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### 5C Patent Law Session. International Patent Developments

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**Emily C. & John E. Hansen Intellectual Property Institute**

**TWENTY-EIGHTH ANNUAL CONFERENCE  
INTERNATIONAL INTELLECTUAL PROPERTY  
LAW & POLICY**

*Friday, April 9, 2021 – 10:30 a.m.*

**SESSION 5: Patent Law**  
***5C. International Patent Developments***

***Moderator:***

**John Richards**

*Ladas & Parry LLP, New York*

***Speakers:***

**Robin Jacob**

*Lord Justice of Appeal of the Court of Appeal, London (retired); Faculty of  
Laws, University College London, London*

***New Uses for Old Medicines: How to Incentivise Research***

**Christopher Floyd**

*Lord Justice of Appeal of the Court of Appeal, London (retired)*

***Regeneron: Adequate Protection for Ground-Breaking Inventions?***

**Lennie Hoffmann**

*Second Senior Lord of Appeal in Ordinary (retired); Queen Mary University  
of London, London*

***Of Mice and Law Lords: The Regeneron Patent***

**Dirk Bühler**

*Maiwald, Munich*

***SPCs – Recent Case Law of the European Court of Justice Foreshadows  
Challenging Times for Innovators***

**Heinz Goddar**

*Boehmert & Boehmert, Munich*

***Second Medical Use Patents and Compulsory Cross-Licenses***

**Gustavo de Freitas Morais**

*Dannemann Siemsen Bigler & Ipanema Moreira, São Paulo*

***Enforcing Patents in Brazil***

*Panelist:*

**Shlomo Cohen**

*Dr. Shlomo Cohen & Co., Bnei Brak, Israel*

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JOHN RICHARDS: This session will focus on international patent development. It's going to have a significant pharma aspect to it. We have a number of very eminent persons from England speaking, also contributions from Germany and Brazil. It's going to be an interesting session, I think. First of all, we have Sir Robin Jacob, retired Lord Justice of Appeal in England who is going to tell us about the problems of getting patents on new uses of old drugs. Robin?

ROBIN JACOB: Okay. Right. I want to talk about a problem which I think is a very serious problem about the limits of the patent system. To a doctor, a new found use for an old substance, particularly an old medicine, is for all practical purposes, a new medicine. If he can treat something which he couldn't treat before or treat it better, he's got an import new medicine. Patent law regards that which has gone before as old and unpatentable and, in its basic form which used to be the law in England, that was the end of it. You've got no right in a thing itself just because you found a new use for

The European Patent Office has created a fudge for that in the European system—that you can patent the old thing for a new medical use by saying it's for something new. You pretend that which is old has suddenly become new.

It's not a satisfactory fudge. First of all, there is the problem of a defendant who is selling it only for the old purpose. Doctors and others may still, nonetheless, use it for the new purpose because they know it can be used for the new purpose. In some countries where you have to pay for it yourself, they may say, “Well, the patient can't afford the patented price so I will prescribe it all the same and they will be able to buy the generic version.” In Europe, you can't patent a method of medical treatment itself with the old medicine—that's not allowed. That's considered a very bad thing indeed, although, I've never understood why. In America, you can, but the problem remains the same.

What you want is two different prices, one for the new use and one for the old use. Patent law doesn't do it very well at all. We had cases in Europe, the pregabalin case,<sup>1</sup> where the Supreme Court in effect aligned itself pretty closely to Germany which said, “Well, unless the defendant is selling it for the new use, it isn't for the new use.” Which is obvious nonsense, if, in fact, it is going to be used for the new use. There are cases where the only use will be the new use. It looks to me, and I'll be very grateful for people's views on this, there are limits to what the patent system can do here.

That has profound implications, notwithstanding the brigade that says, “Oh, patents for medicines are a bad thing, it's been keeping prices up,” and so on and so forth. This is a living example of the fact that if you can't get a patent for things, people don't do nearly as much research as they could do and would

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<sup>1</sup> Warner-Lambert Company LLC v. Generics (UK) Ltd t/a Mylan and another [2018] UKSC 56 (Eng.).

do—not least because the amount of research you need to establish a new use for an old medicine, and all the regulatory requirements, is a very different order.

You no longer go into safety and side effects. You know about all those because the old use established all those. You only have to establish it works. It's cheaper, it's faster, and there are a whole lot of practical new uses for old medicines out there not being researched because patentees can't get proper protection. Is there another solution?

Can regulatory systems somehow deal with it? Well, up to a point possibly. Regulatory systems aren't there to provide monopolies. Monopolies may be an incidental effect however. Thus, if only one company has regulatory approval for sale of a known medicine for a new use there could be some monopoly effect.

But what's to be done properly? Well, the best I've been able to devise is that the payers should be required to find out how much is used for the new and how much is used for the old. When I say the payers, in my country it would be the National Health Service. In many other countries, it would be insurance companies. They should be paying different prices according to whether it was for the new use or the old use. One way of finding out what medicines were actually used for, would be from prescriptions.

Now, certainly, that raises a whole bunch of problems. It's actually very desirable that prescriptions do say what that medicine is being prescribed for. They do it in one or two countries. Denmark, I think. Because then you can get all sorts of interesting data as a result of finding out what happened to the patients on a collective basis.

Then you will find people saying, "Oh, it's a great infringement to people's liberties to know what a patient is getting the medicine for." Of course, the pharmacist will know in most cases all those of medicines have only one use. I believe the objection to be overstated but what I'm really putting forward to you here is that our beloved patent system designed to promote innovation has its limitations. We've got to find ways of promoting industrial research to get around the limitations of patent law itself. It's most important in the field of new uses for old medicines. I stop here, within time.

JOHN RICHARDS: Thank you, Robin. Does anybody on the panel want to pick up Robin's challenge? Of course, in this country, we're still waiting for the Federal Circuit to come down as to whether the sale of a drug within the scope of a skinny label can be an infringement of a patent, which relates to the stuff which is outside that skinny label.<sup>2</sup> We'll see what the Federal Circuit does with that very shortly. Any comments from anybody else? No?

ROBIN JACOB: Seems none.

JOHN RICHARDS: You've stunned everybody Robin, as usual. Thank you. Our next speaker is Christopher Floyd who together with Lord Hoffmann, who's going to follow him, will address the *Regeneron*<sup>3</sup> decision of the UK Supreme Court, which certainly stunned me when it came down. Maybe, I'll get better clarification as to what it was all about and why we needed it or did not need it. Thank you, Christopher.

CHRISTOPHER FLOYD: Thank you, John. In June 2020, the Supreme Court in the UK handed down the *Regeneron v Kymab* decision. It was, by that stage, common ground that Regeneron had made a groundbreaking invention,

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<sup>2</sup> GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 976 F.3d 1347 (Fed. Cir. 2020).

<sup>3</sup> Regeneron Pharmaceuticals Inc v. Kymab Ltd [2020] UKSC 27 (Eng.).

which solved a significant problem in the production of therapeutic antibodies for human pharmaceutical use.

Just a bit of background, it was well-known that therapeutic antibodies could be produced from mice by insertion of genes into the murine genetic code. The insertion of those genes, however, led to a reduced immunological response which they called, in the art, immunological sickness of the mice. Regeneron's solution was to insert a hybrid gene structure consisting of murine constant regions and human variable regions. This is called the reverse chimeric locus and the claim for present purposes can be taken as the claim for the mice with a reverse chimeric locus. Amongst a whole host of attacks launched by *Kymab*, there was only one which succeeded, and it arose from the fact that, at the relevant date, gene insertion could be achieved only with a small part, and by no means the whole of the human variable region.

The Supreme Court held, by a majority of 4 to 1, reversing the Court of Appeal, that the patent was invalid for insufficiency because the invention could not be performed across the entire range of potential inserts, which fell within the scope of the claim. I need to declare an interest because I was a party to the decision of the Court of Appeal in that case.

The Supreme Court founded its decision on seven propositions which I'll take fairly rapidly.

First, the requirement for sufficiency exists to ensure that the patentee's monopoly corresponds to his contribution to the art. Two, in the case of a claim to a product, the contribution to the art is the product rather than, they say, the invention. Thirdly, the disclosure required of the patentee must be sufficient to enable the skilled person to make substantially all the types or embodiments of products within the scope of the claim. Fourthly, the above principles are subject only to *de minimis* exceptions. Fifthly, the patentee doesn't have to demonstrate that everything within the scope of the claim has been tried and tested. He can rely on a principle of general application to make a prediction, but he takes the risk that, when challenged, an opponent will be able to show that some embodiments cannot in fact be made. Sixthly, a claim will not be defeated on this principle by dividing the claim into a range denominated by some wholly irrelevant feature. The requirement to show sufficiency of a range only applies to a relevant range, not an irrelevant one. I shall come back to that in a moment. Seventhly, enablement is not shown by a demonstration that all the claimed products will show the claimed benefit if they can be made. The Supreme Court held, applying these principles, that the size of the insert was a relevant range, claiming everything from a minimal insert all the way up to the whole of the human variable region. Therefore, the patent was invalid. In other words, well done, Regeneron. A pat on the head, but not good enough—you haven't invented enough.

It's fair to say, coming from where I do come, that I don't agree with that reasoning. It's true that in the case of some objections to the validity of a patent, it's a correct proposition to say that everything that falls within the scope of protection of the claim has to fulfil that particular requirement. It's often said that anything which is an infringement must be novel and non-obvious. There's no *de minimis* or indeed any other exception to that rule. If the claims are wide enough to encompass just one thing which was old or obvious, it is invalid.

But you simply can't apply that approach to the objection of insufficiency. The requirement that you must enable everything which falls

within the scope of the claim isn't just subject to *de minimis* exception. It's extremely well established that the claimant can cover improvements which are inventive, and that fact alone does not render the patent insufficient. Sometimes, the defendant will say, "Well, I've got a very clever infringement and you don't teach how to do that." But that doesn't give rise to the objection of insufficiency. There's a very large exception to the principle that an invention must be enabled all the way across the scope of the claim.

Now, the problem is in defining how big is that exception. The Supreme Court correctly identified that some types of non-enabled embodiments were relevant and some irrelevant. As the Court said, no one would say that the claim should fail because the claim includes mice with very short tails but fails to disclose how to make such mice.<sup>4</sup> Of course, that's an advocate's extreme example designed to elicit the response: "Of course not." Where is the line to be drawn in a case like this? The very notion of relevant and irrelevant features begs the question. Relevant to what?

The Court thought that the length of the insert was relevant because longer was better. They pointed to the fact it took many years after the invention for the reverse chimeric locus to be deployed in a situation where the whole of the human variable section was inserted. Lord Briggs describes the inability to do this at a priority date as "the inventive shortfall"<sup>5</sup> and "a shortcoming in the invention."<sup>6</sup>

But why should any of that be treated as relevant when the novel and inventive idea of the reverse chimeric locus could be made at the priority date, albeit with a short insert? The ability to deploy the invention in more challenging circumstances was not a shortfall or shortcoming of the invention. The length of the insert was not a component of the invention at all. To my mind, the correct approach is to ask whether the feature, which is said to make the claim insufficient, is relevant to the patentee's contribution to the art or the inventive concept. Anything else is truly as irrelevant just as is the length of the mouse's tail.

One can make this final point that despite their adoption, as their first principle, that the requirement of sufficiency is to ensure that the patentee gets the protection which corresponds to his contribution to the art. The Court's decision results in a scope of monopoly narrower than the contribution to the art. All an infringer has to do, in order to make use of the Regeneron invention, is make a slightly longer insert. Despite the fact that he's making use of the inventive idea, he can do so for free.

JOHN RICHARDS: We're back to the contribution made by the patent owner and Lord Hoffmann in *Biogen v. Medeva*<sup>7</sup> from I'm not sure how long ago. There's a question which arises, where if you have a very broad claim deemed to be enabled and further invention is required to get that invention operable in some parts of that broad coverage, whether the original owner or the original inventor should be entitled to stop the subsequent improvement or just have to pay for it in some way? Which brings us back to our question on injunctions earlier on but anyway, Lord Hoffman.

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<sup>4</sup> *Id.* at [21].

<sup>5</sup> *Id.* at [46].

<sup>6</sup> *Id.*

<sup>7</sup> *Biogen Inc v. Medeva Plc* [1997] RPC 1 (Eng.).

LENNIE HOFFMANN: Thank you, Christopher, for telling me what the case was about because I'm also going to talk about the same case. My message is that the Supreme Court got the answer entirely wrong. But we don't have to worry about that because they didn't get the law wrong. What they did was misconstrue the claims. Now, it appears that the mouse DNA, which codes for the relevant antibodies that they were trying to make, consists of two chains called constant regions and variable regions. Before the priority date, people have been trying to swap as much as they could of human DNA in substitution for the various chains in the mouse DNA.

What the inventor discovered was that if you left the mouse with its constant regions untouched, then you could change as much as you like of the variable regions, and the mouse wouldn't suffer any immunological damage as a result. Previous to that, mice were, as a result of these changes, becoming what was called immunologically sick and they didn't work very well. The invention, therefore, was to say, leave the mouse with the constant chains. If you can do that, you can change as much as you like of the variable ones.

Now, the claim, therefore, was, and I'll read it, "A transgenic mouse that produces hybrid antibodies containing human variable regions and mouse constant regions," and then these are the critical words, "wherein said mouse comprises an *in situ* replacement of mouse [variable] regions with human [variable] regions."<sup>8</sup> The mouse had to produce hybrid human and mouse antibodies but with only the variable regions having been replaced in the mouse.

Now, how much of the variable regions did the invention contemplate would be replaced? There appeared on the face of this to be agreement between the Court of Appeal and the Supreme Court. They both said it meant "all or any"<sup>9</sup> of the variable regions. The evidence was that if the object of the exercise was to ensure that the mouse wasn't immunologically sick, it didn't matter how much of the variable regions you replaced.

However, in those words, "all or any," was concealed an ambiguity. Did it mean that for the purposes of working in the invention, all or some unspecified part of the variable regions had to be replaced—didn't matter how much—or did it mean that the patent enabled you to replace all or any of the variable regions, if that enabled you to replace the whole lot? Until the Supreme Court decision, I think everybody thought it meant the former. It was a patent for a product, the immunologically healthy mouse, which contained an indeterminate quantity of human DNA. It wasn't the patent for a mouse with any particular quantity of human DNA.

Even in the Supreme Court, Lord Briggs said, "True it is that the particular ground-breaking contribution...is the delivery of a means of preventing...murine immunological sickness, to which the range of embedded human variable segments is irrelevant."<sup>10</sup> Nevertheless, he treated the invention as claiming not only that you should leave the mouse with its constant regions, but also you're being able to replace the entire range of its variable ones up to and including all of them.

Now, the specification said nothing about techniques for replacing segments of DNA. A common general knowledge of the priority date enabled a

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<sup>8</sup> *Regeneron Pharmaceuticals Inc v. Kymab Ltd* [2020] UKSC 27 [14].

<sup>9</sup> *Id.* at [27]; *Regeneron Pharmaceuticals Inc v. Kymab Ltd* [2018] EWCA Civ 671 [259].

<sup>10</sup> *Regeneron*, [2020] UKSC 27 [22].

few of the variable segments to be replaced. Lord Briggs treated the claim as covering any method of replacing all or any of the variable segments. The authorities on which he relied were those like *Exxon Mobil*<sup>11</sup> and *Biogen*<sup>12</sup> in which a patentee claims every method of making your product and discloses only one method of doing so. For that purpose, as construed by Lord Briggs, the specification was clearly insufficient.

Now, why did the Supreme Court adopt that construction? I think the clue lies in what Lord Briggs said immediately after having conceded that it didn't really matter how much of the variable regions one replaced. He went on to say, "Murine immunological health is not an end in itself. It is a means to a different end."<sup>13</sup> In other words, may it be all very well for the mice, but what's it to us? A mouse with only a few variable segments replaced is not much use for replacing antibodies suitable for humans.

Presumably, Lord Briggs thought, in order to make the patent useful for human beings, it should be construed as claiming to produce mice with all of the variable regions replaced. He called this the range of products, all of which the specification had to enable. I think here the Supreme Court fell into a trap which is not unknown to supreme courts which consist of judges who have not been appointed because of their knowledge of patent law. That trap is to import into one patent concept another where it doesn't belong. Now, it's notorious that the Supreme Court in the United States has caused considerable confusion by introducing requirements and novelty into the Section 101 concept of patentability.<sup>14</sup>

In *Regeneron*, Lord Briggs' construction of the claim and his consequent finding of insufficiency was influenced by the thought that, at the priority date, it was of little or no practical use. But that's a question which is dealt with separately in patent law. Article 57 of the European Patent Convention says, "An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry."<sup>15</sup> In *Regeneron*, no one at any stage suggested that it wasn't. The patent which the specification must enable is what that claim identifies as the invention. Here, the invention was a transgenic mouse, not antibodies for use in humans. Whether such a mouse was capable of industrial application was a matter for Article 57 not the law of sufficiency.

Where does that leave us? The Supreme Court gave leave to appeal because the case was thought to raise a question of law. But they misconstrued the claims, something they might have done better to leave to a Court of Appeal which had two experienced patent judges. The law remains that the specification, together with common general knowledge, must enable the invention to be performed because of the full breadth of the claim. The full breadth of claim means the extent of the monopoly which the person skilled in the art would think the language it intended to cover. The Supreme Court held that the patent was insufficient only because they construed the claim very differently from the way the skilled person would have done. This conclusion requires quite a close analysis. I think this case is going to be one of those

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<sup>11</sup> Exxon/Fuel Oils (T 409/91) EP:BA:1993:T040991.19930318.

<sup>12</sup> Biogen Inc v. Medeva Plc [1995] RPC 25 and [1997] RPC 1.

<sup>13</sup> *Regeneron*, [2020] UKSC 27 [22].

<sup>14</sup> 35 U.S.C. § 101.

<sup>15</sup> Convention on the Grant of European Patents, October 5, 1973, 1065 U.N.T.S. 199.

wrecks in the channel which needs careful navigation until eventually the Supreme Court declares it officially sunk.

JOHN RICHARDS: Thank you. Heinz or Dirk, any comments on this from the German perspective?

DIRK BÜHLER: I read the decision some time ago so I'm not familiar at that level of detail which you reported it. It is a trend we see also at the EPO that assessment of what the actual contribution is and how that should be or can be mirrored by the claim is one of the central exercises. There is what I perceive to be a general hesitance to grant or accept broad claims and to really assess the functional nature of an invention. Whether the principle really works as it is expressed by the claims, and whether the claims correctly express that principle. At least under German law, as far as I understand it, we're currently a little bit more generous. There is a case, the DP4 inhibitor case,<sup>16</sup> which looked closely at what the contribution was. Whether you can use functional claim language to define your invention and whether a broad monopoly would be justified even if in some instances there would be non-working embodiments. From that perspective, I have the impression that currently, in the UK, we see a trend to push certain issues of plausibility and insufficiency of disclosure where there is a little bit more of a restrictive approach than we see it in Germany. That is my general reading of the case law on these issues at the moment.

JOHN RICHARDS: Heinz, any thoughts?

HEINZ GODDAR: I would make the same observation which Dirk has made already. We think it can be very functional to interpret such a claim which leads immediately to a problem which Sir Robin has talked about. It means you have very, very broad claim language if you accept this. Then, the question is how many potential improvements do you cover by that claim automatically already? Then the next question is, if it is so broad, what do you have to do to still leave the opportunity for others, who will work in this hypothetical and broad rule which the claim covers, to make improvements and to use them?

Then we come to broad experimental use clauses, especially general ones, like Article 11 no. 2 of the German Patent Act,<sup>17</sup> which is much, much broader than a Bolar Exemption<sup>18</sup> for special circumstances only. To come to the problem, how can you then as the improver, who makes this improvement, be sure that you can use commercially what you have invented? A broad claim, whether this is in AI or in pharma or whatsoever is binding. At the same time, the freedom for improvers still to do the necessary experiments and to make further inventions and then commercially to use them should be given. When I speak later on second medical use patents and compulsory licenses, I'll try to dive a little bit deeper into this problem. Thank you.

JOHN RICHARDS: Gustavo, anything from Brazil?

GUSTAVO DE FREITAS MORAIS: Well, I would have many, many comments about compulsory licensing in Brazil, but I prefer to leave them for my speech.

JOHN RICHARDS: Okay, all right.

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<sup>16</sup> BGH, Sept. 11, 2013, X ZB 8/12, juris (Ger.) <http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&nr=65657&pos=0&anz=1>.

<sup>17</sup> Patentgesetz [PatG] [Patent Act], May 5, 1935, last amended by Gesetz [G]. April 4, 2016 BGBl I at 558, § 11, no. 2 (Ger.), [https://www.gesetze-im-internet.de/englisch\\_patg/englisch\\_patg.html](https://www.gesetze-im-internet.de/englisch_patg/englisch_patg.html).

<sup>18</sup> See, e.g., 35 U.S.C. § 271(e)(1).

SHLOMO COHEN: John, if I may add something?

JOHN RICHARDS: Join in.

SHLOMO COHEN: Thank you. I think the Supreme Court decision is another example of a problem of methodology and terminology because under sufficiency, I think some of the judges confused utility and enablement. Those are two completely separate elements. I think Lennie hit it right on the head by pointing to the relevant EPO section. The question was confusing. One should have separated between whether or not the patent at the relevant date could actually support the invention when you properly interpret the claims. This has nothing to do with enablement which is teaching.

The other point here is also that I think one thing that the patent world has yet to face more thoroughly is the question of a pioneering technology. Pioneering technology cannot be subject to the same mundane patent rules as any other invention. Problematic issue, just to mention it.

JOHN RICHARDS: Thank you. Has anybody got any comments on Shlomo's contribution about this difference between pioneering inventions and lesser inventions, which was around when I started off for a long time ago, but has died in recent years with an attempt to have a more uniform approach to patent claim scope?

CHRISTOPHER FLOYD: Well, perhaps I could say something. We used to have an objection called "not fairly based." That was very much focused on what is fair protection, given the patentee's contribution to the art. If you have made a groundbreaking, pioneering, whatever you like to call it, invention, then you shouldn't be limited to just the particular way in which you have described that invention being put into effect in your specification, when it can be clearly seen that the principle that you've invented has wide application.

You don't have to worry about people making improvements and being stopped and invention being cut down. I take Heinz's point about experimental use. If somebody makes an important improvement invention, then he's in a position to do a deal with the patentee and do a cross-licensing deal. That all works itself out in the wash. There's no problem in having a dominating patent and then several other patents, if the patentee has genuinely invented a principle of general application.

JOHN RICHARDS: Is there a risk that you disincentivize people from seeking to make those improvements if the originator patent is too broad?

CHRISTOPHER FLOYD: Well, it didn't stop Kymab. They managed to get the whole human gene. Instead of having to pay Regeneron for the use of their basic idea, they end up getting the whole lot for free, which seems to me to be completely wrong.

JOHN RICHARDS: Robin, you've got any comments?

ROBIN JACOB: Yes, I too think the case was wrongly decided. It will have to hang around for some time, unless somebody boldly takes Lennie's line and say, "Well, they just assumed the construction wrong. This was really because of their wrong construction. It's just a case on its own about deciding on the basis of wrong construction of a claim. They paid no attention to it." That would be a very good idea. I fear it may not happen. Well, not for some time. I see one attempt has already been made to try and explain it by Colin Birss, which didn't involve that explanation.

I don't think there's a difference, Shlomo, between pioneering inventions and smaller inventions. There isn't one rule for one and one for the other, and

we don't need one. I like to take an example of a bicycle. Somebody once invented the chain drive for the back wheel of a bicycle. All bicycles before that, you had to pedal around the front wheel; before that they did not have pedals at all. Somebody thought of that. That covered pretty well all bicycles ever made thereafter.

Would you say, "Well, you can't have a patent for that" because you've only been able to enable this rather crude — I think it was called — the safety bicycle, which came out and it didn't have gears and so on and so forth. It's the same here. The difference is, as Lennie pointed out, that the trouble was, you couldn't actually even make a bicycle anybody could ride with Regeneron's invention here. It's a possible explanation to say, "Yes, it was incapable of industrial application." That's really what drove the court because they seem to think that you had to make everything falling within the claim, however inventive it might be and however many related developments it needed to make that type of thing. If that was correct it would be very, very dangerous for patent law and cannot be right. It will not survive. I agree with Lennie. The thing will be removed from the channel by people whose job it is to remove rubbish from the lanes of traffic.

JOHN RICHARDS: Thank you. Okay, let's move on. Dirk, you're on.

DIRK BÜHLER: Thanks.

JOHN RICHARDS: SPCs.<sup>19</sup> We just got it down to one presentation this year instead of an entire session as we've done in previous years.

DIRK BÜHLER: All right. I think as everybody knows, SPCs are Europe's counterpart to patent term extensions in the United States. They're of course different because they're not extending a patent, they're an adjunct to an existing patent connected to an authorized product, which means you have a triangle of the patent, the SPC, and the active which in itself is a complex setup that might explain some of the difficulties we see in the case law. What I want to report on is a decision which was handed down by the European Court of Justice roughly about one and a half years ago, the *Royalty Pharma* decision.<sup>20</sup> I must declare a conflict here or an interest, better to say, because I represented Royalty Pharma in that case.

The case is on Article 3(a) of the regulation,<sup>21</sup> which stipulates that in order to get an SPC, which prolongs your exclusivity by five years from which the active is authorized, it must be protected by a basic patent. This provision has been hotly debated. It's been subject to a couple of decisions before the European Court of Justice. While a lot of people had hoped that there would be some clarity from the *Royalty Pharma* decision, and I think there may, I think it also will in some respect create more confusion.

To give a brief bit of background here, and I think this ties in with some of the aspects that Sir Robin has already mentioned, Royalty Pharma acquired the patent and the original patentee had identified a new use for an already existing class of actives, which was called DP-4<sup>22</sup> inhibitors. The patentee

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<sup>19</sup> Supplementary protection certificate.

<sup>20</sup> Case C-650/17, *Royalty Pharma Collection Tr. v. Deutsches Patent- und Markenamt*, 2020 EUR-Lex CELEX LEXIS 62017CJ0650 (Apr. 30, 2020).

<sup>21</sup> Regulation Concerning the Supplementary Protection Certificate for Medicinal Products (EC) No. 469/2009 of 6 May 2009, art. 3(a), 2009 O.J. (L 152) 1.

<sup>22</sup> Dipeptidyl Peptidase 4.

showed by a couple of cleverly designed examples that if you inhibit a certain enzyme, you will be able to treat diabetes.

The claim was broad as far as the actives were concerned because they were functionally defined, but it was narrow as regards to the indication. The value of that patent is that this indication was the first authorized use for that group of actives. What happened was that the invention was made in academia, a company was founded, they did the preclinical work, early clinical work, and then partnered with big pharma, which in this case was the American Merck.

Merck didn't find that the original compounds were good, so it set up its own screen. They had licensed the project, so they were a licensee of the patent, and identified another DP-4 inhibitor. But they had started the project to identify DP-4 inhibitors for the treatment of diabetes. Merck got the compound patent and their SPC. Royalty Pharma, who had acquired the patent from the original patentee, was now trying to also get an SPC for Sitagliptin, which is possible under the SPC regulation.

If you think about it, you had an innovator who started the work, which opened the door to that indication for this type of active. They're a cooperating company who then developed the drug. I think you can see scenarios why that would make sense, that both of the parties who actually contributed to the development of this new treatment can participate through SPCs.

What the European Court of Justice ruled here was that Sitagliptin, the active, was not protected by the earlier patent. Now, there was no debate that Sitagliptin had been developed later. But there was also no question that Sitagliptin had been developed in order to be a DP-4 inhibitor and in order to be used for treatment of diabetes. It was not an accidental overlap.

The reasoning of the European Court of Justice was that it is not protected because it is not specifically identifiable. They said it's not specifically identifiable because it's protected by a later-filed compound patent.<sup>23</sup> So, you have the earlier-use patent and you have the later-filed compound patent. The dependent patent, if you want to say, was taken as evidence that the active was not protected by the earlier basic patent.

I think what this decision shows is, first of all, that the European Court of Justice in my opinion continues to mix different concepts of patent law by sticking to established terminology. I think in the context of the extent of patent protection, they're mixing aspects of sufficiency of disclosure and of original disclosure.

What I take from this decision is that I think it's clarifying that the European Court of Justice wants the active to be disclosed in the patent as precisely as possible. While I think that clarity is welcome, I think it will create some more cases, and probably referrals, in the future because this idea that a later-filed patent proves that you were not in possession of the active by the earlier patent will undermine a lot of filing strategies which have been developed in the past where you, for example, have a broad generic Markush claim<sup>24</sup> and then later your selection invention.

What you also see is that a lot of the cases that the European Court of Justice had in the past couple of years were concerned with situations where innovators were having disputes with generics. Now, suddenly you see the

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<sup>23</sup> *Royalty Pharma*, EUR-Lex CELEX LEXIS 62017CJ0650, at 10.

<sup>24</sup> "A 'Markush' claim recites a list of alternatively useable members." U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2117.

extent of protection question swinging to the other end of the spectrum and it's a question suddenly between the early movers and their corporation partners. That I think puts into focus the issue of what you do with these dominating patents that open up the door for a new therapeutic field, for a new class of actives, be it the checkpoint inhibitors which revolutionized cancer patients, or be it RNAi<sup>25</sup> therapeutics where the breakthrough was made 20 years ago and now the drugs are making it to the market.

What I take from that is we're getting some clarity. I think we're also getting uncertainty. But I think we're losing sight a little bit of whether the purpose of the regulation is achieved to actually foster innovation. What I think the question for the panel is that if there won't be any new legislation on SPCs in Europe in the foreseeable future, then how can one engage in a discussion with a court to really look at the national practice and how these concepts have developed in order to bring this into alignment. We don't see a unification or a unifying effect at the moment. I think the patchwork is getting worse across Europe and not better.

JOHN RICHARDS: Thank you. That does tie into some extent with what we were talking about earlier about the best ways to deal with situations where you have abroad initial invention and then improvements on it, and to provide the incentive for producing these improvements. Does anybody want to say anything on Dirk before we go into Heinz? Robin?

ROBIN JACOB: I am the judge who referred *Neurim*<sup>26</sup> to the Court of Justice. I thought it was such an obvious case for SPC that it was astonishing that Richard Arnold thought it was that clear the other way. I'll just remind you of the facts. The prior patent was owned by a different patentee and had proposed using this substance as helping the fertility of sheep through a pill which you inserted in the ear of the ewe.

The human medical use was quite unrelated to that. It was a new invention. The Court of Justice got it right.<sup>27</sup> Although they now say they got it wrong.<sup>28</sup> I said in my judgment that if there wasn't an SPC for this, the system wasn't fit for purpose.<sup>29</sup> I'm afraid the Court of Justice is making the system not fit for purpose. Dirk is absolutely right, they've forgotten the purpose of this thing.

It's more serious than that because they haven't a clue about patents. They don't understand that a patent claim may have within it other things which have not been invented yet. They don't understand any of that. They don't understand patent claims at all. They are living proof of the fact that the UPC<sup>30</sup> was correctly devised as a court so that the Court of Justice should not have jurisdiction over patents and they shouldn't be doing SPCs at all.

I'm sorry, that's my beef about it. The consequence is going to be quite significant. Many important pharma patents, inventions will not get a proper reward and that is not good for humanity. Otherwise, I agree with them.

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<sup>25</sup> RNA interference.

<sup>26</sup> *Neurim Pharmaceuticals v. The Comptroller-General of Patents* [2020] EWCA Civ 228 (Eng.).

<sup>27</sup> Case C-130/11, *Neurim Pharmaceuticals v. Comptroller-General of Patents*, 2012 EUR-Lex CELEX LEXIS 62011CJ0130 (July 19, 2012).

<sup>28</sup> *See* Case C-673/18, *Santen SAS v. Directeur general de l'Institut de la propriété industrielle*, 2020 EUR-Lex CELEX LEXIS 62018CJ0673 (July 9, 2020).

<sup>29</sup> *Neurim*, [2020] EWCA Civ 228 [30].

<sup>30</sup> Unified Patent Court.

JOHN RICHARDS: Thank you. Shlomo, any comments from Israel on that?

SHLOMO COHEN: Yes, just that a solution to some of the problems that we've come up against here is compulsory cross-licensing between the pioneering patent and the down-the-line applications, or selection patents, or whatever you want to call them. The Israeli statute has such a compulsory license requirement,<sup>31</sup> which is not very clear and perhaps is done wrongly. Clearly, this should be the solution, which by the way may in various instances also occur simply because the parties should have an interest in it.

JOHN RICHARDS: Thank you, of course, a compulsory licensing solution will not go down well in the United States. Do we have anybody in the participants who wants to speak from the U.S. point of view on this? Any other comments from the panel?

GUSTAVO DE FREITAS MORAIS: John, can I make a quick comment from the Brazilian perspective?

JOHN RICHARDS: Of course.

GUSTAVO DE FREITAS MORAIS: Apparently, Brazilian law copied the Israeli law concerning compulsory licensing for dependent patents. Shlomo, I have to say, every day I thank God because no one has ever tried these sorts of compulsory license. If this spread out, I think it would be a nightmare and would seriously affect the patent system because, in Brazil, there are maybe tens of thousands of situations where you have a senior patent and junior patents. I think we should use this remedy with lots of caution.

JOHN RICHARDS: Of course, TRIPS<sup>32</sup> does provide for compulsory licensing in cases where the second invention is of major importance as compared to the first. I think this was put in to counter what was happening in Japan back in the seventies and eighties with patent flooding, where people were having minor secondary inventions and demanding cross-licenses from the primary patent owner.

GUSTAVO DE FREITAS MORAIS: The problem in Brazil is we don't have these requirements about being a major improvement. It's just a dependent patent.

JOHN RICHARDS: Juergen, please.

JUERGEN DRESSEL: I want to return to this SPC presentation by Dirk. I understand your anger coming from the patentee's perspective, but I think *Royalty Pharma* brought some welcomed clarity. It is really, really clear now that unless you've specified your product in the patent, you will not get an SPC. I think we should remember what the SPC was for. It was mainly supposed to compensate for the development time of a specific product.

Actually, the European SPC and how the case law developed was very, very special compared to other countries where patent extensions and SPCs were granted. In other countries, it was impossible to get third-party SPCs. I think this *Royalty Pharma* decision will really eliminate third-party SPCs. You actually had a real maze of SPCs granted in Europe. I think a patentee, like *Royalty Pharma* or its predecessor, was entitled to actually have a dominating

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<sup>31</sup> Patents Law, 5727-1967, ch. 7 (Isr.).

<sup>32</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 50 (7), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

patent right and get money licenses during that time. I also could not understand why they should get actually the extra five years for the SPC for that purpose.

JOHN RICHARDS: Thank you. Any other comments on that?

DIRK BÜHLER: Can I just have one comment on that?

JOHN RICHARDS: Of course.

DIRK BÜHLER: Juergen, I see the point on the clarity about the disclosure of the active, no question about that. The problem or the issue that troubles me is taking later-filed patents, which by definition are based on an inventive step, as an indication that the active was not specifically identifiable in the earlier patent. I think there are a lot of situations out there where you have an earlier patent and patent offices and courts would say that is a specific enough disclosure to give rise to an SPC.

Then there is a later selection patent and you will see challenges for the earlier patents. That connection worries me because it's mixing concepts of patent law, which shouldn't be dealt with under the extent of protection proviso of Article 3(a). If they don't like third-party SPCs, they should say so. But they should not use the extent of protection proviso, which is one of the most fundamental terms in patent law, to deal with other issues.

I think that has repercussions that are not foreseeable. I think that would also hurt companies that take the drugs through the clinic. This argument you see, that they should profit for their dominating patent in the beginning—I don't know. These are really door-openers that open access of new treatments. I think for this type of situation, given the contribution and because they have entered contracts, I could see an argument why they should also profit from the drugs that were made.

JUERGEN DRESSEL: John, if I may make one comment. I think you're right. This will create severe issues between genus patents and selection inventions. I can imagine, for example in the biological field, when you talk about antibodies or things like that, it's actually quite difficult to get valid selection inventions. It can be difficult, and where the originator might have made the choice earlier, before this case law, that they actually take their genus patent because it's more valid. And now they might actually lose both. They might lose the selection invention, because it's obvious or who knows what, and they might lose the SPC based on the genus patent because it's not specified according to the SPC regulation.

JOHN RICHARDS: Thank you. I think I think we've done SPCs. Heinz, you're on.

HEINZ GODDAR: Thank you so much. First of all, I feel a little bit lost of course. I'm a physicist, and I'm not a pharmacologist or chemist even. As to SPCs, I know how to spell them, and I know that they are used widely but that's all I know about them.

My idea to talk about something like second medical use patents and compulsory use licenses has a history. Two years ago, in China, I was with Klaus Bacher, now Presiding Judge of the 10th Senate of the German Supreme Court. We talked about artificial intelligence systems and problems they might cause with regard to two aspects. What are they? Are they just tools? Then we might have to think about reach-through [unintelligible] claims for inventions, like AI, creating a situation wherein, for example, by use of an AI-system new turbine blades based on flight data of millions of flights are developed. Then, if

you now use such an AI-system in order to develop other inventions, like improving tire-supports in a car, can you do this or can you not do this?

The general agreement among Chinese scholars, Dr. Bacher, and me on the above-mentioned occasion, has been that we have already in the old good patent system —where also Sir Robin was aiming at— solutions that might be useful for modern problems. This is, first of all, the broad experimental-use clause which can be used to do research on something which has been patented. By doing so, certain new things can be legitimately developed. This does not only apply to pharma world, but also to technical, communications and software items. Now, the next question is how one possibly can make sure that such improvements, legitimately developed by exercising the rights under a general experimental-use-clause, can be commercially used.

In this regard, I had the pleasure—not too long ago—to participate again in a virtual —unfortunately, so it must have been last year—conference which Sir Robin guided in England. Also Dr. Bacher was there again, and we discussed later a little bit of the aforementioned question. I had in this discussion to do with general patents on improvements in pharma, be it just modified substance patents or be it second medical use patents. Furthermore, I have discussed with, [unintelligible], a close Indian friend of mine, Lakshmi Kumaran, whether there might not be a possibility to give access to such patents on improvements by the use of compulsory cross-licensing provisions embedded in many patent laws, like in Article 24(2) of the German Patent Act.<sup>33</sup> All this could solve the problems of giving access to improvements (second-medical-uses) also in pharma.

Let's look at what a patent of improvement could be in pharma: You can first think of somebody who modifies a certain substance which is already known or patented even for a first medical use. You modify it in such a manner that it is better suitable for that purpose. You can also do something else, you can make a patent of improvement out of it, you patent it of course, and hereby you develop a second medical use patent, which is patented.

Now, what do we have to do then in order to incentivize research in that direction? How can we make sure that what has been—by innovation, by inventive activities, whether it is in AI or in pharma research—developed can be commercially used? There I look into German patent law. I'm very happy to hear from Shlomo that in Israel you have a similar thing, as I learned today, that you have in Brazil, which corresponds exactly to Article 24(2) in German patent law. That provision gives, interesting enough, in Germany, a very special kind of a compulsory license.

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<sup>33</sup> “Where a licence seeker cannot exploit an invention for which he holds protection under a patent with a later filing or priority date without infringing a patent with an earlier filing or priority date, he shall be entitled, in respect of the proprietor of the patent with the earlier filing or priority date, to the grant of a compulsory licence from the proprietor of the patent if 1. the condition under subsection (1) no. 1 is fulfilled, and 2. his own invention demonstrates an important technological advance of substantial economic significance compared to that of the patent with the earlier filing or priority date. The proprietor of the patent can require the licence seeker to grant him a cross-licence on reasonable terms and conditions for the use of the patented invention with the later filing or priority date.” Patentgesetz [PatG] [Patent Act], May 5, 1935, last amended by Gesetz [G]. April 4, 2016 BGBl I at 558, § 24, no. 2 (Ger.), [https://www.gesetze-im-internet.de/englisch\\_patg/englisch\\_patg.html](https://www.gesetze-im-internet.de/englisch_patg/englisch_patg.html).

Insofar, we have Article 24(1)<sup>34</sup> of German patent law, which is the usual compulsory license where you need to check public interest in making a patented good available, if a voluntary license by a newcomer cannot get from the patentee of the primary or dominant patent. In the situation discussed here, however, we have to look at Article 24(2) of the German Patent Act, which explicitly—and you can read this in the materials how this article was been developed in German law—does not require checking any public interest.

Rather, it is generally accepted that something which is an important technical progress—that is the definition in the law—of high economic importance is developed and you have patented this, then you are entitled in a very special kind of a compulsory license. It's the exact thing Shlomo mentioned. In a compulsory cross-license, that cross-license does not come for free. Rather, the conditions of the cost of the license, which may accompany the cross-license must be determined like in Germany by the Federal Patent Court, the famous or infamous one. We all know that Federal Patent Court from bifurcation procedures and injunctions, of course. [unintelligible].

First of all, let's discuss, in this context, the improvement of, say, a second medical use patent. If you get that patent, you have already proven that a technical progress has been achieved, because if the second medical use “innovation” would not be technical, it would not be patentable. Now, whether it is important and whether it is of high economic value, has to be determined by an institution authorized to do so, which in Germany is the Federal Patent Court, who then decides whether a compulsory cross-license should be given.

If it is given, it does not mean at all that this should be cost-free i.e. that the dominant patent owner and the secondary patent owner would be able to use the patent improvement, secondary patent, or second medical use patent for free. There can be, and regularly will be—although we have not a single decision in Germany on this provision and it has never been used—a balancing payment between the dominant (primary) and the secondary patent owner in order to take care of the different merits and importance of the two inventions, i.e. the primary one and the secondary one. We have, in other words, to determine the value of the two.

This could be a way to make second medical use patents more attractive to obtain and also to use the patented invention for the benefit of mankind. Then you can make sure that the improved product really can, without using ordinary courts, and without looking into the sometimes strange or difficult-to-understand case law, at least in Germany, concerning second medical use patent, under what conditions the person or party or company who has made the improvement or second medical use invention can use the invention. You do not have to care about this in civil courts, rather this all can be done in a more neutral institution, namely a patent-office-like body, which is the Federal Patent Court. There you have technical people essentially supported by legally-trained judges who will decide on this. Then, there's an appeal to the German Federal Court of Justice (“Supreme Court”) again.

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<sup>34</sup> “The non-exclusive authorisation to commercially use an invention shall be granted by the Federal Patent Court in an individual case in accordance with the following provisions (compulsory licence) where 1. a licence seeker has, within a reasonable period of time, unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions, and 2. the public interest calls for the grant of a compulsory licence.” *Id.* at § 24, no. 1.

So, I am claiming that a combination of a generous experimental use clause and a look at the compulsory cross-licensing possibilities, which by the way exist in India, in Russia, and in Greater China—that means both in Taiwan and in the People's Republic of China—would be much easier to use in order to make second medical use patents useful. By this I mean that one can make use of them in the interest of mankind without having to go into usually very expensive and lengthy court procedures. All this could be done inside a patent-office-like body at least.

This is all I wanted to talk about, namely to encourage everybody to look at similar provisions which also are found in TRIPS, of course, and which in Germany are codified at least in Article 24(2) of German patent law. No public interest will be checked, not at all. It is just in order to make improved articles, like second medical use patents, and all the inventions underlying them, available to mankind. That's all. Not cost-free, but together with a balanced payment stream between secondary and primary or dominant patent owners. Thank you very much. That's it.

JOHN RICHARDS: Thank you, Heinz. I think actually similar provisions do exist in many other laws beyond those that you've articulated. I don't think they've really ever been used anywhere. Has anybody got any thoughts on that as to why they have not been used?

HEINZ GODDAR: Actually, I don't understand it. I can't tell you why not. Because reasonable people, as we all see in practice when we go into licensing, will agree voluntarily on a reasonable deal, in the sense of the former U.S. President, how in the best interest of both parties to make these improved products available. Usually, big pharma has a problem, if I may say so, and according to my experiences, the pipeline for new products is running out. Protection is ending somewhere.

There is a need and a desire even to have possibilities to bring improved products into the market for different medical uses for that. There is a big incentive to negotiate, and I think the pure reason why this is never used—in Germany and also in India, although they are starting now—is that they first have to solve the problem, particularly in the interest of domestic industry, that second medical use patents are not achievable in India, which at the moment is not the case.

There, they're starting now to think about whether this is a good idea or a bad idea. It is already voluntarily used. But like compulsory licensing according to Article 24(1) of German Patent Act, the provision of Article 24(2) of German Patent Act has practically never been used in reality. We had two or three cases early last year and a case in 1996, which was something that then was settled during the appeal procedure at the Federal Supreme Court. We never had anything which became practically a guidance in compulsory licensing discussions in Germany.

People are much more reasonable than we think. I think the state (“government”) must always have a possibility, if parties, against reasonability whatsoever, do not agree that it can be made sure that improved products will be made available to the consumer and will be available to the public, et cetera. I think the reason, dear John, is simply the reason for the legislator to have such a provision as discussed above is available in case that the parties in question are not reasonable. Then there should be a possibility to bring them by force, to compel them, to force them, to agree and to come to a solution which makes

good products that have been developed as second medical use patented products available to mankind.

JOHN RICHARDS: Thank you. Anybody else want to make any comment on that? Robin, Christopher, Dr. Hoffman?

SHLOMO COHEN: One quick comment if I may. On the problem of actually connecting Robin's original comments and Heinz now, very often you can patent a second medical use in one way or another. The only problem is in many jurisdictions that I'm familiar with, you cannot get a patent term extension or an SPC because an SPC or PTE<sup>35</sup> will be granted only to a compound that has been registered in the regulatory register for the first time.

With improvement patent later on with a second medical use, the compound has already been registered in the regulatory register and it would be difficult. This is a disincentive. One should consider amending the patent term extension laws to accommodate this.

HEINZ GODDAR: If I may immediately reply, I didn't know this. I'm not an SPC specialist, but I think this would be an obvious measure to improve in order to make this compulsory cross-licensing, balanced cross-licensing provision also available for SPCs. I think it would make a lot of sense.

JOHN RICHARDS: Thank you. I think we do, because of time, need to move on. Gustavo, you're going to bring us up to date on Brazil?

GUSTAVO DE FREITAS MORAIS: Okay. Well, thank you very much. I have some comments about enforcements of patents in general, specifically pharmaceutical patents in this country. First of all, as I already mentioned in the previous panel, we have a bifurcated system in Brazil. Infringement lawsuits are filed and prosecuted before state courts and invalidity lawsuits prosecuted before the federal courts.

In general, the venue of the federal court in Rio de Janeiro is used in order to invalidate a patent, because the Brazilian Patent Office is located there. One also has to designate the Brazilian PTO<sup>36</sup> as a co-defendant in such cases. But there are some invalidity lawsuits filed before other federal courts in this country. In general, talking about infringement specifically, maybe one of the key issues is to line up expert opinions.

Most if not all patent infringement lawsuits in this country will include a preliminary injunction request in the very same petition. I would say that in more than 50 percent of the infringement lawsuits, a preliminary injunction is granted either at first instance or after an interlocutory appeal. We understand that it is very important to have those expert opinions. The more concise and effective those expert opinions are, the more chance of getting a preliminary injunction. One more issue about expert opinions: it's very important to get a Brazilian expert. I know that there are some very renowned international experts in given technical areas, but it is always our advice to get a local expert and if possible from the same state where the lawsuit is running.

Maybe a few comments on venue. There are some courts that tend to be more favorable to patents. Maybe one thing that has to be weighed, especially with regards to pharmaceutical patents, is that the federal courts in Rio de Janeiro may not be the more sympathetic ones for pharmaceutical patents. That is one thing that has to be considered.

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<sup>35</sup> Patent term extension.

<sup>36</sup> Patent and Trademark Office.

We have doctrine of equivalents included in the law not as a case law construction. I would say that almost all of the infringement lawsuits that I represented as an attorney were based on the doctrine of equivalents,<sup>37</sup> especially in cases of formulation patents. In general, there is always a difference with the formulation of the defendants, but this article in the law regarding doctrine of equivalents can be as a rule very handy.

A final comment regarding secondary patents. I see that some stakeholders tend to rely a lot on the composition of matter patents. I agree with that, but sometimes there is no composition of matter valid in Brazil. Sometimes they have not even be filed in Brazil. However, sometimes there are other secondary patents, such as those covering formulations, crystalline forms, particle size, and so forth.

I always tend to recommend that if possible, and if there is a case of infringement, to use those patents. In many cases we have been quite successful. Besides enforcement, if I still have more time, I would like to address the elephant in the room, i.e., the fact that in Brazil we have a very special rule concerning patent term calculation. It is either 20 years from filing or 10 years from grant, whichever expires later.

This rule is now subject to a constitutional challenge, which is a very special lawsuit that is filed directly at the Brazilian Supreme Court.<sup>38</sup> The judgment has been scheduled for last Wednesday and it did not take place. It should be noted that the main federal prosecutor that filed this constitutional challenge in the first place requested one month ago a preliminary injunction on the challenge. On Wednesday evening after the session that did not entertain the constitutional challenge, the reporting justice granted this preliminary injunction. The situation right now is the following: any patents granted in this country, until there is a final *en banc* decision about this preliminary injunction, will have only the term of 20 years for filing. Every Tuesday, the Brazilian PTO decides on a number of patent applications and publishes its decisions. We will be keen to see next Tuesday what the Brazilian PTO's President will do with those patents. The *en banc* decision or judgment is scheduled for next Wednesday. We will probably have news from Brazil next week. Thank you.

JOHN RICHARDS: I think we're more or less out of time. Has anybody got any last comments or thoughts they want to add? In which case, I thank you all. I hope you've enjoyed the session. I have enjoyed it. I look forward to seeing you hopefully live at Fordham next year. Thank you.

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<sup>37</sup> See Lei No. 9.279, art. 186, de 14 de Maio de 1996, DIÁRIO OFICIAL DA UNIÃO [D.O.U.] de 15.05.1996 (Braz.).

<sup>38</sup> S.T.F., Relator: Min. Dias Toffoli, 07.05.2021, DIÁRIO OFICIAL DA UNIÃO [D.O.U], 13.05.2021 (Braz.).