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Antitrust in Life Sciences

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PROGRAM

9:00 WELCOME & BREAKFAST

9:30 #1 MERGERS IN THE HEALTH SECTOR

Rena CONTI | Dean's Research Scholar, Associate Professor, Boston University

Patricia DANZON | Professor of Health Care Management
University of Pennsylvania

Martin GAYNOR | Professor Of Economics And Public Policy
Carnegie Mellon University

Dina OLDER AGUILAR | Vice President, Cornerstone Research, Oakland

Moderator : **Thomas DEMATTEO I** | Counsel to the Assistant Attorney General
U.S. Department of Justice, Washington D.C.

8:00 COFFEE BREAK

11:30 #2 PRICING AND BUSINESS PRACTICES IN THE PHARMACEUTICAL INDUSTRY

Michael COWIE | Partner, Dechert, Washington D.C.

Pauline KENNEDY | Principal, Bates White, Washington D.C.

Moderator: **Thomas HORTON** | Professor of Law & Heidepriem Trial Advocacy Fellow, University of South Dakota, Vermillion

13:00 LUNCH

14:30 #3 THE CURRENT PAY-FOR-DELAY LANDSCAPE

Daniel GILMAN | Attorney-Advisor in the Office of Policy Planning
US Federal Trade Commission, Washington D.C.

Eric STOCK | Partner, Gibson Dunn, New York

Moderator: **Barak RICHMAN** | Professor of Law & Business Administration
Duke University

16:00 COFFEE BREAK

16:15 #4 RECENT DEVELOPMENTS IN THE US AND THE EU

Gwendolyn COOLEY | NAAG Antitrust Task Force Chair and Assistant Attorney General, Wisconsin AG's Office, Madison

Matthew TABAS | Partner, Arnold & Porter Kaye Scholer, Washington DC

Elinor HOFFMANN | Chief, Antitrust Bureau, Office of the New York Attorney General, Albany

Pauline KENNEDY | Principal, Bates White, Washington D.C.

Sorcha O'CARROLL | Senior Director - Mergers, CMA, London

Moderator : **Michael MILLER** | Partner, Morrison & Foerster, New York

17:45 RECEPTION

PANEL 1

MERGERS IN THE HEALTH SECTOR

Thomas DeMatteo
Counsel to the Assistant Attorney General
U.S. Department of Justice
Washington D.C.

This panel will focus on the significant increase in hospital merger activity over the past decade, the issues relating to pharmaceuticals but also of the impact of new developments.

Martin Gaynor
Professor Of Economics and Public Policy
Carnegie Mellon University

In every country, healthcare is a very important sector. In the US, one dollar out of every five is spent on healthcare. The money that is spent in this sector has an impact on health, productivity, and quality of life. The US relies on markets for the provision and financing of healthcare. Therefore, the healthcare system can only work if the markets support it. Currently, the markets do not work as well as they should. Indeed, prices are high and are rising, there is too little organizational innovation. It is a stagnant sector.

Between 1998 and 2017, there were more than 1,600 Hospital mergers. Now, more than half of the geographic areas in the country are dominated by one or two large hospital systems. The risk is that firms will behave anti-competitively, which will harm competition. More importantly, the direct consequence is increased medical expenses for insurers who pass them on to employers, who pass them on to workers. In addition, there is a lot of non-horizontal consolidation. In particular in acquisitions of physician practices by hospitals and hospital systems. The practice size is getting bigger and bigger, and the markets have been becoming more and more concentrated.

How competition in healthcare works and what are its specificities? Firstly, most consumers do not pay for the product directly because they have insurance. Secondly, employers purchase insurance from insurance companies that compete to sell that insurance based on various criteria. The competition between hospitals takes place in two stages. In the first stage, hospitals compete to be included in a network of insurers, and vice versa, insurers must have a hospital in their network to be able to sell its insurances. In this stage, horizontal hospital mergers can harm competition. In the second stage, hospitals in a particular insurance network compete with each other to attract the enrollees of that insurer. In this stage, non-horizontal mergers can have an impact.

Consolidation could lead to efficiencies. For example, the care is fragmented because there is no single information system. There is little evidence that quality improves but no evidence that costs are lower due to the merger. The evidence says that consolidation leads to higher prices and the quality of care is harmed when there are administrative prices like for the U.S Medicare program. Most important, the monopoly kills. One study found that the mortality rate in the year following a Medicare beneficiary's heart attack was 3.37 points higher when the management of the patient was in the most-concentrated markets. This is competitive harm.

Then, for hospital staff, a study by Prager and Schmitt found that hospital mergers in more concentrated markets lead to lower wages for workers with specific skills. However, workers with general skills like janitors were unaffected.

*Marie de Monjour drafted the following synthesis for Concurrences. The views expressed in this presentation are those of the speakers and do not necessarily represent those of the institutions to which they are affiliated.

Dina Older Aguilar
Vice President
Cornerstone Research
Oakland

The FTC has had some recent victories in opposing provider mergers. The first case is *FTC v. Lifespan Corp. and Care New England Health Sys¬tem.* The FTC sued to block the merger between two hospital systems in Rhode Island arguing that the merger would give the parties over 70 percent market share in either of the product markets. It also argued that the merger would raise the Herfindahl-Hirschman Index (HHI), which will lead to raising prices and reducing quality. Commissioners had different opinions. On one side, some of them pointed out the potential impact on the labor market, arguing that the effect of the proposed transaction may be substantially lessened competition in a relevant labor market. On the other side, some of them disagreed but supported the principle of protecting input markets.

The second case is *FTC v. Hackensack Meridian Health.* The proposed merger was the acquisition of a single hospital in New Jersey, by one of the two largest hospital systems in New Jersey. The FTC opposed the merger claiming that there would be a pricing impact because of the acquisition clause which stated that prices will evolve for new hospitals. HMH, the acquirer, had offered to waive that clause. According to her, placing a weight on the impact of that acquisition clause was sort of agnostic as to where that hospital acquisition takes place. The waiver is reflecting the merging parties' belief in the merger, but this did not convince the district court and the FTC. The appellate court upheld the district court decision.

The third case was about the acquisition of Saint Peter's Healthcare System. The ambition of this merger was to create "the first premier academic medical center" in New Jersey so that patients no longer need to travel to New York for care. The project was approved by New Jersey's AG and some local employer groups, but the FTC opposed this merger.

Finally, the fourth case was the acquisition of the Steward Health Care System by HCA Healthcare. The FTC claimed that the merger would combine the first and fourth largest hospitals in Wasatch Front. So, there were some other large hospital systems. The FTC claimed that it was not only about acquiring a hospital but about acquiring a low-cost hospital, without this hospital being qualified as such.

There is a concern about cross-market mergers. This notion must be considered, but it is necessary to examine whether a merger that combines health care providers who are unlikely to compete for patients still has an impact on prices. In addition, the FTC signaled that it would be interested in theories of harm related to cross-market effects. Some of those theories can be split into two groups. Theory 1 is about knowing if the cross-market merger alters the set of provider networks of an insurer. Theory 2 is about knowing if the cross-market merger affects the negotiations between the insurer and provider.

The FTC is conducting a merger retrospective that expands the focus and empirical evidence on non-hospital mergers.

She highlights that mergers have an impact on healthcare workers. An idea could be that healthcare workers, depending on a parti-

cular region or transaction might be willing to travel further than patients.

Patricia Danzon
Professor of Health Care Management
University of Pennsylvania

There have been many mergers in the pharmaceutical industry, including large, midsize, and smaller firms. The standard analysis focuses exclusively on what happens to concentration in individual product markets. It does not consider the potential anticompetitive effects of increasing the overall size of the firm. But firm size creates an anticompetitive risk, at least in the US. This is because in the US, pharma contracts with payers regarding prices and formulary access for their drugs are conducted on a portfolio-wide basis, not simply drug-by-drug. Companies can therefore leverage their "must-have" products, to influence the exclusivity or the rebates on their other products on a payer's formulary.

In high-income countries, drug markets are similar. In their most recent annual report, the Canadian Patented Medicines Review Board notes that prices of on-patent drugs have remained broadly similar in all countries, except for in the U.S., where prices have increased much faster than in other countries for the same brand of drugs.

Mergers and concentration are not the only factor contributing to the increase in drug prices in the US. Reimbursement and payment rules are also very important. There are similarities but also important differences between the hospital sector and the pharma sector. In the pharmaceutical industry, there is no available evidence that mergers have led to higher list prices for drugs. Evidence shows that large pharma mergers have not increased productivity or R&D of the merging firms.. One thing that pharma and hospital sectors have in common is that in both sectors payer-provider contracts cover a portfolio of services. But there are also important differences between these two sectors. First is the importance of pharmacy benefit managers (PBMs), who negotiate confidential rebates off list prices with drug companies, in return for preferred position of their drugs on the PBM's formulary of covered drugs. PBMs retain a portion of these rebates, but PBMs also pass on some of the rebates to payers, and this can translate into lower consumer premiums. This model, where drug companies compete for market share by offering rebates on their drugs, can work in the context of drugs with several close therapeutic substitutes and modest cost. Patients are willing to substitute between these drugs, with little financial or therapeutic effect. This PBM rebating model does not work well for most new drugs that are differentiated, specialty drugs. Patients and their physicians are not willing to switch between these drugs and cost sharing amounts can be significant.

The second major difference between the hospital and pharma sectors is that payers in the drug sector have much less information and ability to control list prices than payers in the hospital sector. Pharma companies simply post their list prices each year and payers, through PBMs, can at most negotiate rebates off the prices. Leverage vs. payers is not necessary to raise list prices in the pharma sector whereas it may be necessary for the hospital sector.

Standard drug market-by-market review should remain the basis for merger review. But antitrust enforcers should also look at cross-market effects in the case of mergers between two large drug firms. In addition, in cases where a large pharma firm is merging with a midsize firm or mergers of two midsize firms,

antitrust review should include heightened scrutiny of the potential for cross-market effects, especially when the merger involves block-buster or "must-have" products, which firms can leverage in cross-market contracting. This is discussed further in my paper, with Michael Carrier, in the Antitrust Law Journal.

Rena Conti
Dean's Research Scholar
Associate Professor
Boston University

Most Americans take prescription drugs. The regulatory authorities are more interested in generic drugs, where there are very large dominant firms and where there have been many mergers and acquisitions, including in the cross-market. There are two important government agencies. The first one is the U.S. Food and Drug Administration (FDA), which approves all drugs to be sold into the U.S. market. Secondly, there are antitrust enforcement activities.

In addition, two important elements need to be clarified. First, the FDA rubric product market is defined by the molecule. Antitrust authorities and the FDA agree that the molecule is the market, but sometimes it creates a limited definition of what the market is. As a result, the market is limited to the branded product defined by its New Drug Application (NDA) and its associated National Drug Code (NDC) with its AB-rated generic that is defined by its Abbreviated New Drug Application (ANDA). NDAs and ANDAs are defined by their route of administration, therefore the molecule can be in pill or injection form. Thus, it is questionable whether these two formulations are in the same market or not. An alternative is to define the product market by clinical use, but from this arise questions such as what means to be a therapeutic substitute.

This is complicated in multiple ways. For example, is it only in the on-label indicated use that the FDA approved, or is it in off-label uses that can dominate sales? Another question is to define a drug manufacturer. According to the FDA, the manufacturer is the company that owns the label. However, the labeler isn't necessarily the manufacturer of these products because there are complex licensing arrangements. Relying on FDA definitions translated into the antitrust space creates challenges.

Finally, context matters. It is important to know who the consumer of these products is and who is prescribing them.

It is necessary to think about mergers and to go product by product without using just simple definitions. There have been very few studies looking at the harms of M&A in the pharma sector. For example, Pfizer bought King Pharmaceuticals which owned the license from Mylan to make EpiPen. A generic EpiPen from Pfizer's subsidiary entered the U.S. market priced 80 percent off the brand. When the merger was completed, the subsidiaries retired the generic, and the brand, EpiPen, retained market dominance. Therefore, consumers are paying higher prices.

The generic drug market is highly competitive in the US. However, there have been some issues with defining entrants in M&A reviews because they tend to focus on who are the approved ANDAs. An award by the FDA is not the same thing as an actual entrant. Manufacturing some products is harder than others. Some firms are viewing ANDAs as an option. All this is a part of a global strategy. There is a fair amount of competition upon the loss of exclusivity of these branded products, but over time there is an exit in these markets and competition shakes out. ■

PANEL 2

PRICING AND BUSINESS PRACTICES IN THE PHARMACEUTICAL INDUSTRY

Thomas Horton
Professor of Law & Heidepriem Trial Advocacy Fellow
University of South Dakota
Vermillion

In the general American view, the pharma companies are ripping people off. Thus, it might be in the interest of the pharma companies to become transparent and to remind the public that it costs $1.5 billion on average to get a new pharmaceutical thanks to R&D.

According to him, there is no case in any industry where just strictly parallel pricing has been enough to get a Sherman Section 1 either indictment or a civil penalty. Those cases are getting dismissed as not plausible if the plaintiff does not present some type of plus factors in its allegations.

One of the biggest criticisms of divestitures has been divestitures to conflicts of interest and that some companies are rewarding whereas they have been previously indicted. When the FTC or DOJ points up a transgression, it is important to have as much affirmative evidence in the file as possible.

Some prescriptions cannot be given by local pharmacists, they are only given by CVS, and if an individual does not have a CVS near them, they must do this by mail.

Pauline Kennedy
Principal
Bates White
Washington D.C.

When in the manufacturing space there is only one drug that treats a particular condition, the PBM is going to have less leverage to use its formulary placement to bargain for a lower price, and that lower net price comes in the form of rebates. The rebate contracts can be organized with the health plans, and with the payers.

According to her, one of the problems in the pharmaceutical industry is that prices are not transparent. There are some unintended consequences, and the most hit people are the one who has high-deductible plans and ends up paying virtually the list price for their drugs. The PBMs are very murky. The only thing left is the list price, which is growing significantly. However, in investigations where parties thought discovery must turn their data over it becomes transparent what their net prices are.

It is important to recognize that the public information about the generic drug price-fixing case indicates that it was not just parallel pricing. There are allegations of communication, at industry meetings and communication with competitors at the time of raising prices. This report deals with shadow pricing which, in an oligopolistic setting, is just profit maximizing for firms to take account of what

competitors are doing in setting their price, whether they are focusing on output or pricing. This is not an illegal practice. However, the additional action consisting of coordination or communication around pricing is problematic. The other thing that matter is to know what is driving those price rises, such as some effect on inputs, an increase in demand in the market that affected competitors equally or not, etc. She underlines that there is criticism that the divestitures are just sort of cycling amongst the same set of firms. But if the firms are not familiar, they are going to be less successful.

The PBMs must negotiate with lots of different parties and must provide a bundle of services to their customers at an acceptable price. Part of their role is, on the one hand, they are squeezing the drug manufacturers, and, on the other side, they are squeezing the pharmacies. They are packaging up a formulary, a set of drugs and they are providing prescription drug coverage.

According to her, branded pharmaceutical manufacturers must innovate. They must continue to innovate on their best-selling products. Obtaining a patent requires innovation and adding value to the product, or patients will turn to generics. There is a greater incidence of large pharmaceutical companies acquiring innovative biotech firms that are doing the early-stage innovation and they are doing that at a price that is incentivizing that innovation further. Thus, the most important is to push innovation, it does not matter if the pharmacies finance or not, carry out these innovations themselves or not.

Michael Cowie
Partner
Dechert
Washington D.C.

According to data published by the Center for Medicare and Medicaid Services (CMS), the expenses in the hospital sector are growing faster than prescription drugs and physicians. Indeed, hospital spending represents 43 percent, physician spending 24 percent, and prescription drugs 12 percent. The hospital sector is experiencing high inflation. As an illustration, the price of hip replacement surgery has doubled in less than 10 years. The attention of the media and politicians is mostly focused on drug companies when the hospital deserves all this attention too. Especially since 80 percent of the hospitals are non-profits.

What matters to employers, including unions and government agencies, is net prices. Drug Channels Institute and IQVIA have shown that net prescription drug prices have declined in each of the last four years. It is not necessary to say that antitrust enforcement should be relaxed because prices appear to be declining or because the hospitals are consuming more spending, but it should be a part of the conversation and background. Overall expenses are increasing because utilization is going up.

One of the leading lobbying groups in Washington is the National Community Pharmacists Association (NCPA). For several years, that lobby has been essentially saying that PBMs are bullying them and that they are driven out of the marketplace. This is not true, the numbers do not move, and independent pharmacies accounted for and still account for about 35 percent of the marketplace. Their trade association publishes reports showing their margins have stayed steady.

Merger policy is a field that is in constant motion. In 2021, the FTC and DOJ announced a pharmaceutical merger working group with the European Commission. In June 2022, both US agencies had workshops on pharmaceutical antitrust. In the last ten years, the FTC has challenged thirty-one pharmaceutical mergers with a deal value of over $300 billion and obtained divestiture of over 200 products. Some of the FTC's data suggest that the FTC's enforcement in the pharmaceutical sector on the merger side has been very heavy.

In terms of merger policy, there are two major developments. One is the potential competition doctrine, especially with the term "killer acquisitions". The most obvious illustration is the FTC's case against Facebook. In this case, the FTC is seeking to unwind the Instagram and WhatsApp acquisitions. The complaint contains only potential competition allgations. In life science, the traditional view at the FTC was that on the branded side, if a firm is in Phase III, it is a competitor. If it is in Phase I or Phase II, the odds of success are relatively modest. Whereas in Phase III, the data shows the likelihood of success is a little bit over 50 percent. From now on, the agency is looking further back in time to earlier-stage research programs as competition. However, it remains complicated to define the standard, to define whether a research program or an early-stage initiative is a competitor or not.

Regarding transparency, and to improve it, the FTC's economists has opposed for years state legislation directed at PBMs. One of the legislations would require PBMs to publicize input costs. However, there is no expectation for the other industries to publicize their input costs. The FTC's economists opposed a lot of the transparency laws directed at PBMS, arguing that they may facilitate collusion.

In the last five years, some criminal indictments of executives in the generic drug industry have been developed. It is a major industry development. This phenomenon has not happened on the brand drug side.

The FTC has studied the success of its past divestitures. It found that those in life sciences were less successful than divestitures in other industries. In 2018, there was a policy change. Now, the FTC says to companies that they must divest the commercialized product given some past failures.

At the pharmaceutical workshops in Washington, we heard a lot of pejorative statements about private equity. These critics are not well supported by empirical evidence. There is some notion that private equity buyers are short-term players, and that they do not have a lasting plan like industrial players. Some think that it is going to be very hard to get private equity approved as a divestiture buyer.

The FTC has initiated a study of PBMs. Before that, they had a public comment period with more than 23,000 comments. PBMs build pharmacy networks and engender competition for favored positions in pharmacy networks. Specialty pharmacy is often via mail order with complex handling of shipments. Employers are often willing to choose to have a single specialty pharmacy to save money.

Recently, DOJ brought a challenge to UnitedHealth Group's acquisition of a company called Change Healthcare, which is based on a vertical theory. This case is important to watch.

It is dangerous to correlate R&D expenditures and price. It does not work out in the defense sector with cost-plus pricing. ■

PANEL 3

THE CURRENT PAY-FOR-DELAY LANDSCAPE

Barak Richman
Professor of Law & Business Administration
Duke University

The FTC's enforcement actions against so-called pay-for-delay agreements have been a signature success of the agency. It also is a policy that raises as many interesting questions as the number of problems that it solves. It is an ongoing policy and legal debate.

The Hatch-Waxman Act offers an opportunity for collusion among competitors. The Act creates a situation in which two parties, a branded and a generic, that are supposed to be competitors, have an opportunity to collude and to impose very significant anticompetitive harm.

Although the agreements themselves take form as a litigation settlement, the FTC recognized that the antitrust laws apply, and the conduct begs FTC policing. The issue reached the US Supreme Court in the *Actavis* case, and the Court ultimately backed the FTC's policing efforts.

Yet the Court also left much open. It could have ruled that the settlements are presumptively illegal or even that they are per se illegal. Alternatively, it could have concluded that the case is about patent law and therefore precludes Sherman Act enforcement. Instead, it pursued a middle path that left many issues for lower courts, the FTC, and the pharmaceutical industry to resolve.

He identifies two areas of agreement between the two speakers: the first one is how to navigate antitrust law that intersects with other areas of law. The second one is a general comfort with the *Actavis* outcome, despite the ongoing work that is now required.

Daniel Gilman
Attorney-Advisor in the Office of Policy Planning
U.S. Federal Trade Commission
Washington D.C.

A pay-for-delay settlement is a particular kind of settlement in a particular context. It is a settlement of a patent infringement lawsuit concerning prescription drugs. This settlement may also be called a «reverse payment» settlement because it reverses the ordinary order of payment in civil litigation settlements. It is sometimes called a «pay-for-delay» settlement because it causes some prejudice at the time it is put in place. The agreement delays the entry of a potential generic competitor beyond the date originally provided for by the Hatch-Waxman Act. These agreements multiplied in the 1990s and the FTC has been interested in them

since 2001 because competition in the prescription drug sector is important and these agreements are harmful and costly for consumers.

It is quite clear that Congress has established a very particular competition/IP/litigation scheme for pharmaceutical drugs. Although the general issue of innovation incentives and patent rights is very broad, the particular rights granted are statutory rights under different regimes and there is a different regime for pharmaceuticals. The Hatch-Waxman Act seeks to balance an interest in static and dynamic competition. What is particularly difficult is both the recognition and testing of drug patents and asserted patent rights. When the FDA approves a drug, the company lists it in the Orange Book and lists related patents, these play a role in subsequent litigation. Congress very clearly wanted to test these elements and, indeed, incentives for litigation were built into the law. It should be emphasized that this is not an ordinary patent case. Indeed, there are elements such as a basic patent term, a patent term extension for pharmaceuticals, or again a variety of market exclusivity that can gain as a regulatory factor independently based on the novelty of the drug. There is also the New Drug Application (NDA) process for approval and the orange Book listings and the Abbreviated New Drug Application (ANDA). The key one is Paragraph IV Certification, where the generic applicant certifies that the patent is invalid or unenforceable, or not infringed by your new product.

The brand has a big incentive to sue. First, because they want to avoid competition from the generic. Second, the infringement suit is launched within 45 days of notice of the Paragraph IV Certification, it triggers a thirty-month stay, so the FDA will not approve any ANDA applicant. However, there can be only one 180-day period of marketing exclusivity for a generic. So once that first ANDA is filed, the incentive for the second-through-nth entrants is diminished.

The framework comes from the *Actavis* case, and there is an illustration from the *Impax* Labs case. In this case, the Fifth Circuit's decision in *Impax* Labs has sustained the FTC. In *Actavis*, the Court agreed with the FTC that reverse payments diminish competition in violation of the Antitrust laws and there is substantial harm to competition and consumers. However, this case is not entirely a victory because the Supreme Court recognized "red flags" or areas of concern that had been of concern to us all along like litigation costs or side deals. In addition, the Court said that the rule of reason must be applied because there are various circumstances where the payment is not a payment for delay, but something else. That went to federal court, and then just last year the Fifth Circuit sustained the position.

He hypothesizes that, after *Actavis*, there is another change in the population of actions being brought, because they recognize that the courts are looking at facts and circumstances. There are some differences with the private plaintiffs. They can't sue to enforce the FTC Act and Section 5. However, they can sue under the Sherman Act and certain provisions of the Clayton Act. There are these presumptions about the patents that have been listed in the Orange Book. For example, there is the scheme of stacks, and stacks of patents all on one simple molecule.

He underlines that under the *Opana* case, there was a payment and the insurance but there was no AG. *Impax* was worried that they might product hop and transition patients away from the brand and then pull the brand from the market. Once the brand is out of the market, off the Orange Book, they can't have a generic for that no-longer-extant product. Now, in the Orange Book, the original Opana ER is gone, there is a bunch of generics.

According to him, it is necessary to enforce rules. Some of the consumer protection rules have significant competing interests that they serve. That is what has been done with Eyeglass Rule, Eyeglass II, and the Contact Lens Rule. It was adopted under the Fairness to Contact Lens Consumers Act, which tells the FTC to implement the Act. These rules are successful and are enforced. He adds that there are advantages of a rule in the abstract, like stability, predictability, or administrability, but they can be very hard to do and not well done. That is why a lot of competition law in the US is done on the rule or reason.

Eric Stock
Partner
Gibson Dunn
New York

One of the biggest victories of the FTC is the battle over naming. Indeed, the Commission chose the term "pay-for-delay". The term can be helpful, however, to think through the issues. We need to determine in these cases whether there has been a "pay", or a "payment", and if so, whether it was "for delay". And each these notions can be questioned. In the *FTC v. Actavis* decision, the Court says that even if there is a payment, it can be justified by saying it is a payment for something else other than delay. So, there can be a dispute over "pay", what the payment was "for," and then, it is a matter of knowing if this payment results in any delay. In this kind of case, it is not generally about knowing if a payment-for-delay is acceptable, then, but rather knowing if there was in fact a payment for delay.

Some concepts have been the subject of litigation on these topics. The *Opana* case illustrates the dispute over delay. *Impax* agreed with Endo not to launch before the agreed-upon entry date. The most interesting question, however, is to know if that was a delay. Endo acquired other patents and it successfully litigated those patents against other generics, and it argued that this settlement with *Impax* let *Impax* into the market early. Indeed, Endo emphasized that if they had known that they were getting these other patents that would be upheld, they never would have let *Impax* into the market. So, Endo had a pretty good case that the patent settlement was more pro-competitive than no settlement; it was more pro-competitive than litigating the case to the end.

Then, the question is knowing what the benchmark for delay is. *Impax* entered the market later than it would have if it had lost the litigation. If that is the benchmark for a finding of delay, then, it is arguably not satisfied in the *Impax* case. But in the FTC case and the private case, the argument is that it is not the right benchmark. The right benchmark for assessing delay is, instead, an alternative settlement that would have been agreed to without the reverse payments. The FTC successfully argued at the Fifth Circuit that the right benchmark is a less-restrictive settlement with an earlier entry date. This all show that pay-for-delay is not a simple question, especially when patents are involved.

California passed a state law that is intended to make the playing field a little more tilted toward the plaintiff in civil litigation. The burden of proof is flipped, so certain anticompetitive effects are presumed once a plaintiff shows that there was some element of value provided to the generic. This state law acknowledges that there are a lot of provisions in patent settlements that convey value to the generic that should not be considered a "payment", or not be presumed to be a payment that would qualify to be an unlawful payment for delay. Thus, California legislation mentions acceleration clauses based on the branded manufacturer's marketing of different dosage strengths or a waiver of damages for an at-risk launch for the same drug that is at issue in the litigation. The California legislation thus raises the question of which kind of payments are improper. The *FTC v. Actavis* decision itself also talks about some limitations by saying that the early entry by the generic itself cannot be a payment for delay. That makes sense because there seems to be no other way to settle these cases.

The question arises as to whether cases that involve even earlier generic entry can be considered as a payment for delay. The most extreme example is acceleration clauses. These clauses say that there is an agreed-upon entry date, but the generic can get in even earlier, for example, if the patents are rendered invalid or if another generic enters. In the *Actos* case, the private plaintiffs tried to argue an acceleration clause was a reverse payment. The judge's answer is clear: the effect of this type of clause is to increase competition, they cannot be considered as a payment for delay. However, these are not easy questions. For example, in the *Staley v. Gilead* case, in which it wasn't a simple acceleration clause, but also a Most Favored Entry Plus (MFEP) clause. The MFEP clause provided that if the brand agrees to an entry date for a second filer, the first filer gets in six months earlier. The Court in *Staley* suggested that maybe that can be part of a reverse payment. But under the rules of *Actavis*, the Court was clear that early entry itself can't be a reverse payment. *FTC v. Actavis* tried to set up a safe harbor for giving early entry to the generic or agreeing on a compromise entry date.

There are also a lot of other issues that can determine the outcome of the cases besides the merits of the case, like class certification. There is some judicial resistance to these cases being brought as class actions.

There is also a multiplicity of enforcers, including the FTC, State AGs, private lawsuits by generics or by customers, and class actions. There could be some benefit to distinguishing between cases brought by a public agency and a private action. In a private action, there is not as strong a case for taking the patents out of the equation. There is a great effort in *FTC v. Actavis* and at the FTC to take the merits of the patent case out of the liability question, but that doesn't work in private cases. Indeed, in a private case, it is necessary to show not only if there is anticompetitive conduct but also that it impacted the plaintiff. If there is no impact, there is no case. This has created a lot of questions about how to litigate one of these cases, including how to address the strength of the patents in private cases, but many of them are unavoidable because it is complicated to figure out the impact that a settlement has, particularly if the branded manufacture would have won the patent case absent the settlement.

This multiplicity of plaintiffs in the U.S. may be one reason why Section 2 law is weaker in the U.S. as compared to Europe. There may be a judicial lack of faith in the private bar to bring good Section 2 cases, whereas, in Europe, the Commission is the only one to bring Section 2 cases. Courts in the U.S. may therefore resist adopting broader standards for Section 2 cases in part out of fear of how private plaintiffs, such as competitors, will pursue them. As an example, the U.S. courts are hostile to predatory pricing cases out of concern that companies will complain about their competitors' low prices. ■

PANEL 4

RECENT DEVELOPMENTS IN THE U.S. AND THE EU

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The topic focuses on recent developments in the United States and the European Union.

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Rx merger review follows standard procedures. The Hart-Scott-Rodino (HSR) threshold requires that mergers exceeding the $100 million threshold be reviewed by the FTC. The FTC's defines the geographic market and the relevant product market. The relevant product market is a factual issue requiring medical and economic expertise. It depends on the set of substitute products for each product that the merging parties have. For generic drugs, this is typically defined as a molecule, form, and strength. For branded drugs, the relevant set of substitutes may fall within a therapeutic class, or it may depend on the set of drugs relevant for a specific type of patient. The FTC looks at where there are overlaps among products produced or sold by the merging parties, as well as overlaps among products that are in the pipeline, (i.e. the intellectual property, R&D, or the drugs on the market). Also, the FTC looks at whether there is a likelihood that the merger will lead to a greater likelihood of collusion between companies in the sector. If there is overlap, typically there is in the remedy proposal for divesting the overlapping products.

According to her, pharmaceutical companies may be contracting out more innovation to biotechs that they acquire but shouldn't be thought of a reduction in the overall level of innovation. Indeed, when an innovative biotech company is acquired, this provides incentives to innovate. Small innovators may not want to bring their products to market, either because they lack some of the expertise or the investment that is needed to bring the products to market.

Since the publication of an article on killer acquisitions that stated that drugs in development were less likely to be developed if they were acquired by a manufacturer that had a drug in the same therapeutic class, there has been greater focus on questions about pipeline drugs. The most compelling evidence is *Illumina/PacBio* which is not in the pharma space but in the life sciences space, where there was documentary evidence of an intention to squash a threatening innovative competitor.

There has also been concern that divestiture partners have not successfully brought products to market. In addition, there is dissatisfaction with assets being shifted around a small group of large pharma companies. The ideal solution is that the company can produce the product quickly and be a viable competitor.

From the PBMs' perspective, the best approach to negotiating prices with pharma is drug-by-drug because they are trying to incentivize competition amongst the pharmaceutical manufacturers for space on the formulary. Both pharmaceutical companies and the PBMs have a lot of data on all their negotiations with all the different parties. They negotiate with pharmacies, pharmaceutical manufacturers, and with payers.

The PBMs receive the net price. About 90 percent of the rebates pass through to the payers, to the plans that are contracting with the PBMs to provide pharmacy benefit coverage as part of their plans. There are other rebates that pharmaceutical manufacturers provide directly to the consumer. Net prices may not be going up, but the list prices are going up.

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Healthcare is not a sector like the others. First, drugs save lives, which creates a certain driver of policy. Second, in this sector, the person who chooses the product, who pays for it, and who uses it are not the same. She highlights that the pressure for change is consistent with what happened in trends in antitrust generally and that maybe the definition of the product market should be broader. Divestitures of overlapping products may still be appropriate in some cases.

According to her, there is an overlapping relationship between dynamic competition, innovation markets, potential competition, and nascent competition. Mergers of large pharma companies may not increase R&D spending among those companies. She considers innovation markets as a form of nascent or potential competition because the developed product is going to be a competitive threat.

Dynamic competition is a form of analysis that is not constricted by static parameters like existing price and output because it looks to the future, for example, the potential for more R&D andmore investment in new products. It is not possible to use the traditional tools of analysis because some elements are not measurable. Therefore, qualitative evidence is very important here. The executive management of the firms often know better than the economists what is going to happen in the market.

In cases where divestitures have been proposed, there are a number of elements to look at. The divestiture buyer must be knowledgeable and able to create and maintain a competitive product. It is also necessary to look at whether a particular buyer might have a blockbuster that he can leverage in negotiations on a portfolio. It is also possible to impose guardrails, like the possibility for the buyer to hold the product for a certain time, to develop the product instead of selling it. The U.S. has pharmacy benefit managers that tend to negotiate with drug manufacturers. This is done on a portfolio basis, not drug-by-drug.

She says there is often talk of how high drug prices benefit not only pharmaceutical companies, but also distributors, as they can increase the discounts, they receive that are not necessarily passed on. They also receive other income streams.

Gwendolyn Cooley

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Commissioner Slaughter created the Pharma Merger Task Force. The current chair works with different agencies like the FTC, the U.S. Department of Justice, State AGs, the CMA,

the DG COMP, and Canada's Competition Bureau. This group thinks to expand the definition beyond just looking at the molecule space.

She underlines that innovation is good. Some small biotech with small molecules may merge with a larger company and thus help navigate them through the FDA approval process, to achieve sales or to achieve distribution. However, acquisition can also stifle further innovation, the large firms only have about 20 percent of the active new substance space. Those large firms acquiring each other makes regulators worry about bundling or cross-market leverage.

The FTC released a paper entitled consisting of self-examination "The Competitive Efficacy of Divestitures: An Empirical Analysis of Generic Drug Markets". This document shows that divestiture markets reduced competitors by 0.21–0.36 relative to a pre-divestiture average of 3.8 competitors. In addition, the divestiture markets increased 420 to 532 HHI points compared to non-divestiture markets. The competitor count differential was mostly explained by lower rates of entry in divestiture markets. According to her, we also need to examine whether either the A or B side of a transaction engaged in «prior bad acts.» Parties who have engaged in past conspiracies, particularly with each other, should be especially scrutinized.

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One of the biggest changes over the past couple of years in the UK is Brexit. Thus, the UK expects to be more involved in pharma mergers than before. It is important to keep in mind that some studies show that some killer acquisitions can have diminished the overall drug development of the industry. Innovation and investment in developing products are key parameters of competition. According to her, the prospect of being bought out can push for innovation. However, it does not mean that those buyouts are enhancing or decreasing innovation.

She thinks that there is a huge degree of alignment, looking at competition in innovation markets and the importance of these dynamic markets. The UK's approach is set out in the Merger Assessment Guidelines. When the CMA looks at dynamic markets where there is this innovation, it describes two potential losses of competition that could result from a merger. One is the loss of future competition, which means that in the future the target company will introduce something in the market. The other is a loss of dynamic competition, which is the competition to innovate. It may be the uncertainty as to the outcome of the innovation that is taking place, but this uncertainty does not prevent the evaluation of the effect of the merger because the dynamic competition itself can increase innovation. It is slightly like the pharmaceutical space. This approach has been confirmed by Competition Appeal Tribunal.

The CMA does not have general thresholds or safe harbors that it applies in merger control because they do not work particularly well and are not included in the guidelines.

To make up for the lack of precedent, specifically in the pharmaceutical space, due to leaving the European Union, the CMA relies on its precedents as well as on the Commission. In addition, the CMA updated some legislation like Merger Assessment Guidelines to help people understand what they wanted and give them some predictability.

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The US antitrust agencies are law enforcement authorities. They have the power to oppose mergers and acquisitions by using the statutes that are on the books. Section 7 of the Clayton Act prohibits mergers and acquisitions where the effect may substantially lessen competition or tend to create a monopoly in a relevant market. Unlike existing, marketed products, products that are in the preclinical phase are subject to the question of whether they will ever reach the market.

Agencies face several challenges. First, potential competition has proven difficult to establish. Agencies have faced challenges in court demonstrating that a future product will impose a competitive constraint. Second, the FTC asks to what extent a transaction can eliminate competition for innovation in general or R&D, outside the boundaries of the traditional pharma product market definition. To the extent that the antitrust authorities focus on these areas, a challenge will be to ensure predictability by making sure that everyone understands the rules of the game. Indeed, parties to a merger typically must analyze the antitrust implications of a wdeal before it is signed. Thus, the predictability will allow them to understand whether a transaction is facially anticompetitive and whether they are going to face some opposition from the agencies. Regarding the analysis of an R&D market, one of the better articulations is in the FTC/DOJ IP Licensing Guidelines, whose definition tries to frame R&D activities while linking them to concrete elements in terms of a product or service that could be launched.

He underlines that if the data suggests larger pharmaceutical manufacturers account for a smaller portion of R&D, then that means that competition is working because there are more innovators out there and potentially more small innovators.

According to him, there will be questions about the divestiture process if the potential buyer is not be competent or has not launched products on the market. In addition, a requirement that the divestiture buyer cannot sell the assets for a certain time may have the opposite effect of stimulating competition. There is a lot of uncertainty about what the outcome is going to be. Parties want to know details to anticipate. ■