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

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Session 5C

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

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

*Friday, April 22, 2022 – 10:35 a.m.*

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

***Moderator:***

**Robin Jacob**

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

***Speakers:***

**Peter Charleton**

The Supreme Court, Dublin, Ireland

***Supplementary Protection Certificates***

**Brian Cordery**

Bristows LLP, London

***Plausibility and Undue Burden – The Fibrogen v Akebia Ruling***

**John Richards**

Ladas & Parry LLP, New York

***Plausibility***

**Heinz Goddar/Melanie Müller**

Boehmert & Boehmert, Munich

***2nd German Patent Modernization Act – On the Way to E-Bay-Scenario in  
Germany***

***Panelists:***

**Eva Ehlich**

Maiwald, Munich

**Kevin McGough**

BioNTech, Cambridge, MA

\* \* \*

ROBIN JACOB: The speakers are going to be in the order of the program, starting with Peter. His subject is going to be SPCs, probably really important for the pharma industry. Sadly, the time taken before you can launch a medicine by and large these days is about five years longer than when they introduced SPCs. Some very interesting research was done on that which means we need 10-year SPCs, not five.

Brian is going to talk about plausibility. I've written views about that. I've come to the inclusion they've got it completely wrong. You're refusing patents for what turned out to be really good ideas, and we want to encourage people to do the research. If you think that the patent's going to stop people doing the research, you're wrong. If there's no chance of a patent, nobody will do the research. It's a big mistake to think that patents stop people doing research. Big mistake.

John is going to talk about much the same subject because it's going to be the question of whether or not you can say, "My invention does work." It might be. If it does work, then you should have had a nice patent. If it doesn't work, who the hell cares? Heinz is going to test about how Germany has finally realized that injunctions are not iron. He will tell us his views, I very much hope, on whether they are close to iron as they really are in the United Kingdom. The idea that you can withdraw and withhold an injunction for a property right is a pretty strong idea not just for patents, but for any other idea. With my introduction, we kick off with Peter and SPCs. Good afternoon, Peter.

PETER CHARLETON: Hello. Hi, Robin. How are you? I'm sorry I'm not there, by the way, to meet you all and see you all again. You tell me when you're putting on the clock and I'll kick-off.

ROBIN JACOB: Now.

PETER CHARLETON: Good. What I'm talking, about special protection action certificates. Why are these important? They're important because they are 25% to the life of a patent. Before we discuss the case law, let's go back and just think about why they were ever necessary. As I understand it, the first country to introduce them was 1984, and this is in a paper which has been circulated. That was the USA. Then in Japan in 1987.

Then the European Union thinking to themselves, "Look, if you can extend the life of a patent in other jurisdictions, then Europe is going to be very much disadvantaged if we don't have SPCs as well, adding potentially 5 years to the 20-year patent protection that's available under the European Patent Convention." Why was that done? Robin has effectively told us. It's all very well to, I suppose, invent a new form of light bulb because you may need to get a standard brought out on the market but that's pretty easy to get.

It's very, very different if you're putting out a medicine because, as we all know from various scandals over the years such as thalidomide, et cetera, what can happen is that a medicine goes on and because of the ontology of different people, it can have disastrous effects, whereas in limited clinical trials, it seems to be okay. I didn't know that it took 10 years now to get a marketing authorization to do all the clinical trials, but certainly when SPCs were introduced, it was taking two, three, four, or five years.

What an SPC effectively does is it says, "This isn't a light bulb, but this isn't a hinge, this is a medicine. You can't put it on the market without marketing authorization from the European Medicines Agency so we're going to give you some extra time." The extra time you get is you have to apply within six months of getting your marketing authorization, but you get up to 15 years. That 15 years can be up to 5 years post-patent. You can effectively get the full 20 years provided you have applied, got marketing authorization, and then been put in a position to put your product on the market within those five years.

Where is the issue here? The issue here has been bubbling around in European courts and the nature of those is in the paper written by myself and by all across, my judicial assistant. On the face of it, the legislation couldn't be simpler because article 3 of the directive says "You can get an SPC, a Special Protection Certificate, if the product which is the active ingredient or combination of active ingredients is protected by a basic patent in force, you have marketing authorization from the European Medicines Agency and the product is not already the subject of a certificate."

Two issues have arisen, which of course markedly difficult and different approaches in European courts. The first is in relation to claims, what you have to claim on the patents. I'm not going to talk about that because I don't have the time. The second is in relation to duplication. Briefly, let me say this, if you invent a drug and in the paper it's F\*, you will get patent protection for that F\* whether it's a monotherapy or whether you market it in combination with any other range of medicines which are in the public domain. When it comes to SPCs, it would seem from a number of cases, including Royalty Pharma, that things are different.

After you get your SPC, a different regime to a patent regime kicks into force. The main authority for that is the one in the paper, its Boehringer. From the recitals in the directive, it seems that what people are saying in the European Court is, yes, it is possible in principle to have a marketing authorization for different products protecting the same SPC. In general, it seems that if you have one SPC already, for instance, for a monotherapy, it's very difficult to get one thereafter for a combination therapy.

Why is that? It seems to be something to do with policy, because the court said at 35 of Boehringer that in order not to compensate the holder fully for the delay in marketing, one has to take into account all of the interests at stake and briefly, those include not only the monopoly holder or the patent holder, but also the requirements of public health. There seems to be a different regime when you have an SPC as opposed to the 20 years that are in patent. What point am I actually making in this paper? The point I'm making essentially is this. It seems to me that an SPC was intended from the start to be an administrative step, not a judicial step or a step implying some new tests such as core inventive test.

If it is an administrative step, then there is no warrant or there seems to be no warranty in European law, whereby on granting an SPC, a different regime to the patent regime would apply. What may be wondered is that since the regulation says nothing about core concepts in patent law and seems to be merely an administrative step, there is a pool towards turning that step into something akin to a new intellectual test, such as core inventive step, for instance. Is there legal

justification for this grant of an extra 25%? Perhaps there is, I don't know, but the regulation itself doesn't say anything expressly or otherwise about the number of SPCs that may be granted in respective products.

What is required is that medicines for humans have passed clinical trials and achieved marketing authorization. The difficulty we face in Europe is there have been a number of cases, and this is my last remark, Robin, if I may, where you can get an SPC for a monotherapy or for a first combination therapy, but the European Court seems to, and I'm not sure, have set its face against getting any further SPCs in respect of the core inventive step, plus a combination whereby the life of the patent may be extended by the SPC.

Everything else I have to say, as written by myself and all across, is in the paper and I hope you enjoy this. That's my rather confusing because this subject [chuckles] is quite a confusing little piece. There you go, Robin. [silence] You need to put your microphone on.

ROBIN JACOB: Peter says they got it all wrong.

PETER CHARLETON: No, I don't.

[laughter]

I couldn't possibly say that. I can't say that. Besides, we have an active case in our court. [crosstalk]

ROBIN JACOB: I say it's all gone wrong. [chuckles]

PETER CHARLETON: You can say that.

ROBIN JACOB: I decided Nuim and looked at the purpose of this legislation. I suggested that Nurim was wrong, is monstrous. I don't know what anybody-- Are there any comments? The audience are invited to join in because I can make these guys answer the questions. If anybody's got any quick Q&A, please put them in right now. I'm looking for them. No open question, that's no good. All right.

JOHN RICHARDS: Robin, the first time you and I interacted was on an application for an extension of a UK patent for unjust enrichment. Should we just drop the whole SPC thing and go back to that?

ROBIN JACOB: What do you think?

JOHN RICHARDS: The way the SPCs are playing out, I'm beginning to incline to think that that might be the best solution.

ROBIN JACOB: I actually think it's the best solution. It was a very satisfactory solution. It didn't work for small inventions because it was an expensive thing to say you hadn't made enough money. You had to have accountants and more. It really mattered for the pharma industry and you've got a longer period of extension. You could go up to 10 years, often did. Heinz, what do you think? Do you think SPC system is working?

HEINZ GODDAR: My viewpoint yes, as long as that does not unduly broaden the scope of protection even beyond what has been originally intended by the patent team. The original intention was if you are delayed to bring your product to the marketplace by some public measure, i.e. if the government doesn't give you approval to market, then you should have a little bit more than the normal duration which your patent would give you. That's it. Then it broadened more and more, second indication, third indication for orphaned drugs and

children drugs. I think that broadening was not good. The simple original idea, yes, I agree it is good.

BRIAN CORDERY: I think it's going to be interesting to see how the UK develops its SPC law. Now we're outside of the European Union. Presumably, Lord Justice Arnold will have something to say. Personally, Robin and I've spoken to a lot of clients in pharma companies, I think 90% of SPCs live an untroubled life if they're okay. Obviously, there are very difficult areas. I don't think the CJEU helps at all by saying the same thing again but using different language because law is, of course, a trade to exploit linguistic differences and you can see that going on all the time. I think the whole area remains still very uncertain and unsatisfactory, although I am informed that, as I say, most SPCs have a quiet life.

ROBIN JACOB: I'm sure, but 90% nowhere near good enough.

BRIAN CORDERY: Maybe it's 99%, I don't know. The large majority, should we say, but I agree with you.

ROBIN JACOB: It's quite comic to read the original document of the European Union, which says this is going to be very simple to administer my patent offices. That would be the end of it. They had no idea about either what patent claims were for or what actually you got regulatory approval for, which is a very, very narrow thing. It's not just a drug. It's not even the particular medicine, it's dosage forms. It's right down to detail. I don't see why you shouldn't have an extension for that if it's a combination which hasn't been marketed before.

BRIAN CORDERY: I would agree. Look, just to comment on something that Peter said, of course, you can get a second SPC but it has to be for the combination. It would have to be the subject of a separate invention, I think. Not even a separate patent, but a separate invention. I think where the objection lies is when you keep adding on A plus B, A plus C, A plus D when B, C, and D are just products which have been known for ages to treat the disease. I think that's where the CJEU has drawn the line - clearly or not, I couldn't say,

ROBIN JACOB: The general consensus of this session is quite clear. It's not in good shape, this system. I think we better move on to the next one because I know that time is so short and that's you, Brian?

BRIAN CORDERY: Yes. I'm just going to share my screen, Robin, if that's okay. Bear with me, one second. [silence] Do you see something, Robin, which is vaguely promising?

ROBIN JACOB: No.

BRIAN CORDERY: No, try again.

ROBIN JACOB: Something's happening. Here we go.

BRIAN CORDERY: It might not be perfect. I'm trying to get the screen with the PowerPoint. I can certainly work from this one if you can see the slide. Can you read the slide, Robin, okay?

ROBIN JACOB: I'm just going to try and make you smaller. That didn't work. Yes. Got you.

BRIAN CORDERY: Look, if you can see them, Robin, I'll start because time is tight. I did practice this earlier and succeeded, but under pressure, I've failed but I'll just go through. Look, what I wanted to say, Robin, on this was first

of all, it's great to be back at Fordham and I can't wait to be back with you guys next year in person. Second of all, Robin happy birthday for Tuesday. Thirdly, this is a presentation about plausibility, which remains a really hot topic in UK patent law and elsewhere in Europe as we'll see a bit later on this presentation.

This case concerns plausibility of claims with a broad scope. It was a dispute relating to treatments for anemia, and in particular, the use of particular inhibitors of an enzyme called HIF-PH to treat anemia. There were two rival companies developing two rival products; Fibrogen and Astellas developing roxadustat, Akebia and Otsuka developing vadadustat. There were two sets of patents in play called family A and family B. Loads and loads of issues. I'm going to focus on one issue in relation to one of the patents in one claim of one of the patents claim 8A of 823.

The numbers don't matter. What does matter is that there was a significant divergence of opinion between two very experienced patent judges. Lord Justice Arnold who'd sat as the judge at first instance, and Lord Justice Birss sitting in the panel of the Court of Appeal supported by Sir Christopher Floyd. For his part, Lord Justice Arnold held all the claims of family A patents were invalid because they were implausible and they also presented an undue burden to the skilled person to work the claim across its scope. There were three issues in play on this that I'm going to cover.

One, how do you construe a claim which has structural and functional features? What's the threshold for plausibility of claims of this nature, and what represents an undue burden? In a very condensed presentation like this, I wouldn't normally set out the claim on the slide, but I think it's really important to do so here. The claim had structural features, which I set out in yellow on the slide, heterocyclic carboxamide compounds, and that integer A and integer B was narrowing that claim of carboxamide, but still an enormous quantity of compounds more than could be counted in many lifetimes.

It also contained functional features which are seen here on the slide. These are what Lord Justice Birss called step one functional features. The compounds had to inhibit this particular enzyme, thereby increasing the production of EPO within the body, and that would in turn treat anemia. The rest of the claim related to the disease to be treated. Let me just go to the next slide. The big difference here is in relation to the how the claim should be construed.

Lord Justice Arnold said that the scope of the claim was everything that was covered by the structural features, so the yellow features in my previous slide. Lord Justice Birss said, "No, the claim is to be construed as covering the structural features and the functional features." The claim only relates to the green intersection on my slide, only compounds in the green are covered by the claim. That was how he construed the claim, and really everything else followed from that.

The Court of Appeal held that Lord Justice Arnold made an error of principle and approach when he held that the claim only covered compounds with the structural features, and then in turn asked whether it was reasonably predictable that all such compounds would treat the disease in question. Lord Justice Birss set out, instead, a three-stage test. What falls within the scope of the



claim? What does it mean to say the invention works? Is it possible to make a reasonable prediction that the invention will work with everything or substantially everything, I should say, within the scope of the claim? If you can say that, the invention's plausible.

On that basis, as I've already said, because the claim was construed to cover only the green intersection of compounds, having the structural and functional features, it was plausible that these compounds would be likely to treat anemia. On that basis, the claim was in fact plausible. When it came to undue burden, Lord Justice Arnold had said basically that it was necessary to identify substantially all the compounds covered by the claim. The Court of Appeal held again that was the wrong approach to take. Instead, you had to make two inquiries.

First of all, can you identify some compounds besides those mentioned in the patent which are within the class and therefore likely to have therapeutic efficacy? Second of all, if the skilled person's given any sensible compound, can they work out if it's a claim compound? Does that compound, given the compound, can you work out using reasonable trial and error if it's in the green intersection or not? On that basis, the Court of Appeal held that the claim didn't represent an undue burden on the skilled person. Sure, it would be a lot of work, but it wasn't an undue burden on that basis.

On my final slide, just very briefly, some reflections and thoughts. I think this judgment is quite friendly to patentees. Fibrogen would have been delighted to have won this claim. I think it's going to be important going forward to distinguish between what Lord Justice Birss called step one functional features and step two functional features, and the latter being the actual disease to be treated. I think it should be possible to work out difference between the two. Interestingly, we're already seeing litigants in the UK shaping their claims and fighting their cases on the basis of Lord Justice Birss's three-step test.

A good example of that I think is the apixaban case, Sandoz versus BMS, where BMS, the patentee, amended its patent to try and create step one functional features, and then the actual disease to be treated. Will this case go to Supreme Court? I know that an appeal that has been lodged to the Supreme Court seeking permission to appeal and hasn't been determined yet as far as I can tell. I think the Supreme Court will take it on that point. I will end my presentation because I think I'm out of time.

ROBIN JACOB: They're quite behind on their applications for permission to appeal. They still haven't decided SkyKicks which went in six months ago. Don't expect anything new on this soon. This is a supreme court who take their time. Q&A. Nobody's got any questions there. What do we all make of this? Is this just a complicated British problem, or is this a worldwide problem?

KEVIN MCGOUGH: I think it's very interesting to contrast the issue in Fibrogen with the enablement issue, which is now on petition to our Supreme Court. In particular, as I read the Court of Appeal decision, it struck me to be quite similar to some of the language that you see in Amgen's petition for certiorari to our Supreme Court. The issue there too relates to enablement under Unites States law, what is required?

Is enablement governed by a statutory requirement that teaches those skilled in the art to make and use the claimed invention, or must it instead be shown that it enables those skilled in the art to reach the full scope of claimed embodiments? That strikes me as a very similar issue. Interestingly, this past Monday, I noticed that our justices in the Supreme Court appear to have sought briefing from the solicitor general, so perhaps that's an indication that our Supreme Court will take this up. It struck me as somewhat similar.

ROBIN JACOB: We're all sitting around waiting for supreme courts, and of course perhaps the Enlarged Board of Appeal of the European Patent Office who are considering plausibility. A strange world where you have to apparently be right in your prediction, but it doesn't have to be a very solid prediction [laughs] Half a hint will do that it might work. I think it's ridiculous. I think we should be asking a really big question, what is best for innovation? That is the question we should be asking answering all these questions. Our commentators, are they going to join in? You're supposed to be commenting. You better comment. Hello, Eva. [laughs]

EVA EHLICH: Hello. No problem. [laughs] I guess I come from a very German point of view here. When I read that decision, it was very interesting. As a German, you are very happy with functional features. I was a little bit astonished by reading that the first decision actually disregarded the functional features, that slide that Brian showed which was just that yellow circle. Then only on the appeal, the functional features were actually taken into account. That's a little unfamiliar to my thinking. We have a German decision. This is the Dipeptidyl-Peptidase case, which was also cited by Birss, I think. He used it for his reasoning.

This is how we view it, that of course, you can define a group of substances not only by a structure but also by a function. I thought this case was not so much on the central question of plausibility because for me when I read it, it looks like that once you have included the functional feature into your thinking and claim construction, it seemed that plausibility was easy to answer. Maybe not the breadth question. There was another question about breadth, whether it's an undue burden because it's too broad and you will in your lifetime never be able to produce all of these compounds that are in there.

The plausibility in itself was no question anymore because there was a clear concept that the first functional feature would actually result in the second one. That's a very familiar thinking for me. I think it's important we have this possibility to claim by a function because, otherwise, claims will be reduced very much. If we are limited to just structure, I think that's going to be very difficult for patentees to enforce their inventions in terms of patents because then you will have to go via equivalence.

If you have a compound claim and you have to go via equivalence we know how difficult that is. I think function is very important. It's going to be a difficult debate each time whether there is a concept fit for generalization that allows such a broad concept. I think the functional language is nevertheless an important one.

JOHN RICHARDS: In the United States outside the pharma field on functionality, of course, we're still having problems as to how you construe claims which say a thing which does such and such. Again, outside pharma, with a situation where you've got to associate the thing which does such and such with something structural, otherwise, you're limited to the particular structures you've described in the specification. As I said, we haven't really had that applied to in a pharma case, at least not at the Federal Circuit level yet. It's going to be interesting how that plays out in the general question of functionality.

ROBIN JACOB: Jurgen Dressler is asking the following question. Would Richard Arnold have decided it differently if the claim hadn't got any structural feature to begin with?

BRIAN CORDERY: It's a very interesting question. There are examples of such claims like *Idenix v Gilead* where they're just purely functional. It's typical of Jurgen to ask such a challenging question, and the answer is, I suspect probably not. One of the big topics in the UK at the moment or what I think we're grappling with, although for me it's not a big issue but it seems to be amongst the community, is if you just have a claim that claims a compound, is a use implied?

That's a question we seem to be grappling with. Sorry. It's a slightly off point, but if I just claim compound X, if compound X was obvious, is the patent obvious even if it wasn't obvious to use it for a particular treatment even though that actual treatment is not in the claim, but is talked about in the specification?

ROBIN JACOB: People keep worrying about all sorts of things that have been sorted out years ago. We decided we were going to have product claims for chemicals sometime around about 1920, rather ahead of Germany actually. Once you've done that, there is a big illogicality because you claim this chemical for whatever purpose. It might be a great oil additive, but you've claimed it as a pharmaceutical. Doesn't matter. If it's old as an old oil additive, it's not new for a pharmaceutical. It's as simple as that. Principles of patent law seem to be under permanent attack.

Any more questions from the audience? No. How are we doing time-wise? We're doing quite well really. You audience, you better get your socks up and think of a few questions. Does anybody else want to add anything to this very difficult question? No. Okay. Now then, the next one is John Richards on plausibility and the Enlarged Board of Appeal, and probably more generally in the United States and around the world. It's a major question of patent law when somebody made an invention. John, you tell us. [laughs]

JOHN RICHARDS: Thank you, Robin. It's just going to be Europe and the US, I think. Following rereading the *Fibrogen* case, I just wonder whether I should change the title from plausibility to reasonable predictability, which raises the question whether those two things mean the same thing, particularly your case law in the United States which has said that mere plausibility is not enough, but hasn't really explained what you get beyond that. Then I thought, predicting the future is always a bad game, Yogi Berra or whatever, so I pull back, in which is just going to be plausibility.

The case which is going to the Enlarged Board of Appeal in the EPO is on whether additional information put into the patent office after filing can justify an

establishment of inventive step. To non-Europeans, I think the whole question of how inventive steps and plausibility come together is a bit of a mystery. It comes out of the problem and solution approach that the EPO has to assessing inventive steps and says you've got to have a solution to a problem. The case law, going back to the Johns Hopkins case, says that that includes it being plausible that what you're stating in the solution is in fact a solution to the problem. Therefore, it does kick in on the question on inventive step.

In the referral to the Enlarged Board, the appeal board in T116/18 identified three separate lines of cases in the EPO on how to deal with that question as to whether you have in fact established an inventive step by what you have in the specification in terms of either a description of what the invention is or by data. The Enlarged Board, I think the referring board indicated three particular lines of cases. Those requiring *ab initio* plausibility, those requiring no *ab initio* implausibility, and those which have said plausibility is not something to worry about at all.

In the typical case of the first group, the T1239/04, the board had held there is not enough evidence in the application to make it at least plausible that the solution was found to the problem that was purportedly solved. In the typical case in the no *ab initio* implausibility, T578/06 is the case which I selected for this, it is necessary to establish whether the ascribed activity has been made sufficiently plausible.

The board reemphasizes in this context, however, that the case law considers the establishment of plausibility only relevant when examining inventive step if the case at hand allows the substantiation of doubts about the suitability of the claimed invention to solve the technical problem addressed. Thus far from straightforward that the claimed invention solves the fundamental problem.

Then the third line, the whole thing is irrelevant. In case 231/18, the sign of argumentation appears incompatible with the assessment to inventive step according to the problem and solution approach. It can indeed not be expected from a patent applicant to include an extensive number of experimental evidence corresponding to all technical features that can possibly be claimed in the application as filed, and which can possibly cause or constitute a future invention.

Those three lines are sitting out there at the Enlarged Board I think in deciding whether you can put in additional evidence. It's going to decide what was the significance of whatever evidence, whether it's experimental data or whether it's an explanation of how the invention works in order to determine whether inventive step has been met and whether additional information can be supplied in order to complement what was in the specification as filed.

What's the position in the United States? Traditionally, we took the view that this was a utility issue and that the specification should be regarded as being credible unless there was reason not to, *In re Marzocchi*, which Judge Newman has in fact referred to fairly recently. We moved on from that. In 2010 in *Ariad v Eli Lilly*, which is the case which really established the requirements of 35 USC 112 are twofold. There's a separate written description requirement and a separate enablement requirement. The court in getting that point says that we shouldn't be

giving patents for people who have mere ideas. They got to actually perform the difficult task of invention.

In that case, it was found that the difficult task of invention had not been carried out and thus the written description requirement had not been met. Most recently on the written description side, we have BASF Plant Science against CSIRO earlier this year where the claims were to genetically modified plant cells. There were claims to plant cells in general which have been genetically modified, and claims to canola or rapeseed cells which have been genetically modified. The distinction between the two types of claims was not really brought out by the parties in the litigation, but the Federal Circuit itself sua sponte pointed out there was a difference.

The information in the specification had been sufficient to make it predictable that canola plant seeds can be modified in this way and have the desired result. It was not sufficient information in the specification for all other types of plant seeds, so they held that the broad claims to plant seeds in general lacked a written description, whereas the plant cells for canola did meet the written description requirement.

The other half of the thing which came out of Ariad that we're going to look at enablement is something different from written description grew out into the Rasmusson/SmithKline Beecham case where the Federal Circuit basically said mere plausibility that something will work is not enough for enablement. If mere possibility were the test of enablement, applicants could obtain patent rights for inventions consisting of little more than respectable guesses as their likelihood of success. Once upon a time, that was what you needed. The Supreme Court back in 1940 said you needed a flash of genius to get a patent, which I think probably was a more guess. That was it. Now we seem to have gone the other way.

In the 318 patent litigation case, the enablement issue was put to that you've got to have sufficient information in the specification for one skilled in the art infer that the stated utility would in fact be achieved. Case close to my heart so I repatented it. I think they're wrong, but I'm not sure about how I would justify that in this context. All of this leads, I think, to a number of issues that we really need to start grappling with.

We need to avoid, I think, having major differences in the approach whatever heading we use; enablement, inventive step, utility, industrial applicability, all of which pass on to this which results in people having to do different things in their applications when they file the application and possibly even file their applications at different points in drug development. That will be a disaster. Secondly, we need to take account of the fact that small pharma doesn't really have the ability or the money to go out and do vast amounts of experimental work to support its statements of expected utility.

Then we need to look at situations where the invention works, but the reason why it actually works is totally different from the reason somebody sent out in the specification should you be entitled for a patent under those circumstances. You've done something which as a result of the pattern, people invested in to develop it, but you just got the wrong reason of why it was going to work in your original application. Firstly, I would say we need to try and work out

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what exactly we mean by plausible or reasonable or predictable if those are the terms we're going to use. Then do we need to try to balance the rights between first step inventors and follow-on inventors, which was part of the discussion in the last session. I know Heinz had some thoughts on this last year. How does that tie into the plausibility of reasonable predictability balance? I hope I'm in time. Thank you.

ROBIN JACOB: Very good. Really I feel you've done a lot of work on this one. [chuckles] Anyway, Heinz, you want to chip in now?

HEINZ GODDAR: I would like to add the following: If and as long as somebody can work the patent with information therein and does not need to become inventive himself in order to exercise a basic form of the claimed invention, that is sufficient. There is no need to have anything else in the patent. If now somebody comes and adds something to this and uses some idea, which is not disclosed, not contained neither implicitly, nor explicitly in the patent then you should get a secondary "patent" on this. The secondary patent T should then have the right to exercise the secondary patent if he wishes so.

Trips provides for this. British law as well as German law article 24(2) of Patent Act gives the right to exercise this "secondary invention". If the patentee of the primary patent in this case doesn't give a license immediately, there should be, for the secondary patentee, the right to get a cross-license, which is not to be checked for public interest. It's always of public interest that then the new product, adding new ideas, new things, which are not in the primary patent, should become available to the public. This works only by cross-licensing and therefore compulsory cross-license without checking of public interest would open the way for this. The primary patent would cover also the subject matter of the secondary patent, the latter being a "dependent patent" forever, insofar.

If somebody now does something more, what is not contained in the primary patent, she/he should also get a patent on this. The two of them, i.e. primary patentee and secondary patentee would be forced by something like article 24(2) of German patent act provides for. They should cross-license. They should talk about such a solution and if they can't agree, the sovereign must have the right to force them to make the secondary product available to the public. That's my idea. I think that that one has to include information in a patent, as long as it is not publicly available data, which is necessary to exercise the patent. If there is certain information necessary to exercise a patent, where even today's manufacturers say, that you cannot exercise our patent without additional know-how, but we don't tell you, and your slot is a patent, then it is probably an invalid patent.

One should think of a trustee-controlled, "depository" for this additional know-how where somebody, like in case of biological material, would be forced to put the additional know-how not contained in a patent. That know-how, from the depository could then be made available to somebody who wishes to do experiments on the patent to find out i.g. further embodiments, like second, third, fourth indications. I think this is something that we should be thinking of --

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ROBIN JACOB: Let me just try this one along the panel. Man takes out a patent and he asks a simple question. He puts in his patent, this chemical, which is a new chemical will cure headaches. That's all he says. [chuckles]

HEINZ GODDAR: That's still a new one.

ROBIN JACOB: It's quite easy to make this chemical once what it is but currently the European patent office would refuse to patent because they say it's not plausible. Eva, what do you want to say?

EVA EHLICH: [chuckles] Thank you.

HEINZ GODDAR: You have a patent office, the boards of appeal. You have one fraction and the other one. They are fighting and waiting for God to solve this somewhere, but I'm sure that will not happen. Somewhere the courts will have to step in. I don't think so, but there is no court--

ROBIN JACOB: Let's hear what Eva has to say.

EVA EHLICH: Thank you. I'm afraid I do have a little bit of a different opinion there. I think this whole question comes out of the pharma field and it comes out of use patents. Also, we treat inventive step for product claims at the moment, the same way as we treat the use claims where the effect which is concerned with plausibility is actually part of the claim. I think the main issues come out of the use claim structure.

The first cases came out of medical application claims. There, we have to say that the essence of the invention is the effect. You wouldn't get the claim as Robin said, if you wouldn't have shown that the headache is treated, you wouldn't get a claim because the substance was old. The entire invention is actually the effect. I find it difficult that you can just put this out there without any reasoning that you had actually had this effect.

ROBIN JACOB: Let me put the case against you. It's this, it's either true or it's not, but you have no idea. The ordinary person reads this patent and says, well, I have no idea whether it clears headaches or not. People then do research and they find it does, in which case the patent has become a valuable patent. If they find it doesn't, it doesn't matter. It's not renewed and that's the end of that patent. Which is the better, that somebody gets a patent for researching. This is really what we're saying, a patent is a bit like gold perspective. You can have an area to look for, see if there's any gold in there. You look at that and you've got a certain time to find out, is it better we do that? Or better that we don't do that? I think it's better.

It's quite different if the claim is too big. If the man says well, all organic compounds will cure headaches and then that's another matter. You chuck him out cause he's old or some new class. Something with a tail more than 455 groups in it. If you have a straightforward thing, if we are thinking about humanity, because when I think that what really best for innovation that is the test we should be adopting and making it up and saying in plausibility. Which is not anywhere in any statute in the world and saying, "Well, that's the key test," seems to me to be outrageous.

EVA EHLICH: Can I answer to that? Oh, sorry.

ROBIN JACOB: Yes, go on.

KEVIN MCGOUGH: I'm sorry. I would just say that on this point, I would recommend that everyone read judge Lori's very powerful dissent last month in the Federal Circuit decision, *Biogen v Mylan* where a written description was not found to be satisfied. I'll just quote one sentence from him, "To summarize claim one is directed to a method of treating a particular disease, multiple sclerosis by administering particular compounds, DMF, or MMF at a particular dosage, 400 milligrams per day. That's precisely what the specification discloses." It was all there. Some argue that an operability criteria has now been dragged into written description.

ROBIN JACOB: I've got a few more comments coming in here. For John Richards for the plausibility discussion. Another pressure on plausibility was the increasing obligation to disclose clinical trial information in advance of the trial. Innovators, therefore need to file early. That's the problem of clinical trials. If you've got to do them before you can put a patent in because it's not plausible until you've done them. You're between a rock and a hard place.

KEVIN MCGOUGH: I agree.

EVA EHLICH: I fully agree with this, but if I follow your first approach, then, if I have a lot of money, I just file hundreds and hundreds of individual patents. I don't know whether it will work. Later on, I do the research and find out which one works. I find that also difficult. I think you would have to have something. It doesn't mean that you have to have a clinical study.

It is clear in the case law to me that the EPO doesn't require you to have human data. You just need to have something, it could even be a plausible theory, but you need to have some reason why you think this works. I'm not sure whether that's too much. I'm talking about use claims. I'm not talking about substance claims. I do think there is a certain difference because.

ROBIN JACOB: I think you might be right about-- If this was confined to use claims, I think I'm on your side much more. We had an old English case where the chap had a theory, it was all about light bulbs and they had carbon filaments and they thought the filament evaporated, and you've got dark carbon on the outside. He said, "Put tungsten instead. That will eliminate the unnecessary carbon," and actually it did work, but not for the reason the theory given in the patent. The court said, "I don't care about your theory being wrong. It works so the patent is valid." I'd rather like that but I think if the invention is a second use, there is a problem. Even so, second use is very difficult to research except with clinical trials.

EVA EHLICH: Depends. I think therefore one has to judge this each time and before the background of each case, but to have nothing I would say it is too less because that is then only putting out mere theories everywhere. If you have a lot of money, you can put out a lot of theories and that is no good for the small entities, but only good for the big entities who can afford such big filing strategy. I do think there should be something tangible disclosed in case of a use claim.

A product claim I think is different, and coming back to that plausibility referral. I think there's some indication at the end of it that there is some difference between a product claim and a use claim. The referral says it's so difficult for the European case law because we have a wealth of case law where



you could adjust actually your problem. If there's new prior art, you adjust your problem. Then you may not have the data in your case. That's right. While you can adjust your problem, you cannot change a use that you have never disclosed so this problem doesn't arise with a use claim. I think there are differences and it's probably not right that we put the issue with product and use claims always on the same level.

ROBIN JACOB: Well, I think I could live with a world where this doctrine was confined to use claims.

BRIAN CORDERY: I think as Eva said a low threshold test, just something in animals, or even a plausible theory, but I think just a use claim with nothing is a step too far for me.

ROBIN JACOB: A bridge too far for patenting. I have been asked this question, why does the additional information submitted after filing to prove the technical effect is in fact obtained. They don't actually require that, do they? All they want is additional evidence would be sufficient if it was just turned that which was said to be implausible into something that was plausible. Plausible is quite a difficult word. It's may not translate very well, but it means believable, supposing this patent is taken out by a Nobel top prize winner. Is it more believable than if it's taken out by Joe Soap?

JOHN RICHARDS: Can I just come back to the facts of my 318 case. We had no data in the application, we had some tests going on, animal tests as treatment of Alzheimer's, which has not been competed for the patent office, granted the patents. We never got to put them into the record, which the federal circuit criticized, I'm not quite sure why. I did the actual search on this before we filed the application. There were few references to the compounding question in recovery from anesthesia in Eastern Europe. There has been a trial for it in polio, but that was about it. I think I got four references out of chemical abstracts.

After patent came out, there were hundreds of papers coming out, quoting the patent and it opened a whole new area of research, which is still going on. There was something in the BBC news the other day about growing daffodils in Wales to produce that compound for treatment of Alzheimer's disease. There it was to the real world credible, it just wasn't credible to the federal circuit.

ROBIN JACOB: Well, I think we better move on now. I see we've got about 20 minutes left. We better have Heinz telling us whether the change in law in Germany is a major subject transforming German law into an E-Bay country, or whether in fact, it's not going to make any difference at all except in the most extreme places or is it going to be something in between?

HEINZ GODDAR: Thank you so much. I would like to restrict myself to only one observation and you will see this when you look at the slides, which Melanie, my partner, and also doctrine on this subject at Bremen University will talk about in detail. You look at her slides, you find a question mark. After on the way to E-Bay scenario in Germany, question mark. [crosstalk]

ROBIN JACOB: Stop, We haven't got her slides. How are we going to do that? Melanie?

HEINZ GODDAR: Melanie, you will put up?

MELANIE MULLER: One moment. Can you see them?

HEINZ GODDAR: You will see there's a big question mark, very important and in the printed program, there's no question mark anymore. It seems to me that in our whole presentation, which Melanie will now give, there should be a question mark or not? Are we on the way to E-Bay, and what does this mean? I would like to leave it entirely to you, Melanie. I know that the time is very short, six minutes to develop your wonderful observation of what this new law in Germany could mean, should mean, and what actually the legislator had in mind. We will see. I would like to leave it really to Melanie and I think it'll be exciting. Thank you.

MELANIE MULLER: Thank you, Heinz. I will now start with the current developments in our German patent law, which are raised by the second patent modernization act, which entered into force last year's summer and which concerned injunctive relief, which was now modified. As you know the German practice is characterized by the quasi-automatic injunctive relief, which was granted in patent law infringement cases because objections such as the disproportionality or the good faith objection, quasi never have been successful, never been granted by the courts. This granting of a quasi-automatism is not appropriate to the recent developments in our technical sectors, especially in the automotive sectors or smartphone technologies.

Nevertheless, there has never been a rethinking from the sides of the courts, the Bundesgerichtshof (our federal court of justice) stated this in the Wärmetauscher decision in 2016. The result was that our legislator was obliged to act and therefore the second patent modernization act came into force and changed our legal norm, which regulates the injunctive relief under section 139 German patent Act; which entered into force on August the 18th of 2021.

When we take a look at the wording of our legal norm now, which regulates the injunctive relief under para 1, we can see that the sentences one and two are still the same. What is new are the edited sentences three and four. Sentence three includes now the objection of disproportionality and sentence four, now the claim for compensation. When we compare the conditions of the injunctive relief before the second patent modernization act and after it, we can see that the conditions are still the same. What is needed is a patent infringement and the risk of repetition or risk of a first infringement act.

The new included sentence three, which means the proportionality test, which is marked in red, as you can see, is or has to be dogmatically qualified as an objection. Technically an objection is a German instrument, which has to be noticed by the court ex-officio. This means also that the burden of proof lies on the infringer. The infringer must present all relevant facts to the court which are necessary to make a decision on the disproportionality. It has also been noted that the disproportionality test under sentence three is an exception. This follows from the wording.

Disproportionality has been ruled out by making a balancing of interest between the interests of the patent holder and the one side and the infringer or third parties on the other side. Relevant factors there could be, whether they're on the side of the patent holder, whether he's practicing entity or non-practice entity, or even a patent role. His subjective elements, or his impending damages, which

would result out of this patent infringement and the economic importance of the patent for his product.

On the side of the infringer, there are always also subjective elements relevant. For example, if it was impossible for him to avoid the infringement act. For example, if there are patent tickets and there was factually no possibility to make a freedom to operate analyze. On the other hand, it could be relevant if there are SEPs involved, but it could be difficult to determine the relationship between the SEP's objection and the disproportionality objection. But there is room for the disproportionality objection because there could be cases where the conditions of an SEP are not fulfilled, then the section 139 could become relevant.

Also, impending damages could be from importance and also negative or potential negative prognose about the continuance of the patent. Also, third party's interests could be relevant if there are fundamental rights and this could be on the one side medications on the other side essential infrastructure.

The results of the exclusion of the injunctive relief because of disproportionality are that the patent infringement still remains unlawful. The wording which says "insofar" allows us to exclude the injunctive relief only partially. On the other side, it's also possible to make a permanent exclusion of injunctive relief, but it can only be the case for an ultima ratio which means when the patent is about to expire for example.

Now, we come to the big question, whether we have an approach to the US law? Especially to the jurisdiction of the E-Bay situation. Regarding the E-Bay case, there's a Four Factor Test needed, which means that the patent holder must show that the following four conditions I brought down are fulfilled. As you can see by noticing my explanation the German system is different. The burden of proof for the patent holder in Germany is just about two conditions, the patent infringement and the expectation that another infringement will happen.

The objection of disproportionality there a burden of proof lies on the infringer - not on the plaintiff, not on the patent holder. We have a completely different system which excludes an approach to the US law. What is also important to note is the new edited compensation claim I mentioned under sentence four of the German patent act. This is a claim sui generis and an absolute novum under our German law because it is a claim which can run parallel to the claim for damages, which means during the same time period.

We have the problem that we have no strict rules about the calculation or the assessment of such a compensation amount. According to the wording, it's only an adequate compensation in money, but what does this mean? The starting point for the calculation could be the license analogy and after the determination of this amount we can make considerations in the adequacy, which means we could take into count increasing factors or decreasing factors. For example, increasing factors could be if the infringer acted willingful. He wanted to cause a damage to the patent holder.

Decreasing factors, for example, could be if there's an existing patent thicket and the infringer had no chance to avoid this infringement or if the patent owner or patent holder is a non-practicing entity and he just wanted to achieve a production stop so he wanted to cause a damage for the infringer. What my

question is, in these cases, could it be relevant to create factors like in Georgia-Pacific to provide for legal clarity and certainty? I finished with my overview and thank you for your attention.

ROBIN JACOB: Thank you very much, Melanie.

MELANIE MULLER: Thank you.

ROBIN JACOB: Can we get back to seeing you now. We've --

MELANIE MULLER: I try to stop it now. Yes.

ROBIN JACOB: Yes, it's funny.

MELANIE MULLER: Thanks.

ROBIN JACOB: Where does one see that? First of all, let's keep the Germans out of this. Do we think this change in German law, we're not Germans, think it's a good idea? What do you think Kevin?

KEVIN MCGOUGH: I'm actually not clear of how much of a difference it is to the existing German law. One question I do have for Melanie and for Heinz is really what is the practical effect on a non-practicing entity. Then secondly, just an observation with respect to E-Bay and where that stands, there's a great 2015 law review article by a Professor Zeman in the Iowa Law Review, where as of 2015 he looked at the effect of E-Bay on preliminary injunctions in the United States.

What really drives the data is whether or not the defendant is a non-practicing entity. E-Bay is not the prohibition against preliminary injunctions that a lot think it is. Finally, I'll just mention there's a great decision from the Northern District of California two weeks ago in Illumina v BGI, where the district court does a nice job lining up what it takes to get an injunction under E-Bay and it gives you some practical insights. Those are just quick thoughts.

ROBIN JACOB: Mel?

MELANIE MULLER: First of all, I would like to add as I've said, the construction of this legal norm as an absolute exception means that there will not be such a big difference from the situation we had before. Because our legislature wanted that this is a situation of an absolutely exceptional case. The other aspect I would like to mention is what we could expect is that procedures could be extended and become more costly because now we have to determine the damages in injunctive relief cases, which mean we need experts and they are very costly for example.

To the point with the NPEs, in my point of view, NPEs should not be per se a criteria to say that the interests of the patent holder are lesser because even the NPE could have substantial interest and not practicing, for example, universities or others. They have even their intellectual property right which is protected under German law so far.

ROBIN JACOB: Eva, How about now? What do you think is going to happen? Is this going to be raised in every case in Germany or is it in fact going to turn out to be an exception.

EVA EHLICH: Asking--

HEINZ GODDAR: Go ahead.

EVA EHLICH: No, no, no, please.

ROBIN JACOB: Eva goes first.

HEINZ GODDAR: I would just like to add one thing. The point is this is one of the very few laws, I think in Germany where this was to look into the materials, why the law was made. If the German courts, the first instance courts, if they would've applied German culture since 2016 properly with the necessary diligence, no problem, but a certain class "group" of German first instance courts didn't apply at all. They did not just use it.

They were not looking at this proportionality. I remember when Law Justice Arnold said publicly in a lecture in German University about three years ago, "Germany is permanently violating what ECJ wishes to happen. There should be a proportionality look according to the enforcement directive, but the courts did not. The intention of the "materials" of the new law, as you can see this from the first draft of the Ministry of Justice, has been to solve also the questions of third parties' interests

ROBIN JACOB: Eva, here you go.

EVA EHLICH: I'm German, you asked me because I'm also German?

ROBIN JACOB: Yes.

EVA EHLICH: I don't see that there's so much excitement about it, but that may also be because I'm not from the automotive area where this resulted from. I'm more from the pharma medical area, and I do see that there is some application in this area as well, because there can be situations where you are under constraints. We always have this very difficult interlink between regulatory law and patent law, which kind of collides sometimes with second medical indication claims in particular. There could be constraints because an infringer doesn't have the complete control over his product leaflet or the SmPC which is governed by regulatory law. He/she may not be able to avoid infringement for a small part of its label.

I think there is some applicability. We do have compulsory license law. I don't think that helps anyone here because that's really restricted to very, very few cases and I think that's good and we shouldn't change that too much. I think a proportionality consideration can be helpful but as Melanie actually said it must be the exception where an enforcement of an injunction would actually lead to over rewarding the patentee.

ROBIN JACOB: Yes. Well, that's quite complicated when you say over rewarding. I own a strip of land. Everybody else around has sold to the big developer, but I won't sell. I've just got two meters by two meters square. And if he wants to buy me out, I can charge him a lot of money. Am I being over-rewarded? [chuckles] What is over-rewarded?

EVA EHLICH: Well, when I think over rewarded, I'm thinking if a second medical use patent just concerns a very small part of a label. A little subject group or you can think of a little aspect, should this then stop the entire product because you can't take it out of your label?

ROBIN JACOB: It's always second medical uses which cause the trouble, isn't it?

EVA EHLICH: It is.

JOHN RICHARDS: Surely, the remedy to this is to look at exactly what we can do with skinny labels and get that law right.

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EVA EHLICH: Yes, but that's only available to my knowledge, for a generic situation but not for an originator.

ROBIN JACOB: The problem with the second medical use is whether it's generics or not, it doesn't matter. It ought to be a separate branch of law and taken out of ordinary patent law altogether, but it isn't.

EVA EHLICH: Yes, I think we need to align regulatory law with the patent law here.

ROBIN JACOB: Yes.

JOHN RICHARDS: Yes.

ROBIN JACOB: I'm going to tell you what I thought was quite a good joke and I wrote in an article a few years back. When the general view in Germany was patent infringed injunction. Automatic. So I said to a friend of mine: "Well what happens if it's a medicine and the big factory has burnt down. The patentee factory has burnt down. And there are all these patients out there, no compulsory license. It's still an injunction." I said, "It's a bit like George Bernard Shaw sitting next to a lady at dinner." And he turned to her and said, "Would you sleep with me for a million pounds?" And she thought, "Maybe." He said, "How about a shilling?" She said, "What do you take me for?" He said, "We've already established the principle."

[laughter]

And that's true. If you're going to have an exception to injunctions it's got to be very narrow. But I think nearly always it's got to be a third party, like patients.

JOHN RICHARDS: I think there are two aspects, there's the public interest issue where an injunction would not be appropriate. The city of Milwaukee, pumping sludge into Lake Michigan is the classic US example. And the other is where we just don't think it's fair, that somebody who is really just using a patent as a sword rather of a shield to defend its own investment, could hold the rest of the world up to ransom. They're two different issues.

ROBIN JACOB: Well, perhaps they are. I'm not entirely sure the second one is. You are holding the world to ransom with your patent, that's what they're for. [chuckles]

JOHN RICHARDS: I said but a lot of people perceive that as being unfair. And that's the thing which we need to get scripted.

PETER CHARLETON: Could I perhaps make a-

ROBIN JACOB: Yes, yes, please, Peter.

PETER CHARLETON: Yes, a brief comment. Robin, both you and I would have sat on the bench as first instance judges doing injunction cases. You can set out these four tests, as in the American case, or can you set them out as an American cyanamide. But if you're actually a trial judge and you're sitting there, there are so many variable factors it becomes like the Chancellor's foot. It becomes what's the right thing to do in these particular circumstances. And you get any number of criteria you want, but really they fall aside in terms of actually looking at the thing.

Now, by the Germans introducing balance into it, it seems to me there's a discretionary element introduced but without the existing tests in American law,

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English law, Irish law, that are there, that perhaps will guide people who are advising clients toward some kind of prediction as to results. So this is something that working out of which we just won't know. But what German law has done it seems to me, is put power into the hands of judges.

ROBIN JACOB: Okay folks, our time is up.