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NORTHERN DISTRICT OF CALIFORNIA

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10
11 **UNITED STATES DISTRICT COURT**
12 **FOR NORTHERN DISTRICT OF CALIFORNIA**

13 C 04 1511

14 JOHN DOE 1 and JOHN DOE 2, on Behalf of
15 Themselves and All Other Persons Similarly Situated,

16 Plaintiffs,

17 v.

18 ABBOTT LABORATORIES,

19 Defendant.

Case No.

BZ

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

20 **INTRODUCTION**

21 1. Plaintiffs John Doe 1 and John Doe 2, on behalf of themselves and all others
22 similarly situated, bring this action against Abbott Laboratories ("Abbott," "Defendant," or the
23 "Company") for injunctive relief under the antitrust laws of the United States and for such other
24 relief as appropriate under California Business and Professions Code Section 17200, *et seq.*, and
25 common law.

26 **JURISDICTION AND VENUE**

27 2. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337
28 and by Section 4 of the Clayton Act, 15 U.S.C. § 15(a). This Court has supplemental jurisdiction

1 over the state law and common law claims pursuant to 28 U.S.C. § 1367.

2 3. Defendant transacts business, maintains offices, or is found within the state of
3 California. The interstate commerce described in this Complaint is carried on, in part, within this
4 District. Venue is proper in this District pursuant to the provisions of 15 U.S.C. §§ 22 and 28
5 U.S.C. § 1391.

6 **PLAINTIFFS**

7 4. Plaintiff John Doe 1 is a citizen of the state of California, residing in the City and
8 County of San Francisco. John Doe 1 has sued using a pseudonym to protect his privacy. John
9 Doe 1 purchased Norvir for use as a booster to a protease inhibitor after December 3, 2003 and
10 was thus injured as a result of Abbott's alleged violations.

11 5. Plaintiff John Doe 2 is a citizen of the state of Georgia, residing in Cobb County.
12 John Doe 2 has sued using a pseudonym to protect his privacy. John Doe 2 purchased Norvir for
13 use as a booster to a protease inhibitor after December 3, 2003 and was thus injured as a result of
14 Abbott's alleged violations.

15 **DEFENDANT**

16 6. Abbott is a corporation organized, existing, and doing business under the laws of
17 the state of Illinois. Its office and principal place of business is located at 100 Abbott Park Road,
18 Abbott Park, Illinois 60064. Abbott is engaged principally in the development, manufacture, and
19 sale of pharmaceuticals and health care products and services. Abbott had sales of \$19.3 billion in
20 2003, of which \$4.3 billion was attributable to its anti-viral pharmaceuticals. Abbott operates in
21 130 countries and has facilities in 14 states, including at least 3 in this District.

22 **TRADE AND COMMERCE**

23 7. During the Class Period defined below, Abbott marketed and sold Norvir as a
24 booster for protease inhibitors in a continuous stream of commerce to customers located in states
25 other than Illinois, where it resides. Abbott also marketed and sold Kaletra as a boosted protease
26 inhibitor in a continuous stream of commerce to customers located in states other than Illinois,
27 where it resides.

28 8. Abbott's business activities that are the subject of this Complaint were in the flow

1 of, and substantially affected, interstate trade and commerce. Abbott frequently used interstate
2 transportation and communication in connection with the marketing and sale of these
3 pharmaceuticals.

4 **FACTUAL BACKGROUND**

5 9. Abbott has been a leader in HIV/AIDS research since the early years of the
6 epidemic. In 1985, the Company developed the first licensed test for HIV antibodies in the blood
7 and remains a leader in HIV diagnostics and treatments.

8 10. Abbott is one of several pharmaceutical companies making protease inhibitors
9 (“PIs”). Protease inhibitors are considered the most powerful weapons to date against HIV. This
10 class of drugs works by blocking the action of protease, an enzyme needed for HIV to reproduce
11 and infect other cells.

12 11. There are a number of PIs currently on the market, including:

13 a. Invirase (saquinavir), manufactured by Roche Laboratories, approved by the
14 Food and Drug Administration in December 1995;

15 b. Crixivan (indinavir), manufactured by Merck, approved March 1996;

16 c. Norvir (ritonavir), manufactured by Abbott, approved March 1996;

17 d. Viracept (nelfinavir), manufactured by Agouron Pharmaceuticals, approved
18 March 1997;

19 e. Fortovase (a saquinavir reformulation), manufactured by Roche
20 Laboratories, approved November 1997;

21 f. Agenerase (amprenavir), manufactured by GlaxoSmithKline, approved
22 April 1999;

23 g. Kaletra (lopinavir + ritonavir), manufactured by Abbott, approved
24 September 2000;

25 h. Reyataz (atazanavir), manufactured by Bristol-Myers Squibb, approved
26 June, 2003; and

27 i. Lexiva (fosamprenavir), manufactured by GlaxoSmithKline, approved
28 October 2003.

1 12. Each of these PIs, like any anti-HIV drug, will eventually lose efficacy as the virus
2 develops resistance to it. When such resistance occurs, the failed PI must be replaced with another
3 PI that is able to overcome the virus' resistance. Because successive PI regimens must be used in a
4 sequence carefully calibrated to reflect the virus' evolving mutations in individual patients,
5 preserving a maximum number of PI treatment options for physicians to choose from is of
6 paramount importance to the survival of people with HIV.

7 13. Norvir, a drug patented, produced, distributed, and sold by Abbott, is indispensable
8 for virtually all PI therapies.¹ Abbott developed Norvir with the assistance of a National Institutes
9 of Health grant and spent only about \$15 million of its own funds on pre-approval clinical trials
10 for the drug. Abbott is the sole maker of Norvir, and there are no generics or functionally
11 equivalent formulations on the market. By the end of 2001, Norvir had generated cumulative sales
12 for Abbott of more than \$1 billion (more than sixty times the estimated cost of its pre-approval
13 outlays). Securities analysts have estimated that, even without the price increase that is the subject
14 of this Complaint, Norvir would generate more than \$2 billion for Abbott over the next ten years.

15 14. Norvir was originally developed as a PI and was approved for use as a stand-alone
16 drug or for use in combination with other PIs in March 1996. Serious side effects prevented
17 Norvir from ever being successfully marketed as a PI. However, small doses of the drug were
18 found to dramatically improve blood levels of other PIs, decreasing the side effects associated
19 with those drugs and "boosting" the antiviral effect of PIs against even resistant strains of HIV.
20 Other advantages of Norvir-boosted PI regimens over regimens without Norvir include
21 convenience in terms of pill burden and reduction of food restrictions for patients, both important
22 factors in ensuring adherence to antiretroviral therapy.

23 15. Perhaps even more importantly, recent research has shown significant benefit for
24 the use of boosted PI regimens, especially for patients who experience failure of treatment
25 regimens combining PIs with other anti-HIV drugs. Such treatment failures are marked by the
26

27 ¹ Of the nine PIs currently on the market, only Viracept, because of its distinct metabolism, has not
28 benefited from Norvir "boosting."

1 emergence of drug-resistant mutations that limit the benefit of other drugs in the future, because of
2 cross-resistance between HIV medications. When patients experience failure of initial boosted PI
3 regimens, there is no evidence of PI resistance and, moreover, there is less resistance to the other
4 drugs in the regimen. Hence, by using Norvir to boost PI regimens, physicians can maximize the
5 treatment options remaining for the patients experiencing treatment failure.

6 16. In addition to Norvir, Abbott also markets its own boosted PI, Kaletra. Kaletra,
7 like nearly all PIs, depends on the boosting properties of Norvir. Kaletra has significant side
8 effects, however, most notably hyperlipidemia, rendering patients significantly more vulnerable to
9 heart attacks and strokes.

10 17. Prescriptions for Kaletra had steadily risen since its September 2000 introduction,
11 and by June 2003, new prescriptions and total sales of the drug had reached an all-time high,
12 securing Kaletra an approximate 75% share of the boosted PI market. However, Kaletra's
13 domination of the boosted PI market was about to be seriously threatened.

14 18. With the June 2003 introduction of Bristol-Myers Squib's competing PI, Reyataz,
15 a new PI boosted by Norvir, Kaletra's share of new PI prescriptions began a precipitous decline.
16 By October 2003, the press reported that Kaletra had "topped out." Furthermore, Kaletra
17 prescriptions, as a proportion of the overall market of boosted PI prescriptions, began to plummet
18 in the two months following the introduction of Reyataz. To make matters worse, October 2003
19 saw GlaxoSmithKline's introduction of Lexiva, another new PI boosted by Norvir. Both Reyataz
20 and Lexiva began to make made steady inroads against Kaletra's boosted PI marketshare.

21 19. Abbott acted quickly to stanch these losses and maintain its dominant position in
22 the boosted PI market. On December 3, 2003, barely five weeks after the release of
23 GlaxoSmithKline's Lexiva and more than seven years after Norvir's introduction into the market,
24 Abbott abruptly announced that it was raising the wholesale price of Norvir from \$205.74 to
25 \$1,028.71 for 120 100 mg capsules – an *increase of approximately 478%*.

26 20. By means of this staggering price hike, Abbott added drastically to the cost of
27 regimens using Norvir to boost competing PIs. The annual cost of the Norvir needed to boost
28 these drugs increased by \$6,258 per year for PIs such as Lexiva requiring twice-daily doses of

1 Norvir. For Tipranovir, a PI currently in development by Boehringer-Ingelheim, the optimal
2 Norvir booster dose would increase by more than \$12,000 per year.

3 21. In a *coup de grace* against competitors' PIs, Abbott did not raise the price of the
4 Norvir used in its own Kaletra. As a result, Kaletra became the least expensive boosted regimen
5 on the market. By leveraging its power in the booster market, Abbott unlawfully maintained and
6 even extended its monopoly in the boosted market.

7 22. Abbott's actions also had a chilling effect on the research efforts of competitors
8 such as Boehringer-Ingelheim which seeks to develop future generations of PIs and is heavily
9 reliant on Norvir's boosting properties. As one pharmaceutical company research scientist
10 recently stated in the press, "[w]hy bother investing in these areas if Abbott has effectively priced
11 you out of the market in the US?" The same scientist suggests that, by pricing others out of the
12 market, Abbott will effectively shape the research evidence base in such a way as to ensure that all
13 roads lead to its products.

14 23. Abbott's monopolistic intentions were immediately apparent to an outraged public.
15 The Attorneys General of Illinois and New York launched investigations into the price increase.
16 The Illinois Attorney General stated in a February 6, 2004 press release:

17
18 Critics of this price jump by the suburban Chicago-based drug giant say the
19 increase is aimed at undercutting competitors' products and helping Abbott gain a larger
20 market share for its new combination of all-Abbott drugs to suppress HIV. In the past,
21 Abbott's Norvir has been combined with other drug companies' products in HIV
22 suppression "cocktail" combinations.

23 24. Physicians prescribing PIs overwhelmingly agree with the fears expressed in the
24 Illinois Attorney General's statement. The Organization of HIV Healthcare Providers,
25 representing physicians collectively treating approximately 85,000 patients with HIV, stated in a
26 January 20, 2004 letter to Abbott that in hiking Norvir's price Abbott was "taking advantage of a
27 monopolistic situation, where [its] product is the only effective protease inhibitor boosting agent."

28 25. The effects of Abbott's anticompetitive activities are already being felt by an
extraordinarily vulnerable population. According to New York physician Howard Grossman

1 quoted in the *Dallas Voice*, at least one hospital that has already revised its formulary — the list of
2 preferred drugs that physicians may use — because of cost, to give preference to Kaletra and
3 restrict physicians' options to use other drugs.

4 RELEVANT MARKETS

5 26. All but one of the protease inhibitors currently prescribed for the treatment of HIV
6 require some type of “booster” in order to maximize the blood levels of the drug and minimize
7 toxic side effects. Virtually all of the PIs currently in use and all boosted PIs in clinical trials use
8 Norvir, Abbott’s antiretroviral drug, as that “booster.” For that purpose, Norvir is not reasonably
9 interchangeable with any other drug. Indeed, many public health assistance programs require the
10 use of Norvir as the booster for a PI regimen. Abbott has virtually a 100% share of the
11 multimillion-dollar PI booster market in the United States. Plaintiffs allege that Abbott intended
12 to leverage its monopoly in this booster market to obtain, maintain, or extend a monopoly in the
13 market for boosted PIs.

14 27. The market Abbott attempted to monopolize is the market for boosted PIs. Abbott
15 has its own Norvir-boosted PI product, Kaletra, which is prescribed to patients with HIV.
16 Kaletra’s share of the boosted PI market began falling due in part to competition from new
17 boosted PI drugs. Plaintiffs allege that Abbott’s recent exorbitant price hike for Norvir was an
18 attempt to eliminate competition in the market for boosted PIs.

19 28. The United States is the geographical market.

20 29. Plaintiffs allege that Abbott, through its recent pricing of Norvir has, or is
21 dangerously close to having, a monopoly in the boosted PI market in the United States

22 CLASS ACTION ALLEGATIONS

23 30. Plaintiffs bring this action on their own behalf and as a class action under the
24 provisions of Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure on behalf of
25 the following class:

26 All persons or entities (excluding Abbott, its parents, subsidiaries, and affiliates, and
27 governmental entities) who purchased Norvir indirectly as a booster to other PIs and
28 who paid all or part of the increased cost of Norvir, from December 3, 2003 to the
present (the “Class Period”).

1 31. Plaintiffs do not know the exact number of class members. Due to the nature of the
2 trade and commerce involved, however, Plaintiffs believe that the class members are sufficiently
3 numerous and geographically dispersed throughout the United States that joinder of all class
4 members is impracticable.

5 32. Except as to the amount of individual damages each class member has sustained,
6 all relevant questions of fact and law are common to the class, including, but not limited to, the
7 following:

8 a. Whether Abbott unlawfully attempted to monopolize the market for boosted
9 protease inhibitors during the Class Period;

10 b. Whether Abbott engaged in anticompetitive conduct in order to leverage its
11 monopoly in the protease inhibitor booster market to obtain, maintain, or extend an undue
12 monopoly in the market for boosted protease inhibitors;

13 c. Whether the geographic market for both protease inhibitor boosters and
14 boosted protease inhibitors is the United States;

15 d. Whether the product market in which Abbott has a monopoly is the market
16 for protease inhibitor boosters;

17 e. Whether the product market Abbott was attempting to monopolize is the
18 market for boosted protease inhibitors;

19 f. Whether Abbott intended to monopolize the market for boosted protease
20 inhibitors or to maintain or extend an existing monopoly on the market for boosted protease
21 inhibitors;

22 g. Whether there was a dangerous probability that Abbott would succeed in
23 monopolizing the market for boosted protease inhibitors;

24 h. Whether Abbott had pro-competitive reasons for its conduct;

25 i. The effects of Abbott's attempted monopolization on prices of boosted
26 protease inhibitors; and

27 j. The appropriate measure of damages sustained by Plaintiffs and class
28 members.

1 33. Plaintiffs are members of the class, and Plaintiffs' claims are typical of the claims
2 of other class members. Plaintiffs will fairly and adequately protect the interests of the class.
3 Plaintiffs' interests are coincident with, and not antagonistic to, those of other class members. In
4 addition, Plaintiffs are represented by counsel who are competent and experienced in the
5 prosecution of antitrust class action litigation.

6 34. The prosecution of separate actions by individual class members would create a
7 risk of inconsistent or varying adjudications, establishing incompatible standards of conduct for
8 Abbott.

9 35. The questions of law and fact common to class members predominate over any
10 questions affecting only individual members, including legal and factual issues relating to liability
11 and damages.

12 36. A class action is superior to other methods available for the fair and efficient
13 adjudication of this controversy. Treatment as a class action will permit a large number of
14 similarly situated persons or entities to adjudicate their common claims in a single forum
15 simultaneously, efficiently, and without the duplication of effort and expense that numerous
16 individual actions would engender. Class treatment will also permit the adjudication of claims by
17 many class members who could not afford individually to litigate an antitrust claim such as is
18 asserted in this Complaint. This action likely presents no difficulties in management that would
19 preclude its maintenance as a class action. Finally, the class is readily ascertainable.

20 **FIRST CAUSE OF ACTION**
21 **Sherman Act § 2 (15 U.S.C. § 2)**

22 37. Plaintiffs incorporate allegations set forth above, as if fully stated here.

23 38. At all relevant times, Abbott possessed a monopoly over the market for protease
24 inhibitor boosters.

25 39. Protease inhibitor boosters and boosted protease inhibitors constitute separate,
26 relevant product markets.

27 40. Abbott possessed and acted with specific intent to achieve an anticompetitive
28 purpose, including the intent to eliminate competitors from the market for boosted protease

1 inhibitors.

2 41. Abbott engaged in one or more of the predatory or anticompetitive acts alleged in
3 this Complaint

4 42. There is a dangerous probability that Abbott will be successful in achieving or in
5 unlawfully maintaining a monopoly in the market for boosted protease inhibitors.

6 43. There is no pro-competitive justification for Abbott's actions.

7 44. Abbott acted with an anticompetitive purpose resulting in an anticompetitive effect.

8 45. Abbott's acts and conduct were committed for the following purposes:

9 a. to eliminate competitors from the market for boosted protease inhibitors;

10 b. to chill the development of potentially competing PIs that require a booster
11 such as Norvir; and

12 c. to monopolize and attempt to monopolize the market for boosted protease
13 inhibitors.

14 46. These acts by Abbott have restrained or prevented competition and threaten and
15 continue to restrain and prevent competition.

16 47. Plaintiffs and class members have been injured in their business or property by
17 reason of Abbott's antitrust violations. Their injury consists of being forced to pay higher prices
18 for Norvir, which is an essential element of their HIV treatment, than would otherwise occur in a
19 fair and competitive market. Those injuries are of the type the antitrust laws were designed to
20 prevent and flow from that which makes Abbott's conduct unlawful.

21 48. As a consequence, Plaintiffs are entitled to a permanent injunction, restraining
22 Abbott from engaging in additional anticompetitive conduct, to judgment pursuant to 15 U.S.C. §
23 15, and to recover the costs and expenses of this action, including reasonable attorneys' fees.

24 **SECOND CAUSE OF ACTION**

25 **(Fraudulent, Unfair, and Deceptive Business Practices)**
26 **(California Business and Professions Code § 17200, et seq.)**

27 49. Plaintiffs incorporate allegations set forth above, as if fully stated here. This cause
28 of action is brought on behalf of propounded class members who reside in the state of California.

1 50. Beginning on a date unknown to Plaintiffs but at least as early as December 2003
2 and continuing up to and including the date of the filing of this Complaint, Abbott committed and
3 continues to commit acts of unfair competition as defined by California Business and Professions
4 Code § 17200, *et seq.*, by engaging in the acts and practices alleged above.

5 51. The acts, omissions, and practices alleged in this Complaint constitute a continuous
6 course of unfair, unlawful, and/or fraudulent business practices within the meaning of California
7 Business and Professions Code § 17200, *et seq.*, including but in no way limited to the following:

- 8 a. The violations of Section 2 of the Sherman Act set forth above; and
- 9 b. Other unfair, unconscionable, misleading, or fraudulent conduct as alleged
10 above.

11 52. Plaintiffs and each class member are entitled to full restitution and/or disgorgement
12 of all revenues, earnings, profits, compensation, and benefits obtained by Abbott as a result of the
13 alleged unfair or unlawful business practices.

14 53. The illegal conduct alleged in this Complaint is continuing, and there is no
15 indication that Abbott will not continue this conduct into the future.

16 54. Abbott's unlawful and unfair business practices have injured, and present a
17 continuing threat of injury, to members of the public in that Abbott's conduct has restrained
18 competition and has caused and continues to cause Plaintiffs and class members to pay supra-
19 competitive and artificially inflated prices for the Norvir booster.

20 55. As alleged in this Complaint, Abbott has been unjustly enriched as a result of its
21 wrongful conduct and by its unfair competition.

22 56. For that reason, Plaintiffs and class members are entitled to equitable relief
23 including restitution and/or disgorgement of all revenues, earnings, compensation, profits, and
24 benefits obtained as a result of those business practices, as provided under California Business and
25 Professions Code §§ 17203 and 17204.

26 **THIRD CAUSE OF ACTION**
27 **(Unjust Enrichment)**

28 57. Plaintiffs incorporate allegations set forth above, as if fully stated here.

1 58. Abbott benefited from its unlawful acts through the receipt of overpayments by
2 Plaintiffs and other class members. It would be inequitable for Abbott to be permitted to retain the
3 benefit of the overpayments, which were conferred by Plaintiffs and class members.

4 59. Plaintiff and class members are entitled to the establishment of a constructive trust
5 consisting of the benefit to Abbott of such overpayments from which Plaintiffs and class members
6 may make claims on a pro-rata basis for restitution.

7 **PRAYER FOR RELIEF**

8 **WHEREFORE, Plaintiffs pray:**

9 1. That this action be declared a class action under Rule 23 of the Federal Rules of
10 Civil Procedure;

11 2. That Abbott’s conduct be declared a violation of Section 2 of the Sherman Act, the
12 California Unfair Business Practices Act, and common law as alleged in this Complaint;

13 3. That injunctive relief be ordered, preventing and restraining Abbott and all persons
14 acting on its behalf from further engaging in the unlawful acts alleged in this Complaint;

15 4. That Plaintiffs and class members be awarded restitution and or disgorgement of all
16 revenues, profits, and benefits obtained as a result of Abbott’s conduct;

17 5. That the Court establish a constructive trust consisting of any benefit obtained by
18 Abbott as a result of its conduct, from which Plaintiffs may make claims for restitution;

19 6. That Plaintiffs and class members be awarded costs, interest, expenses, and
20 reasonable attorneys’ and experts’ fees incurred in connection with this action; and

21 7. Such further relief as this Court deems necessary and appropriate.

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JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs hereby respectfully demand a trial by jury.

DATED: April 19, 2004

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