## **ÁLM | LAW.COM**

# AM LAW LITIGATION DAILY

### Litigators of the (Past) Week: A Defense Win for Gilead and Teva in a Rare Trial on Pay-For-Delay Claims

#### **By Ross Todd**

July 12, 2023

rials in "pay for delay" antitrust cases-where branded and generic pharmaceutical companies stand accused of settling patent litigation claims in a way that unfairly props up drug prices-rarely go to trial. Given the dollar figures involved and the prospect of treble damages, the risks are high. That was especially true in a case that wrapped up recently against Gilead Sciences Inc. and Teva Pharmaceutical Industries Ltd. alleging the companies colluded to unfairly inflate the price for two key HIV drugs.

After six weeks of trial, federal jurors in San Francisco late last month found that Gilead didn't have market power in the relevant market. And, although they didn't have to, they went a step further to find there was no "pay for delay" deal between the two companies. Our Litigators of the (Past) Week are Bart Williams of Proskauer Rose and Devora Allon of Kirkland & Ellis who represent Gilead, and Christopher Holding of Goodwin Procter who represents Teva.

Lit Daily: Who were your clients and what was at stake?



(L-R) Bart Williams of Proskauer Rose, Devora Allon of Kirkland & Ellis and Christopher Holding of Goodwin Procter.

Bart Williams: Proskauer represented Gilead Sciences, Inc. as well as its named affiliated companies, Gilead Holdings, LLC, Gilead Sciences, LLC, and Gilead Sciences Ireland UC.

Plaintiffs, a series of health funds and insurance companies, alleged that as a result of a socalled anticompetitive "pay for delay" agreement between Gilead and Teva, they had been overcharged approximately \$3.6 billion. Plaintiffs also claimed that the alleged misconduct warranted trebling their asserted damages, which created a potential exposure of \$10.8 billion.

From an economic perspective, to say that a lot was at stake would be an enormous understatement. Beyond the financial impact for our client and Teva, however, this case also tested U.S. patent and antitrust laws more generally. Had the jury returned a verdict for the plaintiffs, that finding very well could have impacted future patent litigation settlements between innovator and generic companies, where such settlements not only are common, but work to enable early entry for generic drugs and encourage continued innovation for companies, like Gilead, that develop and invest in new and improving therapies.

Devora Allon: Kirkland's client was Gilead Sciences, one of the most innovative pharmaceutical companies in the world. The stakes were enormous. Gilead has done life-saving work developing critical new HIV treatments, yet the plaintiffs were accusing us of deliberately restricting access to our medications so that we could keep prices high. That allegation was not only false, but it struck at the heart of the huge amount of work Gilead has poured into fighting this disease for the sake of people living with HIV since its creation. The financial stakes were also enormous, with the plaintiffs claiming more than \$10 billion in damages. The jury's defense verdict is vindication for the many years of tireless effort, and the many millions of dollars in R&D, that Gilead expended to transform the medical landscape for people living with HIV. And our goal now is to eradicate the disease altogether.

Christopher Holding: Goodwin represented Teva Pharmaceuticals, one of the two defendants. Under antitrust law, Teva and Gilead would have been jointly and severally liable in the event the jury returned a verdict for plaintiffs.

#### How did this case come to you and the firm?

Holding: Goodwin has worked closely with Teva for years, and I have handled many antitrust matters for the company, including other cases asserting reverse-payment claims.

Allon: Kirkland took over as Gilead's trial counsel late in the litigation. The case had been pending for several years and was just a few months away from the scheduled trial. We immediately rolled up our sleeves to get up to speed, knocking out one set of claims on summary judgment, and persuading the court to hold a standalone trial on the plaintiffs' central claim that Gilead paid Teva to delay the launch of generic versions of Gilead's blockbuster HIV drugs, Truvada and Atripla. Then, we got to work revamping Gilead's trial themes and evidentiary presentation, and working closely with Gilead's witnesses to present the most compelling story we could tell to the jury.

Williams: Lead counsel at Kirkland retired unexpectedly. In March 2023, Gilead asked me to take on the role of lead counsel in the reverse payment trial. I was scheduled to begin a lengthy trial just a few days later, but that case ended up settling just before trial.

When I told Gilead that my case had settled, they asked me and my partner, **Susan Gutierrez**, to come in with a team to join the Kirkland firm in the effort. We have been part of the litigation team defending Gilead in a number of product liability matters for a few years, so we are very familiar with the client. We were grateful for the opportunity. Though getting up to speed on such a complex case was certainly a challenge, my team and I have done it a number of times in the past and we just dove in.

### Who was on your team and how did you divide the work?

Allon: We were fortunate to have a team at Kirkland that spanned across offices and expertise. Jay Lefkowitz and Kevin Van Wart, two of our firm's senior trial litigators from our New York and Chicago offices, helped prepare key company witnesses. Ellisen Turner, one of our IP partners from LA, headed up the patent piece. I focused on the economics-market definition, antitrust liability, and damagesalong with incredibly talented junior partner Kevin Jonke. In addition to those I named, we had a terrific team of junior partners and associates that included the New York, Chicago, Dallas and Salt Lake City offices supporting us, so it was a true firm-wide effort. We were also very lucky to have terrific co-counsel at Proskauer and Goodwin, who we worked seamlessly with. And the final, most important element was the absolutely incredible in-house team at Gilead, including the general counsel, head of litigation, and several other senior attorneys. Deb Telman, Keeley Wettan, Katie Rice and Shirley Cantin were with us in the trenches every step of the way. Overall, the Gilead team was very diverse (in-house and among outside counsel)-reflecting Gilead's commitment to inclusion and diversity.

Holding: Goodwin tried this case with a multidisciplinary team, with attorneys who specialized in the particular disciplines involved. Antitrust and commercial litigators (including **Joe Rockers** and **Tucker DeVoe**) focused on industry and economic issues. Patent litigators (including **Daryl Wiesen** and **Molly Grammel**) presented Teva's in-house counsel witness and the scientific-technical experts. Members of our appellate group (including **Brian Burgess** and **Jordan Bock**) focused on motions, jury instructions, and the verdict form in conjunction with Gilead's counsel.

Williams: Susan Gutierrez and I worked alongside a team of exceptional associates, William Dalsen, Om Alladi, Christina Assi, Margaret Ukwu and Genesis Sanchez Tavarez and paralegals Jeffrey Soldridge and Stacy Evans. The Proskauer team took on the hallmark lead roles for Gilead; e.g., handling voir dire, opening statement, closing argument, and multiple key fact witnesses and expert direct and cross-examinations. Kirkland partners and Gilead co-counsel Ellisen Shelton Turner, Devora Allon, Jay Lefkowitz, Kevin Van Wart and Kevin Jonke played critical roles in witness examinations, briefing, and oral argument throughout trial. Goodwin Procter partners Christopher Holding, Daryl Wiesen, Molly Grammel, Tucker DeVoe and Joseph Rockers represented Teva in all phases of the case.

Given the complexity of the issues and time pressures we were under-Judge Chen set a firm 32 hours for the plaintiffs, and 30 hours for the defense-determining which defendant and team member would lead any given aspect of the trial took considerable strategizing and balancing. While some allocations were more natural fits than others-for example, me handling the direct examination of Gilead's former general counsel, and Mr. Holding handling the direct of Teva's in-house counsel-we tried not to typecast counsel by particular subject matters (e.g., having only patent litigators handle patent witnesses). In a jury trial of this type-a case within a case where the legal claim is antitrust violations,

and the embedded case is a patent dispute it's vital to keep the themes and details at a level that is accessible to jurors who have no experience with those doctrines. My rule of thumb is that, if I don't understand it, there's little chance that the jurors will.

### What were your central trial themes and how did you drive them home with the jury?

Williams: A central theme was that patents promote progress-the notion that having patents, patent lawsuits, and patent settlements-are all normal occurrences that our country not only has designed but embraced because it allows science and medicine to move forward. We knew that plaintiffs' counsel would focus extensively on negative perceptions of "Big Pharma" and the price of brand name medications, so we needed to find simple, credible ways to make the point that our system of patent and antitrust laws were created with the intent that innovator companies have exclusivity and the ability to charge higher prices for a limited time, and that is not a bad thing because it incentivizes companies to keep investing in research and development.

In this way, the Gilead-Teva settlement agreement at issue was an example of the patent ecosystem and Hatch-Waxman Act working exactly as intended; namely, a generic company (here, Teva) uses the existing regulatory framework to challenge a brand company's patents; the generic and brand companies litigate the patents' validity and infringement in court; and, as one option, the parties settle the litigation and generic drugs are allowed to enter the market early, before the patents expire. The theme was thus that generic entry was early here, not late as plaintiffs claimed.

Allon: We had to play offense and defense. On offense, we showed the jury that Gilead has been working for years to spur innovation and competition in the HIV space, increasing access to medications that have saved countless lives. That's opposite of the image the plaintiffs tried to depict. We are thrilled that the jury saw through the plaintiff's plan.

We also needed to play defense and show the jury that the plaintiffs' case depended on a series of assumptions-about the supposed weakness of Gilead's patents, and about alternative settlements that Gilead and Teva could have entered—that were strung together by their experts but that lacked any real foundation in the evidence. And then there was market power. With close to a dozen of these generic delay cases that I'm active in right now, it's fair to say that I've given a lot of thought to market power, which is a threshold issue in every Sherman Act claim. And I've also thought market power was a winnable issue because the basic idea behind the defense position is very intuitive-just like you can buy Tylenol or Advil or Excedrin to treat a headache, our products face competition not just from the generic version, but from other brands too. But the economics behind how you define a relevant market are complex. We found a way to make that accessible by highlighting an actual Patient A from claims data to show how that patient switched across multiple products over the course of their treatment history. This proved that the reality of the HIV market is that treatment choices are driven by innovation and a quest to find the best treatment. And Gilead is constantly competing, with other companies,

July 12, 2023

and with itself, to innovate and produce the gold standard of care. This competition is the opposite of market power.

Holding: Teva stressed two central, related themes throughout the trial. First, the 2014 settlement agreement created early entry. Teva agreed to the settlement because Teva believed both (1) that it was likely to lose the patent disputes with Gilead, and (2) that the licensed entry date it negotiated was the earliest date it could get. Second, there was no pay for delay. Teva agreed to, and told Gilead it would accept, the licensed entry date before there was any discussion of any provision that might even conceivably be considered a payment to Teva. That meant Teva did not trade its entry date for any payment.

#### Big Pharma companies. The prices of vital AIDS drugs. How did you deal with the emotional elements of this trial, especially in front of jurors in San Francisco?

Allon: This was a major challenge. Gilead and Teva, our co-defendant, are considered "big pharma." Lots of juries have instinctive negative reactions to big pharma in general, and to drug pricing in specific. Big pharma companies typically rank among the least sympathetic defendants, particularly when the allegation is that they are gaming the system to reap enormous profits. And the plaintiffs put forward a narrative that they were on the side of AIDs activism, and we were against it. But we showed the jury that could not be further from the truth. The evidence proved that Gilead is an innovationbased company that prides itself on pushing science forward and constantly improving

its medicines. Gilead's innovation in the HIV space has saved countless lives, transforming what was once a death sentence into a condition that can be managed for people living with HIV. The fact that this jury sided with us proves that our themes were credible and true to the evidence. It's tremendous vindication.

Williams: Finding ways to embrace those elements and put them into context. Susan and I are firm believers we should embrace, or reclaim, that which our opposing counsel has tried to take away from or spin against our client. Gilead was founded at the height of the HIV/AIDS epidemic. Its headquarters are a short drive from the heart of San Francisco.

While not itself a focus of the trial, it was important that the jury hear and understand how, since the 1990s, Gilead's mission was and continues to be investing and innovating in the field of HIV treatment and prevention. At trial, we did not run from or downplay that the prices of these groundbreaking, often lifesaving medications can be high—instead, it was our job, as trial counsel, to explain that the cost of drugs (either generally or specifically) is part of the patent ecosystem and has no impact on whether or not Gilead is liable to plaintiffs for allegedly "overcharging" on its brand products.

Holding: We stressed that the 2014 settlement agreement led to early entry, not delay. Teva's actions in challenging Gilead's patents through trial, when no other generic company was willing to, pushed Gilead to allow generic entry before its patents expired and thus resulted in lower prices sooner. If, instead, the patent disputes had gone to judgment, Gilead was very likely to have won and generic entry would have been later. Generic companies focus on bringing more affordable drugs to market, and we stressed that that was exactly what Teva did here.

I gather that there was a lot of coordination between the Gilead and Teva defense teams here. But the allegations at play were that the companies colluded in violation of the antitrust laws. How do you cooperate with codefendants at trial without coming off like co-conspirators?

Holding: We were very aware of that risk and were deliberate about addressing it. Teva and Gilead started and ended our presentation to the jury as separate companies. We gave separate openings and closings, led by separate attorneys, and focusing thematically on distinct topics.

We also correctly anticipated that plaintiffs would argue that Teva had "switched sides" from originally trying to invalidate Gilead's patents in 2013 to then, after allegedly getting paid off by Gilead, arguing in the antitrust case that those patents were strong. But the evidence we presented disproved that idea by showing how hard Gilead and Teva had fought in the underlying patent litigation, how Teva understood that it was in trouble in the patent case, and how difficult and contentious the settlement negotiations had been.

Allon: At Kirkland, we were able to draw from our past experience of trying these cases we've now been trial counsel in all three of the reverse-payment cases, the only cases to have gone to verdict (and we're proud to say that the defendants won all three), and we have litigated at least a dozen others right now, and have more coming up. Even among those that have settled, many made it several days into trial or got right to the brink of trial. This is an issue we've dealt with before. Basically, we told the jury that even though Gilead and Teva were on the same side of the "v" for purposes of this trial, the witnesses and the evidence were going to show that outside of the courtroom, we are strong competitors, and we have fought tooth and nail for years. The jury believed us because that's what the evidence proved.

Williams: Cooperating with our co-defendant (Teva) was easy because Mr. Holding and the whole Goodwin team are elite, experienced colleagues who shared our drive to win and work without sharp elbows. Ensuring that that cooperation did not inadvertently feed into plaintiffs' conspiracy narrative in front of the jury, however, took more effort. As with every trial, we conducted ourselves as if the jury is always watching. That meant reacting (or not reacting) to co-counsel in the same manner as we did with plaintiffs' counsel in the courtroom. For example, we took efforts not to mingle with Teva's counsel in the hallway, we had separate breakrooms in the courthouse, kept cross-party notes minimal, and had physical separation at counsel table (one side was for Teva, one side was for Gilead).

The plaintiffs put on some company witnesses involved in the 2014 patent settlement in their own case. How did you prepare those witnesses to tell the companies' story under hostile questioning?

Williams: We had the evidence on our side and some truly excellent mock cross-examiners-

Kevin Van Wart from Kirkland in particular. Based on the allegations and knowledge of our adversary, we correctly anticipated who would cross-examine these witnesses and what style would be employed. We effectively prepared the witnesses to expect hostile or disbelieving cross-examination, to remain calm, and to focus on explaining the evidence without taking the bait and engaging with a similarly aggressive tone. We believe that our witnesses' ability to do this, and to keep the same tone and demeanor regardless of who was questioning them, helped to neutralize the crosses and win over the jury.

Allon: We spend a lot of time working with our witnesses, and here again Kirkland's deep experience with antitrust trials paid dividends. The first thing for us as lawyers is to know the record cold-to know every possible document, email, etc., that could be put in front of our witnesses during cross-examination, and to prepare for how to deal with that. We roleplay, we do mock cross-examinations that are often more difficult for the witness than the real thing. We want them to feel 100% comfortable when they take the stand that there won't be any surprises and that they can handle anything. And, of course, that means we need to make sure their direct testimony holds up under scrutiny and is consistent with the evidence, credible and understandable to the jury.

Holding: In our view, it turned out to be an advantage to us that some of our key fact witnesses, such as Teva in-house counsel **Staci Julie**, were called adversely during the Plaintiffs' case-in-chief. As often happens on "cross," plaintiffs' counsel did not give Ms. Julie an opportunity to explain her answers, even when she asked if she could explain. We used that to our advantage during our questioning, we were able to let her explain her answers completely. In the end, we think that helped the jury to credit her testimony. Moreover, getting an opportunity to tell Teva's story during the second week of a six-week trial, even though plaintiffs did not rest until the end of the fourth week, let us insert what really happened in the middle of plaintiffs' case, which we also think helped.

Mr. Holding, Teva chose to waive attorney-client privilege regarding internal emails about the underlying patent litigation with Gilead. Your team actually put on live testimony from the in-house lawyer who was central to the decision to settle. How difficult were those decisions? And what did those elements add to your defense?

Not surprisingly, Teva's decision to waive was made only after long and careful review. But as we dug through the documents, we found that there was a detailed written record about Teva's assessment of its patent dispute with Gilead and the decision to settle. That contemporaneous record completely undercut plaintiffs' theory of what happened. It showed that Teva's lawyers recommended, and management accepted, the settlement solely to manage the company's risk of losing the existing patent case and follow-on litigation about Gilead's new patents. It showed that the agreement created early entry, because Teva expected to lose its challenge to Gilead's patents and that it had obtained the earliest entry

possible through settlement negotiations. And it showed that Teva did not trade its entry date in return for any supposed payment from Gilead. In other words, there was no pay for delay, and there was no delay, period.

The Teva and Goodwin teams realized how powerful it could be to put those facts in front of the jury, to show what actually happened here. After that, the decision to waive—while not something that is ever easy—seemed clear. From our vantage point, it appeared that the jury found those documents and the testimony from Teva's in-house lawyer to be compelling.

### What will you remember most about this matter?

Holding: After six weeks of trial, and two and a half days of deliberations, the jury returning with a verdict was unforgettable. We were told initially that the jury had a verdict, but when we all got back to the courtroom, it turned out the jury had a question. The judge answered the question, the jury retired again, but it then quickly came back, unanimously finding that there was no pay for delay and also no market power. Nothing like a little extra excitement at the end of a long trial.

Williams: I suppose what I'll always remember is how our Proskauer team really came together during this trial. As you can imagine, to come into a case like this so late was an incredibly challenging thing. Our entire team basically worked really long days, seven days a week for three-and-a-half months. I'm proud of the quality and efficiency of the effort. I'll also always remember that we were told by multiple sources that alleged reverse payment antitrust cases "always" settle, but that we approached the case like we do any other we assume we are going to go to verdict and every action we take is done with that in mind. Here, once we established some momentum during trial, we had a client that was willing to stand its ground in the face of great risk because it was confident that the allegations did not have merit. It was extremely gratifying to learn that the jury saw it the same way.

Allon: Every day, we would start court by making our appearances for the record. Most lawyers say their name, their law firm, and their client. That's how I've always done it, and that's how all the other lawyers did it in this trial. But Gilead did something different. Without any discussion, we each introduced ourselves just by our name and our client. No law firm. It wasn't planned, and it wasn't posturing-we weren't even in the presence of the jury when it happened. It became a reflection of our commitment to teamwork, to our common goal of representing our client with a unified front, to the very best of our ability, regardless of what law firm we were a part of. Now, there's no one who is prouder to work at Kirkland & Ellis than I am. But that moment, repeated each morning for six weeks stands out to me as something I'm the proudest of-our ability to put aside any conceivable difference to serve our client, and in service of our client's mission. That's what I'll always remember-that my name was Devora Allon and I represented Gilead.