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**SESSION 8: COMPETITION AND PATENT LAW
8B. *Supplementary Protection Certificates***

Moderator:

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Speakers:

Marleen H.J. van den Horst

*BarentsKrans, The Hague
SPC Reform in the EU*

Laëtitia Bénard

*Allen & Overy LLP, Paris
Recent Developments on SPCs*

Brian W. Gray

*Brian Gray Law, Toronto
Canada's Certificates of Supplementary Protection: One Year Later*

Panelists:

Jürgen Dressel

Novartis Pharma AG (Ret.), Basel

Hans van Walderveen

District Court The Hague, The Hague

Tom Mitcheson

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MR. JÜNGST: Good afternoon. My name is Oliver Jüngst. Welcome to the Supplementary Protection Certificate (SPC) session.

I am delighted to introduce the speakers and the panel: Marleen van den Horst with BarentsKrans in the Netherlands; Laëtitia Bénard from Allen & Overy in Paris; Brian Gray, a Partner in his own law firm in Toronto; Jürgen Dressel, who recently retired from his work at Novartis; Hans van Walderveen, a Judge at the District Court in The Hague; and, last but not least, Tom Mitcheson, a barrister in London.

We will have our three speakers give their short presentations without an interruption in order to allow better discussion and more time for the panelists and the audience to involve themselves after the presentations have been given.

Without further ado, I would like Marleen to start with her presentation.

MS. VAN DEN HORST: Thank you, Oliver.

I will talk about SPC reform in the European Union, especially focusing on the Max Planck Institute (MPI) *Study and Annexes on the Legal Aspects of Supplementary Protection Certificates in the EU*,¹ a study ordered by the European Commission that resulted in thirty-three recommendations, which I will briefly discuss, and also the response of the European Commission thereto. I will pay extra attention to the SPC manufacturing waiver and say only a few words about the Unitary SPC.

The MPI report was published 28 May 2018. It is 700 pages long and has seven annexes. It was a tremendous study that focused on a legal analysis of the EU SPC system. The analysis was done on the basis of the caselaw of the Court of Justice of the European Union (CJEU), the national courts, and on the decisions to grant in the practice of the national patent offices (NPOs). As part of the legal analysis there was also a fact-finding study. It was a thorough consultation of all the stakeholders using interviews, an online survey, questionnaires, and two seminars. On the basis of all of that, MPI came with thirty-three recommendations, which I would like to summarize for you as follows.

- Consolidate the Medicinal Products Regulation by incorporating provisions from the Plant Protection Products Regulation.
- Distinguish medicinal products for human and for veterinary use either by splitting the Regulation into two or by treating them explicitly as different products.
- Clarify definitions, amongst which is the concept of the marketing authorization.
- Most importantly, and repeatedly given as a recommendation, is to close the gap between the wording of Article 3(a)–3(d) of the Regulation and CJEU case law.
- Clarify whether any patentee or only a patentee who obtained marketing authorization is entitled to an SPC, the third-party problems.
- Allow SPCs for new active substances used in drug/medical device combination.
- Provide for a SPC manufacturing waiver.
- Adopt a uniform *Bolar* exemption in light of the Unified Patent Court Agreement (UPCA).
- Further unification of procedural aspects of SPCs granted by the NPOs.
- Lastly, create a system for granting unitary SPCs.

According to the MPI, the purpose of the SPC legislation was to compensate patent holders for the time lost in obtaining regulatory approval for products containing *new* active substances. The original intention of lawmakers was to grant one SPC per product or combination authorized for the first time.

The MPI continued that the CJEU had by teleological interpretation extended the scope to more SPCs per product, SPCs for new formulations, second medical indications,

¹ *Study and Annexes on the Legal Aspects of Supplementary Protection Certificates in the EU*, MAX PLANCK INST. (May 28, 2018), <https://ec.europa.eu/docsroom/documents/29524>.

and not insisting on the first marketing authorization. According to the MPI, this calls for political decision-making.

If you look at the thirty-three recommendations, how should they be achieved; what should be done with them? According to MPI, they should lead to an amendment of the Regulation as such and/or to the European Commission issuing implementing regulations, and ultimately to providing “soft law” in the form of guidelines. In my opinion, soft law in the form of guidelines is quite questionable because what is the status, what is the weight, that guidelines carry?

The response of the European Commission by Alfonso Calles Sanchez was quite appalling. In a seminar in November last year where the findings and the study of the MPI were discussed by stakeholders and the Commission, it became clear that the Commission was only willing to pick up on one item, and that is the manufacturing waiver, and actually made clear that it was not going to do anything with the study. This is appalling if you think about the fact that they ordered this study and for one and a half years all stakeholders participated. But it is as it is.

Now let us turn to one thing that has been successfully taken up, the SPC manufacturing waiver. The legislative proposal was adopted by the European Parliament last week, on 17 April, and the Regulation amending Regulation 469/2009 is expected to enter into force in July this year.²

If we look at the proposal as adopted, the SPC manufacturing waiver is an exception to SPC exclusivity that allows for the manufacturer of medicinal products for export to non-EU countries to stockpile in the European Union for six months prior to the expiry of the SPC and for any related acts that are necessary in the preparation thereof.

But it is regulated quite strictly, also to keep transparency and protect the rights of the SPC holders. The manufacturer is required to:

- File a notification (standard form which is also published with the proposal) three months prior to starting the manufacture of the product either for export or for stockpiling or for both objectives. This should be filed at the NPO in the Member State(s) where these preparatory actions or manufacture are going to take place.
- Not only should it be filed at the NPO, also the SPC holder should be notified and be kept updated on all the developments related thereto.
- Products that are intended for export should be explicitly labeled as such and there is a special logo that should be applied on the packaging of those products.
- Moreover, the manufacturer of the products has to ensure that there is documented evidence of its due diligence to inform its supply chain (the storage house or the exporter) so that they are aware of the conditions of the waiver and that they comply.

There are also obligations for the NPOs to publish the notification and updates as soon as possible.

Something new is that the European Commission has the task to carry out regular evaluations (every five years) of whether the effects and goals of this manufacturing waiver are indeed achieved.

To finalize my presentation, when does it enter into force? The waiver applies to new SPC applications and to SPCs entering into force three years after the Regulation takes effect.

Thank you.

² Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, 2019 O.J. (L 153) 1.

MR. JÜNGST: Thank you, Marleen.

Laëtitia, please.

MS. BÉNARD: I will be talking about the case law in the last twelve months. A lot has happened in the SPC field, which is not surprising because we say the same every year.

The CJEU has issued two important decisions, one in July 2018 in the *Gilead* case³ and one in March 2019 in the *Abraxis* case.⁴

There are also two interesting referrals: one from the Paris Court of Appeals, which is the first referral ever from France on the SPC Regulation, as to the correct interpretation of the *Neurim*⁵ decision; and another referral from the U.K. courts — which was thought to be the last one before Brexit, but because Brexit keeps not happening, I guess there is still time for an additional referral — on the third-party SPCs.

Given the limited time that I have, I have chosen to focus on the *Teva v. Gilead* decision and the impact of the CJEU's decision in Europe.

Let me remind you of the facts. Gilead holds a patent covering tenofovir for the treatment of HIV and a marketing authorization for a combination product of tenofovir plus emtricitabine. Gilead obtained an SPC for this combination on the basis of a claim covering tenofovir and “optionally other therapeutic ingredients.”

There are two factual differences compared to the *Sanofi*⁶ case. Gilead did not have another SPC for tenofovir alone because the marketing authorization for tenofovir was quickly granted within the first five years of the patent protection. The second difference is that emtricitabine, the second active ingredient of the combination, was discovered after the filing of the patent.

This was, however, not the reason for the referral. Indeed, in the framework of a revocation action brought by Teva in the United Kingdom, the U.K. court stated as follows:

The referring court takes the view that, notwithstanding the judgments delivered by the Court on interpretation of Article 3(a) of Regulation No 469/2009, the meaning to be given to that provision remains unclear.

That court states that, admittedly, it is clear from the Court's case-law that the concept of a “product protected by a basic patent” within the meaning of Article 3(a) of Regulation No 469/2009 refers to the rules governing the extent of protection, not the rules governing infringement.

Nevertheless, the judgments of 12 December 2013, *Actavis Group PTC and Actavis UK* (C 443/12, EU:C:2013:833), of 12 December 2013, *Eli Lilly and Company* (C 493/12, EU:C:2013:835), and of 12 March 2015, *Actavis Group PTC and Actavis UK* (C 577/13, EU:C:2015:165) imply that the principles described in the preceding paragraph are not sufficient for the purposes of determining whether a “product is protected by a basic patent in force” and that it is also necessary to take into account the “subject-matter of the invention covered by the patent” or the “core inventive advance” of the patent. The referring court takes the view that it is not clear

³ Case C-121/17, *Teva UK Ltd. V Gilead Sciences Inc.*, EU:C:2018:585 (July 25, 2018).

⁴ Case C-443/17, *Abraxis Bioscience LLC v Comptroller Gen. of Patents*, ECLI:EU:C:2019:238 (Mar. 21, 2019).

⁵ Case C-130/11, *Neurim Pharm. Ltd v Comptroller-Gen. of Patents*, ECLI:EU:C:2012:489 (July 19, 2012).

⁶ Case C-443/12, *Actavis Group PTC EHF and Actavis UK Ltd v Sanofi*, ECLI:EU:C:2013:833 (Dec. 12, 2013).

from that case-law whether those requirements are relevant for the purposes of the interpretation of Article 3(a) of Regulation No 469/2009.⁷

So the U.K. court sought clarification in that respect.

The *Gilead* case was heard by the Grand Chamber of the CJEU, which is the first time ever the Grand Chamber of the CJEU decided to hear a matter relating to the SPC Regulation.

At the hearing, it was said that “the intention of the Court was to clarify once and for all Article 3(a).” We will examine whether this is the case, and you can guess what the response is.

In this decision the CJEU set out two distinct factual situations in which Article 3(a) is met: a product cannot be considered protected by a basic patent enforced within the meaning of Article 3(a) of the Regulation unless the product which is the subject of the SPC is (a) either expressly mentioned in the claims of the patent; or (b) those claims relate to that product necessarily and specifically.

So there are two different factual situations. The first one is when the claims expressly mention the product; in that case Article 3(a) is immediately satisfied. The other situation is when the product is not expressly mentioned, the claims need to relate to the product necessarily and specifically.

To assess the second situation the Court said for that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent, the combination of those active ingredients must (1) necessarily, in the light of the description and drawings of that patent, fall under the invention covered by the patent; and (2) each of those active ingredients must be specifically identifiable in the light of all the information disclosed by the patent.

So the question is: has the CJEU achieved its objective? Is it settled once and for all? I’m afraid not at all if one looks at the decisions that have been issued by the national courts in Europe since then.

I would like to point out one particular case concerning an SPC owned by Merck covering the combination of ezetimibe and simvastatin, this combination being expressly claimed in one of the claims of the patent. For the sake of transparency, I have been representing Merck in France in that case.

This SPC has been litigated in thirteen countries in Europe. In most of the countries the SPC was deemed valid or *prima facie* valid in preliminary injunction actions, but there are several jurisdictions which ruled in the exact opposite way. Let’s have a look at what has been said in France, Germany, and the Netherlands.

In a decision on the merits in France, the Paris First Instance Court found the SPC valid in view of the *Gilead* decision. It also issued several preliminary injunction decisions removing the generics from the market and expressly said that “the Court of Justice does not impose in view of *Gilead* any additional requirement according to which the two active ingredients or their combination should be an invention of the basic patent or that the combination should be the subject matter of the invention.”

The French court said that the *Gilead* decision may be regarded as “a reversal by the Court of Justice of its prior *Sanofi* decision,” and it added that in that case the defendant argued that given that *Gilead* only relates to Article 3(a), it did not have any impact on Article 3(c). The French court said, “No, the court cannot agree with this analysis, which would lead to admitting two different definitions of the product within the same article, which is clearly excluded by the glossary of the Regulation.”

⁷ Case C-121/17, Teva UK Ltd. V Gilead Sciences Inc., EU:C:2018:585 (July 25, 2018).

The Düsseldorf Court of Appeal ruled in a different way. It said that yes, Article 3(a) is met but Article 3(c) is not met, and the court said that the CJEU's preliminary decision in *Teva v. Gilead* says nothing on this.⁸ It was issued exclusively with regard to Article 3(a) and for this reason alone is of no significance for the interpretation of Article 3(c). So an exact opposite ruling compared to the French court.

Finally, The Hague Court of Appeal reached the same conclusion as the German court but with a totally different reasoning, saying that even if the combination is expressly claimed, it does not meet the requirement of Article 3.⁹

I find it really concerning to see that after this decision from the CJEU was issued by the Grand Chamber — which was supposed to settle Article 3(a) once and for all — we are seeing such diverging decisions in Europe.

MR. JÜNGST: Thank you, Laëtitia. Indeed the last one is a very interesting case. Laëtitia and I have been presenting different sides of this and we have both been successful. So good news.

To add another layer of complexity, not only the various national courts that Laëtitia has mentioned — Germany in particular, very close to our friends from the Netherlands; in France it was decided differently — but even in the Austrian Oberlandesgericht, the Commercial Court, different chambers have decided differently in the very same case. So you can see that this is really a complex issue.

Brian?

MR. GRAY: Thank you. Now Canada has entered the weird and wonderful world of patent term extension. I'm not so sure I'm looking forward to it.

Canada was dragged kicking and screaming into the patent term extension system. It was the last of the G7 countries to do so, and it was really forced to do so as part of the Canada-European Union Comprehensive Economic and Trade Agreement (CETA). It came into force on September 21, 2017.

Just to complicate things, we call it a Certificate of Supplementary Protection (CSP), not the Supplementary Protection Certificate (SPC), but it is the same thing.

The provisions are similar because they were in fact negotiated as part CETA, so the European SPC Regulations were largely adopted.

There are a couple of significant differences.

- The extension was capped at two years.
- The other significant difference is very unusual: you must file the CSP within one year of the first regulatory submission for the medicinal ingredient or combination in the European Union or any Member State thereof, or the United States, Australia, Switzerland, or Japan. So it is an unusual one-year requirement that does not exist in Europe or anywhere else as far as I understand.

- The other unusual thing is that you can only have one CSP for each drug product no matter how many patents or patentees there are, which may result in some competing applications, and there is a bizarre system for determining priority of competing patent term extensions.

I would like to speak now about two rejections that are currently under judicial review. I am not going to say anything more about the specifics of our system.

⁸ Landgericht Düsseldorf [District Court of Düsseldorf] Oct. 1, 2018, Merck Sharp & Dohme Corp. vs. ratiopharm GmbH et al., 4b O 39/18 (Ger.).

⁹ Gerechtshof [The Hague Court of Appeal] Oct. 23, 2018, Merck Sharp & Dohme Corp. / Teva Nederland B.V., Pharmachemie B.V. and Centrafarm B.V., C/09/552040 (Neth.).

The first of the rejections relates to a GlaxoSmithKline (GSK) application for the vaccine SHINGRIX. SHINGRIX, as you may know, is a suspension containing varicella-zoster vir glycoprotein E (gE antigen) adjuvanted with GSK AS01a adjuvant.

Actually the patent was relating to the commercial product. This is a thing that as a patent attorney I have difficulty understanding. I can sort of understand sometimes when the claims seem to expand beyond what was invented maybe, but in this case the claim was for the commercial product, which was the active ingredient, the gE antigen, along with an adjuvant.

But the Minister rejected this on the basis that it didn't contain an eligible claim under the regulations. The Minister determined that the medicinal ingredient in SHINGRIX is limited to one medicinal ingredient, the gE antigen, and the adjuvant is non-medicinal. Therefore, notwithstanding that the claim was directed to a commercial product, the product that was specifically marketed, nevertheless the Minister has so far denied the SPC for this product.

This is like the situation as I understand it in Europe for a similar GSK vaccine that was adjuvanted in the case CJEU C-210/13.¹⁰ That application was also rejected.

But I ask myself as a naïve patent attorney, an ingenué in the area of patent term extension, why a patent claim that is directed to the commercial product should be denied protection because it has a non-medicinal ingredient in it, where in fact the claim is not actually extending beyond the monopoly because the claim is directed to the medicinal ingredient and a non-medicinal ingredient in combination, so that by extending it is not going to interfere with any monopoly of anyone else unreasonably.

The next case I want to talk about is relevant to this provision, which is also, I believe, a provision similar to the provision in the European Union, which is the question of the scope of a CSP. It has the same rights as a patent — this is the quote from the Canadian law but I believe that at least the principles are similar in the European Union — “only with respect to the making, constructing, using and selling of any drug that contains the medicinal ingredient or combination of medicinal ingredients, set out in the certificate, by itself or in addition to any other medicinal ingredient.”

This seems to suggest that the scope of a CSP is limited, but it also is limited to the combination when used by itself or in addition to any other medicinal ingredients. Therefore, one would think that a combination similar to the one in the *Teva v. Gilead* case should be extended.

But, aha! There is a second judicial application that is now under review in the Federal Court of Canada, *ViiV Healthcare v. the Minister of Health*.¹¹ This case involves two owners that both had patented medicinal ingredients; ViiV had one and Janssen in partnership with a Japanese company had the other. So each party had its own patented medicinal ingredient. They marketed the product as JULUCA®, a combination of dolutegravir and rilpivirine.

It is similar to the problem in *Teva v. Gilead*. In this case it was a combination of two active ingredients and there was no claim to the combination. However, both of the combined ingredients were individually patented. So I ask myself again: Is it right to not allow a patent term extension for that product?

I am reminded of Mr. Justice Arnold's statement in the *Gilead* case. He was asking himself what the CJEU intended in the *Teva v. Gilead* decision. He said, “What the Court is saying is that the purpose of the SPC Regulation is to enable the holder of the basic

¹⁰ Case C-210/13, Glaxosmithkline Biologicals SA v Comptroller Gen. of Patents, ECLI:EU:C:2013:762 (Nov. 14, 2013).

¹¹ *ViiV Healthcare v. the Minister of Health*, [2019] T-353-19 (Can.).

patent to obtain supplementary protection for what the patentee actually invented and not for what the patentee did not invent.”

Well, it is hard to disagree with that, but I thought that claims were in fact written to cover what the patentee actually invented. So I find it difficult. I find the system now is not protecting what the patentee actually invented. I understand this disjuncture between patent claims and approved products, and we’ve got to fix it.

Now, unfortunately, in Canada, because we copied your darn European rules, we have the same problems now ourselves that we have to sort out. I hope that you guys can sort it out for us.

Thank you.

MR. JÜNGST: I’m not so sure. Thank you, Brian.

I loved the reaction of parts of the audience when the term “Brexit” was used. I am tempted to say it again.

Tom, what is the current state of play regarding referrals from the United Kingdom? We know that the U.K. courts have referred quite a few cases to the CJEU. Is there still something going on?

MR. MITCHESON: There is. Richard Arnold referred a case in February, and he did it in record time, because at that stage there was still a risk that the United Kingdom would leave on the 29th of March. Thankfully, we didn’t. But, in case we were going to, he ordered the parties to come to court, agree on the question, and get it off to the CJEU in record time, so that the reference was in. This is the reference in the *Genentech v. Lilly* case¹² about third parties. So, at least while Richard Arnold is still a judge, there will be references made regularly by the United Kingdom to the CJEU.

Before we open up to the floor, I would like to perhaps explore why there is so little harmonization and why there is such dissatisfaction with the CJEU’s caselaw on SPCs. I think there are three interrelated reasons.

First of all, the drafters of the legislation way back didn’t have many of the issues which are now causing difficulties in European courts in their minds when they drafted the legislation. They didn’t think about combinations or vaccines; they didn’t think about the third-party issue; and they didn’t think about biologics in functional claims because all they had at that time were small molecules. That is the first problem.

Second, I think the CJEU suffers because it has to deal with these matters on a piecemeal basis only. The judges are not familiar with patent law, there is no EU patent yet, and the CJEU is a bit like a supertanker — it has difficulty changing its view on things. It won’t cast aside old judgments even if the Advocate General says, as it did in the recent *Abraxis* case, that the *Neurim* decision was wrong. It refuses to change course. This causes it problems.

For instance, in the *Medeva* case,¹³ which is perhaps the origin of many of the difficulties we have under Article 3(a), one of the options for the Court was to have an infringement test for Article 3(a) and then a narrow test under Article 3(b). That would have solved many of the problems that the courts face at the moment.

But because there’s a previous decision, the *Farmitalia* decision,¹⁴ where Article 3(b) had been held to be broadly construed, the CJEU had to go down the other route and select a more restrictive interpretation of Article 3(a). Instead of a simple infringement test,

¹² Case C-239/19, *Eli Lilly and Co. v. Genentech Inc.*, ECLI:EU:C:2019:687 (Sept. 5, 2019).

¹³ Case C-322/10, *Medeva BV v. Comptroller Gen. of Patents*, ECLI:EU:C:2011:773 (Nov. 24, 2011).

¹⁴ Case C-392/97, *Farmitalia Carlo Erba Srl*, 1999 E.C.R. I-05553.

we now have all the difficulties with the wording of the various judgments, and that is a problem that we all have to grapple with.

Finally — and this is reflected, I think, in the Max Planck report, which if you haven't looked at I would urge you to do so — many of these issues are not really issues for the judges, the poor judges who have to interpret the legislation; they are policy issues and they should have been dealt with in the legislation originally and they should be dealt with in a revision of the legislation.

One of the judges in the CJEU's *Lilly v. HGS*¹⁵ hearing asked the Commission, "When are you bringing forward the new legislation?" The Commission had no answer then and it still has no answer.

All we have is the minor change for the manufacturing waiver. We have none of the additional improvements which the Max Planck Institute report commissioned by the Commission has suggested.

Until we get that wholesale reform of the legislation, I don't think it is possible for the poor judges to square the circle and come up with a solution based on the current wording of the legislation.

A unitary patent will help. A unitary SPC will help. Until we have reform, we are likely to be having these meetings year after year and discussing the difficulties and the lack of harmonization across Europe because it is an impossible task with the legislation that we currently have.

Anyway, I'll be interested to hear what other people think about that.

MR. JÜNGST: Thank you, Tom.

Brian, I think that was in response to your question. Have we sorted out things for Canada? Probably not, not yet.

Laëtitia mentioned, absolutely rightly so, that the *Teva v. Gilead* case was decided by the Grand Chamber, which is not often the case, and that there was hope, I understand, that now things at least regarding Article 3(a) of the Regulation 469/2009 are sorted out.

Hans, you reacted to that. Is that not your view? Are there still other open questions?

JUDGE VAN WALDERVEEN: I agree with Laëtitia that it is not that clear yet, as apparently the CJEU thought that it would be. I have two issues.

This poor judge was drafting his judgment in the *Searle v. Sandoz*¹⁶ darunavir case during the Christmas period. That is the same case was dealt with by Mr. Justice Arnold in the U.K. High Court and by the U.K. Court of Appeal, which referred a question to the CJEU.

At that time I only had *Gilead* because *Abraxis* was rendered later in February and my judgment is from January 8th, so I had to reread and to rethink the *Gilead* case. It says, as I understand it — and that's what I decided in summary proceedings, and I have learned that no appeal has been filed — they use a two-step test:

(1) They require that if the active ingredient is not expressly mentioned in the claims of the basic patent, then one of those claims must relate to it "implicitly but necessarily and specifically." What that means — nobody knows. That is one of the open questions.

¹⁵ Case C-493/12, *Eli Lilly and Co. v. Human Genome Sciences Inc.*, ECLI:EU:C:2013:835 (Dec. 12, 2013).

¹⁶ *Rechtbank Den Haag* [District Court of the Hague], Jan. 8, 2019, *G.D. Searle v. Sandoz B.V.*, C/09/56199 (Neth.).

(2) The Court goes on and says that “[f]or that purpose, the active ingredient must, from the point of view of a person skilled in the art and in the light of the description and drawings of the basic patent, necessarily fall under the invention covered by that patent.”

To summarize, the first step is that the active ingredient product must be covered by the patent in the sense that it must be covered by the invention of the patent. Maybe that is the same as what Arnold and Floyd call the “core inventive advance of the patent.”

The second step is that the CJEU said that “the person skilled in the art must be able to identify that product specifically in the light of all the information disclosed by that patent” — and this is the other issue that is unclear for me — “on the basis of the prior art at the filing date or priority date of the patent.” So the product should be identifiable.

But as I mentioned in my summary judgment, as did Justice Arnold, I think that this is a slip of the pen and that the CJEU meant to say here “the common general knowledge.” If this would be correct — and I must say that they use the term “the prior art” not once but several times in the judgment— this would mean that many more SPCs can be issued because that is a very different thing.

Furthermore, in my darunavir case I had to decide whether darunavir was covered by the invention of the patent — I said yes, like my English colleagues did — and subsequently I had to decide whether darunavir was identifiable at the first priority date. There was no mention of darunavir in the patent whatsoever, so nobody denied at the hearing that darunavir falls under the claims of the patent. But whether this second test was met is something that I decided in the negative.

This leaves open the question: if you have a Markush formula, which could cover millions of compounds, — the darunavir case had a Markush formula — how should you draft your patent in order to get an SPC? More particularly, how should we apply the “identifiable test” in these cases?

MR. JÜNGST: Thank you, Hans. That sounds all very complicated and complex, and indeed it is, and not because you have presented it in that way, definitely not. I find myself often in a situation that I am in each and every case reading the decision again, trying to understand what the CJEU meant.

Are there, Jürgen, any ideas, any chances, of making things simpler, to be more predictable, to be easier? What are your views in that regard?

MR. DRESSEL: Possibly.

Let’s return to what actually the SPC Regulation tried to achieve. It wanted sufficient time for the originators to actually be rewarded for their R&D. It was supposed to actually enhance R&D. For that you need:

- First, more time; and also legal certainty so you actually can rely on this time.
- For the internal market a harmonized procedure in each and every country.
- And you don’t want to make it too difficult for the granting authorities. What is going to happen should be predictable when you apply for an SPC.

I think at the time when this legislation was created, they tried to cover very different types of industries. They tried to cover human and veterinary vaccines and agrochemicals, all of which have very different requirements.

When you look, for example, at vaccines and agrochemicals, very often you actually have combinations which contain new chemical entities as the first product to enter the market. You want to inject the vaccine not fifteen times into the baby, but what you rather want to have is a cocktail of different vaccines which you can use to vaccinate a child.

Similarly, when you put something onto the fields, what you want is something that kills all different kinds of weeds. You do not want the farmer to go into the fields fifteen different times applying fifteen different types of weed killers. So also there are

combinations very often that come for the first time when the first approval of a new chemical entity is done.

The CJEU, I think, in its teleological interpretation tried to do justice to all these different interests of industry, and they did things in a way, I think in retrospect, that the SPC Regulation could also have been interpreted differently. They didn't really have to appease all these interests. For example:

- They gave new SPCs, additional SPCs, for combinations. I don't think that is absolutely necessary when you read the SPC Regulation.
- They gave the SPC to third parties. Okay, the SPC Regulation is silent about that, but you don't really have to do it.
- They at least have language in their decisions that you could use to interpret second medical uses or new formulations as a possibility for additional SPCs.

All this has led to many, many different decisions and huge confusion. I think we all agree that we are not much wiser with each new decision that comes out.

Unfortunately, I have the impression that the CJEU is also not very diligent in the choice of its words. Sometimes they say "identified in the wording of the claims" or "specified in the wording of the claims," and everybody is starting then to wonder *Do they mean something different now?* Or they used the word "priority" and everybody starts thinking *My gosh, what do they mean by that? Is there a teleological reason behind that?*

I am wondering about whether this uncertainty, which also suddenly starts to affect formerly granted SPCs which seemed rock-solid, whether we bought additional possibilities for additional SPCs which are probably very weak, on one hand, and thereby also endangered previously strong SPCs, on the other hand, because suddenly people don't know any more whether the SPCs granted really will serve their purpose; or whether, for example, an SPC based on a genus claim is not right any more, it might be invalid; or you suddenly have to choose selection inventions, which are notoriously weak, and therefore can and will be challenged. So you run into trouble there.

I wonder whether we shouldn't return to the origins, where you actually only got one SPC for any new chemical entity whether it is first approved as a mono-product or as a combination product; and whether you should only allow SPCs with the agreement of the marketing authorization holder, so you basically would have no third-party SPCs unless the marketing authorization holder, for example by taking a license, agrees to that.

I think it doesn't really make sense to grant all those SPCs for second medical uses for combinations and who knows what because these exclusivities are not really that solid, they can be easily challenged, and I would suggest that therefore you cannot really make business decisions on them. I think one needs something different for these types of innovations, maybe something like an additional regulatory data protection.

I understand that many of these things I say were already in the Max Planck Institute proposal. You'll notice that the European Commission did not take those things up; they only adopted the SPC manufacturing waiver. I can understand the concern of originators to actually open this can of worms and open the SPC Regulation at a time when IP for pharmaceutical companies is already under strong attack. So everybody is afraid that you actually might end up with much less than you started out with. I can understand that.

I think we are at a time where each and every new CJEU decision adds additional confusion and I cannot really see how it can be resolved. I cannot really see it. Therefore, I suggest we go back to the roots.

MR. JÜNGST: Before we open the floor to the audience, I want to ask for comments from the panel. I am interested in your thoughts, comments, observations.

JUDGE VAN WALDERVEEN: As I mentioned, I agree with Laëtitia and I agree with Jürgen that a lot of the jurisprudence of the CJEU is not clear. But I think that things have become clearer in the meantime. That is a difference between your opinion and mine.

I forgot to mention one other thing. I said apparently the CJEU thinks that *Gilead* is a very clear case. Why do I think that they have that idea? Because in the darunavir case they sent a so-called notification of a judgment having a similar effect. The CJEU sent a letter to the Court of Appeal asking whether or not it was still necessary to have a decision on the question referred. That same notification was sent to the Bundespatentgericht on the sitagliptin case. Both the Court of Appeal and the Bundespatentgericht refused to withdraw their referring questions because they both think that it is not clear yet.

MR. GRAY: I'm sorry to say I don't agree with your view about a single claim for the essential first composition. It seems to me that you ignore the question of, let's say, a picture claim, or let's say the SHINGRIX situation, where you have a product that was not really useful until it was adjuvanted so that it had a commercially successful product, and it was inventive because a claim was issued for the combination.

Let's take the simple situation of a picture claim, if you know what I mean. You've got a claim for A + B + C. It's very specific. It's about the first patent for the composition. It may be that A is old, B is old, and C is old, but you've got a claim for A + B + C.

What is the political and policy reason why you shouldn't extend the term of that patent under a patent term extension because you are not in fact interfering with any other person; you've got a claim for a specific product and it is limited to that product and you are extending the patent in that case? And, if you don't allow that, then it seems to me you are disincentivizing people to actually combine drugs together and make commercially successful products.

I understand the *Teva v. Gilead* situation is complicated. The *Teva v. Gilead* situation is different. There you got a patent for A and you didn't get a patent for B and the commercial product was A + B. There the problem of extending the term for the claim for A is that you will possibly interfere with the commercialization of somebody using A not combined with B. So that I understand, and that's a complicated situation.

But what I don't understand is why you wouldn't allow the extension of a patent that is directed to what I would call or patent attorneys would call a "picture claim," a very narrow claim directed to the combination.

MR. DRESSEL: May I respond immediately to you, Brian, and I also have something to say to you, Hans?

I think there is no dispute, Brian, that innovations like these combinations are good and important. But when you look at the policy reasons for which kinds of pharmaceutical innovations should be rewarded, you are talking about fixed-dose combinations. When you look at the clinical development of these fixed-dose combinations, they were actually developed as a free combination first. And then some drugs, especially in the cancer area, stay free combinations. So actually the R&D effort went into the free combination, but nevertheless you can only get an additional SPC for the fixed-dose combination. That seems inherently unfair to me.

I would suggest that you cannot really solve each and every problem regarding innovation of SPCs, especially if you base them on a possibly inherently weak right. You are talking about a basic right: A + B + C + D.

Do you know how difficult it can be to actually maintain such a patent? You are talking about something that expires ten years from now, and then you add another five years on top of that, but in the meantime your basic patent has been killed by the courts because of lack of inventive step or who knows what.

I think you need a different type of incentive for that. That's why I actually suggested perhaps a separate regulatory data protection for that. I guess you guys in Canada don't have such a strong regulatory data protection.

MR. GRAY: We have data protection, but not as long.

MR. DRESSEL: While I am all in favor of actually compensating originators for these types of innovations — also second medical uses and who knows what — I think the SPC is not the right tool for doing it, and actually what you are getting instead now is something which weakens even your strong SPCs for the NCEs.

As I said, you have situations where you have a Markush genus or a functional genus and you don't really know whether you actually can get a valid SPC based on that one. The other courts do disagree.

Now regarding what you said, Hans, that actually the picture has become clearer, I strongly doubt that, and when I look at the reaction in the audience I take some comfort that there appear to be more people here who also strongly doubt that. Each and every time the CJEU was asked to clarify the situation, I think they added an additional point of lack of clarity.

They usually were very clear in what they did not want. They clearly said, "We do not want an infringement test," which was actually the clearest and easiest test in the past. It had its problems, true, because it also led to a certain unfairness in combination situations, as I said before, in the agro and vaccine industry.

JUDGE VAN WALDERVEEN: But the Court said "no."

MR. DRESSEL: However, it was extremely clear. It is easy for patent offices to ask, "Is it covered by the formula or by this functional term" or who knows what.

And when you look at decisions — I think it was the French decision where they combined this. I never remember the name of this one component. Was it ezetimibe?

MS. BÉNARD: Ezetimibe and simvastatin

MR. DRESSEL: With simvastatin or atorvastatin?

MS. BÉNARD: Simvastatin.

MR. DRESSEL: The first one was simvastatin and the second one was atorvastatin. They were all based on the same basic patent, three SPCs based on the same patent.

MS. BÉNARD: There is no SPC for atorvastatin.

MR. DRESSEL: Not granted. So we have to deal in the Court of Appeal or wherever with the rejection.

MR. JÜNGST: Sorry, Jürgen, Hans, and Tom. I think we have debate in the panel, and that's good, but it would also be great to have some debate with the audience. So please, if you have questions, comments, or observations.

PARTICIPANT [Judge Rian Kalden, Court of Appeal of The Hague, The Hague]: I have a couple of observations.

As to the clarity of the CJEU judgment, I happened to be at the meeting at the Max Planck Institute in November. The meeting started off with a presentation by a lady from the Legal Department of the European Commission who has been involved in advising the CJEU in all of these SPC judgments from *Medeva* on. She told us that we should stop referring questions because now it was entirely clear.

Then I raised my hand and I asked, "Well, can you then please tell me whether, under the first of the two questions, we should understand that to mean that the product must be within the scope of protection of the claim or that the product incorporates the core of the invention, in accordance with the inventive advance test that was suggested by Richard Arnold?"

She said she was not in a position to answer that question.

Then, when I gave my presentation and I made the same comment as Hans did, saying that it was quite unclear whether the CJEU actually meant that the prior art had to be taken into account or just the common general knowledge, I noticed she was sort of shocked. After my presentation, she raised her hand and asked, “What’s the difference?”

I think that actually makes it very clear why it’s still unclear, because the CJEU does not have any idea about patent concepts, and without such knowledge it is very difficult to give clear guidance to us.

My second observation is about Jürgen’s proposals. Although I sympathize with the expressed need to have something which is very clear, that will require new legislation, and it is very unlikely that that is going to happen.

So the only thing that I can think of, if you really want to get rid of all the unclarity after *Medeva*, is that, along the lines as the European Commission did for the patents on plants situation, that they issue a notification or clarification or whatever that we should reintroduce the infringement test. But that is very unlikely to happen too.

MR. JÜNGST: Thank you.

Is there a further question?

PARTICIPANT [James Love, Knowledge Ecology International, Washington, D.C.]: The patent extension is expensive for society. I mean the patent itself is expensive, but the extension is also expensive.

There should be a means test. You shouldn’t really get any patent extensions if your global revenues are large. Giving a patent extension to Humera, for example, I think is just absurd.

The other thing is that the patent extension is an inefficient way to incentivize innovation because it comes very late and, because of the way companies discount cash flows, the present value of a patent extension is not as high for the company as it is going to be in present value terms for society.

So wouldn’t it be better if the government wanted to incentivize innovation to provide cash bonus innovation inducement prizes, things like that, as opposed to patent extensions, which are essentially the product of just how good your patent lawyers are and, as the panelist demonstrated, turn on relatively arbitrary issues unrelated to the investments that are involved or the therapeutic value or even the need for the incentive?

MR. JÜNGST: Thank you.

PARTICIPANT [John Richards, Ladas & Parry, New York]: Just one quick observation on that. Up until 1979, the United Kingdom had a provision in the statute for extension of patent term for failure to make enough money out of your patent that appeared to have existed because of circumstances beyond your control. Would something like that address the issue just raised?

PARTICIPANT [Christine Kanz, Hoyng Rokh Monegier, Düsseldorf]: I would like to help promote a position that Peter Meier-Beck from the Federal Court of Justice in Germany has been making in writing and in some presentations. I think that position helps make things a lot clearer.

He is saying that we do not have a two-stage test and that all the CJEU wanted to say since *Medeva* is that we have to apply Article 69, and we have to apply it not as an infringement test but as a subject-matter test, so the only question that needs to be answered is whether a combination or whatever falls under the claims. That is a very classical Article 69 test, and it makes perfect sense because patent law is not harmonized. The CJEU does not have the competence to ask for an additional test on constructing claims.

To me that is the only sensible interpretation. What we are trying to do is make sense out of words like “identified,” “specified,” “implicitly but necessarily.” But that is not what the CJEU wants. I think that would bring a lot of clarity back to the issue.

MS. BÉNARD: I want to reply to that. Actually, the *Gilead* decision is very clear about the fact that Article 69 needs to be taken into account. Despite that, three jurisdictions ruled in very different ways when arguably applying exactly Article 69. So I don't think that that will solve anything, unfortunately.

MR. JÜNGST: Trevor?

PARTICIPANT [Trevor Cook, WilmerHale, New York]: Given that it seems the Commission has set its mind against doing anything to sort out this mess, and given that it is almost a matter of diminishing returns when courts make references to the CJEU and it just makes the situation worse and worse, is this something that national judges should be getting together on to try to find some common approaches amongst them, really almost sidetracking the CJEU from this point of view?

JUDGE VAN WALDERVEEN: That is definitely not done. What we can do in fact is to keep referring questions and explain how we think that Article 3(a) should be applied. But when we get the answers back they see it differently.

MR. MITCHESON: I've heard of this thing called the Venice Conference, though. Is this not something you could discuss next time they meet?

PARTICIPANT [Robin Jacob, Former Lord Justice of Appeal of the Court of Appeal, London; Faculty of Laws, University College London, London]: We go to enjoy ourselves. [Laughter]

PARTICIPANT [Judge Klaus Grabinski, Federal Court of Justice, Karlsruhe]: I would like to pick up on Mrs. Kanz's comment. I was never really convinced of the infringement test.

I was much more convinced of an approach that was first taken by Robin Jacob in an early case, the *Takeda* case,¹⁷ which is simply saying: "You have two components in the patent, A and B, and of course a product that has A + B + C is infringing, but it is not infringing because there is C; it is only infringing because there is A and B. That is not a justification to get an SPC for A + B + C."

In that approach I think the CJEU in principle is right.¹⁸ This is a bit also what Peter Meier-Beck said, with which I fully concur: A + B yes; everything else is disclosed in the patent; possibly also equivalents to A + B because they are identifiable as long as they are obvious — that is the equivalents test to some extent. Along that line you could interpret the case law of the CJEU.

Like Rian, I was at the meeting at the Max Planck Institute, and I happened to moderate the panel on Article 3(a). At least all the people who were on the panel came to the conclusion that any amendment of the current Article 3(a) would only increase confusion, so better let it be there and try to further develop the approach of the CJEU. I fully agree we are not there, that is absolutely clear. That is a fairy tale.

But I think there is a way. I'm really doubtful that if we would amend and add other words or have another definition in the Regulation then it would become clearer. I think the confusion would be greater then.

I agree with Hans saying the approach of the CJEU needs to be further developed and it is a difficult issue.

MS. VAN DEN HORST: I also have a short comment. Tom mentioned that the judges of the CJEU might not have enough intense knowledge of patent law, and I think Rian's remark also hinted at that.

¹⁷ *Takeda Chemical Industries Ltd's SPC Applications (No 3)* [2004] RPC 3.

¹⁸ *See Case C-322/10, Medeva BV v Comptroller Gen. of Patents*, ECLI:EU:C:2011:773 (Nov. 24, 2011).

But what I don't hear is the knowledge on regulatory law. I do believe strongly — and I was also at the Max Planck Institute seminar and I kept on repeating this — that regulatory law is an essential component in SPCs because it is clear that the SPC protection was created to compensate for time lost as a result of the regulatory process.

We have seen not as much legislation and case law on Articles 3(b) and 3(d), and *Neurim* was in my view very erroneous, not taking into account the regulatory aspects and the differences between human and veterinary products and the concept of first marketing authorization. I urge courts to take the regulatory aspects of SPCs into account more.

To come back to a comment of the Max Planck Institute, they said that reform is necessary because the CJEU is asked through preliminary questions to deal with every aspect of, for example, Article 3 separately; so it's either 3(a) or 3(c) or 3(b) or 3(d), but not in a comprehensive way. If we would deal with Article 3 and all the components in a comprehensive way, it would allow us to bring some balance there.

MS. BÉNARD: Just to add to what Marleen just said — and yes, of course, the judges in the CJEU are not specialized in patent law — I think the problem is that we are trying to apply patent law to an SPC, which is not a patent. It is something different. This is why I have been saying that the core inventive advance is not the right test. This is why I like Rian's proposal to apply an infringement test, which would be easy to apply for nonspecialized patent judges.

MR. JÜNGST: Thank you very much.