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**Panel 3
Emerging Issues in Competition Law and Health Care**

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PROF. SOKOL: Let me start by thanking
everyone here at Fordham who have put on a great

conference. Let me thank the morning panelists and the keynotes. I think we've learned a lot. Wonderful presentations.

I think in many ways when people think about populism and antitrust, the first thing that they think about, since they don't know anything about antitrust or competition law, is think about their own personal health. Health care is a fascinating area, and we're going to get started now.

I have wonderful practitioners and practitioners/academics on this panel, actually technically two practitioners/academics because Scott also spent a year here in New York.

To my immediate right I have Fiona from Baker McKenzie, who has come all the way from Europe; I have Scott, who has come all the way from downtown; I have Steve, who has come from Washington, D.C.; and I have Reiko, who has come from Tokyo. Combined, literally we span the world in terms of time zones.

With that, we are going to start by going

into big-picture issues to frame the rest of the discussion.

Scott, let me start with you.

PROF. HEMPHILL: Great. Thanks to Danny for the introduction, and to James and the folks at Fordham for organizing what's always a really outstanding conference.

I would like to spend the next few minutes discussing two emerging issues that I think are of great importance for health care and antitrust.

The first really isn't a health care issue at first blush at all, the recent *AT&T/Time Warner* merger challenge by the DOJ. It might seem like an odd place to start. It's not a health care merger, of course. But the case has quite important implications for health care that I want us to think a little bit about.

Second, the increasingly aggressive approach to monopsony – that is, to agreements and mergers that harm sellers through the enhanced exercise of power by

buyers. This is already an important issue, and I think it's going to get bigger as time goes on.

Let me start with the *AT&T/Time Warner* merger. As this audience knows, Time Warner owns Turner, a video programmer which operates several networks, and AT&T owns DirectTV, a major video distributor. DOJ's main argument in challenging the merger has been that Turner's common ownership with DirectTV would lead Turner to raise its prices in its license negotiations with other distributors.

This concern is based on an economic model, a model of bargaining pioneered by John Nash, the Nobel Prize winner. In that Nash bargaining model upstream and downstream firms negotiate over whether the upstream firm's products are included in a bundle of inputs offered for sale by the downstream firm. The model supposes that the parties bargain over the division of surplus from reaching an agreement compared to what each party would get if they failed to reach a deal.

To simplify it somewhat, the key issue in these models is bargaining leverage, and bargaining leverage affects the magnitude of the surplus the parties divide and derives from each party's outside option – that is, their best alternative to a negotiated agreement (BATNA), or their walkaway value if the parties fail to reach a deal.

The anticompetitive effect of a merger in these bargaining settings derives from the increased bargaining leverage. If a party can improve its outside option through a merger or if it can worsen a counterparty's outside option, then the party can increase its profits at the expense of the counterparty.

As an example, imagine a negotiation over whether the Turner networks will be included in some other distributor's offering to consumers – Dish, say. If the negotiations failed, there would be what's called a "blackout" of Turner content on Dish.

In response to a blackout, some customers

would switch to DirecTV. That is the key move that drives DOJ's argument here, which is that from Turner's perspective the extra benefit to DirecTV, now a corporate affiliate, would soften the negative consequences of a blackout and thereby improve Turner's outside option and enhance its bargaining leverage in negotiations with Dish, giving it both the incentive and the ability to insist on a higher price.

You know the conclusion of this story so far, which is that the court rejected the conclusion that Turner's bargaining leverage would actually increase post-merger. The court reasoned that blackouts are pretty costly to Turner, very costly, and so a blackout would not be a credible negotiating threat. The court also observed that long-term blackouts don't happen that much in practice.

Here's where health care antitrust comes in. The economic theory of bargaining is also a powerful, commonly used tool for evaluating health care mergers. We see this all the time in hospital cases. A merger

of competing hospitals is typically analyzed by asking whether the merger worsens the outside option of payers, and thereby increases the hospital's bargaining leverage in negotiations.

The outside option changes because if the insurer, the payer, fails to reach a deal, it's now missing multiple hospitals from its provider network rather than just one. The FTC's successful stream of hospital merger challenges, going back to *ProMedica*, is premised on this theory.

So the *AT&T* court's hostility to bargaining theory may raise some questions about the use of this model in other mergers, such as mergers of hospital or mergers of payer.

To be sure, the *AT&T* opinion is the view of a single district court in a particular factual setting, and the district court did say that it accepted the economic theory of bargaining. In any event, the district court doesn't have the last word here. The case has been appealed to the D.C. Circuit.

What I want to emphasize for those of us who care about health care antitrust is that the D.C. Circuit is now in a position to make a powerful statement about the role of Nash bargaining in merger analysis, with effects on health care, and really any other industry where bargaining plays a major role.

The second item I want to touch on briefly is the increased importance of monopsony and allegations that agreements or mergers enhance a firm's ability to exercise such power. By way of disclosure on this issue, I've served as an expert in litigation examining the alleged enhancement of monopsony power.

As you all know, there has been a recent resurgence of interest in monopsony. DOJ has brought cases alleging no-poaching/no-hiring agreements in other areas, such as tech workers and rail equipment suppliers. These days we think of no-hire agreements as being subject to criminal liability.

This is going to keep coming up in health

care antitrust cases. It came up in the *Anthem/Cigna* merger challenge, which contained an allegation of enhanced monopsony power. It has been raised in the context of FTC's evaluation of pharmacy benefit manager mergers.

There are a couple of things to keep in mind, a couple of developments to keep an eye on for the future.

First, as the DOJ continues to bring and win these buy-side cases, settle favorably these buy-side cases outside the context of health care, I think it is going to become increasingly difficult for defendants, for example in health care mergers, to argue that squeezing suppliers through the reduced rivalry of the purchasers is a source of procompetitive benefit rather than itself being a cognizable form of anticompetitive harm.

The second development to keep an eye on is the prospect of Justice Kavanaugh. We're in the middle of confirmation hearings. As a D.C. Circuit

judge, Judge Kavanaugh offered a view about monopsony in the *Anthem/Cigna* merger. For those of us who think of monopsony as a real problem that we need to be paying attention to, his views I think are half-full/half-empty.

On the one hand, the judge was very concerned about the possibility of what economists typically call enhanced "classical monopsony power," as a harm that we would want to pay attention to in a merger, and presumably in conduct cases as well.

He was a bit more cryptic on enhanced bargaining power, I would say. One reading of his opinion is that he's more skeptical that antitrust has a role to play in those cases, a view that if it became broadly shared by the Supreme Court might have some important implications.

PROF. SOKOL: Scott, that was a wonderful overview.

We're going to actually move time zones. Reiko, I'd say the audience is least familiar with

developments in Japan, so I want to give you some time to maybe fill us all in on what does health care mean in a Japanese context.

MS. AOKI: Thank you, Danny, for inviting me to be part of this panel, and also Fordham for putting on this lovely, very instructive conference. I also appreciate the opportunity to introduce you to the health care market in Japan very briefly.

First of all, as many of you may know, many markets in Japan are shrinking because our population has started to shrink. However, the health care sector would be one of the few that is not shrinking, and some markets, such as long-term care for the elderly, are actually expanding markets.

First of all, everyone in Japan has publicly funded health insurance, and this includes long-term care. Because the government is the insurer, the retail price in health care is basically regulated by the government, including pharmaceuticals.

Growing public expenditure on health care

because of the increasing proportion of elderly in the population and the price of health care is of great concern to the government, which I think is common in many countries. There have been public policies, therefore, to decrease price. However, there is reluctance in Japan to rely on competition to reduce price based on the wrong belief that competition reduces quality. Also, there is skepticism about for-profit organizations providing health care.

I already mentioned that pharmaceutical prices are regulated. They are reviewed twice a year for generics and four times a year for pioneering drugs.

Pioneering drug prices take into account the price of same or similar therapy and class, both in Japan and abroad, and foreign prices therefore are very important for determining new drug prices. I thought this was very unique to Japan, but over lunch I was talking to Fiona, and evidently this is an international thing to look at the prices abroad, so

there is nothing special about Japan there.

Generic drug prices in Japan are 50 percent of the pioneering drug at the entry. Currently, generics have about 60 percent of the market, and the government's goal is 80 percent by 2020, and this is probably achievable.

There were about 200 generic manufacturers in 2007. They all tend to be very small, about one-tenth the capitalization of a pioneering drug company on the average. So, basically, generics are very important to reduce price but they really don't provide any competition in terms of innovation to the pioneering drug.

Wholesale prices are not regulated, and therefore, with declining retail prices as government policy, the wholesale margins are declining for the wholesale companies. However, they are protected by separate pharmaceutical supply chain guidelines issued by the Minister of Health, Labor, and Welfare. That guideline tends to focus on protecting the small and

medium generic firms and also the wholesale companies. For those of you who know it, it has a flavor similar to the subcontracting law that's in Japan for protecting medium and small businesses.

Long-term care in Japan is also regulated, and in this case not just the output price but also many of the input prices. For instance, also the wage of the long-term care service providers, the individuals.

JFTC did a market study a few years ago suggesting competition in the long-term care industry was very limited. For instance, long-term care market entry is open only to nonprofit firms, subsidies by local governments for long-term care are limited to qualified institutions, and it is not possible to provide funding and privately funded services together in a single institution. The report suggested that a more procompetitive environment probably would help to increase both the quality and price of long-term care.

But, as I mentioned before, the whole

society is very skeptical about quality in competition, and unfortunately this report was criticized by many people and in the public. I hope that what I learn from this panel I can bring home and try to increase the quality of health care in Japan.

Thank you.

PROF. SOKOL: Thank you.

Now I want to move to the private practice side, two practitioners who are both eminent, both at global firms, who both know their jurisdiction, and, simply because the firms are in fact global, know just about every jurisdiction around the world.

Fiona, let me start with you. Overview thoughts.

MS. CARLIN: It just so happens that this year is the tenth anniversary of the EU Pharmaceutical Sector Inquiry, a rather traumatic experience for anyone who lived through it. That sector inquiry was looking at a dearth of innovation coming through the pipeline as many blockbusters were coming off patent,

and fears that originators were abusing the patent system to stifle innovation as well as to delay generic market entry.

In the last decade the tables have really turned on the innovation front, and that's a topic that I'll be talking about later. Scientific breakthroughs over the last couple of years really mean that the debate today is no longer about where is the innovation but can society actually afford to pay for it.

Innovation is to be encouraged. It is a political priority of the European Commission, no doubt for some of the reasons that were so eloquently explained in the session before lunch.

We will talk about the novel innovation theory of harm in the *Dow/DuPont* case. That case also triggered a lively debate on issues like the commonality of shareholders in a sector and the role of high margins in a sector.

High margins also feature in the enforcement

context. We are just seeing the Commission's first foray into excessive pricing in the pharmaceutical sector. Those cases focus on generic conduct and really bad behavior that doesn't pass the smell test.

I don't think the fact that the Commission has just opened an investigation into Aspen means that we will be seeing excessive pricing probes in the on-patent market anytime soon, but there is a lively debate in Europe at the moment around pharmaceutical pricing generally.

I think the uncontroversial piece in all of this is that competition law does have an important role to play in making sure that society benefits from the savings to be accrued from early generic entry on patent expiry.

On both sides of the Atlantic I think we're seeing a lot of enforcement in relation to life cycle management strategies alleged to have crossed the line, practices with highly suggestive names like evergreening, product hopping, sham litigation, and

denigration. There is little time to get into most of that today, but we will be talking about patent settlement agreements with value transfers, and I'm looking forward to a very interesting debate.

Thank you.

PROF. SOKOL: Thank you, Fiona.

Steve, let me move on to you.

MR. SUNSHINE: Thank you, Danny.

I am from Washington. Some of the remarks that I might make today could be deemed to be critical of the Trump Administration, and I'm a bit concerned about retaliation, so I thought, instead of speaking, I would just write an anonymous op-ed. You'll see it tomorrow in *The New York Times*.

I do think in the area of health care we have a bit of a repeated game problem. Scott mentioned Nash bargaining. I've learned everything that I need to know about Nash bargaining from Russell Crowe. [Laughter]

I think that in health care we have some

problems of a repeat game being played over and over. We see that in mergers. We see that in reverse payments.

We have a lot of predictability. We know how the agencies are going to act in these areas. That's good in some respects, in that we have predictability, but I'll suggest two thoughts on those areas.

One is that maybe we're not getting the best welfare-enhancing outcome in these reviews, in the mergers, in reverse payments, and in other areas.

Second, some of the challenges that we are facing – Fiona mentioned life cycle management, some of these more advanced distribution issues – these tools may not be all that well suited to deal with concerns going forward. So we'll talk about innovation, we'll talk about competencies, and really what leads to long-term development.

With that, I'd like to reserve my last twenty seconds, Mr. Chairman.

PROF. SOKOL: Absolutely, and we'll get to that in the Q&A period.

We've heard hints of pay-for-delay. Actually, Steve, let me start by coming back to you. Let's talk about pay-for-delay. Where do we stand now post-*Actavis*? We're now a few years into that. Is it more of the same?

MR. SUNSHINE: Obviously, we've been in the trenches on pay-for-delay, as you call it, for quite some time. I will disclose that I was part of the initial *Actavis* case that went to the Supreme Court.¹

I think the first lesson that we should all learn from it is that this is largely a relic of the past. As far as we can really tell from the industry, nobody is seriously doing these kinds of settlements today. In some ways you can say that the battle has been won. We'll come back to that in a bit.

The cases that are going on in the private sector, and I think there are close to eighteen now –

¹ *Fed Trade Comm'n. v. Actavis, Inc.*, 570 U.S. 136 (2013)

and this may sound a bit like defense counsel bias, and so if it does I hope you'll pardon me in advance – but I think those eighteen sets of class actions are basically plaintiffs' lawyers now making money off settlement agreements that were all done at a time when there was at least a legitimate argument that these settlements were per se lawful if they were within the scope of the patent.

There has been a lot of litigation back and forth over all these settlements. Almost all of them are settlements that occurred before the *Actavis* case was decided, and in fact I think almost all of them were before the circuit split with the *K-Dur* opinion in the Third Circuit. So, just to get that out as framework, we're all fighting about the past on things that aren't happening anymore.

The *Actavis* decision as a decision is amazingly successful in being completely ambiguous and meaning to the reader whatever the reader wants to behold. There are issues that are being debated still

to this day, with district courts coming out in different places on a number of issues:

(1) Is it a rule of reason case or not? If you can show that a settlement is a penny over avoided litigation cost, do you have an irrebuttable presumption that the settlement must be adverse to competition?

(2) Do patent merits actually matter? We have some cases saying that patent merits don't matter at all and some cases saying that you can infer by the size of the payment whether patent merits are relevant. You have other cases that say it's actually an antitrust causation issue if the plaintiff can't show that the defendant was going to bring the product to market. These are still open issues.

(3) There is an open issue about market definition: Do you need to define a relevant market? What is the relevant market? Is it the listed product and an AB equivalent, or can you look at other products that become involved? There are cases that

are going different ways on this direction.

The FTC is still fighting three of these cases. They're fighting the *AndroGel* case, the *AbbVie* case, and the *Lidoderm* case, so these cases are still being litigated by the FTC, although there really isn't anything at stake in those cases per se other than a clarification of the law. Those markets have cleared and have had generic entry.

What I worry about from reverse payments going forward is *Actavis* was pretty clever in the way that it tried to incorporate all of prior law in the patent area and in the antitrust area, and *Actavis* came to the conclusion that what had been a tension between a patent's innate right to exclude – obviously that's what a patent is – and antitrust principles, that those two principles should be balanced.

In the *Actavis* decision there was an express judgment that the policy of antitrust overcame some of the rights of the patent holders. That is a pretty novel concept. That can be applied a lot of places

outside of the very narrow Hatch-Waxman context.

Courts have been slow to do that. It has been argued in a few places. We will talk about some of the other areas now where this highly activated plaintiff's antitrust bar, and the agencies for that matter, are looking to provide some basis to say, "Let's get in and start picking winners and losers. Let's get in and start regulating innovation. Let's get in and see if we can after the fact decide that, 'Gee, there should have been a better outcome.'"

I think this is a very dangerous area going forward. Once we get out of the Hatch-Waxman context, the tools that the plaintiffs were relying on — mandatory state substitution, exact equivalence of products because that's what the Food and Drug Administration requires — those are gone. Then we'll be back to our basic antitrust tools that we've been talking about.

I would like to go to the more general question: Is the world a better place now that we have

this rule about reverse payment settlements? A branded company making a settlement with a generic should negotiate that settlement only on the basis of entry date and avoided-litigation costs.

As I said, virtually all settlements have gone in that direction. That's how they're now settling cases. There are very few, if any, reverse payments. Is the world a better place? I think that question is still out for debate.

A client who I do a fair amount of work for, Teva, the world's largest generic manufacturer, challenges patents as part of its business. They have an entire budget for developing abbreviated new drug applications (ANDAs). They have a litigation budget, and they have a portfolio of cases that they have to manage within that budget.

The question is: At the end of the day are we shaving more years off patents and getting earlier entry under the system we have today than under the old system where settlements could be helped along by

some kind of other payment or consideration? I'm not saying that the answer to that question is unambiguously "Yes, we would," but I've seen enough to say: "Hm, that's a good question."

Look at Teva. Its financial problems have been all over the financial press. It is constricting their litigation budgets. It is in a much tougher place. It can't afford to litigate these cases. A simple case can cost \$15 million. Is that a better outcome, to force them to litigate?

Branded companies have historically been extremely risk-averse and happy to settle. If you make them litigate more cases to conclusion, are they going to win more, and no years will be shaved off the patent?

I think it's very easy to focus after the fact of a settlement and say, "Oh gosh, look at this generic company out there trying to act for the benefit of consumers." It is a private company that invested its money, and to now say, "We think we can

get a better outcome in this case after the fact," I think is a topic that is worth further study.

I will stop.

PROF. SOKOL: Thank you. That was great.

I used the non-neutral term pay-for-delay, which you corrected me very nicely by calling it a reverse payment. We'll call it reverse payment from now because, regardless of what you read elsewhere in the newspaper about what's happening in the United States, here at least we're going to be civil.

Fiona, why don't you offer us a European perspective because reverse payments have also been quite fascinating. You've been also involved in these issues.

MS. CARLIN: In Europe we have two decisions from the European Commission, both of which are under appeal to the European courts, and a third case which has recently been referred from the UK Competition Appeals Tribunal for a preliminary ruling to the European Court of Justice.

I would describe the situation in Europe as messy.

In the first *Lundbeck* decision of 2013, I think the Commission shortcuts the analysis by condemning reverse payment settlements as a restriction of competition by object, to all intents and purposes a per se infringement. They achieved that, I think, through a sleight of hand by determining quite quickly that the originator and the generics entering the market at risk during the period of patent exclusivity were potential competitors. It follows from that conclusion that any agreement to delay generic market entry can be equated with a hardcore cartel. With this, the burden of proof is reversed, and the cards are firmly stacked.

The *Lundbeck* decision at the time was quite surprising. The facts around the settlement had been on the radar of the competition authorities for years. The 2004 Technology Transfer Block Exemption Guidelines that were in place at the time stated quite

clearly that "parties to a valid dispute that find themselves in a one-way or two-way blocking position cannot be considered as competitors."

If you take that logic to the next step, it would follow that, as long as there has been no fraud in obtaining the patent and as long as the patent dispute is a genuine dispute, the parties should be free to settle without risking the cartel-style prosecution of a by-object restriction.

In the subsequent decision one year later in *Servier*, the Commission hedged its bets. It determined that the patent settlements in that case were a restriction of competition by object, but also by effect, and for good measure they threw in that it was an abuse of a dominant position.

In the short time available I'm going to briefly outline the main issues at the risk of oversimplifying.

First, just a comment on the notion of potential competitors. I am going to quote the

Lundbeck judgment of the General Court, which I think regrettably is one of the worst judgments I've ever read coming out of Luxembourg. The court in that case said: "Patents are presumed valid until they are expressly revoked or invalidated by a competent patent authority or court." So far, so good.

But then the circular reasoning comes in and the court says: "This presumption of patent validity cannot be equated with a presumption of illegality of the generic products validly placed on the market which the patent holder deems to be infringing." I don't know what to say to that logic. I think generic entry at risk cannot be considered lawful until proven to be infringing without fundamentally undermining the patent system.

The General Court then compounded the problem in ruling that the patent holder cannot rely on a subsequent ruling from a patent office upholding the patent's validity to escape the finding that the generic at the time the agreement was signed was a

potential competitor.

The Commission in the *Lundbeck* case recognizes that settlements without financial inducement are usually outside the scope of the competition rules altogether. It would seem then that it's the value transfer, it's the monetary value that's transferring, that is sufficient to tip an agreement outside the competition rules into a hardcore cartel-type territory, and it's not at all clear why that's the case.

Settlements within the scope of the patent are limited to potentially infringing products. Generics are free to enter with a noninfringing product. I don't think that that situation meets the standard of revealing a sufficient degree of harm to competition to trigger a per se classification.

Post-*Lundbeck* but before the General Court's ruling in that case, the European Court of Justice delivered a landmark ruling in the *Cartes Bancaires* case. That case ruled that the by-object

classification requires a proper analysis of the agreement, its objectives, the economic and legal context, including a close look at the nature of the goods affected and the real conditions of the functioning and structure of the market in question.

The *Lundbeck* General Court pays lip service to *Cartes Bancaires* but concludes that the citation I've just mentioned does not concern the specific category of an agreement in a particular sector, and it is apparent from the broad logic of the Commission's decision that the Commission applied the concept by-object in the economic and legal context. In short, the General Court essentially disregarded the *Cartes Bancaires* standards.

Another comment: Payments often reflect the genuine legal uncertainty around the outcome of a patent dispute, the patchy or nonavailability of injunctive relief, and the asymmetric risk that the parties are taking. The generic has very little to lose, but the originator stands to suffer irreparable

harm because once an unlawful generic comes on the market, the price falls, it never goes back up again, and there are pricing repercussions in other markets as a result of international reference pricing. The Commission and the General Court recognized this irreparable harm but concluded that it is a "normal commercial risk." In Europe we don't have the Hatch-Waxman clearing-the-way-type mechanism.

I think the General Court in *Lundbeck* ignored *Cartes Bancaires* and ignored the legal and commercial reality.

In the *Servier* decision, the Commission repeats the same errors in the by-object analysis. In the by-effect analysis it compounds the problem by cross-referring to the by-object analysis. So if the elimination of potential competition is the counterfactual in the by-effect analysis, the rest is a foregone conclusion.

I'm not going to get into the market definition and the dominance issues, but all of those

issues are now pending before the Court of Justice in the reference from the UK Competition Appeals Tribunal that was made in March. The fact that that reference has been made just confirms that *Lundbeck* is not fit for purpose.

To conclude, I think the challenge is to craft a by-effect standard for these types of agreements that allows us to distinguish a patent settlement that is a blatant cartel from a patent settlement that is a perfectly reasonable way of resolving the uncertainties of patent litigation without getting into an assessment of the validity or value of the patents in dispute.

I'll stop there.

PROF. SOKOL: Thank you.

Apparently there is a lot of clarity in law and policy both in the States and in Europe is how I would summarize our discussion up until now.

Reiko, I'm sure Japan is just as clear in terms of what's going on, yes?

MS. AOKI: Actually, it is.

PROF. SOKOL: Okay. That's worth writing for *Global Competition Review (GCR)* and MLex and anyone else who's here. I just want to make sure. Okay, go ahead.

MS. AOKI: I'll first explain to you how it works in Japan.

In Japan regarding generics there is a policy called "patent linkage for generic drugs." This says that the Pharmaceuticals and Medical Device Agency (PMDA) will approve a generic only after the substance patent and the pharmaceutical patent, the efficacy patent, have expired, and this is exactly to avoid infringement disputes.

But the outcome of this rule is that it is basically the same as reverse payments in that it delays entry, so the consumers are just the same as in the world of reverse payments. The only difference is how the surplus is split between the pioneering drug manufacturer and the generic manufacturer. In Japan

there is no payment from the pioneering drug to the generic manufacturer. The pioneering drug keeps all the surplus from the prolonged monopoly.

It goes back to the question that Steve posed: Is the world better off with reverse payments? You can have a very clear system, like Japan, but there is still much to be warranted in terms of trying to increase the consumer surplus.

The JFTC did a study about generic drugs and innovation. I won't go into the details, but partly due to this rule that they have there, the generic manufacturers really don't pose any threat to the pioneering drug manufacturers in terms of innovation. They showed empirically the variable that seemed to affect the R&D expenditure of pioneering drugs is actually competition abroad; if they have large sales abroad, then their R&D is large. But the existence of generic drug manufacturers or how many generic drugs have entered the market doesn't seem to affect the innovativeness of the pioneering drug.

I'll stop there.

PROF. SOKOL: Thank you.

We're going to now move from reverse payments to something else that I think is very exciting for people, mergers. Once again, I'm going to start with Steve, who still has twenty seconds left that I haven't forgotten about. Reiko has some time left, too; I'll give that back to her. James will tell me when we're really going to stop based on any number of things, but we're not there yet.

Steve.

MR. SUNSHINE: Thank you.

Mergers is a topic near and dear to my heart. I think in the area of mergers health care is pretty fascinating for a number of reasons.

Let me start first with pharma. In the United States it's almost unique – perhaps it is unique. We have to do a comprehensive survey, but we also know the future in the pharmaceutical world.

Why do we know that? Because the FDA

pipeline is so gosh-darned long. We know for a product that, once it gets out of research and into the clinic, we have five or six years to see. Usually antitrust enforcers would look and say two years is a pretty good framework. The Merger Guidelines seem to favor that approach, obviously longer in places.

We know all about potential competition. We arguably know all about innovation. So we have this great crystal ball.

The FTC reviews pharma mergers in the United States. The FTC acknowledges, "Well, of course projects in development fail," but the FTC's position – and I don't think it's incorrect – is: "As long as the project has some reasonable probability of coming to success we want to preserve it, and so we want to continue to treat it as a separate asset." Whether you call it a potential competition theory or an innovation theory, we have this crystal ball that allows us to look into the future.

However, we have a second problem in the

pharmaceutical area: it's one of the most inelastic markets out there. There are certainly examples where drugs compete with one another - I'm not saying that they're not - but there are so many instances with our system, with multiple payers, with the physicians having tremendous input, where a decision is really not made on the basis of price. That leads to extremely narrow markets.

We have some precedents that say the market has to be the same molecule, it has to be the same mechanism of action, it has to be the same indication, but we're left with this very narrow look at what markets are.

That means that if two pharmaceutical companies are going to merge, it's actually pretty easy to go through and say: "You are going to have problems here, here, here, and here. But not to worry. These are pretty narrow products. We'll just divest the smaller of the two. We'll get our \$20, \$30, \$40 billion merger though, and we'll have to sell

a dozen products or whatever. Life goes on." From a merging company's perspective that's great.

There are questions. Are we missing the bigger picture? Are there areas where companies have unique competencies that really can't bring those products to market? As a random example, say that there are only three or four companies that can really make vaccines. Should we think about vaccines in some broader area of competency?

The problem in most of health care is that a lot of the big companies now are actually exiting out of early-stage research, and that's being done more and more in universities and small startups and in other kinds of areas. So you don't necessarily have a match of all the assets that you would look for in a true innovation market.

If I think back to some of the innovation market work that the DOJ was doing in the mid-1990s, they were looking at identifying sources of innovation and trying to find areas where there were very limited

sources of innovation. In early pharmaceutical development maybe there are a lot of sources of innovation out there, so you want to look in these areas at where there are sets of competencies where if you don't have that set of competencies, you can't bring those products to market.

In the area of oncology and big molecules, it is very difficult to understand how two molecules are actually going to act inside of a patient. That's why to this day we don't have generic biologicals, because how you cook the molecule actually matters. These are enormous molecules compared to the traditional ones, and it's not just what they are constituted of, but it's actually their structure and their polarity, and they may act completely differently inside the body. If you do that, you almost get to the area of saying each molecule is its own market, and we know where that leads us.

One area in pharma now that is becoming more and more of an issue is the question of collaborations

and combination products because these large molecules treating things like antivirals or oncology discovered that putting some of these products together is the way to get the best patient outcomes. So if Large Pharma Company *A* is developing molecule *A* and Large Pharma Company *B* is developing molecule *B*, they don't compete, but together they form a very good combination drug that really knocks out the disease.

Is it a good thing that they merge? What about Companies *C*, *D*, and *E* out there that may have one of those two complements that is arguably a better product – or a worse product – that are now being denied access? So we are going back to all of those vertical theories that we have talked about before in an area where it is very difficult to predict the future.

I agree with Scott that the *AT&T/Time Warner* decision is not going to provide any precedent going forward. I do think, in fairness to the case and to DOJ and to Dr. Shapiro, who testified for the DOJ, the

bargaining model was completely accepted by the court. The problem was that the results of the bargaining model were a very small anticompetitive effect, and there was a lot of evidence in dispute about: (1) the dynamics of the market that might overcome it; and (2) the efficiencies.

I think what the court did was a very careful balancing of reams and reams of evidence. If I was to criticize DOJ, it was almost too much reliance on Dr. Shapiro and not enough on other kinds of evidence that would support that overall conclusion. As a result, in *AT&T/Time Warner* what we got was one case where there was no really new law developed and there was a failure of proof without a rejection of the bargaining model as a theory.

If I use my additional one minute and twenty seconds and I translate that into the health care area, I think we are going to have the same proof problems in some of these areas in oncology where these products often are not even in patients yet, or

they are in early-stage studies where maybe fourteen patients have been treated. Therefore, understanding what the effects of these mergers are going to be in these very early-stage markets will be extremely difficult.

I worry about the other side of innovation, which is getting companies to invest in these enormously expensive projects.

Let me stop there.

PROF. SOKOL: Thank you. That's really a spectacular overview.

I'm going to mix things up. Instead of going to Fiona next, I'm going to go to Reiko next. That way it stays exciting.

MS. AOKI: I am going to say something different from what I've prepared. I was going to briefly go over the mergers in Japan, but I don't think there is anything special about them.

The one thing I do know is that in Japan only firms are required to report mergers in advance

and be examined for questionable mergers. But in Japan, as I said, for-profits are under suspect, so all hospitals in Japan are called "medical service agencies." For that reason, hospital mergers are never examined in Japan. That's something that is unique to Japan.

I would just like to go back to the first comment that Steve made about how narrow the pharmaceutical market was. Pharmaceuticals are only a part of a broad spectrum of different methods of addressing an ailment, and actually there are choices other than just giving drugs to a patient to fix the ailment.

Should the market be defined perhaps even larger – to fix a particular disease you can use this drug or do this exercise or eat this or that – and shouldn't that be the whole market? In that case, perhaps drugs are costing too much compared to the alternatives.

This vast investment that you mention that

has to be recovered maybe socially is an unnecessary investment when you just concentrate on fixing the particular disease. It's just a comment, and that's all I wanted to say.

Thank you.

PROF. SOKOL: Great, thank you.

Fiona?

MS. CARLIN: There is a bit of a cottage industry opening up in Europe at the moment looking at consolidation and innovation in the pharmaceutical sector.

The trend started in 2016 with two economists from the Düsseldorf Economics Institute publishing a paper where they said they looked at sixty-five pharma mergers and found that every single one of them reduced competition and innovation between the merging parties. They went further and noted that average patenting and R&D expenditure fell across the relevant sector, not just between the merging parties, by more than 20 percent within four years of any deal.

The European Commission has a tender out for a study on the impact of more than one hundred pharma mergers between 2010 and 2013. I think we can expect a lot of debate going forward on these studies and what conclusions can safely be drawn from them.

I just wanted to point out very quickly the new German and Austrian deal value thresholds that have recently entered into force. I am not going to get into the details, but just flag them for people who may not be aware that they catch not only the acquisition of biotech startups potentially but also the acquisition of IP portfolios and even, if I've understood correctly, exclusive IP licenses. That's just something to be aware of.

Those types of laws are likely to be copied elsewhere. I think the Koreans are already legislating similarly. I think you might ask the question whether it's using a sledgehammer to crush a nut, whether it's a proportionate response to a perceived gap in the current rules. But it certainly

doesn't make life any simpler in relation to companies seeking to do transactions.

I want to spend the majority of my time on the innovation theory of harm in *Dow/DuPont*. I think it's an astonishing case in many ways.

The Commission will say I'm exaggerating, that "*Dow/DuPont* was very fact-specific, there were lots of bad internal documents showing plans to drastically cut R&D expenditure, and that the economic theories developed in the decision are really just there to lend a bit of rigor to the legal analysis, and that no early economic model was actually applied in the case – so, Fiona, don't worry."

I take some reassurance from that response from the Commission, but I do think it is important to have a proper debate about the issues raised. Just a couple of points.

The decision in *Dow/DuPont* relies very heavily on the economic literature to establish a presumption of harm in concentrated sectors with high

entry barriers, high contestability, high appropriability, and a high degree of cannibalization between the products of the merging party.

To me that describes most innovative sectors, not just crop science, but pharma, industrial engineering, tech, and chemicals. So broad application, and that's why I think this needs a debate.

Second, the case goes far beyond the conventional approach, looking at overlaps in product and product pipelines, and goes right back to the research direction of travel at the basic R level in the R&D. So the question is not whether the companies merging have competing molecules in development but whether they are researching a solution to the same problem.

The notion of innovation spaces comes in. They are not markets, but apparently that does not prevent the Commission from assessing the impact of the merger on the level of innovation efforts not only

between the merging parties but also across the sector.

My favorite paragraph of the decision is Paragraph 3053. I'm going to quote it if I may: "Although the Commission cannot identify precisely which early pipeline product or research the parties would discontinue or defer or redirect, and thus which innovation spaces would be harmed, the Commission nonetheless considers that the reduction in innovation effort by the parties would affect a large number of innovation spaces."

I think that is problematic because, with this presumption of harm in an undefined innovation space that doesn't constitute a market, the burden of proof switches to the parties to come up with quantifiable, verifiable efficiencies arguments to offset that presumption, and that simply cannot be done.

The decision also is quite interesting in that it assumes harm in the overall sector in which

the merger is taking place and for good measure a lot of other stuff is thrown in there. The Commission notes that past consolidation in the crop science sector meant that the Big Five had reduced their R&D spend as a percentage of revenue by 1.7 percent over the last eight years; output had decreased but profitability had increased; R&D spend in Europe fifteen years ago used to be 33 percent of the total – that was down to 10 percent by 2010. Common institutional investors holding minority shareholdings across competitors was also flagged as a problem. So a lot of stuff in there, none of which was apparently relevant to the ultimate outcome of the case.

The debate is not going away, and I don't think it's limited to the specifics of *Dow/DuPont*.

The Commission's Chief Economist last summer came out with two papers further developing the model, and this summer some leading independent academics from some of the leading universities in Europe critiqued the Commission's economist's work and have

concluded that presumptions are immature and that more economic work, including empirical work, needs to get done to develop a proper theoretical framework for any basis of an innovation theory of harm in merger control.

They point out some of the features that the initial modeling of the Commission did not consider, and if Danny will give me two minutes, I'll tell you what they are.

PROF. SOKOL: Yes.

MS. CARLIN: Just one or two examples.

The first is that there is a possibility that a merger actually incentivizes innovation where the merging parties seek higher profits through product differentiation as a way of avoiding cannibalization. That's one new element.

Streamlining R&D efforts within the merged entity can actually help parties be better placed to win an R&D race in certain circumstances. R&D insights shared between the merging parties may be

nonrival and applicable over a broader range of products and encourage demand, expanding innovation and not just increased profits.

Those are some of the additional factors that the academics conclude should not be considered second-order effects and relegated to an efficiencies defense. It is really important that they are brought into the front end of the analysis.

I think the Organization for Economic Co-operation and Development Secretariat's paper that was published around the June 2018 meeting on this topic does suggest that efficiencies arguments should be considered at the same time as innovation harm and there should be a neutral presumptive approach. It would be really helpful if the European Commission would endorse that that is indeed the correct conceptual framework.

In short, while economists debate these interesting theories, in practice companies contemplating a merger, especially in regulated

sectors with high margins and strong patent protection, should expect ever-closer scrutiny.

Just a note by way of an anecdotal bit of fun at the end. In clearing the *Bio/Monsanto* deal, the European Commission's press release proudly noted that the Commission had reviewed 2.7 million internal documents. That's problematic, but also problematic are these theories that have simplistic presumptions and that put the burden on the merging parties.

It is worrying because in Europe effectively there is no judicial review of merger control. I think, therefore, it is incumbent on the Commission to take a very disciplined approach when it comes up with these types of theories.

I am not saying that innovation is not a genuine area for exploration, but, because of the lack of effective judicial review, I think real discipline and much further study needs to be done.

Thank you.

PROF. SOKOL: Thank you.

Fiona started us off by talking about a study from the economist of Dynamic Integrated Climate-Economy (DICE). I think we can suggest that her comment – intervention essentially – is DICE/no-DICE. [Laughter]

I want to continue with that metaphor with Scott, who starts at no-DICE and moves to DICE. Let me explain. For the first six years of Scott's career I would say the R&D was primarily in reverse payments, a series of papers. This gets adopted in terms of the framework of the FTC in many of their cases that they keep on losing – no DICE.

Then, all of a sudden, something happens. It turns out Scott may have been right, where the FTC starts winning, and then we see ultimately victory in *Actavis*, and now we're in the world of DICE.

Steve told us that there is lack of clarity. But it turns out that, DICE or no-DICE, Scott probably has some thoughts on how things have developed.

Scott.

PROF. HEMPHILL: A couple of thoughts.

First, I'm happy to use the term "reverse payments" to satisfy Danny and it sounds like others on the panel. I think it's fair to say, though, that in cases where it is in fact so that the brand pays the generic hundreds of millions of dollars to stay out of the market until patent expiration, and if we all agree that those are the facts, let's imagine that is reasonably accurately described as paying for delay. At least in those circumstances we could agree that that would be an okay label.

I was struck, Steve, by your comment that, if I caught it right, that generics like Teva are highly risk-averse. That may well be right.

MR. SUNSHINE: Brands, I said.

PROF. HEMPHILL: I thought you were talking about generics as well? No, just brands. Okay. You're on brand then. Most commonly plaintiffs are arguing that generics are on the risk-averse side.

I'm struck by Steve's comment wondering

whether we're in a better place after all of this fighting. I think there are a few good reasons to think yes.

One, there is just a straight prediction of economic theory, which I think is pretty robust, that if payment is permitted, that brands will have an incentive to pay, pay, pay, pay for the generic to stay out until patent expiration. When you recognize that often these cases involve multiple patents with overlapping entry dates, where the equilibrium leads is it could be a date that's pretty far out.

This isn't just economic theory. In some of these case – not all of these cases – we have pretty good documentary evidence. I've been involved with some of these cases that what the parties really understood was that they were either taking a payment or making a payment in order to induce or accept a pretty extensive delay.

Finally, I think there is a certain "proof is in the pudding." I have two ideas here.

One, we no longer, I think, see some of the very extreme settlements that we once upon a time saw. By way of disclosure, I worked as a plaintiff's expert in one of these very old cases from the 1990s, *Cipro*, which involved the hundreds-of-millions-of-dollars payment that I have in mind. I am not aware of any post-*Actavis* – or for that matter post-*K-Dur* – settlements where a brand would pay a generic nearly \$400 million to stay out until the expiration of the last patent, more or less.

That could be regarded as a benefit aside from the markers that we're laying down for what the rules of the road look like in the future.

This is for me a very provocative question, are we better off? I think there is a source for doubt – although I'm not sure it's Steve's source – which is you can do a lot of work – or harm or damage, depending on how you look at it – without using an observable payment. This tracks a little bit the defense to cartel cases that goes, "Well,

interdependence is really easy in this market, and so therefore we could achieve elevation without the communications that you caught us making." Are things that much worse in the cartel world than they would be in the but-for world?

Here I think it is the case that a generic, even if limited to the instrument of selecting an entry date, has an incentive to take a late entry date simply by virtue of dialing up its probability of getting the 180 days from whatever it would do – I will say "rolling the dice" in litigation, versus feeling pretty comfortable in a settlement that they will actually be able to come in on some date certain.

That outcome can in fact be worse from a consumer welfare standpoint than litigation. That raises the question: "What are ultimately the incremental welfare effects of getting rid of cash payments but still having a variety of other instruments to reach a settlement potentially with adverse effects to consumers?"

MR. SUNSHINE: First of all, I'm glad that I was provocative. At least I accomplished one of my goals for today's discussion.

I hear Scott's argument. I've heard it before. My criticism of the argument is that he is taking a microscope and looking just at the exit out of patent litigations and not looking at the bigger picture, which is the question: How many patent litigations are brought, how many investments are made in R&D, and are we achieving the right balance between innovation and years off the patent?

It is easy to say after people have made investments, after people have committed to litigation, that you don't like the exit strategy out of a particular settlement, but I submit that misses the bigger question of are we achieving the right balance.

I think there is a whole other question. Our patent system is generally conceived to be too permissive; we patent too many things. But what is

the right balance on the ability to challenge those? How do we incent the generics to basically do those challenges and to get out of those questions? I think that looking just at the exit is too narrow of a question.

The second thing is I agree with Scott that if a brand company pays hundreds of millions of dollars, let's say, a day before the patent expires and gives them cash or bullion or whatever, that that's anticompetitive. I'm not here arguing that it should be per se legal.

But I think if you take the *Actavis* case itself and you ignore the facts that the Supreme Court assumed – which actually were not in the complaint and incorrect – there was actually no cash paid in the *Actavis* case. There was a co-promotion agreement that was entered simultaneously that had value to it for sure. The question is how much value was in it, but the estimates of the value of that case are still being litigated. The estimates of that value are all

less than \$100 million for a product where, even under the settlement agreement, five years were shaved off the patent.

It seems to me a true rule of reason analysis would allow those elements to be examined and discussed in a lot more detail.

PROF. SOKOL: Thank you, Steve.

I'll take questions.

MR. KEYTE: I'll start with one. It's on the bargaining issue in mergers. I'll give it to Scott, who described it in detail.

Doesn't that kind of theory just open up the merger world back to potential conglomerate mergers and portfolio effects? Essentially, it doesn't really matter if the firms involved are competitors. The hospitals cannot even be competitive in terms of the historical overlaps. As long as they are dealing with the same insurance company, the company is bargaining.

Therefore, Section 7 just turns into essentially condemning increases in bargaining

leverage irrespective of the underlying competition and lines of commerce. Is that a concern?

PROF. HEMPHILL: I don't think that's a fair characterization, at least of the cases that have been brought. I think I understand where you're going.

In the real-world cases that we have seen, the firms that we are talking about actually are rivals for inclusion in the counterparty's bundle. You can imagine if I've got this network, maybe I don't need this other network; if I've got this hospital, maybe I don't need this other hospital. We don't in those cases necessarily confront your parade of horrors.

But certainly it is true that one can construct models and come up with empirical results where the hospitals could be across the country and they are still jointly bargaining for inclusion, and then there may be an improvement in your bargaining position by virtue of affecting outside options.

In those cases I understand the point that

the way in which we normally talk about competition is in some sense attenuated.

There is a version of this in some of the Federal Communications Commission's broadcast double options where there is some evidence. I wrote a working paper on this topic. I think they observe effects both within the same municipality, within the same metropolitan statistical area, but also across them. In that latter case, I think one is forced - the FCC, not Clayton Act necessarily - to confront exactly the point that you're raising.

MR. KEYTE: I think it's something to watch for, given how the law went away from attacking conglomerate mergers and the idea of post-merger bundling can be taken care of by other statutes.

PROF. HEMPHILL: But just to be clear, I think it is common ground between us that the actual FTC cases that have been brought - and, for that matter, payer mergers like *Anthem/Cigna* - do not raise the conglomerate concern that you are raising.

MR. KEYTE: Only by focusing essentially on the insurance companies that can be very powerful themselves rather than the consumers that are actually getting the services, and that seems to be a road that can be applied to any number of things where there is not real consumer-level competition.

PROF. SOKOL: I want to wrap up. This was a wonderful panel discussion. We are going to continue over cocktails. But that's what you are really wondering about, competition in health care. The competition I want to focus on now is red versus white, Argentine versus French versus German versus Spanish in terms of wines.

James, do you want to have some final comments?

MR. KEYTE: No, I don't.

It has just been a wonderful day. It was a very full day, and thank you everybody. I think it was great attendance, and everybody paid great attention to these wonderful panels, and this was a

fantastic panel to end the day on.

Move on over to cocktails, please, and then I hope to see you all tomorrow. We have two other great keynotes and two other great panels tomorrow morning. I'll see you at cocktails.

[Adjourned: 4:37 p.m.]