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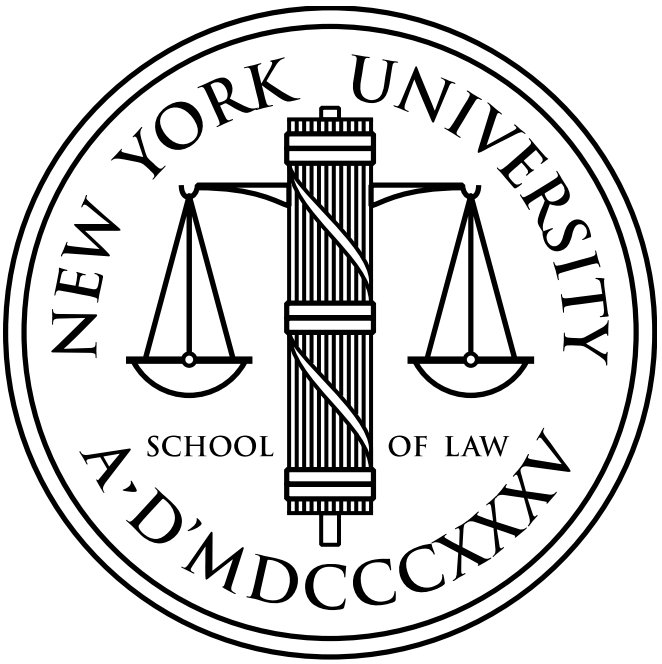

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ASSESSING STRATEGIES TO DELAY GENERIC DRUG ENTRY

MODERATOR: SCOTT HEMPHILL

PANELISTS: ROBIN FELDMAN, JAY LEFKOWITZ, SEAN NICHOLSON, AND JUDGE WILLIAM G. YOUNG

On March 10, 2021, our journal partnered with the Engelberg Center on Innovation Law and Policy to host a symposium addressing the role and impact of U.S. innovation policy on access to medicine. Our 2021 Symposium Issue—Volume 11, Issue 1—captures that event.[*]

The following article represents the fourth of four panels. This panel assessed strategies to delay generic drug entry. The panel was moderated by Professor Scott Hemphill of NYU School of Law. The panelists included Professor Robin Feldman of UC Hastings Law School, Jay Lefkowitz of Kirkland & Ellis, Professor Sean Nicholson of Cornell University, and Judge William G. Young of the District of Massachusetts.

SCOTT HEMPHILL: Hi everyone. It's a pleasure to get to convene this distinguished group and talk about these important issues.

Our topic is "Assessing Strategies to Delay Generic Drug Entry." We have in mind our generic—typically, bioequivalent, for those steeped in the jargon—versions of branded drugs. This is the cheap and cheerful alternative that you get at

[*] This transcript was modified for editorial purposes. A recording of the panel is available at NYU Journal of Intell. Property & Entertainment Law, *2021 JIPEL Symposium - Access to Medicine: The Role and Impact of U.S. Innovation Policy (Panel 4)*, YOUTUBE (Apr. 3, 2021), https://www.youtube.com/watch?v=XrD16RKx204.

the pharmacy, which is automatically substituted under state law or the practices of insurers. When the generic comes in, the average price tends to fall. Now, as one can imagine, that has an important effect on the innovator's profits and on branded profits. In response, a variety of strategies have been advanced over the years—both individually and in combination—to forestall the entry of generics, generating a robust debate about which of these practices are legal, appropriate, beneficial, or their opposite.

We'll be talking about a few of these different strategies, including what is sometimes called a pay-for-delay settlement, or a reverse-payment settlement, where the brand is forestalling generic entry by paying the generic to abandon patent litigation that, had it been successful, might have brought earlier generic entry. We'll be talking about thickets of patents—something we typically associate with other industries but have arisen in biopharmaceuticals—where dozens or hundreds of patents may be brought to bear in ways that some observers find troubling. Sometimes the strategy is as simple as denying access to the samples that a generic needs to perform the FDA-required tests to get on the market, thereby making life quite difficult for some generics.

So, first we've got a set of strategies that we'll be thinking about and evaluating over the next hour. Second, we have a new development that has arisen over the last few years, whereby not just federal antitrust law, but also state law is being brought to bear as an additional tool for thinking about these questions, raising a number of interesting questions in both law and policy. Fortunately, we have an all-star panel to help untangle this. I'm sure at the end, we'll all have clarity and be on the same page about these important questions.

First, Robin, let me turn to you. When we think about this terrain—this broad set of strategies to delay generic entry—can you give us a lay of the land? How big of an issue is this? What are the major components as you see them? And importantly, since we sometimes see multiple strategies being deployed on the same drug, how do you think about their intersection and combination to the extent they might generate synergistic effects?

ROBIN FELDMAN: I'm thrilled to hear that we're going to have full clarity and solve all problems by the end of the hour.

[Laughter.]

In terms of what you were asking, there are two things we know for certain about the pharmaceutical industry. The first is that generics bring prices down. The FDA tells us that a single generic brings the average price of a drug down about

40%, and when you get four generics in, prices come down about 80%.[1] So, we know if you have generics in the market, that's reducing a drug's price. Second, delay tactics *do* pay off. Drug companies don't need to keep a generic competitor off the market forever; just the delay itself can be worth its weight in gold.

Consider the narcolepsy drug Provigil. The company paid $300 million to generics to stay off the market.[2] Then it paid $1.2 billion in fines because of the pay-for-delay settlement.[3] And then it paid another $69 million settlement to the state of California in a case that's just finishing up now.[4] All in all, the pay-for-delay strategy cost the company about $1.6 billion. That sounds really painful—but not so fast. The company executives estimated that delaying the generics brought them an additional $4 billion in sales. So, even after paying more than a billion dollars in fines and case settlements, the company still netted a tidy sum of more than $2 billion. These tactics pay.

You also don't need a single tactic that is a knock-out blow to your competitors. Stringing these life-cycle management strategies together is highly effective, and it really is business as usual in the pharmaceutical industry. To give you one snapshot: 78% of the drugs associated with new patents are not new drugs coming on the market; they are existing ones.[5] In other words, the patent system in pharma is largely recycling and repurposing existing drugs. Recycling old drugs can have value, particularly for some patients at some times. But when a company makes a secondary change to a drug, the R&D investment is generally far less than what's required for the drug's initial development. A company should be able to earn its reward in the market for that.

More importantly—this really is critical—some of the claims in these piles of patents are of questionable validity. But the more you have, particularly with a biologic drug, the more expensive it can be to challenge them. In other words, the piles of patents and the piles of delay tactics can have synergistic effects in which

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[1] Generic Competition and Drug Prices, U.S. FOOD & DRUG ADMIN. (last updated Dec. 13, 2019), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices.

[2] Rebecca R. Ruiz & Katie Thomas, *Teva Settles Cephalon Generics Case With F.T.C. for $1.2 Billion*, N.Y. TIMES (May 28, 2015), https://www.nytimes.com/2015/05/29/business/teva-cephalon-provigil-ftc-settlement.html.

[3] *Id.*

[4] Mark Terry, *Teva to Pay California $69 Million in Pay-To-Delay Deal Settlement*, BIOSPACE (July 30, 2019), https://www.biospace.com/article/teva-endo-and-teikoku-settle-with-state-of-california-over-generic-drugs.

[5] *See* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J. L. & BIOSCIENCES 590 (Dec. 7, 2018).

the whole effect is even greater than the sum of the parts. Antitrust law has a very hard time handling synergistic effects and tends to look at each individual behavior. I have a piece coming out with Mark Lemley at Stanford that's titled *Atomistic Antitrust*.[6] We look at how modern antitrust law struggles to handle the broader picture even though companies themselves consider all their activities in these broad life-cycle management strategies.

My favorite example of the way current law struggles with seeing the full picture comes from last year's *Humira* decision, where the court noted that the company filed a total of 247 patent applications.[7] I will just pause here to say: that is *a lot* of patent applications. Out of those 247 applications, that yielded 132 patents. Again, *a lot* of patents on a single drug. Ninety percent of those patents were granted more than 12 years after the drug got to market. Now, the court described this as a "batting average" of 0.534—New York baseball fans will appreciate that—or about 50%, which the court said was too high to allege bad behavior.

Regardless of whether you think a 50% success rate is the right number for finding good behavior—I have my doubts—there's a more fundamental problem with this type of logic. If you just count up the number of petitions that were granted versus the number of petitions that failed, it entirely misses the point of the possible synergistic effects of all the company's behavior. I like to say that one cannot understand the magnificence and the power of a symphony by counting the individual notes, nor can one understand the full effects of multiple delay strategies without looking at them as a whole and understanding how they work together.

SCOTT HEMPHIL: Great. Thank you. Sean, let me turn to you. There's a balance between ensuring affordable access to drugs, on the one hand, and maintaining adequate, robust innovation. I think that was implicit in Rachel's comments at the end of the previous panel. How should we think about this balance as it might bear on some of these debates about barriers to generic entry? How much of the value of these new drugs do consumers hold on to? Any thoughts that you might have about how that balancing question bears on the antitrust analysis of evaluating strategies to delay generic entry would also be most welcomed.

And one more thing on the table since it was in Robin's comments: thinking about small molecules versus biologics, is the story different? A lot of our battles have been in small molecules. Of course, we are moving into a world of biologics.

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[6] Mark A. Lemby & Robin Feldman, *Atomistic Antitrust*, SSRN (Feb. 26, 2021), https://papers.ssrn.com/abstract_id=3793809.

[7] *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811 (N.D. Ill. 2020) (claim of sham litigation under *Noerr-Pennington* doctrine dismissed without prejudice).

Do the same intuitions and battle lines carry over to the new context, or are there important differences that change the state of play in some important way?

SEAN NICHOLSON: Thanks for inviting me, and thanks for the great question.

I will start with a little theory, and then I'll quickly get to the empirics that you mentioned on who is capturing the value. From a policy perspective, what policymakers are trying to do is allow pharmaceutical firms and biotech firms to have an effective market exclusivity length. I'm using that term as the amount of time from when the FDA approves the drug to when the generics actually enter, not when the patent expires. They want that period of time to be sufficiently long so that pharmaceutical firms and biotech firms will invest the hundreds of millions of dollars that it often requires to bring a drug to the market. But they don't want that amount of time to be so long that the pharmaceutical firms are making "excessive profits." That's the theory.

The government is trying to balance that. Make it sufficiently profitable. Let those profits accrue for sufficiently long that it merits investing the money to get the drug to the market but not give away the ranch, essentially. I mean, that's hard. The government is doing it by allowing patents and issuing laws like Hatch-Waxman that regulate the way the generic firms enter.[8] How long is that market exclusivity period? Remarkably, it's been pretty stable at an average of about 12 years. That's an average—of course, you'll have drugs that have market exclusivity longer than 12 years, and some less, but the average has been pretty stable.

Most people think it's really two offsetting forces. One is to Robin's point: you have the evergreening behavior from pharmaceutical firms of patenting like crazy. They would argue that it's justified. Then, you have very aggressive litigation on the part of generic firms because the incentives of being the first and getting the market exclusivity on the generic side is really strong. Those two forces have tended to offset one another and keep that market exclusivity at about 12 years. That doesn't mean that 12 is optimal. That just means that it's been pretty stable.

To look at the optimal, I can think of four fairly well-done studies that look at how much value a drug brings to society in terms of health gain: how much is captured by the consumer patient, and how much is captured by the pharma firms. They're kind of on opposite ends of the spectrum. For HIV/AIDS and statins, the studies show that a majority of the value is captured by the consumer. It's not even

[8] *See* Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman), Pub. L No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 301, 355, 360cc).

close in those two examples. According to studies, about 90 or 80% of the value accrued to the consumer. Then you've got a couple other examples—one of which I was involved in: multiple myeloma and colon cancer[9]—where the pharma firms, at least when the patents were in place, were capturing almost all of the value. The story would be that when those patents expire, consumers might then capture the value. But, at least for that first 15 years, the pharma firms were pricing the products to extract most of that value.

I'll finish with your biosimilar. In 2009, Congress tried to think carefully about the right balance for biosimilars.[10] They decided to make the minimum market exclusivity 12 years. Obviously, the average will be larger than that, in part because the patents are probably easier to work around if you're a biologic company. In practice, it's not until the last couple of years that we've seen substantial biosimilar entry in the U.S. and prices coming down. It's taken about ten years from the 2009 law for everybody to understand how the biosimilar patent litigation is going to work. I would say that, even though there haven't been a lot of studies, most of that value is being captured by the industry on the biosimilar side.

SCOTT HEMPHILL: Great. Thanks. Just picking up on one of the things you said at the end: I wonder whether ease of avoidance has turned out to be higher in the biosimilar context than it was in the small molecule.

Let me turn to Jay. There has been a lot of activity in this space—not just in reverse payments, but other areas, too. I'm wondering, from your perspective, what are the main issues that are being litigated today? Are there trends or outcomes that have surprised you, or that seem to be headed in the right or wrong direction?

JAY LEFKOWITZ: I think *Actavis* has basically set forth a few very clear guidelines and left an awful lot unclear.[11] Judges, like Judge Young, have to figure it out on the fly. Right now, we don't have that many cases being litigated; in fact, very few patent settlements (according to the FTC's last report[12]) actually on paper

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[9] Darius Lakdawalla et al., *Quality-Adjusted Cost Of Care: A Meaningful Way to Measure Growth in Innovation Cost Versus the Value of Health Gains*, 34 HEALTH AFF. 555 (Apr. 2015).

[10] Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001-03, 124 Stat. 119, 804-28 (2010) (codified in scattered sections of 21 U.S.C., 35 U.S.C., and 42 U.S.C.). The Biologics Price Competition and Innovation Act (BPCIA) was enacted as part of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 804 (2010).

[11] *See* Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136 (2013).

[12] Fed. Trade Comm'n Bureau of Competition, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement and Modernization Act of 2003: Overview of Agreements Filed in FY 2017* (2020),

violate *Actavis*. The FTC only identified three settlements out of 226 in their last report that raised any type of trouble at all, and they weren't the kinds of lump-sum payments that we used to deal with. But we are now seeing a lot of litigation on other related issues: settlements that have exclusive licenses, accelerator clauses, most favored nation clauses, situations where the brand will give three, four, or five different generics part of its authorized generic supply. I think the wave that we're in right now includes all of those types of cases, and yet they still present the same sets of issues, in theory, that *Actavis* has.

The real issue is that a dollar doesn't necessarily mean the same to a generic or to a brand. If you and I are having a dispute over $100, and we decide to settle for $80, we both know what that $80 is worth. We might settle for $80 because I think I can't collect the $100, and you think you might not keep the $100. So, maybe we'll settle for $80.

But when you're settling a patent case, and the patent has 10 or 15 years to go, and you're litigating today, you have to pick some entry date. Any particular entry date is just as easy to be seen as a delayed entry as it is to be seen as an early entry because it's in the eye of the beholder. The time value of that period of exclusivity is obviously worth much more to the brand than it is to the generic that simply is going to get 180 days of exclusivity—or really, co-exclusivity with the brand—before the market opens up. So, sometimes other things have to be taken into account in order for them to reach a settlement. We all want settlements because if there is no settlement, then the brand monopoly persists until the end of the patent term.

What judges have to do is look at the ultimate questions, which are often questions of causation. What we're seeing right now in these litigations is, on the one hand, that we don't want to re-litigate the patent case in the antitrust case. On the other hand, patent issues are obviously important. If you have a generic and a brand suing each other, and the generic knows that three other generics have lost that same invalidity case to the brand, you can understand why the generic is going to take almost anything it can get in a settlement. Or if the generic has some problems with the FDA and knows it can't get a drug approval, that's another causation issue.

We're seeing a lot of the wrinkles coming out of the *Actavis* decision, and of course, we're now also starting to see some more aggressive FTC enforcement. They just filed a lawsuit a few weeks ago against one of my clients in a case that wasn't even a typical reverse payment situation. I think we're going to see a lot of regulatory

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https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf.

activity and a lot of private litigation in the coming years on the margins of the *Actavis* decision.

SCOTT HEMPHILL: Great. Thanks.

Judge Young, let me turn to you. Reactions to what you've heard so far? One question that I want to ask you, either now or as a follow-up, is what do you make of trying to deal with these complex issues in a courtroom, staffed by a generalist judge with lay jurors if it's a private damages case?

JUDGE WILLIAM G. YOUNG: That, of course, is the basic challenge. It's a very worthwhile challenge for the justice system. Let me speak directly to it. What do I make of it? You sort out the issues as best you can. You depend upon competent counsel and an adversary presentation so that they may be presented to a jury, and you accurately instruct that jury to reach out for justice.

These are extraordinarily complex economic and policy issues. One of the desirable things about the *Actavis* decision is that the law that you are applying is *an opinion* of the Supreme Court.[13] You don't have various—even Federal Circuit—nuances; in the antitrust area, you don't have different degrees of persuasion. You've got the Supreme Court. And, of course, you ask yourself, "Mother of God, what do they want us to do here? What were they thinking of?"

I started out saying I didn't try this case very well, but I did try it fairly. Part of that was I didn't even understand the case until we got going. I had made rulings on summary judgement.[14] Those rulings were wrong. They were just how the jury came out, but they were wrong. So, I listen to those who are skilled—far more skilled than I—and I'm making notes here as we go. I'm thinking to myself, "Well, these really are the issues." The reverse payment, if we can talk about it—Jay has already very skillfully laid out—doesn't need to be monetary. You're rarely going to see that. It's going to be far more complex than that.

I looked at the verdict slip I gave the jury. Imagine the jury being asked this question: "Was AstraZeneca's Nexium settlement with Ranbaxy unreasonably anticompetitive? That is, did the anticompetitive effects of that settlement outweigh any procompetitive justifications? Answer no/yes." Well, that really boils it down, doesn't it? People could go on for a long time about that.

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[13] *See* Actavis, 570 U.S. at 136.

[14] *In re* Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231 (D. Mass 2014) (order denying summary judgement), *aff'd as harmless if error*, 824 F.3d 34 (2016).

Here's a take-away, though, as a sitting judicial officer, and this I would state very strongly: delay. There is too much delay in the litigation of these cases. The delay that's been talked about is delay pre-litigation. But once the complaint has been filed, there is too much delay. That's on us. I take the position that these cases should go to trial no later than 13 months after the complaint is filed. Frequently, you will find in these types of cases that the parties want a preliminary injunction. I always find that interesting because under Rule 65(a) of the Rules of Civil Procedure, you can collapse a preliminary injunction with trial on the merits.[15] I try to do that routinely. That causes everyone to tear their hair and focus on the real issues.

Now, I'm biased as a sitting judge. I'm biased in favor of our dispute resolution system, and I stand to be challenged on it. But I'm here to take the position that we *can* handle these complex issues, and we can handle them in a *timely* fashion. "Timely" for me is about a year or a year and a half.

SCOTT HEMPHILL: All right, Judge, let me follow up on that.

First, as to the verdict questions that you were just reading from, I put that on a PowerPoint in my Antitrust class and show it every year. For people who don't know, what Judge Young just did was greatly simplify the series of questions that was offered. And, to plug into Jay's comment about causation, one of the many aspects that makes this case so interesting is that the jury basically said the conduct was unreasonable. The payment to induce a delay was unreasonable. So, the jury found that the defendant was bad across the first three or four questions. Then the trial court asked, "Okay, *but for* this conduct, would the plaintiff have gotten an entry date before the entry date that occurred?" The answer to that, the jury said, was *no.*[16] So, you're left trying to figure out, what were they thinking? Some of the post-verdict briefing and opinion writing got at that.[17]

Now, in the last paragraph of *Actavis*, Justice Breyer said, "As in other areas of law, trial courts can structure antitrust litigation so as to avoid" all kinds of problems, including litigating a patent case inside of an antitrust case.[18] Basically, "District courts can figure this out on their own. Just work out your own procedure. You can engage in shortcuts. You have a lot of flexibility. Go for it." How do you

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[15] Fed. R. Civ. P. 65(a).

[16] Jury Verdict, *In re* Nexium (Esomeprazole) Antitrust Litig., No. 1:12-MD-02409 (D. Mass. Dec. 5, 2014), ECF No. 1383.

[17] *See, e.g.*, *In re* Nexium (Esomeprazole) Antitrust Litig., 309 F.R.D. 107 (D. Mass. 2015) (order denying new trial).

[18] *See* Actavis, 570 U.S. at 159-60.

feel about receiving a kind of general instruction like that? This is not uncommon in antitrust cases, by the way. After *Leegin*,[19] the Supreme Court basically said, "We're going from *per se* liability to the rule of reason. District courts, go put some meat on these bones that we've offered you. Just do your best to structure and come to the truth in whatever order you think makes sense." Do you find that liberating? Do you find that frustrating? What do you make of a pronouncement like this when you're then faced with this sprawling, complicated case that you have to boil down in a way that jurors will be able to make sense of?

JUDGE WILLIAM G. YOUNG: The short answer is: I find it liberating. The discharge of that duty is daunting because it presumes a very high degree of economic knowledge. I realize that I do not have the sophisticated economics background that many others do. I am an advocate of the adversary system. One fortunate aspect of these types of cases, because the stakes are very high, is that they attract outstanding advocates—outstanding advocates across the board, and that is delightful. So, you learn a great deal.

SCOTT HEMPHILL: Jay, let me turn to you. As I've mentioned, you've litigated a lot of these reverse payment cases, including *Nexium*. You were essential in the *Nexium* case that Judge Young was talking about. Where do you see the causation discussion ending up?

JAY LEFKOWITZ: The Supreme Court, at least Justice Breyer, was trying to strike a middle ground.[20] If you remember, the companies went into that case saying, "Scope of the patent. As long as we have a patent, we can do absolutely anything to exploit our patent. It doesn't matter." That was one extreme. The other extreme was the government position, which was essentially *per se* liability. And the court was very clear. It's hard to always understand. I probably read that decision a thousand times, and I gleaned different things every time I read it. But I think the author was trying to strike some kind of middle ground and then give it to trial judges to do this.

What happens, largely because of the billions of dollars in liability, is that the issue tends to collapse on the question of "is it a large and unexplained payment?" That's the threshold question. You can have a large and unexplained payment—although unexplained and unjustified don't necessarily mean the same thing in the context of that opinion—but then the question is, "if you have a large, unexplained payment, that doesn't actually mean you have liability, at least according to the Supreme Court rule?"

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[19] Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 887 (2007).

[20] *See* Actavis, 570 U.S. at 136.

There are a lot of folks out there (like the FTC) that would like to take the position that it is *de facto* liability. We have one case right now in the appellate court that's going to tee up that specific issue. But if you look at the rule of reason, then it just shifts the burden. At that point, you have to look at procompetitive benefits and justifications. Then, you still have to look at least restrictive alternatives: was there some other way to achieve these benefits?

The problem is the companies have a hard time staying in the game as long as AstraZeneca and Ranbaxy stayed in *Nexium* because of the overwhelming potential exposure. So, not many of these cases get litigated. I've had one other case that's been litigated, but it settled prior to the jury making a decision. Other than the *Nexium* case, every other case has settled. As we get some more ground rules from some of the appellate courts about how you conduct the rule of reason analysis, it will breathe more life into the fundamental question, which is causation: what would've happened in a but-for world? Then you'll start to see the law percolate a little more.

SCOTT HEMPHILL: Robin, let me turn to you and move toward the underlying empirics here.

We've already heard mention of FTC studies about frequency and how frequency has fallen over time. There's also an FTC study estimating the costs from settlement, which they may have put at $3.5 billion a year.[21] I might be off by a bit, and it may be lower than what some of us would've expected. We've talked about individual drugs, like Nexium, where on a $3 billion drug, a year of delay might be associated with a consumer harm that's also north of $1 billion. So, we could have a number that gets up pretty fast depending on how we cut the data. How should we think about the size of the potential issue?

ROBIN FELDMAN: You're right about the Federal Trade Commission study. It was more than a decade ago, they published a report on pay-for-delay, and they estimated that pay-for-delay settlements cost American consumers $3.5 billion a year.[22] That number has been cited by everyone since. There's a lot of information that's still hidden, but there's much more public information about pharma pricing and lawsuit settlements available today than there was a decade ago. Like Scott, I

[21] Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[22] *Id.*

thought that the $3.5 billion figure was not just *old* but *off*, so I set out to calculate an updated cost.[23]

There are different ways one can measure these things. I wanted to be as fair as possible, so I used six different sets of calculations, using different kinds of approaches that you can find in the literature. All six methodologies yielded results that were much higher than the old FTC figure. Rather than the $3.5 billion a year that was estimated in 2010, the lowest result from the six methods that I used yielded an updated cost of roughly $26 billion a year. The others were much higher; it tops out at about $169 billion. So, to put this in perspective, even the lower-end figure is *seven times* the old FTC figure.

As the basis for all those calculations, I used 16 pay-for-delay deals in which there's sufficient public information available. I looked at the list price. I looked at the out-of-pocket cost. I looked at the overall Medicare cost. I sliced and diced this thing six ways from Sunday. But the point is simply that the cost of these deals for society is much greater than anyone has thought, and it's worth thinking about those impacts.

SCOTT HEMPHILL: Great. Thanks.

JUDGE WILLIAM G. YOUNG: Could I ask a question?

SCOTT HEMPHILL: Yeah, Judge.

JUDGE WILLIAM G. YOUNG: Professor Feldman, I'm going back to your first presentation, which I found so helpful. I understand your concern about what you call "thickets of patents."[24] But of course, it is our policy to give these limited patent monopolies, and we have a procedure for granting them. If we were in a case where that argument was made in an antitrust context, I would say, "So what? The Patent Office has given them these patents." Where does the liability lie?

ROBIN FELDMAN: If we had confidence that everything issued out of the Patent Office is of good value, that might be a different story.

Now, legally, there is a presumption of validity. But empirically, if you look at how often patents fall (particularly the secondary patents), you'll find that the value of the patents coming out of the Patent Office is not so great. That should give

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[23] Robin Feldman, *The Price Tag of 'Pay-for-Delay,'* SSRN (2021), https://ssrn.com/abstract=3846484.

[24] *E.g.*, Robin C. Feldman et al., *Viral Licensing: Ensuring the Public Interest when Taxpayers Fund Pharmaceutical Research*, 59 SANTA CLARA L. REV. 641, 659 (2020).

you pause when you see a huge number of patents being thrown at a particular drug in a way that raises the cost for any individual generic to come on the market. If you break down what is in these patents, it's not an inspiring vision.

JUDGE WILLIAM G. YOUNG: Have you got any judge who has expressed that view? I'd be interested since that judge is saying, "Well, we've got a Patent Office, but they make a lot of mistakes. Look at what they're doing with their patents." I'm interested in your argument; where's the authority?

SCOTT HEMPHILL: Judge, I'm going to let Professor Feldman respond, but I just want to add another element here: even if that were granted, there's a second front that's opened, which is that a duly-issued patent might not be infringed by a generic product, or an alleged infringer. So, even if you thought that they were all valid patents, you might still be worried that a plaintiff would misuse them and engage in vexatious or knowingly frivolous litigation in order to throw sand in the gears.

So, the fact that you have a duly-issued property right doesn't tell you whether it's pertinent or not in itself to a generic product. On these secondary patents, it's often a question of infringement. Maybe the granted patent is valid, but they'd use some other strategy to come to market that doesn't implicate it by the patent. Especially as to these patents that issue long after the therapy has entered the market, a suspicion arises that because that therapy is prior art, maybe the patent that's filed isn't essential to practicing the therapy.

JUDGE WILLIAM G. YOUNG: I'm familiar with patent misuse. I know it's pompous when I just say that, but I am.

SCOTT HEMPHILL: But I don't mean to make a misuse argument here.

JUDGE WILLIAM G. YOUNG: This argument's a little different. This argument is the "thickets of patent" argument that I'm asking about.

SCOTT HEMPHILL: I mean to be addressing "thickets of patents." A piece of the puzzle is: you can have 100 patents, 60 of which have to do with your drug but aren't actually practiced by the drug. If someone is trying to offer a very close version of the drug, they too might not be using the technology as to these patents that are valid and yet not infringed. That can be troubling for reasons that don't need to implicate misuse. Robin, you were actually addressed.

ROBIN FELDMAN: You have a wonderful response there.

In terms of an interesting piece of authority, the state law that just passed in California specifically says that the court should not presume that the patents are valid as a reason to say that the behavior is appropriate.[25] I'll have to look at exactly what the language is, but they are addressing exactly the question that you're thinking about. I'm not sure whether Oregon has some similar language, but that's part of what states are beginning to look at because they're hitting their head against that issue.

Practically speaking, if I've got a big bag of weapons, I can just keep throwing those until one of them sticks. Frankly, I don't even need 50% of them to stick. I only need, as a patent holder, *one*: you only have to have one claim standing at the end to be able to block that generic. So, it's in my interest to have a huge bag and just keep throwing and hoping something's going to last. That's not really a good way to run a patent system or a competition system.

SCOTT HEMPHILL: Let me bring Sean in with comments, and then I want to turn to Jay since the California law was raised—among other things, something that would reverse a statutory presumption of validity seems like something Jay might want to weigh in on.

SEAN NICHOLSON: I'll be brief. I just want to add my sympathies to the judges and juries in these reverse settlement cases because I think it's a difficult issue. To attempt to explain why, there are some situations where, without a reverse payment, the generic firm and the branded firm are not going to be able to come to an agreement on an entry date. Imagine that the branded firm thinks there's a 95% probability that if the patent or patents are fully litigated, they're going to prevail: it's going to be proven valid. But just that 5% probability of seeing their potentially multi-billion dollars of profits disappear is going to get them willing to pay substantially. "Pay" can mean allowing an earlier entry date than they otherwise would *and* adding some sort of compensation. But how do you figure that out? You can't just measure risk aversion. That's not something judges and juries are used to doing.

I think there are situations where reverse payments can be merited, but I sympathize with trying to figure out when that's appropriate and when it isn't.

JAY LEFKOWITZ: I think Robin is correct in terms of characterizing what the California statute does. It does a variety of things that are very interesting. Just to be candid about this, I've challenged the constitutionality of the statute, and I'm waiting for a decision from the judge. It raises serious questions of federal

[25] *See* Cal. Health & Safety Code § 134002 (West 2020).

preemption because it takes a presumption of patent enforcement that comes from Congress, and it flips that burden. It also says that an exclusive license is presumptively unlawful even though Congress has said in Section 361 of the Patent Act that you have an unqualified right to have an exclusive license.[26]

As interesting as the preemption tension is in the California statute, the bigger problem with the California statute is that it purports to hold conduct that takes place entirely outside the state of California unlawful. We're all familiar with California having environmental laws that impact the auto industry—they can say, "You can't sell a car in California that doesn't have certain emissions," for example—but they couldn't well say that a Michigan manufacturer couldn't sell an automobile to a New Yorker without those emissions. And yet, what California's law would do is tell two companies who are not California citizens, who are entering into a settlement in a case that's pending before Judge Young in Boston that their settlement violates California law.

If this case is litigated in much the same way that a recent case that we litigated in challenging the Maryland law gets litigated, it's likely to be found invalid. It's not that California doesn't have enormous antitrust tools. We know that when state antitrust law is substantively the same as federal law, then the extraterritorial doctrine may well give way based on an implicit understanding that the Sherman Act was intended to allow states to regulate intrastate commerce. But the problem is when a state tries to project its power and regulate an economic transaction entirely outside of its boundaries. That runs up against the Commerce Clause.[27]

I think the laws in California and Oregon are in jeopardy both because of preemption considerations and Commerce Clause considerations.

SCOTT HEMPHILL: Thank you. Robin, you've testified in favor of arming states with new tools. Why do they need them? Why isn't the current set-up enough?

ROBIN FELDMAN: Sure.

Before I answer that directly, I pulled up the California law. Just to clarify, it says that as the parties are trying to defend their behavior, the factfinder shall not presume "that any patent is enforceable and infringed by the non-reference drug filer in the absence of a final adjudication binding on the filer of those issues."[28] In other words, when you're trying to think about the different parties' behavior and what

[26] *See* 35 U.S.C § 351.
[27] *See* U.S. CONST. art. I, § 8, cl. 3.
[28] Cal. Health & Safety Code § 134002(b)(2) (West 2020).

you're doing, don't presume—unless you have a finding on that—that this is enforceable and is infringed in the circumstance. Judge, those are the types of concerns that I was talking about.

In terms of "what do the states need? What does the law need? Do we need any more?" I would say the following: the *Actavis* case opened the door to antitrust liability in cases of pay-for-delay, but the legal system just keeps banging its head on the door jamb.[29] In particular, there seem to be difficulties in fighting each of the terms: "pay" and "for" and "delay."

We also know from the Federal Trade Commission reports that there have been roughly 1,100 settlements between brands and generics in seven years. The vast majority of those involve an agreement by the generic to stay out of the market for some period of time. We also know that the number of settlements between brands and generics each year has more than doubled across that time.

There are, as Jay mentioned, some troubling signs about anticompetitive aspects of these agreements. In the most recent year, for example, 76% of the settlements between brands and generics contained some form of acceleration clause. Acceleration clauses can discourage other generic companies from entering because other potential generics know if they enter they're going to face immediate entry from the generic who settles. It's one way a brand company can get additional bang for their buck: you settle with a generic manufacturer, and you discourage others from entering.

There are hints of other anticompetitive aspects of the deals: if you look at the most recent FTC report, 90% of the settlements involve the generic receiving rights to patents not subject to any litigation between the parties. Rights like those could easily be the vehicle for transferring value or sharing markets. The bottom line is that there's good reason to believe that *Actavis* did not solve the pay-for-delay problems, and that additional clarification is needed.

Regardless of whether you think the California law is right—some people think California gave up too much with the exceptions it allowed, and others think the legislation is too strong—there's a lot of additional work that remains to be done in pay-for-delay. We really haven't solved it.

SCOTT HEMPHILL: Thank you. I have a question for Sean, and then I'll give Judge Young the last word.

[29] *See* Actavis 570 U.S. at 136.

Sean, one of the questions that comes up—you could imagine it coming up in reverse payments or in other contexts where we're concerned about delayed generic entry—is: where are the purchasers in all of this? I don't mean individual cash purchasers who have no insurance and find themselves paying some extremely high price at the pharmacy, but rather pharmacy benefit managers (PBMs) who presumably have some power to insist on particular prices or particular terms of dealing as a condition for being put on a formulary. Couldn't the PBMs engage in some kind of self-help to protect themselves against entry-delaying conduct? Is this a feasible alternative? Is this pie in the sky? How do we think about it?

SEAN NICHOLSON: I think what PBMs *are* doing and can *continue* to do is be amazingly effective at shifting market share from the branded drug to the generic drugs as soon as entry has occurred. More than 95% of market share is going to shift very quickly. But I really don't think PBMs can do much more than that.

Imagine that a PBM becomes convinced that a branded firm is engaging in inappropriate activities to delay generic entry. The PBM has the power to say, "We're going to move that drug to the fourth tier, and it's going to become expensive in the eyes of the patient. We're going to stick it to the pharmaceutical firm," but that's harming the health of the enrollees. I would see that as not being an effective strategy for the customers they're supposed to be looking out for.

SCOTT HEMPHILL: Judge Young, final reactions to what you've heard here?

JUDGE WILLIAM G. YOUNG: Well, I'll be very brief. I hope this has been recorded because, aside from me, what a marvelous grouping of people who truly care and are raising profound issues, both economic and policy issues, in our healthcare field. These are matters in which the Federal Trade Commission, Congress, and the courts, as well as the Patent Office, share responsibilities for reaching out for justice. I have no answers beyond seeking to discharge my duty with respect to a particular case in controversy, but it is fascinating.