CRA Insights: Life Sciences

CRA Charles River Associates

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CRA's Life Sciences Litigation team provides periodic summaries of notable developments in litigation. In this issue, we share notable cases from 2021 and several to keep an eye on in 2022.

Edwin Hardeman v. Monsanto Company, Northern District of California, No. 3:16-cv-00525-VC

On May 14, 2021, a panel consisting of three Circuit Judges affirmed the district court's judgment in favor of Edwin Hardeman in his action alleging that Roundup, the pesticide marketed by Monsanto Company (Monsanto), caused his non-Hodgkin's lymphoma (NHL). Monsanto, which has been owned by Bayer AG since 2018, has since filed a petition for a writ of certiorari with the US Supreme Court.

Background

Hardeman sued Monsanto in 2016, alleging that his use of Roundup from the 1980s through 2012 led to his NHL diagnosis in early 2015. This case was the first to go to trial of about 5,000 cases alleging that Roundup causes NHL. Roundup's active ingredient is glyphosate. The pretrial proceedings were separated into general causation, addressing whether glyphosate can cause NHL at exposure levels humans might experience, and specific causation, addressing whether Hardeman's exposure to Roundup caused his NHL. Monsanto's motion to exclude Hardeman's general causation experts was partially granted and partially denied; three experts were allowed to testify.

The trial was bifurcated. The first phase addressed whether Roundup caused Hardeman's NHL, and the second phase addressed liability and damages, and included information about regulatory decisions regarding glyphosate. The jury was instructed that it must find that glyphosate exposure was one of two or more factors that could have independently caused his cancer. Under Phase Two of the trial, Monsanto moved to exclude evidence from the International Agency for Research on Cancer's (IARC's) 2015 report classifying glyphosate as probably carcinogenic to humans. The district court ultimately excluded the report but admitted IARC's classification of glyphosate.

Verdict

After Phase One of the trial, the jury returned a verdict that Roundup exposure was a substantial factor causing Hardeman's NHL; after Phase Two, the jury found that Monsanto had

failed to provide warnings about Roundup's NHL risk and that Hardeman was entitled to punitive damages. Hardeman was awarded $5,267,634 in compensatory damages and $75 million in punitive damages. The district court later reduced the punitive damages award from $75 million to $20 million, noting that $75 million was constitutionally impermissible because Monsanto's conduct was not particularly egregious under the Due Process Clause.

Monsanto appealed to the circuit court, which found, among other conclusions: the district court applied the correct legal standard under *Daubert* in admitting Hardeman's general and specific causation expert testimony; the district court's decision to admit IARC's glyphosate classification was not an error; and punitive damages were permissible because Monsanto acted with malice. The panel noted it was aware that the appeal was from the verdict in a bellwether trial for potentially thousands of federal cases but emphasized that many of its holdings were fact-specific. The US Supreme Court is currently considering Monsanto's petition, which hinges on a question of evidentiary standards, and has issued an order requesting the views of the Solicitor General on behalf of the United States.

In Re: National Prescription Opiate Litigation, Northern District of Ohio, No. 1:17-md-02804

Opioid trials against drug manufacturers have continued on a large scale for years. A settlement proposed in July 2021 may be the path to end many of these trials.

Background

Numerous state and city governments have sued opioid manufacturers, distributors, and retail pharmacies over their role in the opioid epidemic, claiming that drugmakers misrepresented the risks of opioids in their marketing materials and concealed the risk of addiction. The multi-district litigation case names over 110 plaintiffs and 700 defendants.

Settlement

In July 2021, AmerisourceBergen Corp., Cardinal Health Inc., and McKesson Corp. announced a proposed settlement agreement whereby the three distributors agreed to pay up to $26 billion over the next 18 years, contingent on the number of states and territories that agree to participate in the settlement.[1] The settlement proposal includes a $5 billion contribution from Johnson & Johnson. Washington, DC, 46 out of 49 eligible states, all eligible territories, and 90% of eligible local governments have signed on to the deal, which will go forward. Alabama, Oklahoma, and Washington chose not to settle.[2]

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[1] Doctor, Vanessa, "Drug Companies Settle Opioid Lawsuits with $26 Billion Paid Over 18 Years," *BioSpace*, July 22, 2021, https://www.biospace.com/article/major-drug-distributors-u-s-states-agree-on-26-billion-settlement-to-suspend-opioid-related-lawsuits/?s=78; Overley, Jeff and Emily Field, "Despite Fanfare, $26B Opioid Offer Far From Finish Line," *Law360*, https://www.law360.com/articles/1405358/despite-fanfare-26b-opioid-offer-far-from-finish-line.

[2] Field, Emily, "J&J, Drug Distributors' $26B Opioid Settlement Is Finalized," *Law360*, https://www.law360.com/lifesciences/articles/1468378?cn_pk=e4d08ec9-1fa0-49d8-9ff8-d44879dd474a&utm_source=newsletter&utm_medium=email&utm_campaign=custom.

State of Hawaii v. Bristol-Myers Squibb, Hawaii Circuit Court for the First Circuit (Honolulu), Civil No. 14-1-0708-03-DEO

In February 2021, the Hawaii Circuit Court for the First Circuit (Honolulu) ordered Bristol-Myers Squibb Company (BMS) and Sanofi-Aventis US LLC, Sanofi US Services Inc., and Sanofi-Synthelabo Inc. (collectively, Sanofi) to pay a civil penalty of $834 million to the state of Hawaii for conducting misleading marketing of Plavix and failing to warn patients of East Asian and Pacific Island origins of potential health risks due to genetic variants.

Background

On March 16, 2014, Hawaii's Attorney General filed suit against BMS and Sanofi, manufacturers and distributors of the prescription drug Plavix. The suit alleged that BMS and Sanofi falsely labeled and advertised Plavix, failing to disclose that "Plavix has a diminished or no effect on approximately 30 percent of the population because they metabolize the drug poorly, due to their genetic traits or because they take other drugs that affect the body's ability to metabolize Plavix."[3] In February 2021, the court concluded after a four-week bench trial that BMS and Sanofi misleadingly marketed Plavix and failed to properly warn consumers in Hawaii about its health risks. It entered judgment ordering Defendants to pay over $834 million. Defendants subsequently moved for an amended judgment or new trial.

Decision

In May 2021, Defendants' motion for an amended judgement or new trial was denied.

Bayer Healthcare LLC v. Baxalta Inc. et al., US Court of Appeals for the Federal Circuit, No. 19-2418

On March 1, 2021, the US Court of Appeals for the Federal Circuit (CAFC) denied a motion by Defendants Baxalta Inc. and Baxalta US Inc. (collectively, Baxalta) for judgment as a matter of law or a new trial. This decision upheld the 2019 decision of Judge Andrews of the US District Court for the District of Delaware awarding Bayer Healthcare LLC (Bayer) $173 million in a patent dispute.

Background

On December 5, 2016, Bayer filed suit against Baxalta and Nektar Therapeutics (Nektar) for infringing US Patent No. 9,364,520 (the '520 patent). The '520 patent covered Bayer's process of manufacturing a hemophilia treatment, Kogenate. Bayer accused Baxalta of using the '520 patent to manufacture its own hemophilia treatment, Adynovate. In February 2019, the jury found in favor of Bayer and awarded damages in the amount of $155 million with a reasonable royalty rate of 17.8% for the period between June 2016 and November 2018. In a later motion, Bayer asked for an additional $27 million in damages and interest and was ultimately awarded $173 million in total.

[3] "Attorney General Files Lawsuit Against Manufacturers and Distributors of Plavix," *Hawaii Reporter*, March 19, 2014, https://www.hawaiireporter.com/attorney-general-files-lawsuit-against-manufacturers-and-distributors-of-plavix/.

Baxalta appealed the verdict to the CAFC on September 20, 2019, arguing that Judge Andrews misinterpreted Baxalta's explanation of its process, which it believed differentiated its treatment from Bayer's. Baxalta also claimed that Judge Andrews erred by allowing the jury to decide the royalty rate that Bayer was awarded.

Decision

The CAFC found that Baxalta infringed the '520 patent and ruled that allowing the jury to select the royalty rate within a presented range is within the district court's discretion. CAFC Judges Pauline Newman, Richard Linn, and Kara F. Stoll denied Baxalta's appeal, determined that a new trial was unwarranted, and thus affirmed the district court's decision.

In Re: Purdue Pharma L.P., United States District Court for the Southern District of New York, No. 7:21-cv-07532

On December 16, 2021, Purdue Pharma's Chapter 11 bankruptcy plan was overturned by US District Court for the Southern District of New York Judge Colleen McMahon. Judge McMahon pointed out that the plan, which was originally authorized by US Bankruptcy Court Judge Robert Drain, relied on the court to authorize a shareholder release, which is not permitted in bankruptcy court.

Background

On September 1, 2021, Judge Drain authorized Purdue Pharma's Chapter 11 bankruptcy plan in the US Bankruptcy Court for the Southern District of New York. The ruling granted the former owners of Purdue Pharma, the Sackler family, immunity from future related opioid litigation and distinguished the family as separate from the company. In exchange for immunity, the Sackler family was required to hand over Purdue Pharma to designated entities and to contribute to opioid abatement trusts that will be used to satisfy personal injury claims related to Purdue Pharma's opioid drug, OxyContin. This ruling intended for Purdue Pharma's value to be reorganized among nine trusts that will financially aid those affected by OxyContin and fund opioid abatement efforts.

Decision

Judge McMahon overturned Purdue Pharma's bankruptcy plan noting that a shareholder release is not authorized in bankruptcy court. Purdue Pharma is in the process of appealing Judge McMahon's decision to the Second Circuit. In the meantime, Purdue has reached an agreement with eight states and the District of Columbia which did not support the original bankruptcy plan. This agreement is contingent on the Sackler family contributing at least $5.5 billion to opioid abatement trusts instead of the originally suggested $4.325 billion. Purdue will present this new settlement to the court.[4]

[4] Sullivan, Vince, "Purdue Reaches Final Terms on New $5.5B Ch. 11 Settlement.", *Law360,* March 3, 2022, https://www.law360.com/articles/1470392/purdue-reaches-final-terms-on-new-5-5b-ch-11-settlement.

Below are two cases outside of the Life Sciences industry, but with implications that affect many of the cases encountered in the industry.

Shure Incorporated and Shure Acquisition Holdings, Inc. v. ClearOne, Inc., District of Delaware, No. 19-1343-RGA-CJB

In a matter before the US District Court for the District of Delaware, the Court had excluded Plaintiffs' damages expert's reasonable royalty opinion finding its *Georgia Pacific* analysis deficient. On October 28, 2021, the Court subsequently ruled that this exclusion did not preclude presentation of damages evidence and allowed for Plaintiffs to call Defendant's expert (but not its own) to testify about the reasonable royalty, even if the Defendant refused to call the expert.

Background

Plaintiffs sell professional audio equipment, including a line of ceiling array microphones. The US Patent and Trademark Office issued to Plaintiffs US Patent No. 9,565,493, titled "Array microphone system and method of assembling the same," allegedly covering the inventions embodied in its products. In July 2019, Plaintiffs alleged patent infringement by Defendant's sales of certain microphones.

The Court had previously granted Defendant's motion to exclude Plaintiffs' damages expert's reasonable royalty opinion. However, the Court ruled to allow Plaintiffs to call Defendant's rebuttal damages expert to testify on her reasonable royalty analysis, even if Defendant refused to call her. The Court provided the following ruling and reasoning:

> Since [Plaintiffs' damages expert's] *Georgia Pacific* analysis rests upon the faulty proxy, it is either irrelevant or confusing. Thus, [Plaintiffs] cannot call [their own damages expert] to opine on a reasonable royalty rate. Further, I agree with [Defendant] that a presentation of general factual evidence does not provide sufficient evidence for a reasonable royalty, especially when [Plaintiffs' damages expert's] opinion has been excluded. [The Court] will, however, allow [Plaintiffs] to call [Defendant's rebuttal damages expert] if [Plaintiffs so choose]. It is within [the Court's] discretion to allow [Plaintiffs] to call [Defendant's] witness even if [Defendant] refuses to call her. In making this discretionary decision, courts weigh the interests of the party seeking to call the expert and of the court in reaching an informed decision against the possible prejudice to the party who originally retained the expert. In this case, [Defendant] is unlikely to be prejudiced. [Defendant] is clearly knowledgeable about [its own expert's] opinions on the reasonable royalty rate and well prepared to respond to it … Allowing [Plaintiffs] to call [Defendant's expert] is particularly appropriate as the exclusion of evidence is an 'extreme sanction.[5]

Verdict

On November 3, 2021, the jury found that Defendant did not infringe Plaintiffs' patent.

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[5] Shure Incorporated, et al., v. ClearOne, Inc., In the United States District Court for the District of Delaware, Civil Action 19-1343-RGA, Memorandum Order, October 28, 2021, pp. 1-2.

NexStep, Inc. v. Comcast Cable Communications, LLC, District of Delaware, No. 1-19-cv-01031

On September 16, 2021, US District Judge Richard G. Andrews of the US District Court for the District of Delaware granted Comcast Cable Communications, LLC's *Daubert* motion to exclude the opinions of NexStep, Inc.'s expert witness on damages. Although this case does not involve the life sciences sector, the damages issues addressed in this decision (namely, the starting point for reasonable royalty negotiations) often arise in life science patent cases.

Background

On June 3, 2019 NexStep, Inc. (NexStep) filed a complaint alleging that Comcast Cable Communications, LLC (Comcast) infringed nine US patents relating to personal computing devices and services to control, combine, and integrate telephone and video services. NexStep subsequently dropped its assertion regarding one of its patents. Defendant's motion for summary judgment of non-infringement was granted for the remaining asserted patents with the exception of two patents, referred to collectively as the "Customer Troubleshooting Patents."

Comcast moved to exclude NexStep's expert witness's opinions regarding damages as arbitrary and contrary to Federal Circuit precedent. NexStep's expert witness stated in his expert report that the appropriate reasonable royalty rate for the Customer Troubleshooting Patents is based on Comcast's cost savings. NexStep's expert witness further noted that "[i]t is reasonable to conclude that a 50/50 split of the cost savings would be a reasonable starting point for a negotiation of the sharing of the cost savings."[6] Finally, NexStep's expert witness applied the *Georgia Pacific* factors to "determine their effect on the 50/50 split"[7] and arrived at a royalty rate of 40% after a downward adjustment.

The Court stated that "the facts offered by [NexStep] could be true of a negotiation of cost-savings technology (or anticipated profits) by any two parties, meaning that they are not particular to the facts of this case."[8] The Court also noted that the Federal Circuit rejected a 50/50 starting point based on the Nash Bargaining Solution "without sufficiently establishing that the premises of the theorem actually apply to the facts of the case at hand"[9] and that although NexStep's expert witness did not mention the Nash Bargaining Solution, his defense of the use of a 50/50 split as "reasonable" without support by facts specific to these parties fares no better.

Decision

Judge Andrews granted Comcast's *Daubert* motion to exclude NexStep's expert witness's damages opinions and testimony for failure to support a 50/50 starting point with facts specific to the case at hand.

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6 NexStep, Inc., v. Comcast Cable Communications, LLC, In the United States District Court for the District of Delaware, Civil Action 19-1031-RGA, Memorandum Opinion, September 16, 2021 ("NexStep Opinion"), p. 4.

7 NexStep Opinion, p. 4.

8 NexStep Opinion, p. 5.

9 NexStep Opinion, p. 5.

Below are several cases to watch in 2022

Opioid cases will continue to be prevalent in 2022, including the settlement proposal mentioned above. Additionally, several life sciences cases, including *Amgen v. Sanofi*, have petitioned the Supreme Court for certiorari. Also expected in 2022 are rulings on the No Surprises Act related to medical bills, the beginning of Juul litigation, and another Theranos trial. There are also likely to be significant implications of Supreme Court decisions outside of the life sciences industry expected in 2022. Outlined below is what is at stake in one Supreme Court case to watch.

American Hospital Association, et al., v. Xavier Becerra, United States Supreme Court, No. 20-1114

Background

On September 5, 2018, the American Hospital Association filed a complaint in the United States District Court for the District of Columbia challenging certain aspects of a final rule issued by the Centers for Medicare & Medicaid Services (CMS) for Medicare hospital outpatient services. The final rule reduced Medicare reimbursements to public and not-for-profit hospitals and clinics under the 340B Program by nearly 30%. On May 6, 2019, the Court concluded that both the 2018 and 2019 340B reimbursement rates were unlawful and chose to remand the issue to the agency without vacating the 2018 and 2019 Outpatient Prospective Payment System rules. A panel of the US Court of Appeals for the DC Circuit reversed this decision, and the appellate court chose not to rethink the decision in October 2020.10 Plaintiffs submitted a petition for a writ of certiorari in the US Supreme Court on February 10, 2021, and the Supreme Court granted certiorari on July 2, 2021.

Under federal law, the reimbursement rate paid by Medicare for specified covered outpatient drugs is set based on one of two payment methodologies. If the US Department of Health and Human Services (HHS) has collected adequate data, it sets the reimbursement rate equal to the average acquisition cost for the drug and may vary that rate by hospital group. However, if HHS has not collected such data, it must set a reimbursement rate equal to the average price for the drug, as calculated by HHS. In 2017, CMS proposed lowering the government payment rate for drugs purchased under the 340B program from average sales price (ASP) plus 6% to ASP minus 22.5%, stating that a lower reimbursement rate would better reflect the acquisition cost of the drugs. At issue in this case is whether *Chevron* deference permits HHS to set reimbursement rates based on acquisition cost and vary such rates by hospital group without collecting adequate hospital acquisition cost survey data.

Potential Implications

Under *Chevron* deference, an administrative agency's interpretation of an ambiguous statute is entitled to judicial deference. HHS claims that its change in reimbursement rates to hospitals participating in the 340B program is entitled to judicial deference under *Chevron*. The Supreme Court may look to use this case to overturn *Chevron* altogether.[11] A decision is expected in 2022.

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[10] Lidgett, Adam, "DC Circ. Won't Rethink HHS Cuts To Medicare Drug Program," *Law360*, https://www.law360.com/articles/1320536/dc-circ-won-t-rethink-hhs-cuts-to-medicare-drug-program.

[11] Nachmany, Eli, "SCOTUS Faces a Chevron Decision Tree in American Hospital Association v. Becerra," *Yale Journal on Regulation*, August 9, 2021, https://www.yalejreg.com/nc/scotus-faces-a-chevron-decision-tree-in-american-hospital-association-v-becerra-by-eli-nachmany/.

Editors

Justin Ho
Principal
+1-202-662-3926
jho@crai.com

Sean Sheridan
Principal
+1-312-377-9237
ssheridan@crai.com

Erin McDermott
Associate Principal
+1-617-245-3070
emcdermott@crai.com

Ana Curtis
Consulting Associate
+1-202-662-3991
acurtis@crai.com