form methanesulfonic acid addition salt of imatinib, it appears that Ciba-Geigy terminology simply used “CGP 57148” or “CGP 57148B” or “imatinib mesylate” or “methanesulfonic acid addition salt of imatinib” to refer to methanesulfonic acid addition salt of imatinib in the non-needle crystal form; those terms were not used for the imatinib mesylate in any other polymorphic forms. (In a much later patent

application, Novartis would refer to the non-needle shape as the "β-crystal" form of imatinib mesylate). This complaint uses the Ciba-Geigy terminology, *i.e.*, the imatinib mesylate salt is always presumed to be in the non-needle shape unless otherwise indicated.

128. The compound imatinib mesylate, the mesylate salt form of imatinib (later given the tradename Gleevec), is a heterocyclic tyrosine kinase inhibitor which contains basic nitrogen functional groups.

129. In or around early 1992, Ciba-Geigy scientists concluded that the results of tests showed that the CGP 57148 compound was potent, selective, and cellularly active against Abl.

3. Ciba-Geigy Applied for a Swiss Patent

130. On April 3, 1992, Ciba-Geigy filed Swiss patent application 1083/92 for imatinib (CGP 57148) and its salts.

131. Subsequently, on October 1, 1993, Ciba-Geigy filed a second Swiss patent application, number 2966/93, which was also for imatinib and its salts, including the mesylate salt. In describing salt forming groups of the compound, the application refers to methane-sulfonic acid.

132. The Swiss patent application came into the public domain on October 6, 1993 with publication of European equivalent patent EP-A-O 564409.

E. The 1993 – 1994 Facts

1. Druker Tests CGP 57148B in CML Cells

133. In 1993, shortly after deciding to leave Dana Farber, Druker called Lydon and asked whether the Ciba-Geigy group had any Bcr-Abl kinase inhibitors. Lydon told Druker that they had a candidate with strong activity against Abl. The candidate had only been screened against Abl, the naturally occurring enzyme, and not against the fused Bcr-Abl protein that

existed inside CML cells. Lydon asked Druker if Druker wanted to test the candidate in CML cells.

134. In or around August 1993, Druker's new laboratory at Oregon Health Sciences University received samples of CGP 57148B (*i.e.*, imatinib mesylate) and three other compounds from Ciba-Geigy, and began testing those compounds.

135. In February 1994, Druker reported to the Ciba-Geigy team that his test results showed that CGP 57148B inhibited 90% of CML cells in vitro. Druker also informed Lydon, Zimmerman, Buchdunger, and others that the compound was killing only the cells with the Bcr-Abl kinase and not affecting the normal blood cells.

2. Ciba-Geigy Applied for a U.S. Patent that Claimed Imatinib, Including the Mesylate Salt Form

136. On April 28, 1994, Ciba-Geigy filed the first U.S. patent application for imatinib, numbered 08/234,889 ("the '889 application"), entitled Pyrimidine Derivatives and Processes for the Preparation Thereof, claiming priority to Swiss application 1083/92, and listing Zimmermann as the inventor.

137. The '889 application disclosed a number of N-phenyl-2-pyrimidine-amine derivatives, including imatinib in free base form, as well as pharmaceutically acceptable salts thereof, and their use as tumor-inhibiting agents.

138. The '889 application disclosed that "Compounds having at least one basic group [such as imatinib] . . . may form acid addition salts," and then, by way of example, named a number of acids that may be used to create suitable pharmaceutical salts.

139. The '889 application expressly stated that the compounds disclosed therein included their respective salts. In the specification, the application stated that "[o]wing to the close relationship between the novel compounds in free form and in the form of their salts,

including those salts that can be used as intermediates, for example in the purification of the novel compounds or for the identification thereof, hereinbefore and hereinafter *any reference to the free compounds should be understood as including the corresponding salts*, where appropriate and expedient."

140. The patent specification specifically referred to salts formed with methane sulfonic acid:

> Salt-forming groups in a compound of formula I are groups or radicals having basic or acidic properties. *Compounds having at least one basic group . . . may form acid addition salts*, for example with . . . *aliphatic sulfonic acids, such as methane-*, ethane- or 2-hydroxyethane-*sulfonic acid* . . . When several basic groups are present mono- or poly-acid addition salts may be formed.

141. Each of the 23 claims in the '889 application included – in addition to the free base form of the compound – the limitation "or a salt" or "or a pharmaceutically acceptable salt of such a compound having at least one salt-forming group."

142. Claim 21 of the '889 application specifically claimed imatinib and its salts, stating "a pharmaceutical composition for the treatment of tumours in warm-blooded animals including humans, comprising, in a dose effective against tumours, a compound of [imatinib] or a pharmaceutically acceptable salt of such a compound having at least one salt-forming group, together with a pharmaceutical carrier."

F. The 1995 Facts

1. Ciba-Geigy Submited Articles Disclosing their Discoveries

143. In or around 1994 or 1995, Druker and the Ciba-Geigy scientists submitted papers based on Druker's 1993-94 testing of imatinib mesylate to the journals *Science* and *Nature*. Both were rejected.

144. On July 31, 1995, Buchdunger, Zimmermann, Lydon, and Druker submitted an article to *Cancer Research* entitled, "Inhibition of the Ab1 Protein-Tyrosine Kinase in vitro and in vivo by a 2-Phenylaminopyrimidine Derivative." (The article was ultimately published in 1996, and is discussed below).

2. Druker Presented His Findings to the American Society of Hematology

145. On December 4, 1995, Druker gave a talk on CGP 57148 at the American Society of Hematology's 37th annual meeting in Seattle, Washington, entitled "Preclinical evaluation of a selective inhibitor of the Abl tyrosine kinase as a therapeutical agent for chronic myelogenous leukemia." Scientists from the Oncology Research Department of Ciba-Geigy Limited, Basel, Switzerland, were listed as co-authors of the study under discussion.

146. The presentation abstract particularly disclosed CGP 57148 as a "potent and specific inhibitor of the ABL protein tyrosein kinase" demonstrating "specific killing of the BCR-ABL expressing cells by CGP 57148" in vitro and in vivo, and concluded that the compound "may be useful in the treatment of CML and other BCR-ABL positive leukemias."

G. The 1996 Facts

1. Ciba-Geigy Discloses the Methane-Sulfonate Salt Form in *Cancer Research*

147. On January 1, 1996, *Cancer Research* published the article by Ciba-Geigy scientists Buchdunger, Zimmermann, Lydon, Druker, and others titled, "Inhibition of the Ab1 Protein-Tyrosine Kinase in vitro and in vivo by a 2-Phenylaminopyrimidine Derivative."

148. The article mentioned that Ciba-Geigy scientists had made a series of compounds that inhibited tyrosine kinases, and went on to describe a single compound, CGP 57148 (*i.e.*, imatinib) that showed potent inhibition of the Abl kinase associated with CML. CGP 57148 was one of the group of compounds covered by the pending '899 patent application.

149. Buchdunger went on to explain that Ciba-Geigy scientists had also synthesized a methane sulfonate salt form of CGP 571748, referred to as CGP 571748B: "CGP 571748 and its methane sulfonate salt (CGP 57148B) were synthesized by CIBA Pharmaceuticals Divisions, as will be described elsewhere," citing "J. Zimmerman, manuscript in preparation."

150. Importantly for these purposes, Buchdunger and her colleagues disclosed publicly that they had made a mesylate salt form of CGP 57148 sometime well before July 31, 1995 (the date the article was originally submitted).

151. Not only had they made the mesylate salt, the scientists used the mesylate salt form in all of the *in vivo* experiments described in the article: "All *in vivo* experiments were performed using CGP 57148B." Druker first began his *in vivo* experiments in and around August of 1993 and reported the preliminary results internally to Ciba-Geigy in February 1994, before Ciba-Geigy filed the '889 application (in April 1994).

152. The January 1996 *Cancer Research* article described preparation of the imatinib mesylate compound, storage of the compound, purification of the compound, and in vitro and in vivo testing of the compound. It reported that "CGP 57148 selectively inhibited the *in vitro* activities" of the kinase involved in CML, and that *in vivo* antitumor efficacy was obtained. It specifically suggested that the compound might be used in treatment of Philadelphia chromosome-positive leukemias.

2. Ciba-Geigy Discloses Crystalline Derivates and Typical Synthesis Processes in *Bioorganic & Medicinal Chemistry Letters*

153. Also in 1996, the British journal *Bioorganic & Medicinal Chemistry Letters* published an article by Zimmermann, Buchdunger, Lydon and others from Ciba-Geigy, entitled "Phenylamino-Pyrimidine (PAP) – Derivatives: A New Class of Potent and Highly Slective PDGF-Receptor Autophosphorylation Inhibitors." In that article, Zimmermann noted that the

phenylamino-pyrimidine compounds "show poor solubility in water . . . but are soluble under acidic conditions (4: HCl 0.1N = 3.3 g/l)," and noted, "The crystalline derivatives are slightly basic and are rather lipophilic."

154. In a footnote, the authors described a "typical synthesis" of the phenylamino-pyrimidine compounds, concluding "Filtration, evaporation and crystallization (methlenchloride) gave N-(3-amino-phenyl)-4-(3-pyridyl)-2-pyrimidinamine (9.3 g, 60.9%). A solution of this amine (9.3 g, 35.3 mMol) and benzoylchloride (7.57 g, 53.9 mmol) in pyridine (300 ml) was stirred at rt for 23 h. Evaporation and crystallization (dimethylformamide, water) gave 2.37 g (18.3 %) of l as a yellowish solid."

155. In 1996, the existence of crystalline derivatives and "evaporation and crystallization" as part of the "typical synthesis" process were so routine as to be relegated to a footnote.

3. Ciba-Geigy and Sandoz Merged to Create Novartis

156. In March of 1996, Ciba-Geigy and Sandoz merged to form Novartis, then one of the largest corporate mergers in history.

157. As a result of the merger, the naming conventions for investigative drugs changed. CGP 57148B (*i.e.*, imatinib mesylate) was re-named STI-571, but the compound itself was unchanged.

158. Upon information and belief, from early preclinical testing through the subsequent clinical testing in human subjects, STI-571 has maintained the same chemical formula, structure, and polymorphic form. All clinical trials of STI-571 used the non-needle β-crystal salt formulation of imatinib methylsulfate.

159. The Ceiba-Geigy scientists used known methods to create the β-crystal form of imatinib methylsulfate.

4. Ciba-Geigy Published More About its Discovery in *Nature Medicine*

160. On May 1, 1996, *Nature Medicine* published an article by Druker, Buchdunger, Zimmermann, Lydon, and others entitled "Effects of a Selective Inhibitor of the Abl Tyrosine Kinase on the Growth of Bcr-Ab1 Positive Cells," detailing the design of CGP 57148 and its effect of selectively inhibiting proliferation of Bcr-Abl expressing cells in vitro and in vivo. It described the preclinical studies of the compound and demonstrated that CGP 57148 selectively inhibits the proliferation of the BCR-ABL expressing cells both in vitro and in vivo.

5. The Compound Patent Issued, Protecting Gleevec until July 4, 2015

161. On May 28, 1996, the '889 application issued as U.S. Patent No. 5,521,184 ("the '184 Patent," "the Zimmermann Patent," or "the compound patent"), and was assigned to Ciba-Geigy.

162. Jurg Zimmermann was the sole inventor listed.

163. Novartis listed the '184 patent in the Orange Book.

164. Novartis Corporation is the current assignee of the '184 patent.

165. With extensions (discussed later), the Zimmermann patent protects imatinib mesylate (later brand-named Gleevec) from competition for nineteen years and one month, from May 28, 1996 through July 4, 2015.

H. The 1997 - 1998 Facts

1. Novartis Published Another Article, in *Bioorganic & Medicinal Chemistry Letters*

166. In early 1997, *Bioorganic & Medicinal Chemistry Letters* published a second paper by Zimmermann, Buchdunger, and others from Ciba-Geigy's Oncology Research Department entitled "Potent and Selective Inhibitors of the Abl-Kinase: Phenylamino-Pyrimidine (PAP) Derivatives."

167. The article had been submitted for publication on August 21, 1996. It described development and optimization of the new class of phenylamino-pyrimidine (PAP) derivatives that yielded highly potent and selective Bcr-Abl kinase inhibitors.

168. Notably, the article specifically advised that, in one particular series of the PAP derivatives, "improvement of the aqueous solubility can be accomplished by attachment of a salt forming group on the indole side chain." The article suggested that the compound might be a development candidate for use in treatment of Philadelphia chromosome-positive leukemias.

2. Novartis Filed a New Swiss Patent Application for the Mesylate Salt and Beta-Crystal Form

169. Apparently sometime after the 1996 formation of Novartis, discussions within that organization looked into the existing patent protection for its current portfolio, or at least did so for imatinib mesylate. At the time, Novartis had patent protection for the imatinib compound generally, including pharmaceutically acceptable salts, and among those the mesylate. It knew that the scientists who invented imatinib had not only written articles about it, but that those articles had also publicly disclosed the specific salt form, imatinib mesylate. And they knew that the polymorphic form of that salt, the non-needle form, was either inherent in imatinib mesylate or had been achieved using common formulation techniques resulting in charateristics expected of a non-needle form of the salt.

170. Despite all of this, Novartis proceeded to seek a follow-on, secondary patent for imatinib mesylate. Although it already had a patent that covered imatinib and its salts, Novartis sought a further patent, this time for the mesylate salt of imatinib in a non-needle crystal form. In seeking the follow-on polymorph patent, Novartis was attempting to extend its patent protection on the imatinib mesylate molecule beyond the life of the compound patent. If successful, Novartis might be able to delay entry of generic competition, maintaining its

monopoly on imatinib mesylate longer that it would otherwise be entitled, and cause U.S. drug purchasers to pay for a longer period of time the significantly higher price for the drug.

171. On July 18, 1997, more than a year after the Zimmermann patent issued, more than a year after Druker's presentation at the American Society of Hematology annual meeting, more than a year after the Buchdunger and Druker articles disclosing the scientists use of the β-crystal form of the mesylate salt were published, and significantly after the 1997 Zimmermann paper appeared, Novartis filed Swiss patent application 1764/97.

172. The following year, Novartis filed PCT application PCT/EP98/04427. Both of these patent applications claimed a "beta" crystalline form of imatinib mesylate as a "new" invention, even though the mesylate salt had been in the public realm for well over two years and even though employing a non-needle crystalline form was an obvious choice that had been in use from at least the time of Druker's clinical testing in 1993.

173. These two applications for a follow-on, or secondary, patent were filed for the sole purpose of extending the life of the original imatinib mesylate patent in order to keep generic competitors from entering the market, and they succeeded in doing so.

3. Novartis Publishes Two More Articles, in *Blood*

174. In November and December 1997, two additional articles discussing CGP-57148B were published in the journal *Blood*, the journal of the American Society of Hematology.

175. The first of these 1997 articles appeared in the November 1, 1997, issue. In that article, entitled "The Tyrosine Kinase Inhibitor CGP57148B Selectively Inhibits the Growth of BCR-ABL-Positive Cells," Michael Deininger and three other scientists, including Dr. Lydon from Novartis, again publicly disclosed that CGP 57148B, the mesylate salt of imatinib, was the compound under consideration and testing for its likely "significant therapeutic applications."

176. The second of the 1997 articles appeared in the December 15, 1997, issue of *Blood*. That article, entitled "CGP 57148, a Tyrosine Kinase Inhibitor, Inhibits the Growth of Cells Expressing BCR-ABL, TEL-ABL, and TEL-PDGFR Fusion Proteins," was authored by Martin Carroll and others including Buchdunger, Zimmermann, Lydon, and Druker. This article, while purporting to describe the effects of "CGP 57148," in fact discussed preparation of "[a] stock solution of CGP 57148B" and the effects of that solution on the various cancer-related kinases.

177. On information and belief, from August 1993 forward, the beta crystal mesylate salt form of imatinib, CGP 57148B, was uniformly used in laboratory and clinical testing of imatinib, whether labeled and referenced as "CGP 57148" or "CGP 57148B" or "STI-571."

4. Novartis Began Clinical Trials of Imatinib Mesylate

178. In June 1998, Novartis began Phase I clinical trials of CGP 57148B (*i.e.*, imatinib mesylate in the beta form, now renamed STI-571) at three sites in the United States.

I. The 2000 Facts

1. Novartis Applied for a U.S. Patent Covering the Mesylate Salt and β-Crystal Form

179. On January 18, 2000, Novartis filed U.S. patent application number 09/463,097 ("the '097 application") seeking a follow-on polymorph patent ostensibly to claim the specific mesylate salt of imatinib in the non-needle crystal form. Like its Swiss and PCT counterparts, purported to disclose a "Crystal modification of a N-Phenyl-2-Pyrimidineamine Derivative and Processes for its manufacture and use" as a new invention. The '097 application claimed priority to both the Swiss patent application and the PCT application.

180. Like its Swiss and PCT counterparts, the '097 application purported to disclose, and claimed, the methanesulfonate salt of imatinib, along with a particular polymorphism (the

so-called "β-crystalline" form). Its abstract read, "The invention relates to a new crystalline form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]bensamide of formula 1, which may be used for example for tumor therapy."

181. The '097 application also described the invention as relating to "an acid addition salt of a compound of formula I comprising non-needle-shaped crystals, especially the β-crystal form of the methanesulfonic acid addition salt of the compound of formula I."

a. The Specification Contained Misleading Statements

182. In a section entitled "Background to the Invention," the '097 application stated that in the '184 patent, Novartis acknowledged that the imatinib compound had been disclosed in the Zimmermann patent, but represented that the earlier Zimmermann patent had not "exemplified" any of the salts of imatinib, stating:

> The preparation of [imatinib] and the use thereof . . . are described in Example 21 [the prior compound patent and other] applications in numerous other countries. This compound is exemplified in these publications only in free form (not as a salt).

183. This representation was misleading. While the *examples* in the Zimmermann patent did not use the salt form of imatinib, the patent repeatedly disclosed as part of the invention pharmaceutically acceptable salts of imatinib, and the Zimmermann patent listed amongst the acceptable salts the methanesulfonic acid addition salt. And in any event, Zimmerman and the other Ciba-Geigy scientists had already long before publicly disclosed the specific salt form to be used, imatinib mesylate.

184. Also in the background section of the application, Novartis represented that it had recently "surprisingly" found that imatinib mesylate could be made in a beta crystal form, stating:

> It has now been surprisingly found that a crystal form may under certain conditions be found in the methanesulfonate salt of this compound, which is described hereinafter as β-crystal form, and which has very advantageous properties.

185. This representation was misleading, if not false. The mesylate salt form of imatinib had been formulated in 1992, had been identified at least as early as August 1993 (when it was provided to Dr. Druker for testing), and publicly disclosed by at least July 31, 1995, when the Buchdunger paper was submitted to *Cancer Research* for publication.

186. In the application, Novartis did disclose that a useful shorthand for the β-crystal form of the methanesulfonic acid addition salt form of imatinib is simply to call it imatinib mesylate. As Novartis said, the "the methanesulfonic acid addition salt is always taken to mean the β-crystal form."

b. The Specification Did Not Disclose that Imatinib Mesylate Had Been Disclosed Years Earlier

187. The '097 application did not disclose the above-mentioned Druker, Buchdunger, or Zimmermann articles, nor did it disclose Druker's presentation at the American Society of Hematology, nor did it disclose that the Buchdunger article expressly described the mesylate salt form years before Novartis applied for the '097 application in the U.S.

c. The Specification Did Not Disclose That Mesylate Salts Are Common

188. The choice of a methanesulfonate addition salt for use in formulation of an oral solid (tablet) dosage form was not unusual or novel at the time of the '097 application. Novartis marketed at least four drugs in mesylate salt form that were approved decades before Novartis submitted January 18, 2000: Hydergine, Desferal, Parlodel, and Hydergine LC. Examples of drugs using mesylate salts that were approved by the FDA before Novartis submitted the '097 application include:

- D.H.E. 45 (dihydroergotamine mesylate, approved April 12, 1946, injection),

- Regitine (phentolamine mesylate, approved January 30, 1952, injection),
- Hydergine (ergoloid mesylates, approved November 5, 1953, tablet, marketed by Novartis),
- Cogentin (benztropine mesylate, approved March 5, 1954, tablet),
- Desferal (deferozamine mesylate, approved April 1, 1968, injection, marketed by Novartis),
- Parlodel (bromocriptine mesylate, approved June 28, 1978, tablet, marketed by Novartis),
- Hydergine LC (ergoloid mesylates, approved January 18, 1983, capsule, marketed by Novartis),
- isoetharine mesylate (approved August 21, 1984, inhaler),
- Cardura (doxazosin mesylate, approved in Nov. 2, 1990, tablet),
- Tornalate (bitolerol mesylate, approved December 28, 1994, inhaler),
- Invirase (saquinavir mesylate, approved December 6, 1995, capsule),
- Viracept (nelfinavir mesylate, approved March 14, 1997, tablet),
- Rescriptor (delaviridine mesylate, approved April 4, 1997, tablet),
- Corlopam (fenoldopam mesylate, approved September 23, 1997, injection),
- Anzemet (dolasetron mesylate, approved September 11, 1997, tablet),
- Migranal (dihydroergotamine mesylate, approved December 8, 1997, inhaler),
- Trovan (trovafloxacin mesylate, approved December 18, 1997, tablet),
- Tevaten (eprosartan mesylate, approved December 22, 1997, tablet), and
- Permax (pergolide mesylate, December 30, 1998, tablet).

d. The Specification Did Not Claim that the β-Crystal Form Required Undue Experimentation

189. During the prosecution of the ’097 application, Novartis would have been motivated to make any and all arguments it could in support of patentability of the mesylate salt in the β-crystal form. The original compound patent had already described (at column 3) how to

make salt forms of the patented compounds through routine, ordinary, steps, and it explicitly referred to a methane sulfonate salt (or mesylate) of imatinib. And so Novartis was motivated to describe how its efforts to arrive at the non-needle form of imatinib mesylate were inventive, such as (i) that it took Novartis's scientists an unreasonably long time to develop the mesylate salt and/or the beta crystal form, (ii) that the state of the art taught away from mesylate salts and/or non-needle forms, or (iii) that it was surprising and unexpected to discover that imatinib could form the β-crystal form, or that it was surprising and unexpected that the non-needle form had certain properties (*e.g.*, better flow properties and less hygroscopicity).

190. However, neither the specification nor prosecution history made any claim of any unusual skill or undue degree of experimentation that were required to develop the β-crystal form of the methanesulfonic acid addition salt of the compound. The only reasonable inference that can be drawn from the fact that Novartis did *not* make any of these arguments is that it would have been untrue to do so.

191. In fact, (i) it did not take Novartis's scientists an unreasonably long time to develop the mesylate salt and/or the β-crystal form, (ii) the state of the art did not teach away from mesylate salts and/or non-needle forms, and (iii) it was neither surprising nor unexpected to discover the β-crystal form, nor was it surprising or unexpected that the non-needle form offered better flow properties and less hygroscopicity.

e. One Skilled in the Art Would Have Sought a Non-Needle, Less-Hygroscopic Crystal Form

192. In the description section, Novartis described the "α-crystal" form of the compound as "characterised by needle-shaped crystals" and "hygroscopic" and thus "not particularly well-suited to pharmaceutical formulation as solid dosage forms" because of its physical properties particularly "flow characteristics" are unfavorable. And it pointed out that "it

is possible to obtain" imatinib methanesulfonate "in a crystal form which is not needle-shaped." In the application, Novartis called this the "β-crystal form."

193. The handling problems of "needle" forms of crystalline materials would have made searching for and choosing a non-needle form of a crystal obvious to any person skilled in the art at the time the '097 application.

194. In the application, Novartis also pointed to three advantages of the non-needle crystal form. Due to that form having a "more compact crystal form," the non-needle crystal form "results in substantially more beneficial flow properties and thus in better processability . . . versus the α-crystal form." And while the α-crystal, or needle, form is "metastable at room temperature," the β-crystal form "is the thermodynamically stable form at room temperature," and "greater stability is thus to be expected." Finally, the β-crystal form is "less hygroscopic" than the α-crystal form.

195. Any person skilled in the art at the time the '097 application would have tried to find a crystal form that had acceptable flow properties, was stable at room temperature, and absorbed less moisture from the air (*i.e.*, was less hygroscopic). These are basic requirements for the development of a pharmaceutical product that is to be produced in commercial quantities.

196. Identifying that the "β-crystal" form possessed these qualities does not make the β-crystal form patentable. Anyone skilled in the art at the time would have set out to find a crystal habit with these properties. Put differently, anyone skilled in the art would have known that the needle-shaped crystal form was not suitable for large scale commercial development of a prescription drug, and would have undertaken to find a more suitable, non-needle-shaped crystal form.

197. Novartis did not claim that it is unexpected for a non-needle shaped crystal to possess the advantages of the "β-crystal" form. At the time, non-needle shaped crystals were known to have better flow properties and to be "more compact."

f. Novartis Used Common Methods to Make the β-Crystal Form

198. In the follow-on polymorph application, Novartis described two ways to make the β-crystal form of imatinib mesylate. In one, a crystal or amorphous form of the methanesulfonic acid addition salt of imatinib is digested with a suitable polar solvent (usually methanol) in suspension at a heated temperature. In the other, a crystal or amorphous form of the methanesulfonic acid addition salt of imatinib is dissolved in a polar solvent (usually methanol) at a suitable heated temperature up to the reflux temperature of the reaction mixture, and then initiating crystallization by adding a small amount of the β-crystal form as seed crystal at a heated temperature.

199. These two techniques were, at the time, commonly known methods for developing alternate crystal forms.

g. The Specification Disclosed Many Potential Indications

200. In the application, Novartis described a long list of uses for imatinib (not limited to any particular salt or polymorphic form). Novartis stated that imatinib (i) is "suitable for the treatment of tumour diseases, such as gliomas, sarcomas, prostate tumours, and tumours of the colon, breast, and ovary," (ii) may "be used as an agent to treat non-malignant proliferative disorders, such as atherosclerosis, thrombosis, psoriasis, scleroderma, and fibrosis, as well as for the protection of stem cells," (iii) is "suitable for the treatment of BCR-abl-positive cancer and tumour diseases, such as leukaemias (especially chronic myeloid leukaemia and acute lymphoblastic leukaemia, where especially apoptotic mechanisms of action are found)," (iv) "shows effects on the subgroup of leukaemic stem cells as well as potential for the purification of

these cells in vitro after removal of said calls (for example, bone marrow removal) and reimplantation of the cells once they have been cleared of cancer cells (for example, reimplantation of purified bone marrow cells), (iv) has "useful effects in the treatment of disorders arising as a result of transplantation, for example, allogenic transplantation, especially tissue rejection, (v) is "effective in diseases associated with vascular smooth-muscle cell migration and proliferation . . . such as restenosis and atherosclerosis", and (vi) is "capable of inhibiting angiogenesis."

201. By disclosing these conditions without claiming methods of using imatinib to treat them, Novartis functionally and purposefully precluded others from patenting imatinib to treat these conditions.

2. The Examiner Rejects All Claims

202. On September 28, 2000, the PTO issued a non-final rejection of all of the '097 application's twelve claims.

203. The patent examiner concluded that the claims in the '097 application were both anticipated and rendered obvious by the Zimmermann patent.

204. The examiner stated, as part of her reasoning for denying the patent on anticipation grounds, that the applicant must show that the common procedures described in the Zimmermann patent for making the mesylate salt did not "inherently" produce the β-crystal form: "applicant must show that employing routine procedures for making the Ms salt as relied on by Zimmermann (see col.19), the instant beta form is not inherently produced." The examiner thus shifted the burden to the applicant to show that the β-crystal form of the mesylate salt is not anticipated by inherency.

205. The examiner also rejected all claims on obviousness grounds, and referred to her anticipation arguments but did not offer a separate detailed explanation for her conclusions.

J. The 2001 Facts

1. Novartis Amended its Claims and Responded to the Rejection for the Follow-On Polymorph Patent

206. On March 28, 2001, Novartis responded to the rejection, arguing that its claims were neither anticipated nor obvious, and cancelled and amended claims.

207. Once again, Novartis's response did not disclose the 1996 and 1997 articles disclosing the mesylate salt form, nor did it disclose Druker's presentation at the American Society of Hematology, nor did Novartis's response claim that unusual skill or an undue degree of experimentation that were required to discovery the β-crystal form of the methanesulfonic acid addition salt of the compound.

208. Novartis argued that the mesylate salt was not anticipated because the disclosure of mesylate salt in column 3 of the compound patent was not specific to any compound claimed in the '051 patent, and therefore did not "teach" any specific salt of any compound. Novartis also argued that the compound patent did not teach a preference for a particular salt form, that there are myriad possibilities for salt forms, and that column 3 discloses far more than 32 salts. (In doing so, Novartis did not disclose to the PTO that the specific salt, imatinib mesyalte, had been publicly disclosed elsewhere).

209. Novartis argued that even if the mesylate salt was anticipated, the specific form of the salt covered by the claims is non-hygroscopic, and the specification also discloses a form that is not non-hygroscopic (presumably referring to the α-crystal form).

210. Novartis then, disingenuously, implied that the mesylate salt of imatinib was not actually prepared in Zimmermann. But Ciba-Geigy developed the mesylate salt of imatinib back in 1992, Zimmermann was one of the scientists who developed it, and the '184 patent specification mentions the mesylate salt. But in its comments to the examiner, Novartis worded

its argument very carefully to falsely suggest that the mesylate salt may not have actually been developed as of the time the Zimmermann patent issued:

> Applicants further note that the anticipation rejection does not assert that the mesylate salt of the present compound was actually prepared in Zimmerman. Therefore, the existence of presently claimed [beta] crystal modification is neither taught nor suggested by the reference.

211. Novartis never argued that the properties of the β-crystal form were unexpected, nor that creating the β-crystal form required undue time or skill.

2. Novartis Sought Orphan Drug Exclusivity for Gleevec

212. Novartis also sought Orphan Drug Exclusivity for Gleevec from the U.S. Food & Drug Administration (FDA) in 2001. On January 31, 2001, the FDA designated imatinib as an orphan drug for treatment of CML and afforded it market exclusivity for this purpose until May 10, 2008.

3. The FDA Approved Gleevec Capsules

213. On May 10, 2001, the FDA approved Novartis's NDA for the capsule form of Gleevec. Shortly thereafter, Gleevec capsules were launched into the U.S. marketplace.

214. The PTO later approved Novartis's application under 35 U.S.C. § 156 for an extension of the term of the '184 patent based on the time it took the FDA to review the Gleevec NDA.

4. Back at the PTO, the Examiner Issued a Final Rejection of the Follow-On Polymorph Patent

215. On July 5, 2001, the patent examiner issued a final office action on the '097 application, maintaining her anticipation and obviousness rejections. "Applicants' traverse to the above rejections is not persuasive," she said, disagreeing with Novartis's argument that the salt forms of the invention were not particularly contemplated in the Zimmermann patent.

216. The examiner determined that the present claims were still anticipated by Zimmermann (for same reasons), still obvious in light of Zimmermann (for same reasons), and that claim 12 regarding the β-crystal salt was still obvious in light of Zimmermann and Yu.

217. The examiner did not agree with Novartis's contention that the salt forms in column 3 are not particularly contemplated, and quoted language from the compound patent specification that "any reference to the free compounds should be understood as including the corresponding salts."

218. The examiner noted that it does not matter whether the salt form compound was actually made in Zimmermann; rather, the relevant question is whether its preparation is within the knowledge of those of ordinary skill (citing *Petering*, where isomers of 20 preferred compounds were considered anticipated).

219. In her rejection, the examiner stated "The burden is on applicants not the examiner to show that their particular salt form (the beta form) cannot be made following routine conditions."

220. With the exception of her rejection of claim 12 over Zimmermann in view of Yu, the examiner limited her anticipation and obviousness rejections of the other claims to the Zimmermann patent alone. Meaning, she did not consider any other prior art references.

221. On November 5, 2001, Novartis appealed the examiner's rejection of its claims in the '097 application to the Board of Patent Appeals and Interferences (BPAI).

5. Sun Pharma Files an ANDA for Imatinib Mesylate

222. In late 2001, Sun Pharma filed an application with the FDA seeking approval to market a generic imatinib mesylate. In its ANDA, Sun addressed the Novartis patents by indicating (i) that it would await final approval until the expiration of the original compound

patent, but (ii) the follow-on polymorph patents were invalid and would not be infringed, and therefore it sought final generic approval, and entry into the market, on July 5, 2015.

K. The 2002 Facts

1. Novartis Appeals the Examiner's Final Rejection of the Follow-On Polymorph Patent

223. In its appeal brief, filed on January 7, 2002, Novartis acknowledged that the claims were limited to a specific crystalline form of imatinib mesylate, and "do not claim imatinib mesylate *per se*." Novartis stated that "the present claims would not prevent a third party from making, using, and selling what the Examiner asserts is anticipated by Zimmermann – the mesylate salt of the subject compound. Such claims only prevent the making, using and selling (etc.) of the claimed crystalline form."

224. But Novartis did not disclose the Druker, Buchdunger, or Zimmermann articles, nor did it disclose Druker's presentation at the American Society of Hematology. Instead, Novartis misleadingly stated, "the prior art does not suggest any particular form of imatinib mesylate or suggest that any particular form could be made by a particular method."

225. Novartis also made no claim of any unusual skill or undue degree of experimentation that were required to discovery the β-crystal form of the methanesulfonic acid addition salt of the compound.

2. Gleevec Faces Prospective Generic Competition from Sun

226. On January 15, 2002, Sun Pharma Global FZE sent Novartis notice of a Paragraph IV certification with respect to the '051 patent. In that Paragraph IV certification, Sun stated that its imatinib mesylate product, a generic version of Gleevec, would not infringe the '051 patent and/or that the '051 patent was invalid or unenforceable.

227. On information and belief, Sun included a Paragraph III certification as to the orginal compound patent. Meaning, Sun told Novartis that it would wait to launch its generic version of Gleevec until the compound patent expired on July 4, 2015.

228. On information and belief, Sun was the first company to file an ANDA with a Paragraph IV certification.

3. Novartis Did Not, Then, Sue Sun for Infringement

229. After receiving Sun's Paragraph IV notification, Novartis did not bring suit against Sun within the 45-day period that would have triggered a thirty-month stay.

4. The Examiner Opposes Novartis's Appeal

230. On March 12, 2002, the examiner filed her answer to Novartis's appeal brief. The examiner repeated her arguments for rejecting all claims on anticipation and obviousness grounds.

231. As to anticipation, the examiner stated, "[t]he burden is on appellants not the examiner to show that their particular salt form (the beta form) cannot be made following routine conditions," and "[t]he examiner has correctly put the burden on appellants to show that their compound cannot be made employing routine reaction conditions that would (with some trial and error) ultimately produce the crystalline form claimed herein for which applicants' assignee continues to enjoy a monopoly."

L. The 2003 Facts

1. The FDA Approved Gleevec Tablets

232. On April 19, 2003, the FDA approved Novartis's NDA for the tablet form of Gleevec. In 2003, Gleevec tablets were launched into the U.S. marketplace.

2. The Patent Board Did Not Sustain the Examiner's Rejection

233. On November 24, 2003, the Patent Board issued its decision.

234. In its decision, the Board simply assumed that the compound patent described the mesylate salt: "For the purposes of this appeal, we shall assume arguendo, without deciding that Zimmermann describes the methanesulfonic acid addition salt of imatinib within the meaning of 35 U.S.C. § 102(b)."

235. The Board then overruled the examiner's conclusion that the claims were anticipated by Zimmerman on the procedural basis that the examiner's burden shifting as to inherency was inappropriate.

236. As to obviousness, the Board again simply assumed that the compound patent described the mesylate salt: "Again, we shall assume arguendo, without deciding, that Zimmermann described the methanesulfonic acid additional salt of imatinib."

237. The Board then concluded that the record was not sufficiently developed to sustain an obviousness rejection: "*on this record*, the examiner has not *adequately explained* how a person having ordinary skill would have been led from 'here to there,' i.e., from the methanesulfonic acid addition salt of imatinib to the non-hygroscopic or β-crystalline form of that compound recited in the appealed claims."

238. The Board "[did] not sustain" the examiner's rejections for anticipation or obviousness. But neither did the Board order allowance of the patent. Nor did the Board order or otherwise instruct the examiner to issue the patent. Rather, the Board's decision sent the application back to the examiner for further proceedings.

3. Six Weeks Later, With No Further Proceedings, the Examiner Issued a Notice of Allowability

239. On December 31, 2003, New Year's Eve, the examiner issued a notice of allowance.

240. Under the system in place at the time (before 2010), patent examiners received "counts" for specific actions and had to meet a quota every two-weeks. The examiner was awarded one count when he issued an initial office action (*i.e.*, the examiner issues an allowance or non-final rejection after reviewing the application for the first time) and a second count when he disposed of the case (*e.g.,* the examiner issues an allowance or receives an abandonment). No counts are awarded for second or subsequent office action rejections.

241. Examiners may receive awards ranging between 1% to 6% of their base salary based, in part, on exceeding their quotas at the end of the year.

242. The file wrapper does not reflect any further development of the record after the Board decision. No telephone calls, no amendments, no briefs, no disclosures of additional prior art, no nothing. The only other paper in the file wrapper from this five-week period is a notice that the patent term will be extended by 311 days due to the time during which the appeal to the Board was pending. Five weeks after the Board's decision, on New Year's Eve, the notice of allowance simply issued, without any commentary.

4. After the Appeal Decision and Notice of Allowability, Novartis Submits the Buchdunger and Zimmermann and Improperly Argues *Res Judicata*

243. On March 26, 2004, after the Board issued its decision on the appeal and after the notice of allowance, Novartis submitted an Information Disclosure Statement (IDS) that – for the first time –revealed the 1996 Buchdunger publication and the 1997 Zimmermann publication. The Druker 1995 presentation, the Druker 1996 article, and other relevant prior art (including the articles discussed above) were not disclosed.

244. In "remarks" filed with the IDS, Novartis argued that, because the Board assumed that the methane sulfonic acid addition salt of imatinib was described in the prior art and, with

that assumption in mind, reversed the examiner's rejection, that *res judicata* applies and the patent should issue without further deliberation:

> [T]he Board of Appeals decision in this file … clearly indicates that is decision assumes that the methane sulfonic acid addition salt of imatinib was described in the prior art within the meaning of 102(b). Because the presently submitted publications disclose only what the Board of Appeals assumed was in the prior art, Applicants assert that the principles of *res judicata* require that the claims be allowed over the newly submitted publications.

245. Novartis, its attorneys, and the inventor had a duty to disclose information material to patentability during the prosecution of the patent.[17] Novartis has no excuse for its belated disclosure of indisputably relevant prior art only after it had received a notice of allowability.

246. Novartis compounded its failure to timely disclose this prior art by misrepresenting both the Board's decision and the effect of that decision.

247. First, the Board did not assume that the public prior art disclosed the mesylate salt, it assumed – *without deciding* – that the Zimmermann patent, specifically, disclosed the mesylate salt. That is, the Board accepted at face value – without deciding for itself – that the examiner was right about the Zimmermann patent referring to a mesylate salt and concluded (after making that assumption in the examiners' favor) that the examiner's burden shifting argument was incorrect. The Board did *not* consider whether other prior art disclosed the mesylate salt, in part because the examiner did not consider – let alone base her rejection on – the fact that, for example, the Buchdunger article disclosed the mesylate salt (because Novartis didn't tell her).

[17] *See* 37 C.F.R. 1.56.

248. Second, the Board made this assumption for the very narrow purpose of addressing (i) the examiner's burden-shifting argument in the context of anticipation by inherency and (ii) the examiner's conclusion that the β-crystal form was obvious in light of Zimmermann (only). The Board only addressed the issue of obviousness "on this record" and indicated that the examiner had not yet "adequately explained" how a skilled person would achieve the non-needle crystal. In short, the Board concluded, only, that the basis for the anticipation and obviousness so far put forward by the examiner were not at that point sufficientto reject for obviousness the patent claims.

249. Put simply, the Board did not undertake a substantive review of the validity of the claims in light of the relevant and available prior art. And, even if it had, the decision of the Board reversing the rejections would have been based on a limited record because Novartis withheld unquestionably relevant prior art. The Board's decision could not possibly have been informed by the Novartis articles that disclosed the mesylate salt years earlier, or fact that the 1996 Zimmermann publication disclosed crystalline forms of several selective protein tyrosine kinase inhibitors, because Novartis withheld those publications. And all the Board ruled was that the record was inadequate at that stage.

M. The 2004 Facts

1. The PTO Extended the Term of the Original Compound Patent

250. On January 7, 2004, the PTO approved Novartis's application under 35 U.S.C. § 156 for an extension of the term of the '184 patent "based on the regulatory review of the product Gleevec (imatinib mesylate) by the Food and Drug Administration."[18]

[18] Under § 156, upon timely application, the first product containing a new active pharmaceutical ingredient is generally entitled to an extension of the patent term for a period of one-half of the testing phase for the product, less any period during which the applicant did not act with due diligence, plus the entirety of the FDA review period, the total extension not to exceed five years.

251. In its application for a patent term extension, Novartis represented that the '184 patent covered Gleevec. Novartis stated that the '184 patent "claim[s] a compound or compounds which include the approved product, imatinib mesylate," and that "claim 21 claims a composition containing a compound or compounds which include the approved product, imatinib mesylate."

252. The original May 28, 2013, expiration date was extended by 586 days. The '184 patent expires on July 4, 2015, including an approved six-month period of pediatric exclusivity.

N. The 2005 Facts

1. The PTO Issued the Follow-On Polymorph Patent (the '051 Patent)

253. On May 17, 2005, after yet another late-filed Information Disclosure Statement, the '097 application issued as U.S. Patent No. 6,894,051 ("the '051 patent"). The '051 patent expires on November 23, 2019.

254. At all times the follow-on polymorph patent, the '051 patent, has been in substance an invalid patent, for at least obviousness if not anticipation. In the context of the *ex parte* PTO proceedings where Novartis controlled the information given to reviewers, Novartis was successful in having the PTO mistakenly issue the patent. But in the stark light of patent litigation alleging infringement of the '051, Novartis knew that if a court were to eventually rule on the validity issue after deliberative proceedings, the '051 patent would be held invalid.The Gleevec compound *is* the β-crystalline form of the methanesulfonate salt of imatinib. This was true when Novartis was calling it STI-571, and it was true when Ciba-Geigy was calling it CGP 57148B or CGP 57148. From at least 1993 when Ciba-Geigy was internally researching CGP 57148B and when they provided it to Dr. Druker to test, they were researching the β-crystalline form of the methanesulfonate salt of imatinib.

255. The ’051 Patent was and is invalid because the claimed invention was obvious or anticipated by prior art, including the ’184 Patent, the Buchdunger article, and what a person of ordinary skill in the art at the time knew. Novartis knew when it submitted its application for the ’051 Patent that the claimed invention was obvious over prior art, and/or that the claimed invention merely described the same imatinib mesylate compound that was already covered by the ’184 Patent and other prior art references.

256. Novartis listed the ’051 patent in the Orange Book. By doing so, Novartis knew that the ’051 patent would be an impediment to the launch of generic imatinib mesylate even though the patent had no realistic likelihood of ever being able to stand up in court as a valid patent warranting the exclusion of otherwise infringing products.

O. The 2006 Facts

1. Novartis Applied for a Third U.S. Gleevec Patent

257. In 2006, Novartis submitted yet another application for a patent purportedly covering Gleevec, though the invention still had not changed. Novartis’s application number 11/515,997 issued in 2009 as U.S. Patent No. 7,554,799 (“the ’799 patent”).

258. Identically to the ’051 patent, Novartis’s application for the ’799 patent, again disclosed and claimed the methanesulfonate salt of imatinib, along with its β-crystalline form polymorph. The abstract read, in full, identically to that of the ’051 patent: “The invention relates to a new crystalline form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl] bensamide of formula 1, which may be used for example for tumor therapy.”

259. In a section entitled “Background to the Invention,” the ’097 application stated that in the ’184 patent, the compound is exemplified “only in free form (not as a salt). It has now been surprisingly found that a crystal form may under certain conditions be found in the

methanesulfonate salt of this compound, which is described hereinafter as β-crystal form, and which has very advantageous properties." The '097 application also described the invention as relating to "an acid addition salt of a compound of formula I comprising non-needle-shaped crystals, especially the β-crystal form of the methanesulfonic acid addition salt of the compound of formula I."

260. In its September 2006 application for the '799 patent, Novartis claimed to be "surprised" by the finding that "a crystal form may under certain conditions be found in the methanesulfonate salt of this compound, which is described hereinafter as β-crystal form, and which has very advantageous properties," despite the fact that the same "new" and purportedly "surprising" finding had formed the basis of its January 18, 2000 application for the '051 patent, which was first filed as the Swiss patent application 1764/97 on July 18, 1997. That same β-crystal form found in the methanesulfonate salt of the compound had, in fact, been known to have very advantageous properties at least as early as July 31, 1995.

261. The '799 patent was Novartis's effort to state the claims of the '051 patent more broadly. The '051 patent had claims limited to the imatinib mesylate where the crystal was non-hygroscopic under certain conditions, or which had a β-crystal. The '799 patent (eventually) claimed a non-needle crystal of the imatinib mesylate.

262. The '799 patent was repeatedly rejected the examiner as obvious over Zimmerman (three times). Novartis then pulled its *res judicata* argument (even more disingenuous than the last time), and with that and a terminal disclaimer the examiner relented. The terminal disclaimer meant that the '799 patent would expire on the same day as the '051 patent, November 23, 2019.

263. The ’799 patent is invalid or unenforceable for the same reasons as the ’051 patent.

264. Novartis submitted all three patents (the ’184 patent, the ’051 patent, and the ’799 patent) to the FDA for listing in the Orange Book as covering Gleevec. And again, by doing so Novartis knew that those patents would be an impediment to the launch of generic imatinib mesylate even though the patents had no realistic likelihood of ever being able to stand up in court as valid patents that could lawfully exclude of competing generic products from the U.S. market.

P. The 2009 – 2011 Facts

1. The ’799 Patent Issued

265. The ’799 patent issued on June 9, 2009. Novartis promptly listed the ’799 patent in the Orange Book as covering Gleevec.

2. The FDA Granted Sun Tentative Approval

266. On November 13, 2009, the FDA granted tentative approval to Sun’s ANDA for a generic version of Gleevec, indicating its determination that Sun’s generic Gleevec was approvable, and satisfied all bioequivalence, CMC, and labeling requirements.

267. Why tentative approval instead of final approval? Because Sun had agreed that it would wait to launch its generic Gleevec until after the compound patent expired in July 2015. Put differently, in November 2009, the FDA has signed off on Sun’s product, Novartis has not sued Sun for infringing the ’051 patent, and the only thing preventing Sun from launching then and there was the last few years of protection afforded by the compound patent.

3. Novartis Sought Reissuance of the ’799 Patent

268. On September 21, 2011, Novartis applied for a reissuance of the ’799 patent, which it now described as a divisional application of the ’051 patent. Novartis’s application for

reissuance of the '799 patent again disclosed and claimed the methanesulfonate salt of imatinib, along with its β-crystalline form polymorph.

269. The reissuance purported to correct the fact that the propriety chain described in the '799 patent mistakenly included a patent that should not have been included. Some prior art references were reviewed during the reissuance proceedings, but there is no indication that the obviousness issues previously addressed are revisited.

Q. The 2013 – 2014 Facts

1. The '799 Patent Reissued as the RE '932 Patent

270. On January 15, 2013, the '799 patent reissued as U.S. patent RE 43,932 ("the RE '932 patent" or "the '932 patent"). Novartis listed the RE '932 patent in the Orange Book.

2. India's Supreme Court Rejected Application for Beta-Crystal Imatinib Mesylate Patent

271. On April 1, 2013, the Supreme Court of India affirmed the India Patent Office's denial of Novartis'spatent application for the beta-crystal salt form of imatinib mesylate. The Court found nothing new over prior art in the disclosure of the beta crystalline form and ruled that the claimed invention was both anticipated and rendered obvious by the prior publication of the Zimmermann patent. The Court specifically cited both the Buchdunger 1996 article from *Cancer Research* and the Druker 1996 article from *Nature Medicine* and declared, "In the face of the materials [1996 Buchdunger and Druker articles], we are completely unable to see how Imatinib Mesylate can be said to be a new product . . . Imatinib Mesylate is all there in the Zimmermann patent. It is a known substance from the Zimmermann patent. . . . [I]ts pharmacological properties are also known in the Zimmermann patent and in the article published in the *Cancer Research* journal. . . . "

3. Sun Sued For a Declaration of Non-Infringment or Invalidity

272. On June 7, 2013 – with Sun seeking timely entry into the imatinib mesylate market only two years away in July 2015 – Sun filed an action against Novartis in the United States District Court for the District of New Jersey (docketed as Civil Action No. 13-3542), seeking a declaratory judgment that Sun was not infringing the ’051 Patent and/or that the ’051 patent was invalid or otherwise unenforceable.

273. On July 26, 2013, Novartis filed counterclaims against Sun, alleging infringement of the ’051 patent and also seeking a declaration that the ‘051 patent was valid and enforceable.

274. Novartis never asserted the ’799 patent or the RE ’932 patent against Sun.

275. At the time it filed its counterclaims against Sun for infringement of the ’051 patent, Novartis knew that the ’051 patent was invalid for obviousness or anticipation, in part because its supposed invention had been publicly known through publications by Novartis’s own scientists since at least January 1, 1996, and because the non-needle crystal form was either inherent in the salt or was developed through obviously indicated routine processes.

276. Novartis had enormous incentives to settle the patent infringement litigation and avoid competition. By 2013, Gleevec was a roughly $2 billion drug. Losing a substantial portion of that revenue stream – as Novartis would have if the patents were held by a court to be invalid, unenforceable, or notinfringed – would have drastically affected Novartis’s profits in 2013 and subsequent years.

4. Sun and Novartis Settled

277. On May 15, 2014 (less than one year into that litigation), Novartis and Sun agreed to settle the patent lawsuit. The terms were not revealed, except that both parties announced to the press that under their agreement Sun would be permitted to launch its generic version of

Gleevec as of February 1, 2016. Shortly thereafter, the patent court dismissed the patent infringement case pending between Sun and Novartis regarding Gleevec.

278. Of course, if Novartis had never brandished the '051 patent against Sun, there never would have been the need for the litigation between Novartis and Sun, there never would have been a settlement between them, and there never would have been the agreement to delay from July of 2015 until February of 2016 the entry of Sun's generic imatinib into the U.S. marketplace.

5. The FDA Granted Apotex Tentative Approval

279. On October 30, 2014, the FDA tentatively approved an ANDA for generic Gleevec filed by Apotex.

6. Novartis Faced Competition from Other Generics

280. In or around 2014, other generics filed ANDAs for generic Gleevec that included Paragraph IV certifications as to some or all of the Orange Book-listed patents for Gleevec. These generics notified Novartis of their respective ANDAs and the Paragraph IV certifications, and Novartis filed suit against each of those generics. A chart reflecting dates in that litigation appears on the following page.

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Figure 2: Patent Infringement Litigation Chart

Generic	**ANDA**	**P.IV Sent**	**30-Month Stay Expires**	**Tentative Approval**	**Novartis Sued**	**Patents Asserted**	**Status**
Sun	078340	08/24/07	N/A	11/13/09	7/26/2013, 13-cv-3542 (D.N.J.)	’051	Settled 5/15/14; launch 2/1/16
Apotex	079179	Unknown	N/A	10/30/14	None in U.S.	N/A	N/A
Brecken-ridge	205990	06/13/14	12/13/17	None	14-cv-5729 (S.D.N.Y.)	’051, RE’932	Answer due 6/17/15
Dr. Reddy’s	205565 (tablet); 206898 (capsule)	08/27/14	2/27/17	None	14-cv-157 14-cv-387 14-cv-1076 14-cv-1283 (D.Del.)	’051, RE’932	Answer filed 2/26/14
Ranbaxy	206723	11/19/14	5/19/17	None	14-cv-1526 (D.Del.)	’051, RE’932	Answer due 5/29/15

281. Three additional companies, Breckenridge, Dr. Reddy's Laboratories, and Ranbaxy (collectively the "Additional ANDA Filers"), have filed subsequent ANDAs seeking to bring generic versions of Gleevec to market in the U.S. Novartis timely sued each of the Additional ANDA Filers for infringement of the '051 Patent and follow-on patents. As a result, Novartis has gained 30-month stays to FDA approval as to Breckenridge, DRL, Ranbaxy ANDAs.

282. Breckenridge sent Novartis a Paragraph IV certification on June 13, 2014. Novartis sued Breckenridge in the Southern District of New York (14-cv-5729). Breckenridge's answer is due June 17, 2015 – about two weeks before the compound patent expires. The 30-month stay expires on December 2017.

283. Dr. Reddy's Laboratories ("DRL") sent Novartis a Paragraph IV certification on August 27, 2014. Novartis sued DRL in the District of Delaware (14-cv-157, 14-cv-387, 14-cv-1076, 14-cv-1283). DRL answered on February 26, 2014. The 30-month stay expires on February 27, 2017.

284. Ranbaxy sent Novartis a Paragraph IV certification on November 19, 2014. Novartis sued Ranbaxy in the District of Delaware (14-cv-1526). Ranbaxy's answer is due on May 29, 2015 – A little more than a month before the compound patent expires. The 30-month stay expires on May 19, 2017.

285. Novartis knew at the time of its filing of the application for the '051 patent, and at the time of filing the subsequent applications for the '799 patent and the reissue '932 patent, that the β-crystal form of the mesylate salt of imatinib was not a novel invention over imatinib.

286. Novartis knew that its Orange Book listings for patents purported to cover Gleevec were false and that the patents were invalid and would not withstand the scrutiny of

patent litigation. Novartis's decision not to file a patent infringement lawsuit against Sun in 2007, and its settlement of the lawsuit that Sun filed against it in 2013, were all part of an overarching scheme to maintain its dominant power in the U.S. imatinib market and to delay generic competitors from entering that market.

287. Novartis is now pursuing sham litigation to enforce the '051 patent and subsequent similarly invalid patents against three additional prospective companies that have filed ANDAs for generic versions of Gleevec.

R. Today

1. FDA Approved Indications for Gleevec

288. Because of Gleevec's dramatic positive effects in treating CML as demonstrated in early clinical trials, Gleevec was granted accelerated consideration by the FDA and received approval on May 10, 2001, for treatment of patients with blast crisis, accelerated phase or chronic phase Ph+ chronic myeloid leukemia (CML) who have failed interferon-alpha therapy.

289. Gleevec has since received additional FDA approval for treatment of adults and/or children in eight more indications: newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase; adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL); adult patients with myelodysplastic/ myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements; adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown; adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRα fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1¬ PDGFRα fusion kinase negative or unknown;

adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP); patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST); and adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST.

2. How Gleevec is Prescribed and Dosed

290. Gleevec tablets and capsules are currently sold in scored 100-milligram and 400-milligram tablets. Various factors determine the precise dosages for each individual, but most adult patients take between 400 and 800 milligrams per day in once daily or twice daily dosings.

291. Patients with CML and other forms of Philadelphia chromosome-positive cancers who are treated with Gleevec have normal life expectancies (*i.e.*, they are expected to live as long as they would have without cancer and to die from some other cause). A CML patient whose cancer is successfully treated with Gleevec must continue to take Gleevec every day for the remainder of his or her life or face the rapid recurrence of the disease.

292. There are currently approximately 95,000 CML patients in the U.S., and approximately 5,000 individuals are newly diagnosed with CML each year.

3. Gleevec Sales in the United States

293. Novartis first brought Gleevec to market in capsule form. Gleevec was the only imatinib mesylate available for treatment of CML. Because of its unique ability to treat CML, doctors prescribed Gleevec often, and the drug garnered hundreds of millions of dollars of sales. The FDA later approved Gleevec in tablet form, also for treatment of CML. Once the tablet form of Gleevec received FDA approval, Novartis sold Gleevec tablets in 100 mg and 400 mg dosages.

294. Both the capsule and the tablet forms of Gleevec contain and have always contained the β-crystal formulation of imatinib mesylate salt.

295. Gleevec is currently only sold in tablet form in the U.S. (through the FDA determined that Gleevec capsules were not withdrawn from sale for reasons of safety or effectiveness).

296. Novartis's United States revenues for Gleevec exceeded $2 billion in the companies' 2014 fiscal year.

4. Gleevec's Cost

297. Gleevec currently costs more than $9,000 per patient per month in the U.S. due, in large part, to the lack of generic competition. In 2001, when Gleevec first became commercially available in this country, the price was $2,200 per month; the price has more than quadrupled over the last 14 years.

298. In countries where generic Gleevec is available, the monthly cost is approximately $2,500 per patient per month.

299. Plaintiffs and the other class members will be compelled to pay prices for Gleevec substantially greater than the prices that they would pay absent the illegal conduct alleged herein, because: (1) plaintiffs will be deprived of the opportunity to purchase lower-priced generic Gleevec instead of expensive brand-name Gleevec, and (2) plaintiffs will be forced to pay artificially inflated prices for imatinib mesylate.

300. Direct purchasers or wholesalers buy substantial amounts of Gleevec directly from Novartis and resell it to pharmacies.

301. End payers purchase substantial amounts of Gleevec from wholesalers or pharmacies. End payers include third-party payers (health plans, government entities) and consumers. End payers, as the name suggests, are at the end of the distribution chain.

302. Under federal antitrust law, wholesalers that purchaser drugs directly from pharmaceutical companies are entitled to recover damages for overcharges, *see Illinois Brick Co.*

v. Illinois, 431 U.S. 720 (1977), as well as injunctive relief upon a showing of immediate danger of irreparable loss or damage, *see* 15 U.S.C. § 26.

303. Under federal antitrust law, purchasers are entitled to recover injunctive relief upon a showing of immediate danger of irreparable loss or damage, *see* 15 U.S.C. § 26.

5. Novartis's Unlawful Suppression of Competition Harms Competition

304. But for Novartis's ongoing anticompetitive scheme to delay generic Gleevec competition in the United States, generic entry would occur on or around July 4, 2015. At least two reputable generic companies have tentative approval (meaning they have satisfied all bioequivalence, CMC, labeling, and other FDA requirements). The only obstacle to launching is the Novartis-Sun settlement.

305. Additionally, "but for" the illegal conduct described in this complaint, Novartis could and would launch its own authorized generic Gleevec product at the same time that Sun launched its generic Gleevec, resulting in additional price competition for Gleevec and its generic equivalent(s) during Sun's 180-day exclusivity period.

306. "But for" the anticompetitive, illegal, and ongoing conduct alleged in this complaint, the plaintiffs and members of the class would begin paying less for their imatinib mesylate as of July 4, 2015. Novartis, by its anticompetitive conduct, will injure the plaintiffs and the class by causing them to pay substantial overcharges – potentially hundreds of millions of dollars – on their purchases of Gleevec.

307. The active ingredient in Gleevec is imatinib mesylate. Its pharmacological profile, and thus its side effect and efficacy profile, is different from other prescription and non-prescription medicines that are used to treat the same or similar conditions. Those other drugs are not AB-rated to Gleevec, cannot be automatically substituted for Gleevec by pharmacists, do

not exhibit substantial cross-price elasticity of demand with respect to Gleevec, and thus are not economic substitutes for, nor reasonably interchangeable with, Gleevec.

308. Upon information and belief, neither Sun's nor Apotex's generic versions of Gleevec will infringe a valid Novartis patent.

309. Novartis's prosecution of its counterclaims for infringement of a patent it knew to be invalid and unenforceable constituted sham litigation that was conducted for the illegal purpose of keeping Sun's generic version of Gleevec and other generic versions of Gleevec from competing with brand Gleevec. This sham litigation violated § 2 of the Sherman Act in that it improperly maintained and extended Novartis's market and monopoly power by foreclosing or delaying competition from lower-priced imatinib mesylate.

VI. MONOPOLY POWER AND MARKET DEFINITION

310. At all relevant times, Novartis has maintained monopoly power over imatinib mesylate in that it has the power to maintain the price of Gleevec at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

311. Direct proof exists that Novartis has monopoly power over the price of imatinib mesylate. Such direct evidence includes, among other things, the abnormally-high price-cost margins enjoyed by Novartis prior to entry of generic imatinib mesylate and Novartis's ability to profitably maintain the price of imatinib mesylate well above competitive levels.

312. To the extent Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, the relevant product market is all imatinib mesylate products — *i.e.*, Gleevec (in all its forms and dosage strengths), and bioequivalent imatinib mesylate products. The relevant geographic market is the United States and its territories.

313. A small but significant non-transitory price increase above the competitive level for Gleevec by Novartis would not cause a loss of sales sufficient to make the price increase unprofitable.

314. At competitive price levels, Gleevec does not exhibit significant positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Gleevec.

315. Imatinib mesylate's pharmacological profile, and thus its side effect and efficacy profile, is different from other prescription and non-prescription medicines that are used to treat the same or similar conditions. These differences play a critical role in doctors' selection of the most appropriate treatment for a particular patient. Those other drugs are not AB-rated to Gleevec, cannot be automatically substituted for Gleevec by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Gleevec, and thus are not economic substitutes for, nor reasonably interchangeable with, Gleevec.

316. The existence of other products designed to treat CML or other illnesses treated by Gleevec has not significantly constrained Novartis's pricing of Gleevec. Novartis has never lowered the price of Gleevec in response to the pricing of other branded treatments (or the generic versions of such medications).

317. Novartis needed to control only Gleevec and its AB-rated generic equivalents, and no other products, in order to maintain the price of Gleevec profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Gleevec would render Novartis unable to profitably maintain its current prices of Gleevec without losing substantial sales.

318. Novartis has maintained and exercised the power to exclude and restrict competition to Gleevec and AB-rated generics.

319. At all relevant times, Novartis's market share in the relevant market was and remains 100%, implying substantial monopoly power.

VII. CLASS ACTION ALLEGATIONS

320. Plaintiffs bring this action on behalf of themselves and, under Rule 23(a) and (b)(2) of the Federal Rules of Civil Procedure, as representative of a class defined as follows:

> All persons or entities in the United States and its territories who will, expect, and/or intend to purchase, pay for, and/or reimburse for some or all of the purchase price for brand-name Gleevec, directly or indirectly, at any time during the period July 4, 2015, through the date that the anticompetitive effects of the Novartis's challenged conduct cease.

321. The following persons or entities are excluded from the proposed class:

a. Novartis and its officers, directors, management, employees, subsidiaries, and affiliates;

b. fully insured health plans (*i.e.*, plans that purchased insurance from another third-party payer covering 100% of the plan's reimbursement obligations to its members);

c. any "flat co-pay" consumers whose co-payment for Gleevec would be the same regardless of the retail purchase price;

d. any "brand loyalist" consumers or third-party payers who would not purchase any AB-rated generic Gleevec after such generics became available; and

e. the judges in this case and any members of their immediate families.

322. Certification of the class pursuant to Rule 23(b)(2) is appropriate because Novartis has acted on grounds applicable to the class as a whole and no claim for damages under federal law, incidental or otherwise, is currently asserted on behalf of the class.

323. Because both direct purchasers and end payers of Gleevec have standing under 15 U.S.C. § 26 to seek Rule 23(b)(2) certification, they seek certification as a single class.

324. Rule 23 provides the Court with authority and flexibility to maximize the efficiencies and benefits of the class mechanism and reduce management challenges. The Court may, on motion of Plaintiffs or on its own determination utilize Rule 23(c)(5) to divide the class into subclasses. Subclasses may include a direct purchaser subclass, a third party payer end payer subclass, or a consumer subclass.

325. Members of the class are so numerous that joinder is impracticable. Plaintiffs believe that the class numbers in the tens of thousands at least and is geographically spread across the nation.

326. Plaintiffs' claims are typical of the claims of the members of the class. Plaintiffs and all members of the class will pay artificially inflated prices for imatinib mesylate and will be deprived the benefits of competition from less-expensive generic versions of Gleevec as a result of Novartis's wrongful conduct. Plaintiffs have purchased Gleevec in substantial quantities within the past year and expect and intend to continue purchasing Gleevec after July 4, 2015.

327. Plaintiffs will fairly and adequately protect and represent the interests of the class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the class.

328. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and who have particular experience with class action antitrust litigation involving the pharmaceutical industry.

329. Questions of law and fact that are common to the members of the class predominate over questions, if any, that may affect only individual class members, because

Novartis is acting on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in Novartis's wrongful conduct.

330. Questions of law and fact common to the class include:

a. whether Novartis's counterclaims against Sun constituted sham litigation;

b. whether Novartis's sham litigation and settlement thereof will effectively suppress generic competition to Gleevec;

c. whether Novartis's challenged conduct will harm competition in the market(s) in which Gleevec is sold;

d. whether Novartis possessed market or monopoly power over imatinib mesylate;

e. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

f. whether the activities of Novartis as alleged herein have substantially affected interstate commerce;

g. whether, and to what extent, Novartis's conduct threatens to cause loss or damage to the business or property of the plaintiffs and the members of the class in the nature of overcharges; and

h. whether plaintiffs and the members of the class will suffer irreparable injury for which there is no adequate remedy available at law.

331. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

332. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VIII. INTERSTATE COMMERCE

333. At all material times, Novartis manufactured, promoted, distributed, and sold substantial amounts of Gleevec in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

334. At all material times, Novartis transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Gleevec.

335. In furtherance of its efforts to monopolize and restrain competition in the market for imatinib mesylate, Novartis employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of the Novartis were within the flow of and have substantially affected interstate commerce.

IX. EFFECTS ON COMPETITION

336. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding brand-name drug to which they are AB-rated. As a result, upon generic entry, purchases of brand-name drugs are rapidly substituted by purchases of generic versions of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand-name drug continues to lose even more to the generics.

337. This price competition enables purchasers to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand-name drug at a reduced price. Consequently, brand-name manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

338. Novartis's ongoing anticompetitive scheme as alleged above will allow it to unlawfully maintain a monopoly and exclude competition in the market for imatinib mesylate. But for Novartis's ongoing anticompetitive scheme to delay generic Gleevec competition in the United States, Sun's generic equivalent of Gleevec would enter the market in the United States as of July 4, 2015.

339. Novartis implemented its unlawful scheme by (i) improperly listing the '051, '799, and 'RE923 patents in the Orange Book and (ii) prosecuting sham patent infringement lawsuits against generic manufacturers. These acts, in combination and individually, were anticompetitive.

340. But for the anticompetitive, illegal, and ongoing conduct alleged in this complaint, Plaintiffs and members of the class would begin paying less for their imatinib mesylate as of July 5, 2015. Novartis, by its anticompetitive conduct, threatens to injure Plaintiffs and the class by causing them to pay substantial overcharges—potentially hundreds of millions of dollars—on their purchases of Gleevec.

341. Were it not for Novartis's sham litigation against Sun and its agreement settling that litigation by removing the challenge to validity of the '051 patent, generic Gleevec products would be entering the market in the U.S. on or around July 5, 2015, as opposed to February 1, 2016. This seven-month delay alone is worth an estimated $1.2 billion to Novartis in monopoly revenue.

342. Thus, Novartis's unlawful conduct deprived the plaintiffs and the class of the benefits of competition that the antitrust laws were designed to ensure.

X. IRREPARABLE HARM

343. If Novartis's settlement agreement with Sun is not enjoined, Plaintiffs and the members of the class will suffer substantial and irreparable harm for which there is no remedy at

law. No class member should be expected to suffer injury as a result of illegal anticompetitive conduct.

344. Imatinib mesylate is a lifesaving drug that currently costs more than $9,000 per patient per month in the U.S. due, in large part, to the lack of generic competition. This is compared with a monthly cost of approximately $2,500 per patient per month in countries where generic competition is active, and of approximately $2,200 per patient per month in 2001 when Gleevec was launched. Members of the class, including patients, will be constrained in obtaining imatinib mesylate in the absence of an injunction. With real lives at stake, monetary damages are clearly inadequate.

345. Additionally, even if damages could be calculated in the future, in the absence of an injunction in the interim, purchasers will pay out millions of dollars in overcharges for imatinib mesylate and those unable to do so may die.

346. The threatened injury here is actual and imminent. Though the '184 Patent expires on July 4, 2015, Novartis and Sun have each made public announcements that Sun will not be permitted to launch its generic versions of Gleevec until February 1, 2016. This near seven-month delay will cost approximately $40,000 per patient and will earn Novartis an estimated $1 billion.

XI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Declaratory and Injunctive Relief (15 U.S.C. § 26)
to Remedy Novartis's Illegal Monopolization (15 U.S.C. § 2)

347. Plaintiffs incorporate by reference the allegations above, as if fully set forth herein.

348. As described above, at all relevant times Novartis possessed monopoly power in the relevant market—*i.e.*, the market for sales of imatinib mesylate in the United States. But for Defendant's wrongful conduct, as alleged herein, Defendant should lose its monopoly power in the relevant market on or around July 4, 2015.

349. Defendant knowingly, willfully and wrongfully maintained its monopoly power by inter alia, improperly listing patents under the Gleevec NDA and prosecuting baseless, sham patent litigation.

350. Novartis knowingly and intentionally engaged in an anticompetitive scheme deliberately designed to block and delay entry of AB-rated generic versions of Gleevec to maintain its monopoly power. This scheme included:

a. improperly listing the '051, '799, and RE'923 patents in the Orange Book; and

b. prosecuting sham patent infringement lawsuits against generic manufacturers.

351. Plaintiffs and the class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that Novartis's conduct in seeking to prevent competition as described herein comprises illegal monopolization in violation Section 2 of the Sherman Act.

352. Plaintiffs and the class further seek permanent equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, against threatened loss or damage resulting from Novartis's violations of the antitrust laws, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

SECOND CLAIM FOR RELIEF

Declaratory and Injunctive Relief (15 U.S.C. § 26)
to Remedy Novartis's Illegal Attempt to Monopolize (15 U.S.C. § 2)

353. Plaintiff incorporates by reference the allegations above, as if fully set forth herein.

354. As described in detail above, Novartis engaged in an exclusionary, anticompetitive scheme designed to create and maintain a monopoly for Gleevec and its generics substitutes. This scheme included:

a. improperly listing the '051, '799, and RE'923 patents in the Orange Book; and

b. prosecuting sham patent infringement lawsuits against generic manufacturers.

355. Novartis had a specific intent to monopolize the relevant market and to unreasonably restrain competition.

356. There was and still is a dangerous probability that Defendant will achieve monopoly power in the relevant market at all relevant time and into the foreseeable future.

357. Plaintiff and the class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that Novartis's conduct in seeking to prevent competition as described herein comprises an illegal attempt to monopolize in violation Section 2 of the Sherman Act.

358. Plaintiffs and the class further seek permanent equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, against threatened loss or damage resulting from Novartis's violations of the antitrust laws, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

XII. DEMAND FOR RELIEF

359. WHEREFORE, Plaintiffs on behalf of themseljves and the class, respectfully request that the Court:

a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(2); find Plaintiffs to be adequate representatives of the class; and appoint the undersigned class counsel;

b. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;

c. Declare the acts alleged herein to be in restraint of trade in violation of Section 2 of the Sherman Act;

d. Permanently enjoin Novartis from enforcing any term of its settlement agreement with Sun that would prevent Sun from launching its generic Gleevec product after expiration of the '184 patent;

e. Grant Plaintiffs the costs of suit, including reasonable attorney's fees as provided by law; and

f. Grant to Plaintiffs such other or further relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

Dated: June 22, 2015

Respectfully submitted,

By: **/s/ Thomas M. Sobol**
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