Food and Drug Cases to Watch in 2022

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We asked our Top Cases chapter authors for their picks on which current litigations, regulatory actions, and other developments have the potential to change the food and drug landscape in the balance of 2022. Some of the cases described here are appeals or other forms of continuation of important cases discussed in preceding chapters in this volume; others represent new issues that may result in important new rulings and precedents.

BABY FOOD HEAVY METALS SUITS[1]

A February 2021 report released by the Subcommittee on Economic and Consumer Policy of the U.S. House of Representatives Committee on Oversight and Reform reported data from baby food manufacturers on concentrations of arsenic, lead, mercury, and cadmium in baby foods, concluding that seven major manufacturers of these products contained one or more of these metals at dangerous levels. The results were swift, predictable, and expensive for the companies involved, each of which became the subject of multiple suits that have been consolidated into joint proceedings.

The baby food metals cases are still in early stages, and the industry and legal communities will be watching for developments, whether in litigation or settlement, that will inform how companies in other issues deal with similar litigation fallout resulting from government reports.

ENVIRONMENTAL SUSTAINABILITY SUITS[2]

Several food and beverage companies recently have been the targets of suits seeking to hold them liable for the contributions of their plastic packaging to environmental pollution. In 2021, a suit in California against several such companies, which had been removed by the defendants to federal court, was remanded back to state court.[3] The Northern District of California judge ruled that the case, brought under California law, is appropriately litigated in the courts of that state. The court rejected the defendants' contention that the case invoked issues of "federal common law" regarding interstate

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* We extend extra thanks to these contributing authors to other chapters of this volume who also suggested and summarized cases to watch for this chapter.

1 *In re* Nurture Baby Food Litig., No. 1:21-cv-01217 (S.D.N.Y.); *In re* Gerber Prods. Co. Baby Food Litig., lead case No. 2:21-cv-01977 (D.N.J.); Stewart et al. v. Hain Celestial Grp. Inc., No. 2:21-cv-00678 (E.D.N.Y.); *In re* Plum Baby Food Litig., No. 4:21-cv-00913 (N.D. Cal); Tyler Baker et al. v. Walmart Inc., No. 3:21-cv-00182 (E.D. Ark.).

2 Earth Island Inst. v. Crystal Geyser Water Co. et al., No. 20-CIV-01213 (Super. Ct. Cal., San Mateo Cty.); Earth Island Inst. v. The Coca-Cola Co., No. 2021CA001846B (Super. Ct. D.C.).

3 Earth Island Inst. v. Crystal Geyser Water Co. et al., No. 20-CIV-2212-HSG (N.D. Cal.) (Order Granting Motion to Remand, Feb. 23, 2021).

pollution and public nuisance, although it did not go as far as to embrace the plaintiffs' position that federal common law on these topics no longer exists. As these cases wend their way through the courts, they will be observed closely for their implications for efforts to hold companies liable for environmental pollution involving their packaging.

AMARIN PHARMA V. HIKMA PHARM. U.S.[4]

In last year's Top Cases of 2020 volume, we reported on the *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA* ("*GSK*")[5] case holding that a skinny-labeled generic carvedilol drug product induced infringement of the relevant patent covering the carved-out method-of-use. The beginning of 2022 saw a decision in the District of Delaware in which the judge dismissed a similar case, holding that the specific facts and circumstances that led the Federal Circuit to find liability in *GSK* were absent in *Amarin*; in particular, defendant Hikma did not make the same kinds of statements encouraging physicians to use their drug for off-label uses that would infringe the manufacturer's patents. Merely identifying the generic drug as equivalent to the patented product, without more, was insufficient to trigger inducement of infringement liability, the court ruled.

In February 2022, the parties stipulated for the severing of the now-dismissed inducement claims against Hikma from the main infringement claims against other defendants and the entry of final judgment in favor of Hikma, so that the plaintiffs could immediately appeal the Hikma dismissal. The court declined to do so. The court also denied Amarin and Hikma's request for "a telephonic status conference to obtain the Court's guidance as to the preferred method for affording Amarin an opportunity to immediately appeal the Court's dismissal of the claims against Hikma."[6] It appears, then, that an appeal of the dismissal may have to wait until the conclusion of the case, if it is filed at all. Pharmaceutical industry observers will be tracking this case because of its potential impact on the new rule that was thought to be created by the Federal Circuit in *GSK*.

FOOD PRICE-FIXING CASES[7]

The year 2021 saw significant developments in several antitrust price-fixing cases involving the food industry. Dating back to 2019 and before, these cases allege the existence of old-school cartels in several prominent food areas and are the subject of multidistricted federal proceedings.

One set of cases involves broiler chickens, and the plaintiffs include prominent restaurant chains. They allege that the handful of companies that control 90% of this market have engaged in price fixing for a period of many years. On May 27, 2022, the Northern District of Illinois court handling the multidistricted action granted class certification to classes of direct purchasers, indirect purchasers, and end-user consumers. Portions of the case have already been settled out, including a $181 million settlement between end-user consumer plaintiffs and six of the defendants. Another

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4 No. CV 20-1630-RGA-JLH, D.I. 97 (D. Del. Jan. 4, 2022).

5 976 F.3d 1347 (Fed. Cir. 2020).

6 No. CV 20-1630-RGA-JLH (D. Del. Jan. 4, 2022) (Order on Misc. Motion, Apr. 1, 2022).

7 *In re* Broiler Chicken Antitrust Litig., No. 1:16-cv-08637 (N.D. Ill.) (chicken); *In re* Cattle Antitrust Litig., No. 0:19-cv-01222 (D. Minn.) (beef).

group of cases alleges that the four largest meat-packing companies engaged in a buyers' cartel to depress the prices of beef through collusive bidding and other tactics. The District of Minnesota court handling this case denied a motion to dismiss in September 2021.

These cases follow high-profile price-fixing actions against tuna producers that resulted in criminal convictions in 2019 against major tuna cannery executives, followed by private suits that were temporarily derailed in 2021 by a Ninth Circuit Court of Appeals ruling affirming decertification of a direct purchaser class. Re-hearing the appeal en banc, the Ninth Circuit in April 2022 re-certified the class.[8] Defendant StarKist has indicated that it may seek Supreme Court review of the class certification decision, contending that the decision split with other circuits on the question of whether a class can be certified notwithstanding a significant proportion of non-injured parties swept up in the definition of the class.

This wave of cartel litigation in the food sector may impact the way companies interrelate in many other food and non-food sectors, as well as setting new precedents in class certification and antitrust law. High-value settlements and/or verdicts associated these cases may make headlines later in 2022 and onward.

MALLORY V. NORFOLK SOUTHERN RAILWAY CO.[9]

The U.S. Supreme Court again intends to plunge back into the heady law of personal jurisdiction. This is a consent-based personal jurisdiction appeal. The plaintiff is a Virginia citizen employed by the defendant railway company. He alleged that he was injured when exposed to harmful carcinogens while working at the railway company's sites in Virginia and North Carolina. The railway company was incorporated in Virginia and has its principal place of business there. Plaintiff sued the railway company in Pennsylvania (nothing having to do with the lawsuit occurred there). The claimed basis for personal jurisdiction in Pennsylvania was consent. Like many states, Pennsylvania has enacted a statute that requires foreign corporations to register with the Commonwealth in order to do business there. But Pennsylvania's statute adds that such registration suffices to impart *general* personal jurisdiction over the registrant in the courts of Pennsylvania. (*General* or "all-purpose" jurisdiction allows a court to hear any claim against a defendant, regardless of where it arose.) The trial judge in this lawsuit and, later, Pennsylvania's unanimous Supreme Court ruled the legislature's statute unconstitutional. That holding evidently aligns Pennsylvania with every other state and federal court that has considered the question since 2014—except for Georgia. The plaintiff argues "turnabout is fair play" on corporations that have extracted forum consent from consumers for years. The railway company contends that national uniformity (save Georgia) shows that the country's judiciaries well understand the meaning of *Goodyear*, *Daimler*, and *BNSF* where the U.S. Supreme Court clarified that just "doing business" in a state cannot support an exercise of general personal jurisdiction (rather, the defendant must be "essentially at home" there for such sweeping jurisdiction to exist). This appeal will be heard during the Court's October 2022 Term.

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[8] Olean Wholesale Grocery Co-Op v. Bumble Bee Foods LLC, No. 19-56514 (9th Cir.) (Dkt. 186-1, Apr. 8, 2022).

[9] Docket No. 21-1168 (Sup Ct.).

OPIOID LITIGATION[10]

Recent decisions have erected obstacles to efforts by state Attorneys General to hold pharmaceutical companies responsible for America's opioid abuse academic. In November 2021, a California judge ruled that major drug manufacturers are not liable for California's opioid epidemic, rejecting claims of public nuisance, false advertising, and unfair competition. That same month, the Oklahoma Supreme Court overturned a $465 million bench trial verdict against Johnson & Johnson, ruling the state's public nuisance statute does not extend "to the manufacturing, marketing, and selling of prescription opioids." In the Oklahoma case, other defendants Purdue Pharma and Teva Pharmaceuticals previously had settled for $270 million and $85 million respectively, leaving Johnson & Johnson as the sole defendant.

Other opioid cases continue in courts around the country. Other states are free to find that their nuisance and other laws encompass the allegations of their Attorneys General or other opioid plaintiffs, but against the background of the California and Oklahoma decisions, defendant drug manufacturers have new hopes for successful defenses. Further trials in these cases will be watched closely.

ZANTAC MDL APPEALS[11]

In April 2022, three of the plaintiffs in the multidistricted litigation over the alleged presence of carcinogens in Zantac (ranitidine) heartburn medication argued their appeals before the Eleventh Circuit Court of Appeals. They are appealing the December 2020 ruling of a Southern District of Florida judge that brand-name manufacturers have no liability for allegedly inadequate warnings on generic equivalents of their products, sold by other drug manufacturers, as reported by Bill Janssen in last year's Top Cases volume. As Bill wrote, these cases could have wide applicability across the generic drug sector, and numerous industry participants and observers await the outcome of these appeals.

HEALTH FREEDOM DEFENSE FUND, INC. V. BIDEN[12]

The Biden Administration filed a Notice of Appeal April 20, 2022, of the ruling by a Southern District of Florida judge that its mandate that individuals wear masks on public transportation to prevent the spread of COVID-19 is beyond the legal authority of the Centers for Disease Control and Prevention (CDC), finding that Congress never gave CDC power that "extends far beyond it to population-wide preventative measures like near-universal mask requirements that apply even in settings with little nexus to interstate disease spread, like city buses and Ubers." At issue is whether the Public Health Services Act of 1944, authorizing CDC to issue regulations "necessary to prevent the introduction, transmission, or spread of communicable diseases," includes the authority to require the wearing of masks by passengers and employees in aircraft,

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[10] California v. Purdue Pharma LP et al., No. 2014-00725287 (Super. Ct. Cal., Orange Cty. Nov. 1, 2021); Oklahoma v. Johnson & Johnson et al., No.118,747, 2021 OK 54 (Okla. Nov. 9, 2021).

[11] Cartee v. Boehringer Ingelheim Pharms., Inc. et al., No. 21-10305 (11th Cir.); Williams v. Boehringer Ingelheim Pharms., Inc. et al., No. 21-10306 (11th Cir.); Plumbers & Pipefitters Local Union 630 v. GlaxoSmithKline LLC et al., No. 21-10335 (11th Cir.).

[12] No. 8:21-cv-1693-KKM-AEP (M.D. Fla.).

buses, trains, taxis, airports, bus and ferry terminals, and train and subway stations. The case has important implications for the extent of CDC's authority to enforce national public health measures for the prevention of COVID-19, which continues to spread in 2022, and any future disease outbreaks.

LACKS V. THERMO FISHER SCIENTIFIC INC.[13]

Lacks v. Thermo Fisher is an unjust enrichment suit filed in the District of Maryland in October 2021. The case concerns a line of replicated cells obtained from patient Henrietta Lacks during her cancer treatment in 1951 by a Johns Hopkins research physician. Known as "HeLa cells," an abbreviation of Ms. Lacks' name, these tissues were found to be exceptionally resilient and have been distributed freely for research by Johns Hopkins and, according to the university's web site, have "contributed to many medical breakthroughs, from research on the effects of zero gravity in outer space and the development of polio and COVID-19 vaccines, to the study of leukemia, the AIDS virus and cancer worldwide."[14] The suit, by Ms. Lacks' estate, alleges that Thermo Fisher profited unjustly from the tissue samples and genetic information taken without permission from Ms. Lacks, seeking disgorgement of all of the defendant's profits from sales of products developed using the HeLa cell line and for injunctive relief.

As of April 2022, the case was before the court on Thermo Fisher's motion to dismiss, with its high profile attracting amicus briefs from several public-interest organizations, including the National Women's Law Center and the Lawyers' Committee for Civil Rights Under Law. The amici favored the plaintiff in the suit, arguing for a right to recover for the alleged breach of doctor–patient duties "enabled by the historic, systemic disregard of legal principles regarding medical experimentation as to Black, low-income, and other systemically oppressed groups." Whatever the outcome of the motion and subsequent proceedings, the *Lacks* case will be monitored for its implications for the rights of patients in their tissues and genetic materials as used in scientific inquiry.

IN RE ROUNDUP PRODUCTS LIABILITY LITIGATION[15]

The long-running multidistricted litigation over alleged carcinogens in Monsanto's Roundup weed killer hit a bump in May 2021 when California federal judge Vince Chhabria rejected a $2 billion settlement as inadequate to compensate future victims who have not yet contracted or been diagnosed with cancer or who are otherwise not covered in the $9.6 billion settlement already reached with existing cancer patients. Judge Chhabria called the settlement "clearly unreasonable," citing the length of time that it can take to develop and be diagnosed with Hodgkin lymphoma, and concluded that the deal was too favorable for defendant Monsanto. This decision exemplifies a recent trend toward more active judicial review of the fairness of class settlements.

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[13] No. 1:21-cv-02524 (D. Md.).

[14] *The Importance of HeLa Cells*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/henriettalacks/importance-of-hela-cells.html.

[15] No. 3:16-md-02741 (N.D. Cal.).