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EDITOR'S REPORT

Welcome to the new edition of the ABA Antitrust Health Care Chronicle. We are pleased to present two articles for this issue, the first of the ABA's 2022-23 year. Our first article is an interview with Lindsey Bohl, an attorney at Simpson Thacher & Bartlett in Washington, DC and, recently, lead staff attorney on the Hackensack/Englewood hospital merger investigation and challenge by the FTC. The second article is by Brendan Coffman and Nathan Mendelsohn at Wilson Sonsini Goodrich & Rosati in Washington, DC and Anna Neill at Kenny Nachwalter in Miami, FL which reviews the debate surrounding the privilege waiver by one of the defendants in the recently settled *Glumetza* reverse payment case.

If there is a topic that you would like to see covered in a Committee program or if you have any other suggestions, please contact the Committee Co-Chairs, Lauren Rackow (LRackow@cahill.com) or Amy Ritchie (aritchie@ftc.gov).

If you would like to submit an article for the Chronicle, please contact Paul Wong (paul.wong@nera.com) or Jason Albert (jalbert@secretariat-intl.com).

In This Issue

A Publication of the Health Care and Pharmaceuticals Committee of the Antitrust Section of the American Bar Association, Co-Chaired by Lauren Rackow of Cahill Gordon & Reindel LLP and Amy Ritchie.

ABA SECTION OF ANTITRUST LAW
Promoting Competition Protecting Consumers

ENFORCER INSIGHTS: LESSONS LEARNED FROM HACKENSACK/ENGLEWOOD WITH LINDSEY BOHL, FORMER FTC LEAD INVESTIGATIVE ATTORNEY

Interview by: Amy Ritchie, Attorney, Mergers IV, Federal Trade Commission; Co-Chair of the Health Care and Pharmaceutical Committee[1]

Lindsey Bohl is an antitrust attorney at Simpson Thacher & Bartlett in Washington, DC. She advises on matters involving all aspects of antitrust and competition law, including merger reviews, government antitrust investigations, antitrust litigation and counseling on a variety of competition issues. Her practice focuses on counseling clients considering M&A transactions across a wide range of industries, including healthcare, retail, consumer products, medical devices and pharmaceutical products, and technology. Prior to joining Simpson Thacher (where she also began her career in 2014), Lindsey was a staff attorney in the Federal Trade Commission's Mergers IV Division from 2019-2021. While at the FTC, Lindsey led significant healthcare and retail transaction investigations, including her role as team lead on the 2020 Hackensack Meridian Health, Inc./Englewood Healthcare Foundation investigation, and her core role on the *FTC v. Hackensack* litigation team that prevailed in challenging the proposed transaction both in the District Court of New Jersey and Third Circuit.

Lindsey Bohl
Associate, Simpson Thacher & Bartlett

Lindsey, you led the investigative FTC team that challenged Hackensack Meridian Health's plan to acquire Englewood Healthcare in New Jersey. The FTC won its challenge at the district court level and it was upheld in the Third Circuit. Can you provide a brief overview of the facts?

Absolutely, leading the team in this case was a highlight of my time at the FTC. The *Hackensack/Englewood* case involved one of New Jersey's largest hospital systems, Hackensack Meridian Health, attempting to acquire Englewood Health, a neighboring general acute care hospital about five miles away from Hackensack's flagship academic medical center (Hackensack University Medical Center, or HUMC), in Bergen County, New Jersey. Hackensack already owned or operated two of the six general acute care hospitals in the county, and was the most significant provider of inpatient services in the county, while Englewood was the third-largest inpatient services provider in the county. The FTC's complaint alleged that the acquisition would result in Hackensack controlling nearly half the inpatient general acute care services sold to commercially insured patients in Bergen County, and would eliminate important competition between Hackensack and Englewood, leading to higher healthcare prices and diminished incentives to compete on quality and access.

This was a particularly interesting matter for a few reasons. First, Bergen County (the FTC's alleged geographic market) is very close to a large urban area – New York City. Second, the hospitals' claimed that Englewood, as a smaller community service hospital, was a complement, rather than a competitor to, the much larger Hackensack system. The FTC used various sources of direct evidence to rebut that claim, and to strengthen its case that the merger would harm competition in addition to showing a presumption of anticompetitive harm. Third and finally, the hospitals' claims that the transaction would have significant benefits for New Jersey residents, bolstered by commitments in their merger agreement and the New Jersey Attorney General office's recommendation to the New Jersey Superior Court to approve the transaction through its charitable assets review statute. These topics, among others, were issues the FTC grappled with throughout the

[1] Ms. Ritchie's statements are her own and do not necessarily reflect the views of the Federal Trade Commission or any individual commissioner.

investigation and litigation, and ultimately both the district court and the Third Circuit were persuaded that the FTC met its burden of demonstrating likelihood of success that the proposed merger violated Section 7 of the Clayton Act.

You mentioned Bergen County's proximity to New York City. Why did the FTC allege that Bergen County was the relevant market and not something broader?

Historically, the FTC's healthcare complaints often define geographic markets that align closely with political boundaries, such as counties, so that's nothing new. But Bergen County is a particularly densely populated county in Northern New Jersey with over one million residents. Bergen County sits directly over the George Washington Bridge from Manhattan, and the FTC's analysis clearly had to account for the extent to which New York City hospitals factored into the healthcare landscape. However, what we learned is that Bergen County residents don't visit Manhattan hospitals in significant numbers for most inpatient hospital services, and prefer to stay in the county to receive care.

The FTC arrived at a Bergen County geographic market because that is where the documents from the hospitals, testimony and documents from insurers, and data all pointed. The district court judge credited the FTC's evidence that (1) Englewood and Hackensack University Medical Center, were both located in Bergen County; (2) more than 75% of Bergen County residents receive inpatient care in Bergen County; and (3) Bergen County is an economically significant area for insurers. In particular, the court was persuaded by testimony from all major commercial insurers serving the area, where they explained that they could not sell a marketable health insurance plan to Bergen County residents without a Bergen County hospital – even if the health plan included Manhattan hospitals or hospitals in adjacent New Jersey counties. The court found the FTC sufficiently established that Bergen County was a geographic market that satisfied the hypothetical monopolist test, and the Third Circuit affirmed that finding.

The FTC's Bergen County geographic market was also notable, in that the FTC supported the market using both a patient-based approach and a facility-based approach to measure market shares and concentration in Bergen County. Patient-based means calculating market shares and concentration based on where patients reside (i.e., Bergen County patients), whereas hospital-based means measuring shares and concentration based on the where hospitals are physically located (i.e., the hospitals within Bergen County). Here, the FTC argued that all hospitals serving Bergen County patients were accounted for using the patient-based approach, even those located in New York City and other large health systems with facilities in the surrounding densely populated counties of New Jersey. The FTC's briefing also presented evidence that a geographic market consisting of just the six hospitals located in Bergen County (i.e., using the hospital-based approach) would satisfy the hypothetical monopolist test. The FTC claimed that under either proposed measure, the resulting concentration figures established a presumption of anticompetitive harm under the Horizontal Merger Guidelines.

However, the hospitals and the FTC disagreed about whether the FTC was permitted to define a geographic market using a patient-based approach. The hospitals challenged the FTC's patient-based approach to the Bergen County geographic market, arguing that under the Horizontal Merger Guidelines, a customer- (or here, patient-) based market requires evidence of price discrimination. While the district court found that price discrimination was not

required as a matter of law, the issue of whether the FTC was required to prove price discrimination for a patient-based Bergen County geographic market became a central focus of the hospitals' appeal to the Third Circuit.

What is price discrimination and what did the Third Circuit say about the need to prove price discrimination when challenging a health care transaction?

Price discrimination means the ability to sell a product or service at different prices to different buyers. The hospitals claimed that the Horizontal Merger Guidelines and relevant economic literature required the FTC to show that patients specifically in Bergen County could be charged higher prices for inpatient general acute care services compared with patients living outside the proposed market. The hospitals argued that, here, the method of pricing caused prices to be the same for patients in and out of Bergen County. The hospitals, therefore, argued on appeal that the district court erred as a matter of law by not requiring the agency to demonstrate price discrimination.

The Third Circuit disagreed with the hospitals' reading of the Horizontal Merger Guidelines as mandating proof of price discrimination—there isn't a "rigid" requirement for a patient-based market, and approaches should recognize the unique commercial realities of the healthcare landscape. The Third Circuit explained the two-stage model of competition, in which hospitals and insurers first negotiate to determine whether the hospitals will be included in networks and how much insurers will pay, and in the second stage, hospitals compete to attract patients based on non-price factors (like quality or access to care). The court found that the commercial realities in this case supported the FTC's market based on both patient and hospital locations, citing the factual record that most Bergen County residents receive inpatient general acute care services in Bergen County, and thus insurers feel they cannot offer a plan without Bergen County hospitals in-network. The Third Circuit also relied on the *St. Alphonsus Medical Center v. St. Luke's* Ninth Circuit case, a 2013 challenge to a hospital system's acquisition of a physician group, in which the FTC similarly defined and the court upheld a market based on both patient and provider (or "supplier") location considerations. It, therefore, upheld the FTC's alleged Bergen County geographic market, without requiring evidence of price discrimination.

There is a perception that market shares and HHIs solely drive the FTC's merger enforcement decisions. In *Hackensack*, the Third Circuit noted the "Direct Evidence" that the FTC presented and characterized it as "strengthen[ing] the probability that the merger will likely lead to anticompetitive effects." Can you discuss some of that direct evidence your team gathered as part of your investigation?

The direct evidence showing a loss of competition was a critical component of the FTC's case. Not only did it confirm the HHI presumption, but it also combatted the hospitals' contention that Englewood, as a smaller community hospital, was a complement, and not a competitor to, the larger Hackensack system and its academic medical center in Bergen County. In addition to economic analysis presented by the FTC's expert, Dr. Leemore Dafny, including diversion ratios showing that a high percentage of Englewood patients would choose a Hackensack hospital if Englewood were not available (and vice versa), and willingness-to-pay analyses to measure price harm, the FTC focused on three main sources of direct evidence of anticompetitive effects: (1) the hospitals' own documents identifying one another

as competitors; (2) insurer testimony and documents; and (3) qualitative examples of non-price competition between the hospitals to improve quality and services.

As you noted, this direct evidence all strengthened the FTC's *prima facie* case, and the probability that the merger would lead to anticompetitive effects. A key source of effects evidence cited in the district court and Third Circuit opinions were documents created by Englewood's consultant engaged to analyze transaction partnership prospects, identifying Hackensack as a key competitor that drew patients from similar areas. The courts also found persuasive the insurer testimony and the insurer ordinary course modeling projections that, if Hackensack University Medical Center went out of network, a large percentage of patients would turn to Englewood. Finally, both the district court and the Third Circuit cited Hackensack's historic ability to raise rates at acquired hospitals as evidence supporting the prediction that the merger would lead to anticompetitive price increases. Though the hospitals claimed that Hackensack's contracts allowing them to increase rates were unrelated to the merger, the Third Circuit pointed out that past behavior is often indicative of future behavior, and Hackensack's prior rate increases supported a reasonable inference that it would continue to negotiate higher rate increases after the merger.

Were you concerned about the parties' rebuttal evidence of potential efficiencies?

The hospitals presented strong arguments, but did not adequately substantiate their efficiencies. In addition to traditional cost-savings efficiencies, hospital merging parties often cite benefits such as improved patient quality, expanded capacity, and new service line offerings. This case was no exception, and hospitals argued that the merger would benefit New Jersey residents in the form of healthcare cost savings, expansion of complex service lines, increased capacity, and quality improvements, pointing directly to various commitments outlined in their merger agreement. However, the FTC closely scrutinizes efficiencies claims, holding them to a high standard that includes demonstrating that any claimed efficiencies are verifiable and not speculative, and merger specific. The FTC investigative team found that the parties' substantiated efficiencies were insufficient to outweigh the transaction's anticompetitive effects.

The FTC went into the litigation knowing that neither the Supreme Court, nor the Third Circuit had found efficiencies in a presumptively anticompetitive horizontal merger great enough to offset the anticompetitive harm. In the controlling precedent from the 2016 *FTC v. Penn State Hershey Medical Center* case, an earlier hospital merger litigation, the Third Circuit expressed skepticism that such an efficiencies defense even exists. Revisiting the efficiencies defense five years later in *Hackensack*, the Third Circuit left open the possibility that an efficiencies defense may be viable. The opinion (authored by Judge Fisher, same author of the earlier *Hershey* opinion) expressly disagreed with the *Hackensack* district court's interpretation of *Hershey* as requiring "extraordinary" efficiencies to offset anticompetitive harms in every case where the government establishes its *prima facie* case. Instead, it framed efficiencies as a "sliding scale" in which the magnitude of the efficiencies needed to overcome a *prima facie* case depends on the strength of the likely adverse competitive effects of a merger.

While leaving the avenue for a successful efficiencies defense open, the district court and Third Circuit agreed with the FTC that the

hospitals fell short of substantiating many of their efficiencies claims. First, as to the potential cost-savings, the district court found these too speculative, and heavily weighed the acquiring system's track record from previous acquisitions, citing that the hospitals did not present evidence of historical cost-savings being passed on to commercial insurers or flowing to patients. Similarly the district court also found the hospitals' capacity relief and service line expansion claims to be speculative or not merger-specific, pointing out the hospitals' lack of planning documents as to how service optimization plans would be implemented, ongoing Hackensack expansion projects pre-dating the merger, and available capacity at other nearby Hackensack hospitals. Finally, with respect to quality improvements, while acknowledging that certain capital investments could improve facilities and equipment at Englewood, the district court found that the alleged quality benefits were also not merger-specific, because Englewood was already a high-quality hospital, scoring better than Hackensack on multiple important performance measures. The Third Circuit agreed that most of the hospitals' claimed benefits were speculative or non-merger specific, and the few benefits established did not constitute efficiencies significant enough to offset the likely anticompetitive effects.

The New Jersey Attorney General's office found that the merger was in the public interest under a non-antitrust statute – the New Jersey Community Health Care Assets Protection Act ("CHAPA"). The Third Circuit opinion briefly addresses this finding in its decision. What is your takeaway from that?

The New Jersey State Attorney General concluded that the merger was in the public interest, and recommended to the Superior Court of New Jersey to approve the transaction. Even though this was not necessarily an antitrust review process, it was a challenging needle for the FTC to thread. Many states have charitable asset review statutes similar to New Jersey's CHAPA review, which require a recommendation or approval from the state Attorney General's office for certain types of acquisitions of non-profit hospitals. While the New Jersey CHAPA analysis included a public interest determination, this is independent of an antitrust analysis, and relies on different factors. Under the state's CHAPA review process, New Jersey's Attorney General concluded that the transaction was in the public interest around the same time the FTC filed its antitrust complaint. The hospitals emphasized the state's support for the transaction from this CHAPA review in briefing throughout the litigation, and as you note, the Third Circuit opinion clearly factors this into its analysis. It was also notable that, unlike most previous hospital enforcement cases, the state did not join the FTC's antitrust complaint.

While state Attorney General support for the merger was not the deciding factor in *Hackensack*, the Third Circuit made clear that a court would be "remiss not to consider a state's assessment of the effects of a merger within its borders," and concluded that the district court should have included the interests of the community, as assessed by the state Attorney General, in analyzing the likely effects of a merger. Thus, local stakeholder views and the assessment of a state Attorney General may be something that courts consider more closely in future cases.

You've since left the FTC and rejoined private practice. What advice do you give your clients as a result of your experience in *Hackensack/Englewood*?

Many takeaways from the *Hackensack/Englewood* case have informed my analysis and advice since I rejoined Simpson Thacher

earlier this year, but here are just a few, including some that are more broadly applicable outside of the healthcare context.

First, the FTC does not necessarily apply one specific formula to defining a relevant geographic market and demonstrating that the market passes the hypothetical monopolist test. Market definition is highly fact-specific, and may be informed by a combination of party documents, insurer documents and testimony, and economic analyses. In *Hackensack*, the FTC alleged one proposed market in its complaint, Bergen County, and approached the hypothetical monopolist test, market shares, and concentration two different ways to establish that under either approach, the presumption of anticompetitive harm was met. Antitrust counsel should consider various approaches the FTC may take based on the unique facts and circumstances of a particular case, recognizing that there is no one-size-fits-all.

Second, and this is nothing new, but internal documents generated by the parties and their external consultants in connection with the transaction are critical evidence for the FTC, and *Hackensack* was no exception. For merging parties considering a transaction in any industry, it's important to engage antitrust counsel early in the process as these documents analyzing transaction partners and prospects, and potential merger benefits are generated.

Third, the merging parties' track record, including with respect to insurer negotiations, may be important. The FTC, and subsequently both the district court and Third Circuit considered previous acquisitions as part of the analysis of potential anticompetitive effects and in declining to credit certain efficiencies claims.

Finally, while efficiencies defenses may continue to be challenging once a court finds the FTC has established its *prima facie* case, the Third Circuit opinion leaves open the possibility of a successful efficiencies defense for a presumptively unlawful merger, framing the question as a sliding scale. According to the Third Circuit, the alleged efficiencies' magnitude needed to overcome the government's *prima facie* case depends on the alleged adverse effects of the deal. Based on this benchmark, merging parties will likely be best positioned when they can show that claimed cost-savings will be passed through to consumers and demonstrate robust planning as to how merger benefits will be achieved.

Finally, you undertook this investigation in the middle of the pandemic, shepherding it up to the appellate level. When you reflect on the totality of the experience, what stands out to you?

As much as I enjoyed all of the investigative work at the FTC, leading a trial team along with a group of extremely talented and experienced litigators, and watching investigative findings come together in a trial presentation, was a fantastic experience that has strongly informed my ability to advise clients regarding risk both in the context of merger investigations and likelihood of litigation success. Merger trials don't come along with the greatest frequency, so having that (Zoom) courtroom experience, including up to the appellate level, has been really valuable as a practitioner. I'm extremely grateful for that opportunity and for the wonderful FTC team.

One final observation - hospital merger enforcement in particular is an area where there is quite a bit of established judicial precedent, including at the appellate level across a number of circuit courts. In *Hackensack*, while the FTC cites the Horizontal Merger Guidelines, it also relied on a strong foundation of litigated healthcare provider

merger precedent, including *Hershey* in the Third Circuit, *St. Alphonsus v. St. Luke's* in the Ninth Circuit, and *FTC v. ProMedica* in the Sixth Circuit, among other cases. With the revised Merger Guidelines forthcoming, it will be interesting to see whether there is a change in the theories of harm or types of healthcare enforcement cases the FTC pursues. The Horizontal Merger Guidelines are frequently cited by courts in merger challenges as persuasive but also non-binding. While the current (2010) Guidelines have been met with general acceptance, including by the courts, it remains unknown to what extent the FTC and DOJ will revise those Guidelines and whether courts will similarly adopt the revisions. To the extent there is any tension between the revised Guidelines and the hospital merger precedent, I'll be interested to see how that gets resolved both in terms of the types of cases the FTC brings and how they fare in court.

PRIVILEGE WAIVER BY A DEFENDANT IN A REVERSE PAYMENT CASE: VIEWS FROM THE DEFENDANTS AND THE PLAINTIFFS BASED ON GLUMETZA

In August 2019, plaintiffs representing a class of direct purchasers filed the first complaint in an antitrust litigation that would become *In re Glumetza Antitrust Litigation*, Case No. 19-5822 (N.D. Cal.), before Judge William Alsup. Class purchasers along with opt-out direct purchasers alleged that Assertio, Bausch, and Lupin violated Sections 1 and 2 of the Sherman Act when they agreed to delay entry of lower-cost generic versions of the diabetes drug Glumetza (metformin ER) for up to four years. At the heart of the allegations was an alleged reverse payment arrangement – a result of the 2012 settlement of a patent dispute between the brand patent holder Bausch (Depomed) and the generic challenger Lupin. This settlement licensed Lupin to launch a generic form of Glumetza four years before the expiry of the latest-expiring relevant patents, and it also included "a guarantee that Depomed would not launch an authorized-generic to compete with Lupin for one year, atop the FDA-granted 180 days of market exclusivity from other generic competition."[1]

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Lupin did not dispute the existence of the no-authorized generic (no-AG) agreement. Lupin instead argued that the plaintiffs could not establish a causal link between that agreement and harm to competition because, at the time of the settlement, Lupin believed it was likely to lose the patent litigation and, absent the settlement, Lupin would have been found to infringe the brand's patent. According to this theory, generic entry would not have occurred until expiration of all of the patents. Therefore, the defendants argued, the plaintiffs were better off with the settlement containing the no-AG provision than they would have been absent the settlement. To prove the point regarding the likely outcome of the patent litigation, Lupin took the nearly unprecedented step of waiving privilege as to that litigation,[2] allowing into the record evidence of Lupin's subjective belief regarding its ability to prevail against Bausch at trial. Lupin's decision introduced a number of complications and nuances to the case. On the one hand, how could the plaintiffs appropriately address a selective waiver by a single party to the patent litigation but not the other party, even if both were defendants in the antitrust litigation? Should the non-Lupin defendants be able to benefit from Lupin's waiver? And how could it be ensured that Lupin was not prejudiced from its decision to waive privilege as to this information?

Ultimately, the court denied summary judgment and the parties settled before trial, leaving issues of how the one-sided privilege waiver would have been addressed at trial unresolved. In this article, we lay out some of the main arguments in this ongoing debate.

HOW DOES THE WAIVED MATERIAL AFFECT LUPIN'S SUMMARY JUDGMENT (AND BEYOND)?

In its summary judgment briefing, Lupin argued that, after the Markman decision in the underlying patent case, it had a pessimistic view of the patent litigation – both in its chance of success and the upcoming costs of continuing to litigate. Lupin viewed its noninfringement arguments as significantly weaker. As

[1] *In re Glumetza Antitrust Litig.*, No. 3:19-05822 WHA, 2021 U.S. Dist. LEXIS 87085, at *19 (N.D. Cal. May 6, 2021).

[2] Since the *Glumetza* case, the generic manufacturer defendant likewise waived privilege in the reverse payment litigation *In re HIV Antitrust Litigation*. See, e.g., Motion to Compel at 6, Case No. 3:19-cv-02573-EMC (N.D. Cal.), ECF No. 1200. Summary Judgment is currently pending in that case.

Lupin's patent counsel recalled in his deposition: "based on the totality of the evidence … it's not a winning argument … And my view was we were going to lose every single term … including the case dispositive term that [plaintiffs' counsel] just called the kill shot."[3] Lupin argued that, based on the advice of its counsel, it concluded that the upside of continued litigation was low versus the small likelihood of success. In addition, Lupin argued that it would not have launched its generic product at-risk and faced potentially trebled damages given the low likelihood of success.

The plaintiffs argued that there was evidence that, despite Lupin's patent counsel's assertions to the contrary, Lupin still believed it could win the patent litigation. For example, based on other documents for which privilege was waived, Lupin's demanded entry date actually moved earlier in time after the *Markman* decision, and Lupin's patent counsel urged Lupin not to seek to delay the litigation schedule but rather to push toward trial.[4] Moreover, the plaintiffs pointed to a number of reasons why the jury might find Lupin's patent counsel's current testimony less persuasive that the actions Lupin actually took in 2011 and 2012.[5]

Judge Alsup largely agreed with the plaintiffs. He first concluded that a jury could reject Lupin's arguments as "a pretext" for several reasons discussed below. In addition, Judge Alsup found that even if Lupin's argument was not a pretext, there was additional evidence from which a jury could conclude that Lupin was likely to prevail in the patent litigation, despite what Lupin may have thought about its chances of success at the time of settlement.[6]

The court pointed to three primary reasons for finding that, despite the privileged materials, a jury could still find for the plaintiffs. First, the court focused on "the glaring oddity that only one of our three defendants involved in the underlying suit, Lupin, has waived attorney-client privilege to tell its tale of certain infringement."[7] Second, the court reasoned that *Actavis* had already held that a "large and otherwise unexpected payment" to the generic can serve as a "proxy" that the "patentee has serious doubts about its infringement case" and a jury could reasonably rely on this assumption.[8] Third, Lupin had prepared evidence for the patent trial that showed a chance of success after the *Markman* decision, potentially undermining the evidence cited by Lupin in the later reverse payment trial.[9]

Defendants' View

The court's three rationales are undercut by the practical realities of litigation and by the rationale in the Supreme Court's *Actavis* decision.[10]

First, Judge Alsup seemingly drew negative inferences against the defendants based on the decisions of some defendants to not waive privilege. This reasoning is concerning as parties are normally free to not produce privileged materials without a negative inference. If Lupin had not waived privilege, then there would be no negative inference against it or the other defendants for this decision.[11] The *Glumetza* opinion effectively circumvented this rule by seemingly

[3] Lupin Mot. Summ. J., Case No. 3:19-cv-05822 WHA (N.D. Cal.), Dkt. No. 743 at 9-10.

[4] See Pls.' Opp. Lupin's Mot. Summ. J., Case No. 3:19-cv-05822 WHA (N.D. Cal.), Dkt. No. 732 at 10-12. The plaintiffs also argued that Lupin's subjective belief was not dispositive. First, if the plaintiffs were injured because Lupin would have *actually* won, whether Lupin *thought* it would have won did not resolve this question. Second, Lupin and the brand could have entered a less restrictive settlement regardless of Lupin's beliefs. *Id.* at 43. The district court did not address these arguments in detail as it related to Lupin's privilege waiver.

[5] *Id.* at 10.

[6] *Glumetza*, 2021 U.S. Dist. LEXIS 87085, at *38.

[7] *Id.* at *38-39.

[8] *Id.* at *40 (quoting FTC v. Actavis, Inc., 570 U.S. 136, 171 (2013)).

[9] See *id.* at *41-43.

[10] *Actavis*, 570 U.S. 136.

[11] *See Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1344-45 (Fed. Cir. 2004) (citing cases).

inferring the existence of problematic materials in the brand companies' privileged documents. However, it is unclear to what extent this rationale would be applied after summary judgment and whether this reasoning is even admissible.

Second, *Actavis* used the "large and unjustified" test as a proxy for subjective belief that a patent case is weak.[12] The Court needed a proxy *because* attorney-client privilege normally prevents a court from delving into subjective motivations. As Chief Justice Roberts noted in his dissent: "The Court [assumes] that offering a 'large' sum is reliable evidence that the patent holder has serious doubts about the patent. . . [However] much of the evidence about the party's motivation may be embedded in legal advice from its attorney, which would presumably be shielded from discovery."[13] To the extent that a party produces materials showing its subjective belief, there is no need to use the *Actavis* proxy to guess at these beliefs.

Finally, the court in *Glumetza* cited to various materials prepared by Lupin after the *Markman* hearing to show that Lupin may have thought it could win. But until a party finally resolves litigation, it makes sense that that party would, in fact, continue to litigate. The main document cited by Judge Alsup was a draft expert report.[14] No party in Lupin's shoes would have worked to prepare an expert report stating that its case is meritless. In other words, there will always be *some* materials stating that the party can win, even if the party thought such arguments were unlikely to succeed. Yet the *Glumetza* ruling seemingly treats an argument the party viewed as a "Hail Mary" as sufficient to defeat summary judgment, even if the party's privileged materials state that the argument was weak.

Plaintiffs' Views

While Lupin took a novel approach in choosing to waive the privilege, the court's reasoning on summary judgment recognized that Lupin's subjective beliefs at the time of the settlement, genuinely held or not, were not case dispositive. Further, there are issues with the three principal concerns laid out above with respect to Judge Alsup's opinion denying summary judgment.

First, Judge Alsup's finding against the defendants did not necessarily turn on negative inferences from the non-Lupin defendants' failure to waive privilege. Although Judge Alsup did point out that the other defendants chose not to waive, there was factual evidence, including certain Lupin documents, suggesting that all of the parties – Lupin included – believed that Lupin's noninfringement case was compelling. Perhaps most importantly, the settlement deal that was ultimately struck was quite favorable to Lupin, with a royalty-free licensed entry date four years before expiration of the latest-expiring patent and a guarantee of one full year without competition from an authorized generic when Lupin did ultimately launch. If Lupin's case against Bausch was so weak and all parties knew it, it seems unlikely that Lupin would have been able to extract such a favorable deal from Bausch. Even if the jury were not permitted to draw an inference from the other parties' failure to waive, it could certainly consider this other evidence to conclude Lupin's pessimism was unfounded.

Second, *Actavis*'s instruction concerning "the size of the unexplained reverse payment" is relevant here.[15] *Lupin's* waiver tells us nothing about what the *brand* defendant believed, and *Actavis* specifically tells us that the "unexplained large reverse payment . . . suggest[s] that the

[12] *Actavis*, 570 U.S. at 157.

[13] *FTC v. Actavis, Inc.*, 570 U.S. 136, 172 (2013) (Roberts, C.J., dissenting).

[14] *Glumetza*, 2021 U.S. Dist. LEXIS 87085 at *41-42.

[15] 570 U.S. at 158

patentee has serious doubts about the patent's survival."[16] Moreover, as with the value of the settlement to Lupin, the size of the payment may also be evidence of what *all* parties to the transaction – including Lupin -- believed about the strength of Lupin's case. Lupin's waiver meant that certain documents and associated testimony about what it perceived to be weaknesses in its case would be before the jury. It is certainly fair for the plaintiffs to present contrary evidence, such as the size of the payment, to rebut Lupin's interpretation of its evidence. Simply because Lupin waived privilege does not mean that its testimony is unassailable. Ultimately, it should be the province of the jury to decide which evidence from either side it will credit.

Third, Lupin's own documents prepared in the course of the patent litigation are relevant evidence of what Lupin believed. Lupin's patent counsel testified that the *Markman* ruling meant that Lupin was "going to lose every single term," and yet Lupin did not throw in the towel. Rather, Lupin continued to litigate and refine its arguments, had a world-renowned pharmaceutical formulation expert prepare a noninfringement report, and patent counsel urged Lupin to push towards trial rather than seek any schedule extension. Lupin did not have to do any of these things; if it truly believed that its position was untenable, it could have dropped its challenge to the Glumetza patents. It did not do so, and the resulting litigation strategy and case developments are fair evidence to allow a jury to consider.

Ultimately, though, Lupin's waiver could not be dispositive of causation, because even if Lupin believed that its patent case was hopeless, none of the plaintiffs' three theories of causation depended exclusively on Lupin's *actual beliefs*. Under the plaintiffs' theories, absent the offending payment in the settlement, Lupin would have either (1) launched "at risk" (i.e., before a final decision in the patent case), (2) would have proceeded to a verdict in the patent case and would have prevailed, or (3) would have negotiated an alternative settlement with Bausch with an earlier entry date. Any of these scenarios would have led to Lupin's generic product being sold earlier than it was in the actual world. For the first two causation theories, the plaintiffs' burden at summary judgment is only to "offer *some evidence* of noninfringement or patent invalidity in order to proceed" to trial.[17] Certainly all of the evidence discussed above – the valuable deal Lupin was able to secure, the large unexplained payment made by the patentee, and the litigation record including Lupin's unwavering noninfringement expert – is *some evidence* in support of Lupin's noninfringement defense. And for the alternative settlement theory of causation, jurors are not asked to determine what the actual parties to the illegal reverse payment agreement would have done absent the payment, but rather are asked "to project how *rational actors in defendants' shoes would have proceeded* in the absence of the unlawful settlement term."[18] Therefore, none of the three causation theories hinge on what any defendant actually believed about the likely outcome of the patent litigation.

WHAT ARE THE EFFECTS OF WAIVER ON THE NON-WAIVING DEFENDANTS?

As to the brand defendants, the plaintiffs argued that there are, at a minimum, issues with allowing them to benefit from Lupin's waiver: "[T]he Court will need to address the propriety of multiple

[16] *Id.* at 357 (emphasis added).

[17] *Glumetza*, 2021 U.S. Dist. LEXIS 87085 at *48 (quoting *Apotex v. Cephalon, Inc.*, 255 F. Supp. 3d 604, 614 (E.D. Pa. 2017) (emphasis added)).

[18] *Id.* at *50.

defendants relying on a privilege waiver by one of them while all others strictly maintain the privilege on the same subject, implicitly suggesting that they shared the waiving defendants' views on that subject. *See* Fed. R. Evid. 403."[19] In other words, plaintiffs implied that the brands should not be able to rely on Lupin's waiver. This argument would likely necessitate a jury instruction that Lupin's waived materials should not affect any analysis for the brand. This argument, too, raises several potential issues.

Defendants' View

First, the plaintiffs' argument runs into the practical question – how much can a jury disregard certain pieces of evidence? Of course, Federal Rule of Evidence 105 says "[i]f the court admits evidence that is admissible against a party or for a purpose—but not against another party or for another purpose—the court, on timely request, must restrict the evidence to its proper scope and instruct the jury accordingly." However, evidence must still comport with Federal Rule of Evidence 403 and, if the jury could not fairly consider the evidence solely as to Lupin, it may be excluded as unduly prejudicial or confusing.

Second, even assuming the jury does properly follow any instruction, this framework presents a risk that a jury could reach one verdict as to the generic and another as to the brand. This verdict would be potentially illogical as it would find that the brand entered an anticompetitive agreement while the generic did not, despite both being parties to the same agreement. Courts do generally permit verdicts that appear logically inconsistent if "it is possible to follow the jury's reasoning and to reconcile its specific findings on the verdict form without altering the result."[20] Similarly, in the default judgment context, courts avoid inconsistent verdicts only "where it would be 'logically inconsistent' to hold one defendant liable and another not."[21] The question is seemingly whether such a verdict would be "logically inconsistent" if the jury were advised to consider privileged evidence solely as to the generic – a question that has not been squarely addressed in the reverse-payment context. Even assuming a court finds a jury could permissibly find one defendant liable but the other not, it may choose to avoid such a trial structure to avoid unduly confusing a jury or unfairly prejudicing the parties.

To the extent a court were to accept the plaintiffs' arguments, perhaps the most straight-forward solution would be to have separate trials for the brand and generic defendants. If the brand were not permitted to rely on the generic's privilege waiver, a separate trial would be the only way to entirely limit the evidence presented. While some argue that bifurcating trials across the defendants may be impractical, bifurcation has been approved in numerous other reverse payment cases. Indeed, the plaintiffs in the recently tried Opana ER antitrust litigation argued for *three* trials, which the court rejected and instead adopted a two-trial path.[22]

Finally, the defendants in Glumetza filed a motion *in limine* arguing that they were entitled to a limiting instruction that the jury should not draw adverse inferences against the non-waiving defendants.[23] Unlike the plaintiffs' arguments, this would not require a jury to consider documents only as to one party. However, there would still be a potential for a jury to infer that Bausch's privileged materials were

[19] Opp. to SJ., Dkt No. 732 at 43 n.254.

[20] *Masters v. UHS of Del., Inc.*, 631 F.3d 464, 475 (8th Cir. 2011).

[21] *Shanghai Automation Instrument Co. v. Kuei*, 194 F. Supp. 2d 995, 1008 (N.D. Cal. 2001).

[22] Pls.' Mot. Bifurcate, *In re Opana ER Antitrust Litig.*, 1:14-cv-10150 (N.D. Ill. Feb. 25, 2022), ECF No. 779; Order, *In re Opana ER Antitrust Litig.*, 1:14-cv-10150 (N.D. Ill. Apr. 21, 2022), ECF No. 793.

[23] *See generally* Defs.' MIL, Dkt No. 606.

contrary to its position in the antitrust litigation, as exemplified by some of the remarks made in the District Court's decision.[24] By itself, the defendants' position is likely straightforward to manage as privilege instructions are commonplace.[25]

Plaintiffs' View

As the *Glumetza* court observed in denying the defendants' motion for summary judgment, all of the defendants "tout[ed] *Lupin's* decision to waive attorney-client privilege in the underlying litigation *ad nauseum*."[26] The court described this as a "ploy" that "present[ed] a facially incomplete record" because the brand defendants, who did not waive, were relying so heavily on Lupin's waiver. To avoid this incomplete presentation, prior to trial, the plaintiffs filed a motion *in limine* requesting that the court, *inter alia*, allow the plaintiffs to examine and comment on the lack of subjective beliefs from the brand defendants, and allow the jury to draw an adverse inference as to the brand companies' beliefs.[27] While typically such an inference would be impermissible,[28] nothing about the single-party waiver in *Glumetza* was typical.

The problem, of course, with the single-party waiver is that it permits gamesmanship by the co-defendants. In reverse payment cases, former adversaries can become co-defendants, and once "a brand and generic challenger settle, their incentives align in favor of arguing that the patent was stronger and more clearly infringed" than it actually was.[29] These incentives become even more clearly aligned when the brand and generic are sued together for entering into an illegal reverse payment agreement. And because the co-defendant brand and generic manufacturers generally operate in the antitrust litigation pursuant to a joint defense agreement, they can simply decide together which party has privileged information from the underlying patent case that is more favorable to both parties' position in the antitrust case, and then waive the privilege only for that party with the more favorable information. In that way, both defendants can take advantage of favorable privileged information while protecting unfavorable privileged information. This allows the defendants collectively to use their privileged information as both a sword and shield, which of course a single party may not do.[30]

The parties resolved the *Glumetza* case before trial, and before rulings on the plaintiffs' and the defendants' competing motions *in limine* on this issue. So, questions about how to address the dispute remain. A solution suggested above is to separate the trials for brand and generic defendants, but this may be impractical in an area of antitrust litigation where trials regularly last more than a month and consume enormous resources. Would any judge truly consider holding two such trials when the evidence would be nearly identical in both?[31] Even in the criminal context, where a defendant's intent is relevant,[32] there is a strong preference to try codefendants together, particularly in conspiracy cases.[33] In most

[24] *See supra*, n. 7.

[25] *See, e.g.,* Del. P.J.I. Civ. § 23.16; Massachusetts Superior Court Civil Practice Jury Instructions § 12.10.

[26] *Id.* at *43.

[27] *See* Pltfs.' MIL, Case No. 3:19-05822 WHA (N.D. Cal.), Dkt. No. 601.

[28] *See Knorr-Bremse*, 383 F.3d at 1344-45 (Fed. Cir. 2004) (citing cases).

[29] *In re Cipro Cases I & II*, 348 P.3d 845, 870 n.20 (Cal. 2015).

[30] *See Chevron Corp. v. Penzoil Co.*, 974 F.3d 1156, 1162 (9th Cir. 1992) (citing *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2nd Cir. 1991)).

[31] Antitrust trials are regularly bifurcated on liability and damages, such as in the *Opana ER* case mentioned above, but that is vastly different from essentially holding the same exact trial twice for separate defendants.

[32] Intent is not relevant in the reverse payment context, where a defendant may be liable for entering into an unlawful agreement regardless of whether or not it intended to break the law.

[33] *See, e.g.*, *United States v. Daniel*, 933 F.3d 370, 380 (5th Cir. 2019) ("To promote judicial economy and the interests of justice, the federal system prefers joint trials of defendants who are properly charged in joint indictments, particularly in conspiracy cases.") (citations omitted).

instances a single trial with proper instructions should suffice, as likely would have been the case here.

FURTHER QUESTIONS

A few further questions not presented here are worth pondering. First, if *all* parties produced materials indicating they expected the brand to win (or all parties expected the brand to lose) the patent litigation, what effect would these materials have had on a motion for summary judgment? Second, can the *Actavis* proxy *ever* be overcome at the summary judgment stage via evidence of believed infringement and validity, and, if so, how? Finally, if a party has any documents reflecting a belief it may win the patent litigation, is that also sufficient to defeat summary judgment?

CONCLUSION

Despite Judge Alsup's skeptical view of the probative value of the patent waiver in *Glumetza*, defendants have followed, and likely will continue to follow, Lupin's model in other reverse payment cases.[34] Why would other defendants make this decision if it did not result in a summary judgment victory for Lupin? First, they may simply expect another judge will not be as skeptical of the probative value of the waived materials. Second, there may not be as much evidence contradicting the waived material, e.g., if all the settling parties waived privilege, thereby showing consistent beliefs. Third, Judge Alsup acknowledged that a jury could still interpret the waived evidence in the defendants' favor – even if the evidence was not sufficient for summary judgment, defendants may believe it will persuade a jury at trial. In future cases, we may see whether Lupin's waiver in *Glumetza* started a new trend in defending reverse payment allegations.

[34] *See supra*, n. 2.

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