Judgment for Drug Companies Unlikely the End of the Road in Nexium Case

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The federal district court in Boston has rejected a request from purchasers of AstraZeneca LP's heartburn medication Nexium for a new trial to challenge a "reverse payment" or "pay-for-delay" agreement between AstraZeneca and Ranbaxy Pharmaceuticals to block the entry of a generic version of the drug. Judge Young's lengthy opinion provides an interesting look at the trial and the proceedings that led up to it. In addition, the decision offers a glimpse of the issues that might be raised in a likely appeal.

In December 2014, the jury had found that a patent settlement agreement between AstraZeneca and Ranbaxy was unreasonably anticompetitive under a rule of reason standard. However, the jury saw no causal link between the agreement and the overcharge harms alleged. Although the plaintiffs argued in their motion for a new trial that the trial court improperly limited their causation theory, the court on July 30 ruled that "the trial proceedings were sufficiently fair that one can have a strong degree of confidence in the outcome"

The court acknowledged that, while the verdict came out in favor of the defendants, it was tainted with the jury's holding that the agreement between AstraZeneca and Ranbaxy to settle patent infringement litigation over Nexium was anticompetitive in nature. During the course of the 26-day trial that commenced in

October 2014, two other defending generic drug companies—Teva Pharmaceutical and Dr. Reddy's Laboratories—settled. Thus, the jury only considered the dispute between the plaintiffs and AstraZeneca and "first-filer" Ranbaxy.

Under the challenged 2008 agreement, AstraZeneca agreed to drop a lawsuit against Ranbaxy in exchange for Ranbaxy's agreement (1) to admit that certain of AstraZeneca's Nexium-related patents were enforceable and valid, (2) to admit that Ranbaxy's generic Nexium would infringe these patents, and (3) to delay launching a generic version of Nexium until May 27, 2014. The court charged the jury on the theory that but for the AstraZeneca-Ranbaxy agreement, Ranbaxy would have agreed to a generic launch date earlier than May 27, 2014, which would have allowed Teva—the more launch-prepared generic—to work out a deal with Ranbaxy to take over the generic launch.

The jury concluded that AstraZeneca had market power and that the AstraZeneca/Ranbaxy agreement contained a large, unjustified payment from AstraZeneca and was unreasonably anticompetitive. However, the jury found causation lacking. It responded in the negative as to the question of whether Ranbaxy would have launched a generic earlier but for the agreement with AstraZeneca.

Causation

The court explained that the plaintiffs' evidence of antitrust injury, when "[t]ested against the common sense of actual jurors . . . fell short." To address the jury's critical determination with respect to causation, the plaintiffs in their motion for new trial argued that the trial court improperly allowed them to proffer only one causation theory as to Ranbaxy. The court rejected the argument that it restricted the plaintiffs' theory. In addition, it refused to grant a new trial to permit the plaintiffs to offer a new theory of "involuntary forfeiture." This involuntary forfeiture theory was seemingly based on developments after May 27, 2014—the agreed date for Ranbaxy's generic Nexium launch. After that date, the Food and Drug Administration (FDA) revoked Ranbaxy's first-to-file, 180-day marketing exclusivity period for its Nexium generic, and Teva released an FDA-approved generic version of Nexium.

Although the court rejected the defendants' contention that the plaintiffs were judicially estopped from arguing that post-May 27, 2014, evidence necessitated a

new trial, the court concluded that a new trial was not warranted, even in light of "indisputable post-trial developments." The court held that there were still "obvious (and insurmountable) difficulties" with the causation theory that Teva would have brought its generic Nexium to market sooner if the FDA would earlier have involuntarily forfeited Ranbaxy's 180-day exclusivity period. According to the court, the speculative theory "stretches any reasonable inference from the evidence of record at least a couple of bridges too far." Moreover, there was "no evidence that the events that played out in the latter half of 2014 and early 2015 can simply be transposed entire to an earlier point in history."

Class certification

Due to the "distinct possibility that further proceedings may be ordered," the court articulated the method "devised for culling the uninjured from the injured class members in the event of a damages phase of the litigation." Because these thoughts were not included in the class certification opinion, the court explained that, had antitrust liability been established, the burden of going forward with evidence of lack of injury to particular class members would shift to the defendants, with the ultimate burden of persuasion as to the damages suffered by particular claimants left to the end-payor plaintiffs—the insurance companies.

Permanent injunction

The jury's finding that the AstraZeneca/Ranbaxy agreement was unreasonably anticompetitive did not establish the existence of an antitrust violation, warranting requested permanent injunctive relief. The plaintiffs sought an order prohibiting AstraZeneca and Ranbaxy from again utilizing "no authorized generic" clauses in patent settlement agreements for a period of ten years.

The court noted that the FTC takes the view that no-AG clauses have de facto anticompetitive effects on the pharmaceutical market. However, because causation was not proven, the private plaintiffs were not entitled to the requested relief. Moreover, the AstraZeneca no-AG clause was effectively dismantled when the FDA revoked Ranbaxy's first-filer exclusivity. Thus, judgment was entered for AstraZeneca and Ranbaxy.

In the final 18 pages of his 110-page opinion, Judge Young offers his views on the importance of jury trials. The jurist also went on to deride "forced arbitration [that] effectively stamp[s] out the individual's statutory rights wherever inconvenient to

the businesses which impose them."

The case is *In re Nexium (Esomeprazole) Antitrust Litigation*, No. 1:12-md-02409-WGY.