Okay, thank you very much Tobias for this insight into the situation of the German pharmaceutical industry. I mean it really seems to be very alarming and that's quite interesting to see when we think about the results we have seen in the panel before where Germany's doing quite well as an innovation location. So let me first introduce myself. I'm a project manager of the research center pharmaceutical location in Germany at the Germany Economic Institute and have been analyzing the importance of the pharmaceutical industry for Germany as a research and as a business location for 14 years now. It's for me always a pleasure to see and to hear what other people think about the industry by itself and what's important for them to develop in a healthy way. So, I'm really very delighted to be moderating this panel today and to gain exciting insights from our panelists about the industry itself and the conditions that influence their innovative strengths and competitiveness.

And I'm really, really very happy that I do not have to discuss and that I have the opportunity to learn from others today. So, from whom do we want to learn something about policies for life, science, and innovation? I would like to welcome you again on the panel Tobias Hackman who will discuss with us. Thank you very much for that. As a second panelist, I want to welcome Claus Michelsen from the German Association of Research-based pharmaceutical companies here in Germany who is an economist as well and has been working for quite a long time for the German Institute for Economic Research here in Berlin and has been head of economic policy for the German association of research-based pharmaceutical companies since 2021. Thank you very much. I'm happy to have you here today. And it's a pleasure to have Mark Schultz as part of the panel. I don't think I have to introduce him in depth because he is well-known here to the audience.

But he serves as a senior fellow of the Geneva Network, a UK-based think tank focused on international IP trade and public health. He is the Goodyear Tire and Rubber Company, endowed chair in intellectual property law, and the director of the intellectual property and technology law program at the University of Akron School of Law. Thank you very much. I'm very happy to have you here today. Last but not least, I would like to add a more political view, not completely political. I would like to welcome Cornelia Yzer from the Life Science Acceleration Alliance. So, she has, she has an industrial view on the pharmaceutical industry, and she has a political view due to her work as a member of the German Bundestag for quite a long time. She was appointed as a parliamentary state secretary for several years in different positions. So, I would like everybody to come to the stage so that we can start with the discussion.

So first of all, I want to talk about factors that distinguish the European, the German pharmaceutical industries, and the pharmaceutical research location compared to other regions of the world. We have seen a few points in your presentation to BS, but I want to deepen that point a little bit more. For a long time, Germany was referred to as the pharmacy of the world. And I know you can't hear that expression, but it's quite a fact and it was not undeserved as the origins of the pharmaceutical industry lay in this country. And we have a lot of innovative, very important drugs coming from German companies to the world. But as we have just seen in your presentation, the location is falling behind internationally as a research location, as a location for clinical trials, and as a production location while other countries such as the S and China are outstripping Germany. So, Claus, I have the first question for you. I know the interdependencies are very complex, but from your point of view, what are the main reasons for Germany falling behind, especially as a research location for the pharmaceutical industry?
So, thank you very much for inviting me. It’s a pleasure to be here. So that is a difficult question but also an easy one. So, what we observed over the past decades was the decline of the classical pharmaceutical industry in Germany. So, we were a world-leading production side, but also a world-leading research and development side. And then some good things happened in terms of globalization and in terms of increasing production of pharmaceuticals in other parts of the world, which puts a lot of cost pressure on the German location. So, when we talk about the production of generic medicines, we talk a lot about production in China India, and other parts of the world. So that's where much of the production went to and that's where Germany lost a lot of well production power I would say.

(03:34:08): But this is not the explanation for the decline on a research and development side, I think we have to talk in this context, we have to talk about other topics than just cost comparison between production locations. So, we have to talk about regulatory hurdles, which, as already mentioned in the context of clinical trials, but also in the context of building up well production sites, innovative production, innovative well, yeah, clinical trials in German. For German pharmaceutical developments. We need to talk about bureaucracy that's particularly important when it comes to investment decisions. We need to talk about incentives and research and development tax incentives which are much more favorable in other parts of the world, for example. But we also need to talk about the change in the reimbursement system. So, what we have observed over the past years is a much less innovative or less friendly innovation-friendly environment in the reimbursement system.

(03:35:22): And what happened last year is quite a large threat to our location. But I think we have to talk more, have to talk about more about the opportunities we have here as a production and research and development side and to be, as already mentioned, the good research infrastructure, public research infrastructure. We have some challenges, especially in parts of the sector of digitalization data use. There we see that other sites have done a lot more, but there are opportunities also in personalized in the development of personalized drugs where we can as a German or European location or a production site gain a lot, especially in the context of demographic change.

Jasmina Kirchhoff (03:36:22): Thank you very much. Yeah, I would like to deepen the point, you just talked about this. We are talking a lot about what's wrong with the German location, what are the disadvantages? But I mean when we take a look at Roche as one example of a large pharmaceutical company as many others, and you have a large number of research and production sites in all regions of the world, and when we look at your company's current investment decisions, Germany can't be a particularly bad research and production location for innovative pharmaceutical companies by international standards. So, we talk mainly about Germany’s disadvantages as a research location, but I would like to hear from a business side and a business view, what are Germany's advantages over other locations? Why does a company like Roche still decide to expand or make new investments in Germany?

Tobias Hackman (03:37:43): Yeah, it’s a very challenging question, but I take it so no, just to be honest, or just the first thought I have is that perhaps in Germany we did quite a good job to the global business decision department in Basel because we have to find the arguments. After all, we are also interested in Germany where investments are taking place because they are securing our jobs. No, just kidding. So, we did perhaps a good job here. Now just Germany, as I already mentioned with the positive factors, there are some indicators on the positive side, I can repeat them perhaps it’s again the high quality in research and development and
the cooperation here and the reimbursement system, but more in the past. So, we are working on it in the future, and we still are trusting also in Germany as a big market, Germany is the biggest market in Europe. So, we are working on the framework condition, and we also trust in the government that we find solutions here that will still be attractive in the future.

(03:38:54):
And to be honest at the moment, yeah, that's true, we see investment decisions in Germany, but when we look for example at the capital stock that is already invested in the past, Claus and, we discussed it before the panel here that we have the problem, or we have the point of depreciation. So, we have to reinvest every year, let's say something between two or five or 10% in the capital stock that the capital stock stays constant. So, when we see an investment, it's not a zero-one decision, you need a certain amount of investments to keep the capital stock constant here. And when we see that it is ongoing in the US and China, we see that the potential is much higher in other markets. So, this is our argumentation, but yeah, of course not everything is bad here and we have to work on it. That framework condition is good that more investments are taking place here.

Jasmina Kirchhoff (03:39:51):
Thank you very much. I would like to add a more politically related point of view to the assessment of Germany as a pharmaceutical research location. So, the industry's view of the location, yeah, when we look at the presentation seemed to be very alarming. Now we have some advantages that show us that Germany is quite a good research location for the pharmaceutical industry, but that there are alarming factors so that this could change in the future if we are going this way further. So, Ms. Yzer, you have been involved in the discussion about the need to strengthen Germany as a pharmaceutical location for some time now and in different roles, both from the perspective of industry and from the perspective of politics. So, based on your experiences and insights you've gained in the past, especially as part of German politics, how do you assess the current situation of the research location, and above all given your many years of experience, has your assessment changed over time?

Cornelia Yzer (03:41:14):
Thank you very much for the question I have to say, when I look at the landscape here and the assessment says it's worrying what is going on, we still have strong academic research in Germany. Whether you have a look at Max Planck centers, institutions like the charity here in Berlin. These are still lighthouses even on a global scale. My impression is that the cooperation culture between the pharmaceutical industry and these academic associations and institutions even improved in the last years. We worked for that quite long and it has been successful. There is a new sense of cooperation. Nevertheless, the translation of research results into products does not work more or sufficiently enough. And the research map is changing on a global scale. And even if we hear about some investments in Europe or Germany, this will be not sufficient to change the big picture.

(03:42:48):
We have the traditional competition between Europe and the US with the US always as the winner, but it has always been a competition between strong players. And on the other hand, we have the new kids on the block. We have countries like China, Singapore, and South Korea, that are entering not only the production but also the research arena and they do it quite successfully better than Europe for the time being. And for this reason, I say yeah, we have to speed up and to be, as Hagman has already mentioned, Germany has always been the number two location for clinical trials in the past. Now we are ranking as we know it better, six or seven.

(03:44:01):
We have lost this competition and the players are also changing. Big pharma has been the driver of innovation for decades and I'm convinced will also be a driver in the future. But today the emerging biopharmaceutical companies also represent a significant part of the global drug development pipeline. And these emerging companies rely on their capital, and we see is not available in Europe for these companies. I'm representing the LSA here today. That's the life science acceleration lines, the voice of the investors in the life science sector. We are looking at the regulatory framework from the perspective of those who provide the critical risk capital that enables life science innovation. We are concerned when we have a look at the key figures from 20 years ago, we see financing in Europe represented a 28% share of the venture capital in Europe, the US, and China.

(03:45:36):
Today this share has fallen to 13% and that's also clear evidence of loss of competitiveness that's why we have to look at the pharma legislation, which is on the way with a negative impact on IP with the requirements for the launch of products in all EU member states simultaneously 10, these are new disadvantages, how to be a Hackman has already mentioned them, but we also have to look beyond the pharmaceutical package and all together we have to look at the other framework conditions, the lack of VC capital as I mentioned, lacking liquidity in the financial markets that do not provide exit for maturing companies like other regions of the world do. And this is all due to insufficient regulation. Looking at the European level, again, the European Commission has presented new regulations, the AI regulation, the European health data space, key topics for the life science industry, and they all have the headline strengthening competitiveness. But do they live up to the claim? I doubt it. When you look at the proposals, you'll see that there are many contradictions. Some of the content is incompatible with existing regulations which shall not be changed. So, it's a world of bureaucracy and we have to bring down these worlds of bureaucracy for industry and investors, I think.

Jasmina Kirchhoff (03:47:53):
Thank you very much. Now it's alarming again, but let's take a look at the US as a pharmaceutical location and as we have learned the big old competitor of the European pharmaceutical research and production location. So, I mean the story in the US is quite a little bit different. So, the expenditure by pharmaceutical companies on r and d has been showing increasing growth rates for many years now. Pharmaceutical and biotechnological companies are strengthening their presence in the U.S. The country is the envy of the world for its successful startup scene. Clinical trials are primarily taking place in us, especially in the area of cell and gene therapies. We have all seen that in your presentation. But when you read that list down, you think, okay, the game is done, the US is the winner and will stay on the top of the pharmaceutical research location. But why is the US so attractive as a research location for innovative pharmaceutical companies? I mean, is it simply the size of the market? I doubt it, but I think it's a point. And what does the US do better compared to European countries when it comes to strengthening pharmaceutical research and development? And I think that's a perfect question for you, Mark.

Mark Schultz (03:49:36):
Thank you. I appreciate the chance to be here. Let me make one comment on one of the underlying premises of this conversation we're having now that it's framed in terms of competitiveness. And sure, that's a political reality. We all want our countries to do well, but I would love for everyone's country here to be producing medical innovations because while I'm getting older and health is much on my mind too these days and anything we all can do to help our countries become better environments for innovation, benefits, humanity in this particular discussion, let's set a baseline because it's been hinted
at. But for example, Tobias's great presentation looked at a more recent timeframe. If we go back to the 1970s, Europe was on top, not just, yes, it has been the center of biopharma research for centuries, but as relatively recently as the 1970s European headquartered enterprises introduced more than twice as many drugs as US companies.

(03:51:59):

In the eighties, the US was responsible for less than 10% of these introductions globally. But by the 2010s, more than 60% of new drugs were first introduced in the US. Depending on how you do the numbers, some researchers estimate an even higher percentage of R&D biopharma R&D investment in the US than Tobi has shown as much as 80% of global R&D biopharma investment is in US. Even if you count it as less, it's still a vast number exceeding everyone else. So, what happened, why this changed?

That's the interesting thing. This was the result of several policy changes that I think are fundamentally the product of the government playing a constructive role concerning basic research, but also making things easier for commercialization. So, in that first, I've got I guess about five policies to talk about.

(03:53:06):

The first is government funding of basic research. The US spends more than any other country on funding basic research. The National Institutes of Health is an enormous influence on this kind of research, and it pumps a lot of dollars into universities and other basic research institutions. But it leads me to the second and that amount has increased over the decades, but it leads me to my second point, which is several points about creating a better intellectual property environment. By the late seventies, the US took a good hard look at what it was getting socially and commercially concerning these basic research dollars they were putting into universities and other research institutes. And the answer was very little. It was quite unfortunate. In terms of biopharma alone, we could say that very few, maybe only one drug had ever been commercialized out of this funding, believe it or not.

(03:54:10):

And the challenge that was identified was that the government was keeping all the patent rights to government-funded research. And so, this is where the famous for many of us by DOLL Act comes in, Congress passed the By Doll Act and the By Doll Act kept ownership of patents with universities. Although they can share those rights, they can provide those rights to the researchers, they provide revenue to the researchers. But the point is they not only provided the opportunity for universities to retain patents, but they also encouraged them to do so and to commercialize the inventions. And this marked a tremendous turning point. The Economist magazine once called this the most important piece of legislation of the 20th century in the United States. And this was one of the starting points for a big change. Another big change in the US IP system and the early 1980s was the creation of a specialized patent court.

(03:55:14):

The courts in the US, many of the courts in the US had been hostile to patents up to this point, and the federal circuit was created. This appellate court was created to harmonize the patent law and improve it. Now Germany, by the way, has well-regarded patent courts and in many ways, many corporations prefer them to our courts now. So, a lot of these criticisms we're making are relative. And if you were sitting in Washington, by the way, I suspect my friends in the pharma industry would tell us all the things the US is doing wrong, but relatively on a global scale, Germany's a great location compared to many other countries. The US is doing great, but we can always do better. But so, with a better atmosphere and, better environment for patents, patents became assets that companies could count on. Then there is the issue. The third point is incentives to increase returns to R and D.
So, one of these innovations in the eighties was R and D tax credits. Some of them are particularly targeted, but a lot of them are more general. Some of them are targeted to things like orphan drugs. And then the next point is structural. And very important, this return returns to investment on R and D. US companies can earn returns to their investment in R and D because the US has a more market-based, hardly truly market-based, but a more market-based approach to pricing drugs costs more in the US but the revenue from those costs drives innovation, and drug developments are expensive. And so, between our reimbursement system, between our quasi-market pricing system, companies can earn a return on their investments, and that matters. That's a huge trade-off. Yes, drugs cost more for a while and maybe with respect to certain treatments, you always want to be taking the cutting-edge one.

(03:56:21):
So maybe in certain treatment areas, they're always going to be using the most innovative drug and therefore the most expensive drug. But so many of these drugs we still use today, for example, Taxol to treat cancer, many, many drugs are generic now. So yes, there were exclusivities for a short period, yes, they were more expensive, but then they continue to benefit humanity. And so, this innovation trade-off is you get these vast returns to innovation at the cost of yes, a temporary price increase, but the US has been the most conducive to giving the industry an opportunity for a return on its investment. Okay, the fourth point is regulation. One of the things the US did in the eighties was legislation that, I guess the best way to put it is we created legislation that imposed user fees on the Food and Drug Administration, our drug approval agency for those who are using it, they used those fees to reinvest in resources for the approval process and they cut the time drastically for drug approval.

(03:57:40):
So, in the US now it's an average of 244 days, whereas the average in Europe is 426 days. Those 200 days matter. They matter to people's lives and health, and they matter to return on the investment for the industry. That's 200 more days where the researcher and the innovative pharmaceutical companies are able to get a return on their investment. And finally, let me say something, this is more cultural, a culture where risk-taking is tolerated and there's a tolerance of failure and you can't change a country's culture. So that sounds like a weak policy prescription, but it's important to be mindful of this cultural difference. If a country is trying to copy or implement a particular policy, there are certain assumptions and ways of operating that need to be kept in mind. And so, my example of this is by dole. So many countries have tried to implement this opportunity for government-funded researchers, and universities, for example, to commercialize their inventions.

(03:59:02):
But I was talking to a European researcher, not in Germany, but in another country, and she was a technology transfer officer at university. And she's saying, ah, this bi-style legislation, it's so troublesome and bureaucratic. And I said this is the strangest thing I've ever heard. Tell me more. And she said, well, the way it's implemented on us is these research grants come with a requirement that we patent. And within a certain short amount of time, even as short as a year, we have to get X number of patents. This is a very kind of bureaucratic approach. I get it. You want taxpayer return to taxpayer investments, but you need a more permissive culture that tolerates failure. Tolerate risk gives things time to develop and accepts that some money will get wasted and maybe only wealthier countries can afford that. But innovation is hard. Innovation doesn't always work. There are a lot of failures. You can't beforehand ensure success or demand a certain number of patents. So, if a country doesn't have that risk-taking culture, it needs to keep in mind that it can't implement some of these policy procedures in an environment that's bureaucratic and restrictive. It needs to also keep that openness when it tries to do these policy transplants. Thanks. I know I went on a bit. That was the answer I had the most to say about. So
Jasmina Kirchhoff (04:00:35):
Oh, we'll see. The next question is for you as well, because I mean I would like to talk a little bit more about political interventions and their effects in detail, and especially in Germany during the last, I would say 12 months, a lot has happened when we take a look at different legislations that are discussed right now and that have been introduced. I would like to talk to you about one point, and you said something that I was completely with you and your opinion in the context of the discussion on whether the protection of intellectual property rights for covid-19 vaccines should be suspended. You said IP is the opposite of a barrier, it's an accelerator. So, I mean this sentence is completely true from my point of view, but not from everybody's point of view. So based on this statement, I would be interested in your opinion on one specific point in the European Union Pharma package that has been presented by the European Commission this spring.

(04:02:04):
And this pharma package includes among other things, the plan to shorten regulatory data protection baseline from eight to six years. The idea is that a reduction in the protection period and the possibility for companies to extend this period again, if, for example, the drug is quickly available in all countries of the European Union, would work as an incentive system more precisely an incentive to make innovative pharmaceuticals available to patients throughout the European Union more quickly. So, from your point of view, is such an intervention in IP protection justified? And what impact could such an intervention have on Europe as a pharmaceutical research location?

Mark Schultz (04:02:57):
It's a really problematic idea. It's a bad idea. I'll be more blunt. So, what we're talking about here is essentially an attempt to persuade pharmaceutical companies to launch their drugs more quickly and simultaneously throughout the European market. And this is one of the hallmarks of the EU, as many of you in this room know better than me, but I'll point out, that the EU of course is driven by policies that try to create and encourage a single market. And I mean some of those of course are structural, but sometimes there are regulations about how business has to behave to have a single market. Businesses are supposed to behave the same way in all 27 member countries. And so, this is a concern driven by this is a policy driven by that concern, a policy proposal driven by that concern because drugs don't launch at the same time in every country.

(04:03:58):
We heard that Germany launches drugs faster for its patients and some countries in the EU member countries wait longer. Of course, that is harder on patients, but this is a punitive way of handling it. This is taking away a certain form of exclusivity that S companies would otherwise have. They'd have eight years and it's dialing it back to six, but they can earn it back by launching faster. But imagine if your boss said to you, I'm going to cut your salary, but you can earn it back by being more productive. So, this is an incentive for you. Congratulations. It doesn't feel like an incentive, right? It's a pay cut. This is a cut in the exclusivity term. And the other thing that would happen is if you asked your boss, then well, are you going to hold fewer meetings and impose less paperwork on me?

(04:04:54):
The boss would say that's your problem. I'll work harder and faster. Because the reason that launch times differ, I mean there are a few reasons. One reason is there may be a smaller patient, patient population. Not every country's patients are affected in the same way by certain disease conditions. So, there may be a reason to launch sooner in one place than another. But another reason is differences. The challenges of navigating the pricing and reimbursement system and it's highly bureaucratic. It takes
some expertise, and this is why launch times differ. And that is in the control of national governments, not in the control of the companies. Think about what incentive structure we're creating here, going back to my metaphor about your boss cutting your pay, and the boss also controls how you spend your time to some degree. And if you're getting close to hitting that bonus near the end of the year and the boss just starts imposing more meetings on you and wasting your time, you're not going to be able to hit that incentive.

(04:06:14):
And that's kind of the problem here is if you're trying to launch simultaneously in 27 countries or within a certain number of months and you're also trying to negotiate pricing and reimbursement, you need to be able to navigate that system quickly and effectively to get your exclusivity time back. You're negotiating with somebody who also has the ability to delay and impose costs on you and make your life harder. And so, it's going to potentially suppress the price more because it gives the governments more leverage in these negotiations. So, this is a really difficult and challenging incentives problem. Meanwhile, as the industry often does, it's responded to this proposal by promising to launch within all 27 member countries within two years voluntarily. But if this structure is imposed on them, I think it's going to lead to some of these really bad incentives for the system and probably reduce their return on investment more, which means fewer new drugs, fewer launches here, and that's just bad policy.

Jasmina Kirchhoff (04:07:41):
Thank you very much. I hope somebody from the European Union is here and has heard about your opinion about that very interesting idea they had. But in Germany, the German pharmaceutical industry has not only struggled with European legislation in recent years, but we have also seen a large number of regulatory interventions in the German pharmaceutical market by federal legislation primarily intended to have a cost-containing effect on the German healthcare system. But at the same time, and that's a very interesting situation we are in, there is a strong commitment on the part of politics that the pharmaceutical industry is essential for the business location and should be strengthened among other things. Many see the problem in the fact that healthcare policy and economic policy are not thought of together in this field, especially when we look at strengthening the pharmaceutical industry. So, would a unified healthcare and economic policy help to strengthen Germany as a pharmaceutical research location in international comparison? What do you think, Claus? What are the requirements for this? Is there a possibility that this will happen?

Claus Michelsen (04:09:06):
Yeah, at least we see some good signs that this will be thought. And I think combining healthcare and economic policy can indeed be beneficial for strengthening Germany as an economy, but also strengthen the German healthcare system. So that is, well, from our perspective, from the industry perspective, one of the key issues, is we have to think these things together and we need both. We need sound economic conditions regarding the r and d environments, skilled labor, and centers to invest, et cetera, et cetera. But we need also a market for our innovations as already mentioned here in the panel. And this is determined by regulation, the healthcare system. So, we do a lot of industrial policy, but we do not consider these regulations as industrial policy. And that is a problem from my point of view, because then we may get into a situation where we are less sovereign regarding our technological capabilities, regarding the capabilities to produce new drugs if we don't consider the market for drugs as one element of location choice. So that is, well, one issue we have to solve, and I see some very good signs from the federal government in Germany that at least some politicians think these policy fields together.
And we need long-term strategic planning as an industry, which is, well, we have a long r & d investment or r & d cycle, so we think our products over a cycle of 10 to 15 years in development and we need to know now what the conditions for the production for r & d for the commercialization of these drugs in 10 years are. So that is also very important. And there we need to have political accountability. So that is also for an industry that is r & t and intense, which is highly capital intensive. This is a key prerequisite to invest. So those are the key issues. And I think if we solve these problems, we have, well, a large step, a good step to strengthen the economy and also the healthcare location.

Jasmina Kirchhoff (04:12:08):
Thank you very much. I have another question for you, Tobias, because I think that's often a point that is not really clear and that's hard to understand how that works because when you think about the discussion about the introduction of the, you called it that, oh, we have much more funnier names for legislation,

Tobias Hackman (04:12:41):
We also call it the dark law.

Jasmina Kirchhoff (04:12:44):
No, it's legislation that aims at stabilizing the statutory health insurance financially. So, during that discussion, many pharmaceutical companies warned that they would have to reconsider entrepreneurial investment decisions if this law were implemented and that there would be an exodus. So that law was implemented and here we are. So, with regard to pharmaceutical research, why do regulatory interventions such as these implemented in the giga and in the European Union Pharma package affect companies' choice of research location? What is the connection between the attractiveness of a sales market and the choice of research location from a company's point of view?

Tobias Hackman (04:13:39):
Yeah, thank you for this question. And I think, Mark, you already answered the question very well. So, thank you for that it was a very interesting comparison because you were asked what we are doing differently than Germany. And you also talked about the high level of prices in the US at the beginning. And yeah, in the end, it's when you have a higher cash flow at the beginning, where is this money going to? This is going in investments again, and we see this, and when this money is not anymore there, it's cut and there's less money available in the end. It's very easy. The circle you also talked about is very impressive about IP regulation or the framework condition in the US to Germany. Therefore, I think you give a very good explanation there as to why it is so important and why we are talking about this, and we do, or we did in the last weeks together with Claus and we f this evaluation on this new law, it's only now for half a year implemented.

(04:14:43):
So, we don't see the very big effects at the moment because investment decisions take a lot of time. We will see the big effects in some years probably. So, we already criticized the ministry that we cannot do an evaluation so fast, but we did it. And I think the data clouds you collected from the companies, already show some effects in workplaces, in investments. Also, the first products are not launched anymore in Germany, so that's bad for the patients in the end, everything is said here, very good by you Mark. In the end, companies like Roche, and the others, need stable acceptable conditions, and we had an AMOC system, or we have it now until the year 2011. And the weight indicator shows that Germany
is doing quite well, and our patients are profiting from the system. At the moment we also discussing on
the U level that this will mainly be the system we have in Germany, can they discuss that this will be the
standard all over Europe in the next few days and what are we doing in Germany? We are destroying it
again. So yeah, I think that’s it.

Jasmina Kirchhoff (04:15:55):
Yeah, that’s it. But I mean we have a lot of legislation programs and not every program is so bad as it’s
the gig of our financial stability that I think I will tell that a few more times here, but there are new laws
that are planned that are quite well and not so discussable for the pharmaceutical industry. So, in
Germany, a new law is planned that aims to reduce bureaucratic hurdles in the use of health data for
pharmaceutical companies and facilitate access to research data for companies. So, strengthening
digitization in the healthcare sector, is this a suitable means being taken in Germany to catch up in the
international competition between pharmaceutical research locations? And why is it so difficult in
Germany to implement digitization projects, especially in the healthcare sector? Other countries don’t
seem to have so many reservations about new technologies. I mean, Mark, you just talked a little bit
about it, about the cultural differences, but there must be something else. I don’t think that’s the only
reason why this is such a problem here. And maybe Hugh could tell us a little bit more about that. I see
you like the question.

Cornelia Yzer (04:17:27):
I mean the Health Data User Act, sounds much better than Giga Financial. Nevertheless,

Audience Member (04:17:43):
This,

Jasmina Kirchhoff (04:17:46):
Okay,

Cornelia Yzer (04:17:49):
Much better. First of all, I think it's a shame they're up to now. There are valuable data for health
research or mess in the healthcare sector and we don't use it and cannot use it for research, for the
improvement of diagnostic and therapies. Therefore, all measures undertaken to improve this access to
data are key for the healthcare sector and the pharmaceutical industry in the future. As soon as you
bring big data into research processes, you'll see that they are accelerated, that you get a better quality,
and that you can identify responders, and non-responders very quickly. So, everything we need to
improve R and D and R and D results. That's why we cannot understand why politicians are so reluctant
to open up these databases, which by the way, we will also need to train artificial intelligence and bring
it into R and d processes. And from my point of view, it is key that in the future, everyone who has
legitimate proof of research interest gets access to these data.

(04:19:39):
Not only the public research institutions but also the industry as it is primarily driving innovation in the
pharmaceutical and biotech sector. And that's what the Data User Act has in mind. As I already said, it's
overdue, but it's a good start now. We need this act also as a prerequisite that Germany can participate
in the European health data space. That's another initiative of the European Commission. We need this
harmonization because we have to harmonize standards as most of the data are unstructured today and
for this reason not usable. So, a good approach with the Data Act, but the devil is in the details, and designing this regulation will be hard work because when you look at the national proposal and at the U proposal, you'll see that is still full of contradictions and yeah, is it a drop in the ocean? You asked?

Jasmina Kirchhoff (04:21:20):

Yeah,

Cornelia Yzer (04:21:21):

Perhaps it's a drop in the ocean, but it is said that even a drop can trigger waves that carry to success. So, let's stay optimistic, and let's stay optimistic as well with regard to Germans and digitization. I mean health data are sensitive data and we have to be cautious, no doubt about that. But we have harmonized standards in Europe for data G P D R, it's tough regulation already, but in Germany, we are more restrictive in interpreting it. And then we have German federalism data authorities in each state, which also come up with new restrictions. Perhaps it's very German because we tend, whenever we see a new technology to be risk averse, but digitization is not a new technology anymore. It has to be part of our life and it is part of the life of most people and it should be one of the most important parts of their lives when it comes to their health. But don't forget data, serenity has also to do with power. And what I see in the German healthcare sector is that most of the players get involved in the debate, about how we have to safeguard patient's data. Perhaps we can win if we tell the patient that the data, his data, not the one of the health insurance, not the one of the physicians, and not the one of the states. And patients have to take responsibility for their data themselves.

Jasmina Kirchhoff (04:23:49):

Thank you very much. That was interesting. I have thousands of questions, but I think the most important part I have is time boxing and that everybody in the audience, we'll have a lunch break today by time, but we have a few minutes left for questions if there are questions in the audience. Yes, please.

Audience Member (04:24:16):

Thank you. Thank you very much. And just listen to you, I do agree with a basic statement that the European regulation is anti when they anyway understand what ion is and it is against innovation. Just to point out and maybe to question this, according to our research, something happened with the competition of different branches and industries. So, we looked at the largest corporate r and d investors, and in 2010, the largest corporate R&D investor was Roche with a 7-billion-euro investment. And 2021 Roche was in ninth place with 13 billion. Yeah, one or three. In the meantime, in 2010, Google was on the place 36 by 3 billion. No, 2021, Google is in first place by 28 billion. So just to compare, something happened in the last decade. So, it is more rewarding to spend in digital technologies than in the pharma industry. And that the general, I think it is not connected to but is happening with the German health industry.

(04:25:40):

The second happened in the meantime, our research shows that when you look at how the r and d investment of the biggest companies increased between 2020 seven and 2015 increased almost by 50%, but the number of drugs that were patented decreased by 50%. So, there is the efficiency question which means that when you compare the r and d spending with other branches, let's say with digital branches, it's not so rewarding. On the other hand, the pharmaceutical industry is not that efficient in using the r and d. My question is in that case what do you think, for example, in the case of Roche or other companies, corporate venture capital, means when the large pharmaceutical companies there is
also Roche Venture establish a venture capital fund to tap the ideas of startup or help them, what do you think could be partly a solution or partly help this situation? So, the corporate venture capital funds, and second is more or less the question of how this relative inefficiency can be improved by digital technology, or not digital, and rather with AI technologies. And I think in that case, rather on trial process and so on, which could be maybe sped up by using AI. Thank you.

Claus Michelsen (04:27:38):
So maybe I can start with the last question, how to speed up productivity by using AI, digital technologies, et cetera, et cetera. I think that’s the key to increasing efficiency in the pharmaceutical industry because we have data in this sector. There is so much data, as in I think not so many other sectors in the industry or in the system. And there’s no sector, at least in Germany that uses data less than the healthcare system, which yeah, so there is a lot of room for improvement to use data for the first point. Second point, I think it’s the key to international competitiveness when it comes to R&D locations. These locations or countries will be the most competitive ones that have the most open-minded approach to using data to use AI, to use several other digital technologies. And that at least puts pressure on other countries like Germany, which lags behind other countries in the European Union, which face stricter laws in digital technology. So, I think this is a real game changer for a more mature industry like the pharmaceutical one. And now we have a lot of trial and error, and we can use AI to, well speed up this trial-and-error process and to use big data and machine learning approaches to find new drugs, to find new molecules. And I think that is one key. So that was the easy part of the question. I don't know who is in charge of this first one,

Mark Schultz (04:29:38):
I could tell you about investment patterns a little.

Mark Schultz (04:29:44):
I did a study a few years ago on trends in US venture capital investment by sector over time. The motivation for the study that I did in my early 20s was that there was a sense that the relative percentages of investment had shifted. So overall venture capital investment in the US has increased, but there was a sense among some that the sectors being focused on had changed. And that was the result I got quite dramatically. And I'll tell you why people think this happened in a moment, but what I found is a relative shift away from investment in the life sciences toward things that venture capitalists had traditionally not invested as much in food and beverage lifestyle brands, and social media.

(04:30:46):
And I did to get it causation. It was the kind of data I had that didn't lend itself to more sophisticated statistical methods. But what I could do is I talked to venture capital investors, some of the top ones in Silicon Valley and elsewhere, and what they said was they were very acutely aware of changes to return on investments. There were changes in the US patent system as much as we're applauding it. There were US Supreme Court cases that made entire categories less capable of patenting like diagnostics, and gene patents. There were changes that made it harder to enforce patents and changes that made patents more likely to be invalidated. And so, the end of the story, after looking at that span of data over 15 or 20 years, is that investors follow the return on their money. And it's not out of spite, they just look at where their money's secure while they'll get a return on investment.

(04:31:52):
And while the life sciences can be tremendously remunerative, they're riskier than they were in the past, especially relative to other investments. And as some of these venture capitalists said to me in the end, we have to make money for our investors for the pension funds and other institutional investors and individuals who put money into the venture capital funds. But they said, several of them said, I'd rather be investing in things that change humanity more, but it's just I have a responsibility to my investors, and that responsibility is making me less likely to put money into the life sciences despite the impact it would have. So, I think that's pretty telling. Investors respond to incentives and yes, we all respond to incentives, but when you're managing other people's money at that level and taking those kinds of risks, you are very cognizant of incentives and very responsive to them.

Jasmina Kirchhoff (04:32:57):
Thank you. There was another question over here.

Audience Member (04:32:59):
Yeah, thank you. Looking back, no, three years ago, we were in the middle of an innovation race for the vaccine, and that was, I mean, an exceptional situation. But I was wondering, and maybe you can tell me a bit about that. What changed in the industry or what happened after that experience in terms of innovation, process speeds, and IP protection? Did it make a difference that experience that special situation, or are we basically back to pre-2020?

Tobias Hackman (04:36):
Yeah, good question. So, I think what changed during this time is that the picture, the public opinion on the pharmaceutical industry improved because everybody has seen how fast innovation has taken place in this industry and how important the industry is. We made a study also for Germany, I don't know if you know this study where we looked at how much the COVID test in total for Germany could save G D P, how many lockdowns could be prevented due to the tests in total, how many lives could be set, but also the economic effect of this. And it was on the media, it was on the one-hand side. On the other hand, side, I see a lot of risk when we have this trip waiver discussion. I think it comes from Covid because we've seen that the vaccine was not available everywhere as fast as everyone wished. And so, this discussion came up from countries. I think with the false argumentation, we discussed it very much that it's more an enabler than a barrier. So, we have this discussion at the moment on the table on patent protection, and that was due to Covid. But in the business models in general, I don't see a very big change. We have these changes with new technologies. We have of course changed due to the demographic change in several healthcare systems and the PIs pressure. We have very issues on the expenditure side and governments are under pressure. This we see very clearly everywhere, especially in Germany. But yeah, that's it. Perhaps someone wants to add something from you.

Claus Michelsen (04:35:07):
Yeah, I can add a few points. We also face a discussion about windfall profit taxation. So that is also a good example of how a debate changes over time. So, we saw the extraordinary success of the BioNTech vaccine, and we saw that it increased G D P growth by half of a percentage point in Germany in 2021. But having said that, someone said, well, we need someone to pay for the cost of the pandemic. And then we also landed, that letter also landed on the BioNTech table. Another example is Novo Nordisk, a very successful company from Denmark that now brought a drug to the market that is used for losing weight. So also, very successful in bringing one and a half percentage point growth to Denmark, but also brings the argument on the table, well that these are windfall profits, and do we have
to tax them? So, these are issues. Well, we need to have a reliable environment that is well protects IP that protects also has a clear rule, on what happens to profits. And then we can try to plan and invest in r and d. But when you face discussions about profits in some special cases, then you lose any confidence in the system.

Jasmina Kirchhoff (04:37:01):
We have two more questions on this side. I think you will start and then you will question now. You will ask your question again and then we just finish the round here and go to lunch.

Audience Member (04:37:15):
Alright, thank you.

Audience Member (04:37:18):
You go first. Alright, thank you.

Audience Member (04:37:19):
You. So, following up on the previous question regarding sandbox regulatory jurisdictions, that also has been coming up in the health sector, but we've seen it more happening on FinTech and new bank chartering. One of these problems has been some of these jurisdictions are trying to reach the major markets with a European market, the US market, or some of the Asian markets. However, the process from sandbox to market in major markets seems to be slowed down because it doesn't follow the exact procedure in the case except for the European Union. Is there anything happening there to do internal sandbox regulatory systems within the EU or how do you see that the systems can join to do quicker research to market process for health and medical innovation?

Jasmina Kirchhoff (04:38:41):
When you have to think about answering the question, perhaps you continue with the second question, forget, and then see what happens.

Audience Member (04:38:50):
Very quick questions, but more related to Europe and policy. But first let me start with the provocation because the last part of your talk was more like when I go to a broadband discussion where they complain that there is a gray area where they don't have incentives to invest, so the government should come in. So here it seems you don't have that incentive to invest, so somebody else should do that, but that's a provocation. In terms of Europe, we have kind of two layers in the downstream when you introduce the drug to the market. And it seems that we have 27 different ways of accepting drugs in the European Union. So, we have the ema, the European Medicine Agency at the metaphysical level, and then you have 27 local agencies down. And I see that in Germany, I just recalled the numbers. It takes six months or eight months to be introduced. If take Italy, we take it a bit slower, and it takes two years. Is this impacting innovation first and second when it comes to the patents? Now there is this split or fragmentation of the tribunal that was in London since they left the EU. And it seems that some of the court cases will be in Germany, some in France, some in Milan. Milan is claiming the patent resolution. So again, this unclarity on regulation is impacting innovation and investment.

Mark Schultz (04:40:30):
On the point about the unified patent court, that's a move, an attempt to harmonize the laws. They're going to have different divisions in Milan and the other cities, but it's actually an attempt to create it. It's an attempt by Europe to be competitive with other markets by offering a more attractive place to adjudicate patents that arguably will be more likely to uphold their validity. So, this is going to be an interesting natural experiment. We'll see if Europe’s, not everything Europe does is anti-competitive or anti-innovation. This is an interesting idea that might work.

Claus Michelsen (04:41:10):
And related to your first part of the question, of course, time to market impacts return on investment, and return on investment determines how much you spend on r and d. So, there is a link between time to market and r and d activities of course. And there is of course a link between a large Europe as a whole is a large market for medicine and drugs. There is of course an impact of these differences on r and d activity. But more or less in a global context

Tobias Hackman (04:41:47):
And perhaps to add as a company like Roger others for the industry, of course, we are interested in harmonization in the processes in different countries and the refund processes and there is a process ongoing at the moment H t A level on European Union and we support this process. But what you also made very clear mark, is that we from the industry that it's more government homework to do to harmonize the refund system in the different countries. As an industry, we have an interest in being as fast as possible in the different markets. Yeah.

Jasmina Kirchhoff (04:42:31):
Okay. Thank you very much. I think the answer to the first question, is a further question. Okay. I was instructed for time boxing. Okay. It's a quick question with a quick

Audience Member (04:42:50):
Answer because you were not looking left.

(04:42:55):
So when you said, I think the panel said or you said that the health policy and the economic policy are in sort of not harmonized, that was a comment that was made and I wanted to know that are you looking at health policy as synonymous for pharmaceutical industry policy or is health policy much more than that in the sense that when you're making a health policy, you obviously have concerns about the entire ecosystem which includes the patients. So, health policy presumably will not be the same as pharmaceutical industry policy, and therefore attempts to harmonize that will have social harms. So, what is it in the health policy today in Europe that is anti-innovation and pharmaceutical?

Claus Michelsen (04:44:00):
That is a large question, but just to pick up your initial thoughts of course we have a health policy that is more than just looking at pharmaceuticals, it’s about the provision of healthcare to people. So, we can discuss this in a more global context where it is more or less a distributional question between less developed or highly developed countries. We have to face also in Germany, we have to face distributional issues between patients who have private insurance compared to patients who are in the public insurance system. So of course, this is much, much more and it is determined by the choice of a society, how much healthcare you want to bring to the people. So that is the first choice you make in the
healthcare system. And then you need also to decide how much innovation we want to spur by our spending on healthcare.

(04:45:07):
So that is where the pharmaceutical as industrial policy comes in. So, there we need this connection between, well we discuss health policy sometimes as being not entirely unrelated to economic effects. And that is the thing we want to add to the debate. We need to think about the interrelatedness between health policy, innovation policy, and economic policy. Especially when we talk about things like, well how dependent are we on other markets in terms of technology, in terms of well what happens to Europe if China decides not to provide any drugs anymore to us? So that is also economic policy, and we faced these problems in the Corona crisis, and I think we learned a lot between these interrelated policy fields.

Hubertus Bardt (04:46:11):
So, thank you very much to the panel. Thanks, Jasmin, for organizing that, and thanks to everyone on the panel. Thanks.