Viola Chen:

Hi, welcome back to the second day of the workshop. Future of pharmaceuticals, examining the analysis of pharmaceutical mergers. I am Viola Chen economic advisor to commissioner Slaughter and a staff economist at the federal trade commission. Let me begin with a reminder that this event is being recorded. A video recording and transcript of these proceedings will be available on the FTC and DOJ website shortly after the event. Second, as with any virtual event, we may experience technical issues. If these occur, we ask for your patients as we work to address them as quickly as possible. We will also try to keep you informed of any significant delays. Finally, please continue the conversation with us on Twitter. Our Twitter handle is at FTC and we are using the hashtag future of pharma. Yesterday we heard from FTC chair, con AAG Canter, a keynote by commissioner Slaughter and two lively sets of panel discussions.

Viola Chen:

The first panel focused on concentration while the second focused on remedies. Participants from both panels urged the FTC to reconsider its historical policy of evaluating pharmaceutical mergers on a product by product basis and of accepting consent trees based primarily on structural remedies. Als enpt W*n1.83Qq0 0 6

today. Assessment of innovation aspects and pharmaceutical mergers. Riccardo Ferrari is the assistant director of economics at the UK competition and markets authority. And with that, I will turn it over to you Riccardo.

Riccardo Ferrari:

Good morning. Good afternoon. And good evening, everyone. As Viola said, I'm Riccardo Ferrari and I'm assistant director of economics at the UK competition and market authority. And I'm delighted to be the moderator of this very interesting panel. And I cannot wait to hear what our speakers have to say on one of the most highly debated topics in pharma mergers, which is the assessment of innovation

concerns in merger investigations. To discuss this I'm joined today by fantastic set of speakers. Carmine Ornaghi is professor of economics at the University of Southampton and his research is focused on productivity and innovation with applications in the pharmaceutical industry. Paul Csiszár is director of

Carmine Ornaghi:

So there are no other competitors essentially in the market or when this market power is likely to last longer because of patent protection. What the authors find is that around the 5% to 7% of the acquisition can be considered killer acquisitions. And as we've seen before, there is a large number of

warrant close scrutiny by the agencies in Europe. Our clear mandate from our, my commissioner and executive vice president [inaudible 00:18:45] is to help bringing innovative and affordable medicines to European citizens. Therefore, besides preserving price competition that contributes to affordability we also need to focus on dynamic competition in the sector, how to preserve and foster innovation

Sure. And I also echo and on thanks for inviting me to join this panel and really my deep appreciation to all of our colleagues on the task force for the wonderful work that we have done together. And finally, I'm also going to reiterate what Riccardo noted at the top I'm here being only on behalf of myself and not any commissioner or the commission. So Paul and Ellie did a great job of prescribing their analytical frameworks. And I think we're well aligned with them in the US. So while I may be a bit repetitive in my answer, to the extent that I am, this demonstrates this alignment on the innovation competition issues.

Caroline Holland:

So your US merger law is well recognized as having the goal of arresting monopolies in their incipientancy and preventing a tendency to create a monopoly. Although the FTC today are in the process of revising the guidelines the agencies have been using the 2010 guidelines and those clearly recognize the harmed innovation competition that a merger may pose. Similar to our counterparts in the CMA and the EC product to pipeline and pipeline to pipeline overlaps and product to product overlaps of course must be analyzed, but in order to thoroughly reach all the potential harm from a merger, we need to consider competition at all stages of innovation and separate and apart from any eventual competition.

Caroline Holland:

Ele Yoo:

So for example, in AstraZeneca Alexian, there was an overlap in a phase one and phase two pipeline to pipeline overlaps for a particular type of cancer. We focused in our closeness of competition assessment on reviewing recent internal documents of the parties and clinician feedback. And this merger was eventually cleared on the basis that we felt the evidence showed there was a strong level of pipeline activity for this particular type of council more generally. That would therefore be sufficient competitive constraints on innovation post merger. I think we'll also look at factors like the ability and incentive, as mentioned, of other potential competitors to enter or expand. Thinking [inaudible 00:40:12], which concerned an overlap between a pipeline and a marketed product. We found that there were other suppliers developing a gene therapy treatment and concluded that spark did not offer particulars with advantages of the others and in doing so, placed more weight on forward looking evidence than evidence on past historic performance.

Ele Yoo:

I think just as a final point, [inaudible 00:40:38] also offered some observations on your question, Riccardo, of how far back you should go when looking at pipeline drugs. And one thing we noted in that decision is that pharma markets are obviously characterized by a degree of transparency as to the relevant rivals active in the sector stage of development of arrival firms, pipeline products. And in that context, market players clearly do often begin to react to each other's pipeline products well before commercialization and we made the observation and that decision that affirm at relatively developed stage of R and D for a given treatment is already liable, in some cases, to provoke competitive responses from other market participants.

Riccardo Ferrari:

Thank you, Ele. Camille?

Camille Varcion:

Thank you, Riccardo. I'll probably repeat what Ele just said to some extent, but I will try to give you a practical insight on how the commission assesses pipeline to pipeline overlaps. As Paul already mentioned, we look at pipeline to pipeline overlaps both in terms of potential product and price competition, but also in terms of innovation competition, looking at the risk of discontinuation delay or reorientation of one of the merging companies pipeline drug. I will start to say that there are challenges in assessing pipeline to pipeline overlaps do not apply to the uncertainty Ele mentioned, but this is not a driving factor. And the uncertainty notably is linked to the risks inherent to the development of drugs, but there are also challenges due to the higher asymmetry of information between companies and the commission when it comes to research programs.

Camille Varcion:

That being said, we believe that our current merger control toolbox enables us to assess properly pipeline to pipeline overlaps. And usually we look at several parameters, including the closeness of competition among emerging companies pipeline drugs, but also with competing pipelines. We also look at our promising competing the emerging companies pipeline drugs are, and also the overall number of competing marketed and pipeline drugs available in the market. On this point, I will already say that there is no magic number with respect to the number of marketed and pipeline drugs available in the market that would make us rule out competition concerns. And this will always depend on the disease

Paul Csiszár:

Thanks, Riccardo. This is a very good question. Let me first clarify that policy makers and enforcers should always carefully reflect on any possible chilling effects on investments stemming from any action

Good morning and thank you all for being with us here. This is the last panel, but I think probably the best. I think we've saved the best for last. My name's David Lawrence, policy director of the Antitrust Division. And we're going to be talking for the next hour about prior bad acts as an issue in pharmaceutical merger reviews. And the reason I say I think we're saving the best for last is, we focus so much on the prospective nature of merger reviews, but of course the history of an industry is incredibly important to understanding its future. And so we're going to have a tremendous panel with us to help understand that question today, and to think about those dynamics. Michael Terrier is a distinguished professor at Rutgers Law School, where he specializes in antitrust and IP law. He's co-author of The Leading IP Antitrust treaties, IP and Antitrust Law, and Analysis of Antitrust Principles Applied to Intellectual Property, the author of numerous books and law review articles and chapters, incredibly prodigious academic, and a really intelligent and nice guy.

David Lawrence:

So I think we're going to really look forward to hearing from him on this. Ratsha Kooperam is a senior research assistant at The Washington Center for Equitable Growth. Prior to joining Equitable Growth, she interned at the Federal Housing Finance Agency working with the division of housing mission and goals, and has research interests related to healthcare competition policy and economic measurement. We have Professor Scott Hemple with us today, the Moses H. Grossman professor of law at NYU school of law, and co-director of the Engelberg Center on Innovation, Law, and Policy. Not only because NYU is my Alma mater, we are very pleased, very lucky to have Scott here. He's brilliant, teaches about antitrust and intellectual property as well, and has wide ranging scholarship. And I think brings the sort of interdisciplinary perspective to this that we really need to understand the connection betwee

Yes. So first and most importantly, thank you. To the FTC chair and all the FTC commissioners, and the AEG for antitrust, FTC and DOJ staff, and our international colleagues, this has been a tremendous honor and pleasure to participate in this group, which I think has been a fantastic way for us to have a dialogue about mergers generally, but pharmaceutical mergers specifically. So to conduct, we heard yesterday something like, in the last 30 years over 45% of pharmaceutical assets have changed hands from one pharmaceutical company to another. And something like 55% of pharmaceutical merger parties are also defendants in conduct cases. So that's why we care about this retroactive look.

Gwendolyn Cooley:

And those are cases brought by US DOJ, by the states, by the FTC, and certainly litigation by private parties. Setting that stage for what we're talking about for those of us not in the life of antitrust pharmaceutical land, most of the anti-competitive conduct that enforcers see, relates to carving up a territory or excluding potential rivals. And some of these are part of the way that pharmaceutical markets work. Brand versus brand, brand versus generic, brand name exclusergeBT/TTuadadanmalt. Aneqt25 (ar)1(ar)10(-)5 (o)3 poten 2 792 rE

multilateral conduct, where there are allegations of straight up price fixing or territorial allocation where companies have agreed not to compete to produce generic pharmaceuticals.

David Lawrence:

Thank you. And I wonder Ratsha, you want to jump in? Or others on the panel with thoughts on this intro question of prior conduct?

Ratsha Kooperam:

Absolutely. So I want to add that coordination within the pharmaceutical industry isn't always a bad thing. During the pandemic, we saw companies like Pfizer and Biontech work together to create an innovative vaccine to protect people against COVID-19, but unfortunately this isn't always the case. We don't really see a lot of coordination to bring forth innovation. Rather, we often see coordination to help rake in more profits. Just want to add that.

Scott Hemple:

I'd be happy to jump in here for a minute. When we think about the intersection of mergers and conduct, I mean, I think quite often the causality isn't quite right, but the sequencing is the other way. There's a merger and then there's conduct, right? So there's a merger investigation that uncovers price

And so let me add just one particular example, which is the merger between AbbVie and Allergan. So much of the anti-

David Lawrence:

And so when you're focusing on size in this way, is what we're testing for the ability to engage in the variety of practices that you just went over, that might, even if it's not size within a particular market, be leveraged into anti-competitive effects in a particular market?

Michael Carrier:

So certainly. The existence of prior conduct is relevant. What we focused on primarily were the advantages that uniquely large firms have in terms of the cross market effects of having drugs in multiple markets that PBMs need to include on their formulary. That is a function of how large a company is. And also how many must-have blockbuster products that it has because that increases its leverage when it deals with PBMs.

David Lawrence:

I see. Why don't I open up this question to the broader group and specifically, what is the role of market definition with thinking about the history in a pharmaceutical area and the markets are kind of unfolding or they're evolving, or we're looking to develop a market in the future. How do we connect up these disparate, factual inquiries into trying to understand a market as it evolves or potential markets? I'd love to hear from all of you on this, because it's a great learning opportunity for me. I've been at DOJ, not dealing with pharma for a while, but why don't we start with Scott?

Scott Hemphill:

Yeah, sure. So I guess, I mean my starting point kind of builds on where Mike left off. I'd love to just spend a little bit of time thinking harder about Mike and Patricia's proposal that we should be paying attention to increased bargaining leverage. In some ways this is a new idea. And in some ways it builds, I think on an existing, and I think extremely successful, merger program that FTC has perceived over the last decade. When we think about the hospital merger program over the last decade, the focus there has been on increased bargaining leverage, right? That by combining you could become a must-have with respect to a payer, typically a traditional insurance company and thereby command a higher reimbursement level as a condition of inclusion in a particular insurer's network.

Scott Hemphill:

Now frequently, those, typically, maybe always, those cases so far have been within market in the sense that they were within traditionally defined product markets, but there's important work by economists, making a strong case that even when hospitals are in disparate locations and hence in different product markets, as traditionally defined, that nevertheless there could be the acquisition of increased bargaining leverage that would have much the same kind of harms that the more everyday merger program has been tackling in the FTC. And so what I understand Patricia and Mike to be doing is taking that thinking and bringing it over to pharma and saying, well, just as you could have cross market effects that increase bargaining leverage in hospitals, that could be true over here in pharma. And so we need to take this seriously, need to take a hard look at this. So I just want to offer a minute or two, just think about how might we go about that because healthcare is a complicated business.

Scott Hemphill:

What does it mean to acquire increased leverage? How do we think about the potentially synergistic effects of bundling? If I'm already a must-have, and I've become even more must-have, how does that, if at all, does that affect my bargaining leverage? I think these models get pretty complicated, pretty fast

And I think that supports Scott's very reasonable suggestion for a retrospective and for a look after the fact of what happened. Our assumption was that if you have a combination o

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the access and affordability of drugs that are prescribed to manage diseases that have a high prevalence amongst vulnerable communities.

Ratsha Kooperam:

So, let's take the example of Truvada. Gilead pharmaceuticals is the manufacturer of Truvada, which is one of the most prescribed pre-exposure prophylaxis or prep drugs that can help prevent HIV. In 2014, Gilead entered into a settlement agreement with Teva pharmaceuticals, which is a manufacturing company that developed a generic version of Truvada and this agreement allowed Teva to launch their generic in the fall of 2020. Around the same time, Gilead announced that trial data for an alternative antiretroviral therapy showed signs that it might be safer than Truvada while still effectively preventing HIV. So in 2016, Gilead's new antiretroviral drug, Descovy, was approved by the FDA and then three

nascent competitor is far from certain, that even in that situation, antitrust has a role to play. Second, you asked about buy side harms. I think attention to buy side harms we've talked... Workers were mentioned explicitly. One could also imagine acquisitions of suppliers, acquisitions of these startups, the fewer big pharma firms there are, perhaps the fewer firms there are to fight over in some therapeutic class, a promising startup.

Scott Hemphill:

So, I think unclear whether in the real world, there's an incremental problem because often there's a cell side harm as well in such a case, but it's something to think about as part of amplifying the discussion of buy side harms. Third, we spent some time talking about bargaining leverage recognizing explicitly that enhanced bargaining leverage is an important form of competitive harm and one in which there might not be a demonstrable output effect. Then we can talk about how there's always kind of an output

panelists engaged in a lively discussion, comparing approaches used in their respecti