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Analysis of Abbott Laboratories Antitrust Litigation

BY HOLLIS SALZMAN AND MICHAEL STOCKER
LABATON SUCHAROW LLP

In a May 16, 2008, ruling, Judge Claudia Wilken of the District Court for the Northern District of California effectively extinguished Abbott Laboratories' hopes to avoid trial in a nationwide antitrust class action suit arising from its 400 percent price increase on Norvir, a drug that has revolutionized the treatment of HIV (6 PLIR 598, 5/23/08).¹ The Court's ruling not only offers useful insight into the sometimes-murky issue of inherent anticipation, but also has far-reaching implications for pharmaceutical companies hoping to rely on patents to avoid allegations of anticompetitive conduct.

The Plaintiffs' Sherman Act claims in *In re Abbott Laboratories Antitrust Litigation* are inextricably intertwined in the biology of the HIV virus itself. A long-standing challenge to scientists working to create effective treatments for HIV is the fact that the virus reproduces very rapidly, and mutates as it does so. These mutations permit the virus to rapidly gain resistance to new drugs as they are developed. Accordingly, innovation and competition in the marketplace for new HIV

¹ *In re Abbott Labs Norvir Antitrust Litigation*, 2008 WL 2095516 (N.D.Cal. May 16, 2008).

Hollis Salzman (hsalzman@labaton.com) is a partner at Labaton Sucharow LLP. Michael Stocker (mstocker@labaton.com) is an associate with the firm. Labaton Sucharow represents the Service Employees International Union Health and Welfare Fund in pending litigation against Abbott Laboratories. BNA welcomes other views on the litigation.

treatments is crucial: without it, patients will rapidly succumb to the disease as existing treatments fail.

Beginning in about the mid-1990s, researchers developed a promising new class of treatments for HIV disease called protease inhibitors ("PIs"). The advent of this powerful new class of drugs helped transform HIV disease from a death sentence into a chronic, manageable illness. Physicians used these PIs in combination with other HIV drugs to great effect, halting the disease in its tracks for many patients. However, as soon as PIs became available, the clock began running, as the virus rapidly acquired resistance to the new treatments.

In 1996 Abbott introduced a patented PI called Norvir, the brand name for ritonavir, to be used at a recommended daily dose of 1200 milligrams. Because of the drug's debilitating side effects at this dose, it was rarely used. However, scientists and physicians soon noticed that Norvir had a striking effect on certain metabolic pathways in the liver, dramatically slowing the metabolism of many types of drugs, including PIs. When Norvir was taken with PIs, therapeutically effective blood levels of the PIs could be consistently maintained, and the PIs could be taken at smaller doses, sparing patients many of the severe side effects associated with the drugs. More importantly, Norvir's "boosting" effect greatly impaired the virus' ability to develop resistance to PIs. Norvir is the only commercially available drug known to have this effect.

Indeed, unless a patient takes Norvir together with a PI, the virus can rapidly develop resistance to the entire PI class. Accordingly, Norvir boosting has become part of the standard PI treatment. To enable patients to take these boosted PI regimens, Abbott sells Norvir pills to the public.

In 2000, Abbott capitalized on Norvir's boosting properties by launching a pill called Kaletra, in which it combined a PI called lopinavir with a boosting dose of

Norvir. Kaletra was the only single-pill treatment available that combined Norvir and a PI. While Kaletra was a very effective boosted PI treatment, it was associated with serious side effects, including hyperlipidemia, lipodystrophy, and gastric problems. Notwithstanding these problems, it quickly became the dominant boosted PI prescribed, and one of Abbott's top primary-care products.

In 2003, however, Abbott's lucrative Kaletra business was in peril. New PIs were about to be launched by Abbott rivals GlaxoSmithKline and Bristol Myers Squibb that, when boosted with Norvir, were just as effective as Kaletra, but better tolerated and more convenient.

What Abbott did next has become the subject of enormous controversy. In December of 2003, Abbott imposed a 400 percent price increase on the Norvir sold for use with rivals' PIs, while leaving the price of Kaletra unchanged. Overnight, Kaletra became the cheapest boosted PI regimen on the market. According to Abbott's rival, GlaxoSmithKline, this price hike has seriously affected sales of Glaxo's effective new boosted PI, Lexiva.

In 2004, the plaintiffs in *In re Abbott Labs Norvir Antitrust Litigation* brought suit under Section 2 of the Sherman Act, arguing that Abbott used the Norvir price hike as a means to protect Kaletra from the competitive threat it faced from newer and safer drugs such as Lexiva. Abbott argued in its defense that it raised the price of Norvir in light of the increased clinical importance of the drug, and because it was being used in smaller doses as a booster than it was as a stand-alone PI.²

Abbott also mounted an affirmative defense of patent immunity premised on patents it claimed on the boosting method. In essence, Abbott argued that because it had patents on the method of using Norvir to boost PIs, it was entitled to exclude competitors from the market for Boosted PIs by any means it liked, including a Norvir price hike.

Indeed, Abbott's boosting patents were a source of substantial revenue for the Company. As Abbott itself explained in documents filed with the Court, "[a]t considerable expense, Abbott's four major competitors in the Boosted Market have taken a license to these patents for the express purpose of 'promot[ing] and market[ing] certain of [their] products with Ritonavir for the purpose of co-prescription/co-administration.'"³

After bringing two unsuccessful motions for summary judgment in 2005 and 2006, Abbott filed a third motion in February of 2008, premised in part on its patent immunity defense. The benefits of this tactic seemed obvious. If the Company's motion were successful, the pending case would be dismissed. If it lost, the complex patent arguments would still have to be resolved at trial, scheduled for Aug. 18.

² In 2007, direct purchasers of Norvir and Abbott's rival GlaxoSmithKline together filed six more suits, making similar allegations.

³ Abbott Laboratories' February 13, 2008 Motion for Summary Judgment, Docket No. 445.

In attempting to dismiss Plaintiffs' antitrust claims, the Company risked and lost valuable intellectual property. The Court's decision thus stands as a caution to companies seeking to press intellectual property into service as a defense in antitrust cases.

That there was also substantial risk to Abbott's strategy became apparent when, in response to the Company's motion, Plaintiffs filed both an opposition to Abbott's motion and a cross-motion of their own for partial summary judgment, attacking Abbott's patents as invalid and asking that the Court bar the Company from asserting its patent immunity affirmative defense.

The validity arguments in Plaintiffs' opposition and cross-motion turned in large part on the significance to be accorded language in the preambles to Abbott's patents. Claim 9 of U.S. Patent No. 6,037,157 (the '157 patent) states:

A method for increasing human blood levels of a drug which is metabolized by cytochrome P450 monooxygenase comprising administering to a human in need of such treatment a therapeutically effective amount of a combination of said drug or a pharmaceutically acceptable salt thereof and ritonavir or a pharmaceutically acceptable salt thereof.

Similarly, claim 21 of U.S. Patent No. 6,703,403 (the '403 patent), which is dependent on claim 22 of the same patent. Claim 21 states:

A method for improving the pharmacokinetics of a drug which is metabolized by cytochrome P450 monooxygenase comprising administering to a human in need of such treatment an amount effective to inhibit cytochrome P450 monooxygenase of ritonavir or a pharmaceutically acceptable salt thereof.

Claim 22, in turn, states "the method of claim 21 wherein the drug which is metabolized by cytochrome P450 monooxygenase is an HIV protease inhibitor."

In essence, both claims describe a method of using Norvir together with other drugs in order to benefit from its effects as a metabolic booster. The problem for Abbott, suggested the Plaintiffs, is that these patents were anticipated by U.S. Patent Number 5,674,882, which claims:

A method of inhibiting an HIV infection comprising administering to a human in need thereof a therapeutically effective amount of [Norvir] or a pharmaceutically acceptable salt thereof in combination with a therapeutically effective amount of another HIV protease inhibiting compound.

While all three patent claims describe a method of using Norvir in combination with other drugs, Abbott argued that the '157 and '403 patents differed from the earlier '882 patent in that they claim the method of using Norvir with the intent to achieve a specific result—metabolic boosting.

In determining whether this statement of purpose supported precluded Plaintiffs' anticipation arguments, the Court looked closely at the Federal Circuit's 2003

decision in *Jansen v. Rexall Sundown*.⁴ In *Jansen*, the plaintiff sued a manufacturer of an over-the-counter vitamin supplement containing both folic acid and vitamin B12 for the contributory infringement of a patent which claims:

A method of treating or preventing macrocytic-megaloblastic anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B12 deficiency which comprises administering a daily dosage of a vitamin preparation to a human in need thereof comprising at least about .5 mg of vitamin B12 and at least .5 mg of folic acid.

In determining that the claim was not infringed, the *Jansen* court held that “administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megaloblastic anemia is not practicing the claimed method, because *Jansen* limited his claims to treatment or prevention of that particular condition in those who need such treatment of prevention.”⁵ In this respect, the preamble of the patent claim, describing the purpose for administering the vitamins, “gave life and meaning” to the patent. *Id.*

The Court rejected Abbott’s argument that the preambles to the ‘157 and ‘403 patents similarly gave life and meaning to the ‘157 and ‘403 patents beyond what was described in the ‘882 patent. The Court held that

In *Jansen*, the preamble language was construed as a limitation because it disclosed a specific theretofore unknown use for taking a combination of folic acid and vitamin B12—

namely, the prevention and treatment of macrocytic-megaloblastic anemia. The preamble gave “life and meaning” to the claim because without it, the patent would simply recite a method that was already practiced. Here, the preamble does not disclose a new use for the prior art. . . . The preamble simply expresses one of the necessary results of practicing the existing method. Abbott cannot patent the practice of prior art by framing a necessary result of that practice as a claim-limiting purpose.

The Court’s ruling has dramatic consequences for the Company. Abbott now faces trial on Plaintiffs’ antitrust claims bereft of its principal defense. In light of the fact that Plaintiffs in the *In re Abbott Laboratories Norvir Antitrust Case* seek not only damages but nationwide injunctive relief, a loss at trial in August could have significant repercussions for the Company’s business. Moreover, a verdict against Abbott will also have preclusive effect with respect to many of the factual issues that will be tried in the cases brought by Glaxo and by the direct purchasers.

The Court’s patent ruling also has important strategic implications for industry observers. In attempting to dismiss Plaintiffs’ antitrust claims, the Company risked and lost valuable intellectual property—patents made more valuable by the fact that Norvir has shown promise as a metabolic booster to drugs used to treat other disease states as well, such as hepatitis. Even without the benefit of a victory at trial, Plaintiffs have significantly altered the playing field in the market for boosted PIs by undercutting Abbott’s claims on this crucial new technology. The Court’s decision thus stands as a caution for companies seeking to press intellectual property into service as a defense in antitrust cases.

⁴ 342 F.3d 1329 (Fed. Cir. 2003).

⁵ *Jansen*, 342 F.3d at 1334, cited at page 15 of Judge Wilken’s opinion.