CRA Insights: Life Sciences

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CRA's **Life Sciences Litigation** team provides periodic summaries of notable developments in litigation. In this issue, we discuss a decision on the use of comparable license agreements in patent damages and an opinion on class certification in pharmaceutical antitrust.

Cytiva Sweden AB et al v. Bio-Rad Laboratories, Inc., Case No. 1-18-cv-01899 (US District Court for the District of Delaware)

On June 1, 2021, US District Judge Colm Felix Connolly granted Plaintiffs' motion to exclude Defendant's expert witness from providing damages-related opinions at trial, finding that the opinions relied on license agreements for technology that is not comparable to the technology covered by the patents-in-suit.

Background

In November 2018, GE Healthcare Bio-Sciences AB, GE Healthcare Bio-Sciences Corporation, and General Electric Company filed suit against Bio-Rad Laboratories, Inc. ("Defendant") alleging that Defendant's suite of protein purification systems infringed US Patent Nos. 9,709,589, 9,709,590, 9,709,591, and 9,671,420, all of which relate to automated liquid chromatography. Cytiva Sweden AB and Global Life Sciences Solutions USA LLC ("Plaintiffs") subsequently replaced GE Healthcare Bio-Sciences AB, GE Healthcare Bio-Sciences Corp., and General Electric Company as plaintiffs.

In December 2020, Plaintiffs filed a motion to exclude the expert opinions, testimony, and/or calculations of Bio-Rad's expert witness that were based on prior license agreements with no technical comparability to the patents-in-suit. Defendant did not dispute that the opinions of its expert witness were based in part on nine licensing agreements that are not comparable to the license that is the subject of the hypothetical negotiation in the determination of a reasonable royalty. Defendant argued, however, that its expert's limited discussion of the nine licenses was permissible as "[t]hese licenses are reflective of industry practice, which is relevant to the form of the reasonable royalty." The Court stated that it was not relevant whether Defendant's expert witness' "discussion of the nine licenses is limited or offered merely to confirm his opinion about the form of a reasonable royalty…Defendant 'cannot escape th[e] [comparability] requirement by suggesting that the incomparable licenses only played a minor role [in its expert's analysis], instead of being a driving force in the reasonable royalty estimate.'"

Decision

Judge Connolly granted Plaintiffs' motion to exclude the opinions of Defendant's expert witness based on non-comparable license agreements.

In re Ranbaxy Generic Drug Application Antitrust Litig., Case No. 19-md-2878 (US District Court for the District of Massachusetts)

On May 14, 2021, US District Judge Nathaniel M. Gorton certified classes of direct purchasers and end payors in two class actions against Ranbaxy Inc. and Sun Pharmaceutical Industries Limited ("Ranbaxy").

Background

Between 2004 and 2005, Ranbaxy submitted the first substantially complete Abbreviated New Drug Applications ("ANDAs") for generic equivalents of three branded drugs, Diovan, Nexium, and Valcyte. In 2007 and 2008, Ranbaxy obtained tentative approval from the FDA for these applications. Ranbaxy did not bring its generic version of Diovan to market until 2014, and the FDA revoked its tentative approvals for the generic versions of Nexium and Valcyte the same year. Plaintiffs allege Ranbaxy violated antitrust laws, consumer protection laws, and the Racketeer Influenced and Corrupt Organizations Act ("RICO") by submitting ANDAs with missing, incorrect, or fraudulent information, thereby wrongfully obtaining exclusivity periods and delaying the market entry of generic versions of each drug. But for this conduct, Plaintiffs assert that generic versions of the three drugs would have entered the market and been available. Plaintiffs allege they paid artificially inflated prices for generic versions of each drug.

In November 2020, Plaintiffs filed for the certification of direct purchaser and end payor classes for each drug. Direct Purchaser Plaintiffs' economic expert compared average prices of the at-issue drugs in the actual world versus hypothetical averages in a world without the alleged anticompetitive conduct. End Payor Plaintiffs' economic expert relied on "average prices, average copayments, and average rebates to measure injury." Ranbaxy argued that these averages failed to account for price variability among class members, thereby obscuring uninjured class members. With respect to end payors, Ranbaxy argued that payments made by third-party payors vary widely due to factors such as cost sharing and rebates, and certain payors would be uninjured due to subsidies provided by the federal government.

Decision

The Court found for Plaintiffs, stating that Plaintiffs' use of the economic literature, contemporaneous business forecasts from brand and generic manufacturers, and transaction data was sufficient to conclude that all or virtually all members of the proposed classes had suffered injury. The Court's opinion defended the use of averages as common practice and concluded that variation is more relevant to the extent of injury than the existence of injury. The Court found evidence for a small number of uninjured members of each class and concluded that the existence of a de minimis number of uninjured members is not fatal to class certification at this stage. Finally, the Court opined that "antitrust injury occurs the moment the purchaser incurs an overage, whether or not the injury is later offset."

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