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Antitrust Publications & Events

Antitrust in Life Sciences

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Cleary Gottlieb Steen & Hamilton
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Antimonopoly Committee of Ukraine
Bangladesh Competition Commission
CMA
Competition Council of the Republic of Lithuania
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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 4

RECENT DEVELOPMENTS IN THE U.S. AND THE EU

Michael Miller
Partner
Morrison & Foerster
New York

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

Pauline Kennedy
Principal
Bates White
Washington D.C.

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.

Elinor Hoffmann

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

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

NAAG Antitrust Task Force Chair and Assistant Attorney General
Wisconsin AG's Office
Madison

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.

Sorcha O'Carroll

Senior Director
Mergers, Competition and Markets Authority (CMA)
London

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.

Matthew Tabas
Partner
Arnold & Porter Kaye Scholer
Washington D.C.

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. ■