WIPO-UPOV SYMPOSIUM ON THE CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS IN THE PROMOTION OF BIOTECHNOLOGICAL DEVELOPMENTS
(October 25, 2002)

Panel discussion

Chair: Mr. Peter Lange
KWS Saat AG, Germany

All speakers

Mr. Rolf Jördens introduces Mr. Peter Lange and opens the discussion.

Mr. Rolf Jördens: The idea of this discussion is not to repeat in a short form the presentations which the speakers have given in the course of the day, it is rather the idea to invite the audience, all of you, to raise questions and to join in the discussion with the speakers.

Mr. Peter Lange: It is, of course, not very easy to open such a broad discussion and I will try my very best to structure this discussion so that we are not lost in different issues. It is an honor for me and a pleasure to do this, being surrounded by all the excellent speakers of today. But first of all, please allow me some small remarks. The title of this Symposium is devoted to the co-existence of patents and plant breeders' rights in the promotion of biotechnological developments. The notion "co-existence," to my mind, is too negative, at least for the following reasons: it has a smack of hostility between totally incompatible systems of protection. That is for me comparable with the political endeavors during the cold war to establish co-existence between two incompatible political systems. And we should be totally aware of the fact that there is nothing new within the intellectual property regime in having different choices of protection and different titles which may complement, overlap or even compete with each other. Why not! It has to be clarified that by plant breeders' rights specific plant varieties are protected and that has been already mentioned, whereas an invention is a subject matter of a biotech patent which normally contains generic claims since such an invention may be realized in an undefined number of plant varieties. Last, but not least, and here I would also like to underline the statement of Prof. Straus: in view of the fact that in the plant area actually, at least in Europe, we have only infinitely few field trials with patented plant material, and virtually no cultivation of such plants, are we carrying on a practical or theoretical discussion? Of course, we have to identify the main differences-strengths or weaknesses-between the systems, especially in so far as they protect the same subject matter. Or if they interfere unduly with each other and we have to work for necessary improvements in both. The ongoing review of the TRIPS Agreement under the auspices of WTO requests not only minimum standards for the protection of plant varieties and biotech inventions or just a co-existence of different systems, but demands better harmonization of the systems. To achieve this goal, we have to look at the needs of worldwide market incentives for the development of least developed or underdeveloped countries, and have to consider, the interests of the public. It is my

understanding that the public should comprise a wide range of groups of persons, such as our direct customers, the farmers, the processing industry, consumers and of course the research community. They all should benefit from new knowledge, developments and the really promising innovations in biotechnology and plant breeding within research institutions, the breeding and biotech industry. This will only happen if efficient and adequate, and I would like to add fair, protection systems are available. Thus being the main condition for effective technology transfer. In this sense, I would like to divide the discussion into the following three main domains, which have already been anticipated by the organizers of this Symposium. The first issue would be the question of "Accessibility," and perhaps there we need not twenty minutes, but ten minutes for this issue: "Accessibility of protected inventions and plant varieties for further innovation." I will then come back to this issue, perhaps highlighting some arguments/statements which have already come up here within the speeches and the discussions in the morning. The second issue would then be the issue of "what are the experiences with IP strategies and licensing in the area of patents for biotech inventions and plant breeders' rights systems". The third issue then would be "which measures are necessary for a balanced co-existence or, I would prefer to say, better harmonization of the systems". So I invite now the audience to pose questions to the speakers here at the table, first on the issue of "Accessibility" and, in order to move on or push a little bit the discussion, I think we have to deal with the scope of the research exemption, with the experimental use defense. Is there a harmonization needed especially in the patent regime? Is the scope of breeders' exemption within the plant breeders' rights system sufficient or should it even be diminished? And thirdly, are there consequences with regard to restrictions from contractual use, for instance in the form of bag-tags, or is there a question of validity of such bag-tags involved? Please, now pose your questions to the speakers.

Mr. Huib Ghijsen, Global Manager Germplasm Protection, Bayer BioScience N.V., Astene: I have a question about the American research exemption in the utility patent, because I do not understand how it has developed. I have always understood that a patent is an exchange between a private person or a company and the public: the inventor discloses his invention for teaching and learning of the public and in exchange for that he gets the protection of that invention. And when you see the patent requirements that you have the enablement and the description requirement for teaching and a deposit requirement in the case of biological material, then I cannot understand that experimenting with the invention is not allowed. Jurisprudence in the United States indicates that experimenting with the aim that if there is an improvement of an invention, it may be used in a commercial way. But when it has any dependence with the original patent then you have a case of dependency and there is nothing wrong with that. So, just repeating the question, how has this evolved that this is so narrow an interpretation of something that should be fully allowable in science?

Prof. Charles McManis: I can imagine that my friend Jerry Reichman at Duke University is already preparing a petition for certioari in the case involving Duke University. And while I do not know what he would argue in that case, I think that my argument, if I were to make it, would be based on the fact that patent protection in the United States is to be made available to anyone who invents or discovers any new and useful process, machine, manufacture, composition of matter or any new and useful improvement. How is one to make an improvement of a patented invention without

infringing the basic patent if there is no room to consider improvements? I would suggest that our own Court of Appeals, which likes bright-line rules, whether they are just or not, may be in effect led by its overly narrow view of what is permissible in the way of experimental use and is effectively negating the ability to obtain patents on improvements. Now that may be the right thing for them to do, it may be the right thing for the Supreme Court to do because it may be that an experimental use limitation on patent protection is the province of Congress rather than the Courts. And I believe that to be true. But in any event, it does not seem to me that a patent system which recognizes the patentability of improvements could turn around and say "but of course you can never improve anything that is already patented because then you would be infringing the underlying patent." That seems to me to be contrary to the policy embodied in Section 101 of the US Patent Statute.

Mr. Tim Roberts: If I could just say that the question of the research exemption is a particular problem when you are dealing with biological materials. Because, until I got involved in the biological area, I had never encountered any concern about the research exemption. If you are dealing with a mechanical invention you do not have to start with what your competitor has put on the market, you make your own. The patented feature could be left out or redesigned. But in the case of an invention which is as specific as a plant variety, you cannot start by going to a gene bank and assembling individual genes, you have to start with what is on the market and experimenting with that will involve reproducing it, which will be textually infringement. So there is a particular problem here in the biological area.

Mrs. Victoria Henson-Apollonio: I think an additional comment would be something that Prof. Straus touched on and that is that in the biological community itself, researchers are sometimes assuming that there is a research exemption and that patents are free to use. Also, just to agree with Tim Roberts suggestion that so much of the case law that we have in this area is in fields other than biological fields. Maybe, we are not up, yet, to the level of sophistication to understand the need for the research exemption as far as the judiciary is concerned.

Mr. Peter Lange: Any other questions? Perhaps on harmonization. Is harmonization needed for experimental use defense provisions? I take up also the question of contractual restrictions. What do you feel about this problem? Is it actually a problem using bag-tags?

Mrs. Victoria Henson-Apollonio: This is slightly different than the bag-tag situation, but I thought it was quite interesting. I am reading a paper written by Rebecca Eisenberg who, in the US, certainly could not be construed to be a pro-patent person. Actually, she has written that licensing requirements in some of the access to genetic information are much more restrictive than any of the restrictions placed on that sort of information by patents. And I think this is a real problem. When I was in India a couple of weeks ago with a WIPO representative doing some seminars, there were repeated questions from people who were involved in biological research about mutual transfer agreements and the restrictive components of those mutual transfer agreements. So I think it is something that is a real problem.

Mr. Peter Lange: Could I ask a further question on this? If we have in a country a breeders' exemption as it is used in the European system, would you think that bag-tags would really be valid as the Law prescribes a specific situation and allows for such use for breeding purposes? So I would like to question the validity of such a clause.

Prof. Charles McManis: I come rather late to the discussion of bag-tag licensing, but for anyone in the audience who is not familiar with it, I would call attention to what is going on in the United States with regards to clip-wrap and shrink-wrap licensing in the computer software area if you want an idea of possible things to come. Right now in the United States, there has been promulgated an Act called the Uniform Computer Information Transactions Act (UCITA). It has been adopted in two States and, because after it has been adopted in one State, it is possible to become the choice of law in any computer software licensing agreement, you had better become familiar with the Law as adopted by Virginia and Maryland. These two States have essentially adopted an Act that says that clip-wrap and shrink-wrap licenses are enforceable contracts, even when the terms are disclosed after the transaction has been completed, that is to say the money has been paid. You download the software and up pops on your screen a contract program that says "Surprise! You do not own this copy and you can not sell it, and you can not reverse engineer it, etc." So, I am not familiar with how bag-tags will be enforced, but I am certainly familiar with what is happening with regard to clip-wrap and shrink-wrap licenses.

Mr. Peter Lange: Thank you Prof. McManis. But of course the situation in the US is different from other countries. In a case where you have a strong breeders' exemption in a country, the question arises. That situation is not comparable with your situation, I would say. Is there any opinion on this? So we have to ask the lawyers!

Mr. Mark Shillito, Partner, Agribio Law Practice, Herbert Smith, London: I think under United Kingdom Law, the position would be the same as you have just indicated for Virginia and Maryland, clip-wrap and shrink-wrap would be, I think, enforceable in a United Kingdom Court of Law, and I think, although we have not had any experience of it yet, bag-tag licenses probably would as well, on the same basis. And I would like to answer the question with a question. Do the panel think there is any difference between having a bag-tag license which says "Thou shalt not grow or reproduce this material later on other than to produce a consumption crop" and inserting a terminator gene in the material so that you can not do it anyway?

Mrs. Victoria Henson-Apollonio: I think that use of the terminator technology is just an extension of trade-secret, an extension of hybrid technology and so it is enforceable biologically, whereas obviously the contract is enforceable in some places and not in others.

Prof. Joseph Straus: There is a parallel in the copyright area in Europe with the encryption and whether, because you have a fair use exemption, you can remove that encryption in order to be able to make fair use of that. And maybe even in the terminator case—I am not a biologist—maybe you can alter that again and remove that terminator gene. I think it would depend. You have argued like a United Kingdom lawyer with the implied licenses and so forth, in Germany, since 100 years we have

never accepted this doctrine of implied license because it actually leaves it up to the owner to decide whether something is exhausted. In our Patent Law we have the doctrine of exhaustion and not of implied licenses. I would say that, for the time being, the outcome may differ from country to country in the bag-tag issue.

Mr. Bernard Le Buanec: It is not a question, but maybe a continuation of the discussion on your question. My feeling is that the comparison with software is not completely relevant, as you have exactly said Mr. Chairman, because the software is protected by copyright and, of course, it is obvious that you are not allowed to use it for commercial purposes and that probably is the meaning of the clip-wrap. The question asked by Mr. Lange was we have a plant variety that is protected by PVP, PVP gives clearly an indication that breeders' exemption is allowed and is one of the bases of PVP. Could you by contract or by bag-tags say "No, we consider that there is no breeders' exemption and you can not use our variety for further breeding?" It is a completely different issue and what would be your feeling on a bag-tag saying "You can not use my variety for further breeding" if that variety is protected by PVP?

Mr. Jean Donnenwirth, Pioneer Overseas Corporation, Brussels (American Chamber of Commerce): My comment is a follow up to what Mr. Le Buanec just said. I wonder if there is not a misconception about the breeders' exemption here. My reading of Article 15 of the UPOV Convention of 1991 is that "the breeders' rights shall not extend to" and here is "the act of breeding for creating new varieties." When you read Article 1 of the same Convention, a breeder's right is defined as meaning the right of the breeder provided for in this Convention." Therefore, I submit that there would not be a contradiction or an impossibility to find other legal remedies through bag-tag language, for instance, to prohibit breeding from a protected variety.

Mr. Peter Lange: I think that we will not answer this question finally. I just wanted to ask whether there might be consequences which we have to address.

Mr. Barry Greengrass, Chilly, France: I just wanted to draw attention, following up the very same point about the protected variety, that there is a general principle in relation to the licensing of intellectual property laws that you can not in your license or in some contractual arrangements seek to extend the intrinsic scope of the intellectual property law by provisions in the license. Typical examples are being provisions that require you to source your raw materials from a particular source, or the treatment of improvements. So that if indeed this shrink-wrap type provision was to be struck down it is likely to be struck down perhaps by Competition Law, rather than Intellectual Property Law.

Mr. Peter Lange: I now would like to follow the agenda and come to the second issue which is the question-What are the experiences with IP strategies and licensing in the area of patents for biotech inventions and plant breeders' rights systems? I think it came out during the different speeches and the discussion that we have to tackle in this respect two main questions: first, are the protection criteria, the scope of protection and enforcement and prosecution measures well-suited for the different objects of protection and for the needs which I mentioned before? And I would add, are the systems simple enough to follow the remarks of Mr. Desprez and not too costly? The second question I would like to ask here is on the possible deficiencies in this respect

due to the systems or due to the implementation and administration of the systems. Thirdly, the aspect of management of the EDV concept is also the question of how to enforce the rights which the 1991 Act offers us. I would like to ask you to pose questions on these issues.

Mr. Dick Crowder, Chief Executive Officer, American Seed Trade Association (ASTA), Alexandria, United States of America: My question is to Prof. McManis and also in response to a comment made by Bernard Le Buanec that the US PVPA has not been an incentive to breeding. Two questions. Because the United States is not without some success in breeding and technology as has been discussed, the two questions are "What do you think it would have been without the System?" and two "Would there have been another system that would have been better?"

Prof. Charles McManis: As I understand the way the current US PVPA System operates, it seems to me that the absence of significant licensing and litigation activity suggests that it is not creating incentives. If you have a system that in 70 years has produced 8 litigated infringement proceedings and in 30 years has produced 4, it suggests that there is just not a great deal going on from people who take a bad persons view of the law. And at the same time, the absence of any licensing activity suggests the same thing. Would the system be better or worse without plant variety protection? Well, as I understand the system, it seems to be just giving a bit of backing to contractual trade secret protection-in other words those bag-tag licenses would be there whether there was a Plant Variety Protection Act or not and the question of their enforceability might be more acute in the absence of a Plant Variety Protection Act. But my guess would be that the system without plant variety protection would essentially be no different, there would be more demands than there already are for utility patent protection and there would be more aggressive use of traditional trade secret protection.

Mr. Walter Smolders: This is maybe both a question and a comment. The one reason why PVPA is so weak in the United States is that they are doing searches based on databases and that those databases are really quite imperfect. Now, what is the United States Patent Office doing to examine plant varieties in utility patents – exactly the same. They are searching in germplasm databases which are imperfect and they have no clue on what is happening. Normally, one would expect the patent applicants to draw the attention of the Patent Office to the prior art they are aware of in the relevant area. I am not sure that most applicants do that. So the Patent Office is in no position whatsoever to decide on what is novel or not. They have to rely on the applicant. As a result of that, as soon as they have the benefit of novelty, the implied unobviousness criteria plays a role because as soon as you have a shuffling of a specific non-existing combination that's unobvious, you are getting it. And this is a very problematic issue. Now the question is what could one do? There is another question, when you get a claim on a patent for a deposited material, it is not specified what is being claimed. It just refers to the deposited material and that is all. It does not specify what traits are unobvious, what are surprising. There is a very vague description in the patent application, but that does not identify what is so characterizing or surprising. This is a bit of a reaction to Dick Crowders questions. My question is would it not be better to have a good patent examination system so that the real inventive varieties are being protected and is there no way to keep that under control?

Mr. Peter Lange: Before I give the floor to Tim Roberts, just a small remark. Of course, there might be deficiencies in the implementation in the plant variety protection system in the United States, but although this might be the case, we have a lot of applications of plant varieties, and I think we have to look at the numbers that WIPO has issued. They have the last numbers of issued protected plant varieties in 1999. We have no new figures, but there we have about 10,000 protected varieties. And if you compare, for instance for corn, utility patents, numbers of valid patents for lines or hybrids of corn, you have actually in October 2002, 616, and you have 642 titles granted under the Plant Variety Protection Act. If you compare soybean, you have in October 2002, 765 soybean varieties protected by the plant variety protection system and only 424 patents claiming varieties *per se* under soybeans. So the comparison is not so bad for plant variety protection titles.

Mr. Rolf Jördens: We had yesterday in the Council of UPOV the latest UPOV statistics about titles of protection granted and enforced. We looked at the situation in the United States of America and saw for both forms of variety protection, the plant patent and the plant variety protection system, an increase. A steady increase in fact. I have now forgotten the exact figure, but I believe we had 4,000 titles in force under the plant variety protection system and about 6,000 under the plant patent system. There are, in fact, relevant systems. Your comparison, Prof. McManis, between the overall patent titles granted for the whole range of possible subject matter, and numbers of titles issued for the relatively limited sector of plant varieties is not very relevant. We see that the UPOV system, with now about 54,000 titles in force worldwide is important and is growing in importance. We have a steady increase and this steady increase occurs mainly, of course, in recent member States, where we observe a clear effect of the system. We see in the first instance foreign varieties being protected, but then in a second phase, the national breeding activities take effect.

Mr. Tim Roberts: Just two points. To go back to the original questions of Mr. Crowder. Prof. McManis has said, and I am sure that that is right, that the PVP system in the United States of America is weak. But his evidence in support of that is the absence of licensing and litigation and I do wonder about this. In Europe, we also have an absence of litigation, though not, I think of licensing, and in Europe one of the advantages of the PVP system that breeders have traditionally seen, is that it does not involve lawyers to any great extent most of the time. This is seen as a real advantage! So I am not disposed to accept on its face value the fact that there is no litigation is an implication of weakness. But if we go to the second point, how could the system have been better, I do not think I have anything very original here to say, it's a bit like Professor Higgins, in My Fair Lady, "Why cannot America be more like Europe?" If one had an examination system of side-by-side testing and if you had stronger or indeed any requirements against farm-saved seed, that would be the way to improve the system in the United States of America.

Prof. Charles McManis: I think I had better answer this question before the list gets longer! I am not going to go all the way back to Mr. Crowder, but will respond to Mr. Smolders.' I would quite agree that just because I am criticizing US PVP as requiring too much to get the protection for too little in return, that the converse is not true for US utility patent protection. I quite agree with you that, at the moment, under US Patent Law perhaps applicants are getting too much protection in return for

requirements that are not high enough. Indeed, I would suggest the two phenomena are related and so I would agree that perhaps the Americans could be more like the Europeans on our plant variety protection. That might ease some of the pressures that are now being exerted on our patent protection. On the other hand, I take exception to the view that what we have in the United States at the moment is effective *sui generis* plant variety protection. Simply because it may be that it takes lawyers to litigate, but it does not take lawyers to license. In the United States, in fact it does take lawyers to license, but in any event when you see the absence of business activity, you wonder where is the incentive being created if no licenses are issued. With respect to the figures that I used, I quite agree that in some sense I was comparing apples with oranges. On the other hand, in response to Dr. Lange's question, I would simply observe about the patent record, that looking at the patent record is something like an astronomer looking into space. Keep in mind that you are looking back in time when you are looking at granted patent applications, sometimes as many as five or seven years in time. I would point out that it only became absolutely clear that plants are patentable on December 10, 2001, with the issuance of the Supreme Court Decision on J.E.M. Supply vs. Hi-Bred. So it seems to me that what companies were gambling on before the J.E.M. Supply vs. Pioneer Hi-Bred case is no indication of what you will see happening in the patent system now that J.E.M. Supply vs. Pioneer Hi-Bred has been decided. And indeed, I would argue that the decline since 1999 in plant variety protection applications in the United States may be evidence of an increasing sense of which way the J.E.M. Supply vs. Pioneer Hi-Bred case would go.

Mr. Bernard Le Buanec: As I have been quoted by Dick Crowder I would like to answer as I do not want to be misinterpreted. First of all, I think that we all agree that the US plant breeding has been very successful, that is very clear, but we have to think on what crops. It is mainly in hybrids and vegetables. On other crops it has been rather poor, or not as successful, because the PVP is weak. This is my personal feeling. Because the question is what could we do to improve that it is just simply to have a stronger protection regarding farm-saved seed. To me that is the main weakness of the US PVP Law and it is, of course, the main weakness for breeders working in self-pollinating crops. That was expressed very clearly some years ago when one of the major companies in the USA said we have to drop our breeding in wheat because we have no protection by the PVP. So that is very clear. My second point is that I do not share the views of my neighbor (Mr. Smolders). I am not concerned with the way the PVP system works in the USA and I am convinced that it is not because distinction in US testing is different from Europe that that is a major issue. I am not convinced at all and, to speak frankly, I am even convinced that in the future we will probably have to mix the two systems to be efficient, but that is a very personal view.

Mr. Thomas Kramer, Responsible for Intellectual Property Protection, Seminis Vegetable Seeds, Wageningen: I would like to make two comments. I think for the future of the PVP system, it is very important that we start thinking about an international application and granting procedure. An international application and granting procedure, somewhat similar to the PCT that we have for patents. In order to keep it at a reasonable cost and also to keep it manageable administratively. I would like to add to it that my own thinking at the moment is that such a system, in combination with official testing, would be a very strong system. I agree to a large

extent with the comments made by Walter Smolders, that I would like to see improvements in the US system, but not only in the US, also in many other countries and especially the developing countries. My experience has been that, and now I am making some comments on the remark that was made by Mr. Jördens about total number of titles that are in force-54,000-in some of those countries we have no other option of protecting our material than the PVP system. But this does not necessarily mean that this is effective. Then another comment also related to the official testing, which I am in favor of. We see that it is difficult in a breeding company, at least in our company, to get the breeders to complete the administrative procedures for variety protection. The breeder's main job is to breed commercial, successful varieties and, based on the number of applications in our company that we file in Europe or in the United States, the main explanation for a much larger number of applications being filed in Europe is that the procedure is simple and is not a burden on the breeder. Whereas in the United States, it is a considerable burden on the breeder and our breeders do not like to spend their time filling in the required forms.

Mr. Jean-Christophe Gouache, Directeur scientifique, Groupe Limagrain Holding, Chappes, France: One comment. I was very surprised by what was said about the absence of licensing activity in the United States. I do not believe that this is true. Actually, in the corn and soybean business, a tremendous level of activity of licensing exists through the Foundation Seed Companies and I do believe that licensed varieties from those Foundation Seed Companies to seed companies do represent, in both species, more than 30% market share. So I do not understand what was stated there. I think licensing activity goes on and it's a tremendous amount of business in the US in crops such as corn and soybeans.

Mr. Peter Lange: There is another topic that I would like to tackle, also concerning this issue, and that is the enforcement of the essentially derived varieties (EDV) concept. Do we have any ideas on how to get cases and to enforce this improvement of the UPOV Convention?

Mr. Luiz Antonio Barreto de Castro: When I saw the idea of this seminar and I looked at the title, the impression I had was that co-existence of the laws was being pursued to promote biotechnology and I hope that this is what we are looking for, at least in the long run. These two institutions, WIPO and UPOV, have an important role to play in this direction. But after being here for one whole day, and listening to all these technical discussions, I wish somebody could reassure me that this is the idea at the end. I have followed biotechnology and recombinant DNA for 30 years and I have decided to dedicate the rest of my life as a scientist to promote biotechnology. When early in the 1980s we, in Brazil, had to look for state of the art knowledge in recombinant DNA in plants, we looked for Jeff Schell, in the Max-Planck-Institute and Mark Montague at the University of Gent. When I see Prof. Straus' data on field trials of transgenics in Germany, only fifty field trials last year, it is sad. Really sad. I come to Europe often and my friends, still scientists in many countries, do not have funds to do science in their fields of plant molecular biology with the recombinant DNA methodology. Recombinant DNA technology, or perhaps as we call it today, biotechnology, properly monitored as it has been, is one of the most extraordinary products of science to be used for the benefit of mankind. We should not interfere with the flow of knowledge. Society always loses out when we mix science and

politics. I recently wrote a paper for a Brazilian newspaper, the title was "Lysenko, Stalin and Morgan." I do not have to tell you this story, but that's what I think we should be afraid of. Never mix science with politics. We have to promote the flow of science and act properly to use for the benefit of society. I think I could not go back without at least letting you know the way I feel coming here to discuss this co-existence of the laws.

Mr. Peter Lange: Thank you very much Mr. Barreto de Castro. I think that this is a statement which we would all totally agree with. But of course, we have to discuss these problems which I think became clearer even today through the discussions and I just would like to finalize this issue with perhaps a remark. How to enforce the rights which been offered under the UPOV Convention by the EDV concept? I think this is really a big advantage of the system, but we have to work with it and have to find good rules.

Mr. François Desprez: I think that although we have the feeling that, up to now, this EDV concept has not been used or enforced a lot, I think, in fact within the breeding companies it has been sought after. We have avoided having some more plagiarism for varieties because we have let our breeders know that this concept exists and that they should think about that concept when they are applying for a new variety. And it is a success that we do not have many cases that we are aware of.

Prof. Joseph Straus: Just a small provocative remark. I hope that this EDV concept is not only aimed at providing eternal protection for the owner of the original plant variety. Because if that would be the case, that would not be entirely in line with what has been said so far about the access and of course if you use that system only to this aim then you will never have litigation. Maybe less plagiarism, but for the rest, I think it would not be the ideal way forward for innovation in the plant area.

Mr. Bernard Le Buanec: Two comments to try to answer your question. Firstly, I cannot tell you the details, but I know that a first case on EDV will be before the Courts very soon in Europe, so we will have an answer. Second comment is that in the concept of EDV, what is difficult is not to implement it on a legal basis, what is difficult is to define what is an EDV or not. As soon as you have agreed that it is an EDV, it is extremely simple and there is no difficulty. For instance, in one of the simplest cases, that is an introduction of a gene in a plant protected variety, it is extremely easy. I am sure that it is working very well and that all the companies with patented genes in protected varieties are following the rule of EDV.

Mr. Peter Lange: I would like to add that I also know about a case. So we will have Court cases and I think that it is good to have a clear interpretation of the scope of protection. I would like to come now to the third issue which is the most important and interesting one. "Which measures are necessary for a balanced co-existence, or, I would say, a better harmonization of the systems." In this respect, I would also like to identify some possible statements in the discussion. Do we need a well-defined and broader research exemption, a compulsory license system, an extension of the existing compulsory licensing system, a cross-license system – what do we mean by all this? Or, should we just be confident in the negotiation powers of the market?

Mr. Graham Dutfield, Herchel Smith Senior Research Fellow, Queen Mary Intellectual Property Research Institute, University of London: I have heard about half an hour ago that the UPOV 1978 Act is ineffective in the TRIPS concept because, among other reasons, it allows for the saving of harvested seed. This got me thinking about three questions. One, has the restriction on seeds-saving introduced in Europe in recent years made a different in the rate of plant variety innovation and investment? And what is the evidence? Now I have heard this case of Pioneer closing its research in some kind of wheat program in Kansas mentioned again today. I have heard it mentioned twice. If I hear the same thing said more than once, it makes me wonder if people are stumbling for evidence. Second, what has happened to make seed-saving constitute an ineffective system when it was presumably all right before? And three, linked to that, if the answer relates to changes in the seed business, or changes in scientific technology, then what does it imply for developing countries being encouraged not only to join UPOV, but to accept the 1991 revision rather than the 1978 revision. And finally, just one point. The whole idea that you can separate science from politics to me is impossible. If science is mixed with business, politics is going to intrude whether you like it or not.

Mr. Rolf Jördens: Whether the 1978 Act of the UPOV Convention is an effective system of plant variety protection or not, there may be different views. I do not think that UPOV itself has doubts about effectiveness. It is clear that breeders are looking for a reasonable, or a relatively high level of protection. With regard to the possibilities of farmers saving seed, there are certainly differences between the 1978 Act and the 1991 Act, but this does not permit to say that the 1978 Act is not an effective system. There was also reference made earlier to the fact that the 1978 Act does not require including all genera and species. This does, however, not mean that members of UPOV may not go beyond what is the minimum requirement of the 1978 Act.

Mr. Peter Lange: Although I am the Chairman, I would like to answer from my knowledge coming from the Diplomatic Conference of the 1991 Convention which we had here ten years ago. I would say there are at least three aspects of stronger protection by the 1991 Act. The breeders themselves have very much asked for that. Of course the 1978 Act might be, legally, an effective *sui generis* system according to the definition of TRIPS, but that is a question of interpretation. We, as breeders, think it is not really effective, because, first of all, you cannot protect all varieties, all species, you have not the EDV concept so plagiarism is possible, and the scope of protection has been enormously widened by the 1991 Act, especially with regard to the farmer's privilege because there was an uncertain situation before. Now you can claim as a breeder to get remuneration for such use and I think that this is really justified in the interests of the breeders.

Mr. François Desprez: I think that this farm-saved seed issue is very important. We have said earlier this morning that a good law was a law which was enforceable and which was fair. And it is really fair that a law made provisions for farmers using farm-saved seed to compensate the breeders. Because if it is not the case, the return for the breeders will only rely on farmers using certified seeds and in most countries it turns out that these farmers are the smaller farmers and not the ones taking the better profit of innovation for new varieties.

Prof. Charles McManis: I would like to make two remarks in response and I find myself in a somewhat odd situation of responding perhaps for the developing world, coming from the United States, but the first observation I would make about the TRIPS Agreement is that when the TRIPS Agreement wants to incorporate a specific treaty by reference, it knows how to do that. Indeed it knows how to specify that certain provisions of the Berne Convention will apply under TRIPS and others will not apply. The developing world takes the view, since in Article 27.3(b) there is not a specific incorporation of UPOV 1991 Act, but only an effective system of *sui generis* protection, that that leaves perfectly open to the developing world the adoption of UPOV 1978 Act. Now the other comment I want to make is the irony that the United States believes it has complied with UPOV 1991 Act and yet I would argue that it is an ineffective system. This brings me back to the point that I made in my remarks earlier today. TRIPS requires an "effective" *sui generis* system, but pray what is the test for effectiveness.

Prof. Joseph Straus. Where there is no protection for anybody, can you explain that this is an effective system?

Mr. Peter Lange: Are there any remarks about my suggestion on whether a compulsory license system could be a solution? Or widening this system, not just for public interest, but as it is normally established in the different laws?

Prof. Joseph Straus: I would really like to raise that question. In Europe, as we have seen, we can not have the problem in practice. But how is it in the United States? Is there a real problem with the access so that one should go further with the research exemption we have discussed? But now you have addressed the compulsory licensing system. As far as the access to germplasm is at stake, is there a real problem? We are academics, I have no problems with that, but what do the practitioners say?

Mr. Bernard Le Buanec: Firstly to answer Prof. Straus. I do not know if there are real cases, but there are real threats by companies. When you have large companies threatening small companies saying we will sue you, it is something you have to take into account. But regarding the compulsory licensing, I think that we have to be extremely clear for what the license would be given. Here we are speaking about access and not development of a final product. The compulsory licensing as it is included for instance in the European Directive, is just dealing with the final product because you will have compulsory license if the product is of technical importance. You have first to have the product to implement the license, but if you are not allowed to have access to the germplasm, you do not have the product. So the compulsory licensing as it is included in the European Directive is not for accessing genetic resources, it is after having had access, then to have the possibility of trading the product.

Mr. Peter Lange: I wanted to come in the next step to the question of cross-licensing systems. This is of course, under specific conditions, a compulsory licensing system.

Dr. J.S. Sindhu, Director, Asia and Pacific Seed Association (APSA), Bangkok: I am a plant breeder by profession, so I have got 100% faith in PVP, but at the same time, I

want to put before you the aspects of the users, particularly when you were discussing the measures required for co-existence or harmonization of the two systems. I would like to draw your attention to the way patents are used. Based on human welfare, some of the patents are either put in the public regime, for free-use or restricted free-use for the welfare of the farmers living in the developing world who cannot afford or access these technologies against cost. For the benefit of the third-world countries where the farmers cannot get access to these technologies, the restricted permission to use the PVP and the patents together may be a solution. Perhaps we should try to consider this point when we are discussing the measures required for the co-existence.

Mr. John Gerard, President, Access Plant Technology, Inc., Plymouth, United States of America: I am neither a plant breeder nor a scientist nor a lawyer. I am responsible to my banker. The question was asked, and I would like to answer, are there licensing issues in the United States with germplasm. I have spent the last 35 years of my life professionally in the licensing business in soybeans, corn and wheat in the USA and there has been a phenomenal amount of extensive licensing in the USA. I do not know of one technology in those three crops that have not been licensed and the germplasm licensing is very extensive, has been and continues to be. There are agreements that have to be signed, but it creates the opportunity for phenomenal amount of varieties to be developed, hybrids to be developed. It has been a very extensive and very prolific and, frankly, I consider, a highly successful event. I thought I need to respond to that question.

Mr. Huib Ghijsen, Global Manager Germplasm Protection, Bayer BioScience N.V., Astene: I want to proceed on your question concerning the compulsory licensing. Personally, I do not think this is a good way to go forward, because that means some kind of litigation finally. It may cost quite a lot of energy and money, and when you talk about accessibility and harmonizing the two systems, I do not think that it is a good solution to have a system of compulsory licensing on research.

Mr. François Burgaud, Directeur, Groupement national interprofessional des semences et plants (GNIS), Paris: It seems to me all day that there is a large majority of people who think that it is important to improve the research exemption and to introduce this in the regulation for patents and also at the international level. But, when you regard the discussion in WTO, in FAO, about genetic resources, you have the feeling that there is more discussion about traditional knowledge than about this type of problem. So my question is, you talked about the review of the TRIPS Agreement after Doha, do you have the feeling really that there is a possibility to introduce this problem in WTO discussion and to have a result and to have the possibility to introduce in Article 27.3(b) a compulsory research exemption for all types of intellectual property rights?

Prof. Joseph Straus: If I may, I would not argue along your lines. I think that this type of exemption is covered by Article 30 of the TRIPS Agreement because, if Bolar is allowed, and it is clearly allowed, that is also covered. Something which is clearly dealing with research and further improvement of a technology should be covered. So there is no need to revise either Article 27 or 30. It is covered in the sense as it is regulated in part by the EU Directive already so that would be a question of harmonizing the patent law, either here in the draft Substantive Patent Law Treaty,

which would be at the universal level, or in national laws.

Prof. Charles McManis: I find myself again speaking for the developing world. It is interesting that Prof. Straus said what he did because there was a built-in review of Article 27.3(b) of the TRIPS Agreement. When it was agreed on it was fairly clear that that built-in review was at the insistence of the United States, which said we will compromise on limitations on patent protection for others than micro-organisms now, but in four years we want a review. The interesting thing is what a change has occurred in the world of politics since that time. Because now it is the developing world that is saying "Yes we want that review, but we do not want it to be limited to what the United States of America wants it limited to." And the United States is saying "Well, maybe we do not want a review after all, maybe it is all covered" just as Prof. Straus has suggested. So I think that there is some political chance that the review process, if it opens, will be more responsive to developing country concerns that to industrialized concerns, European or American. The only comment I would put in here is that as I tried to suggest earlier today, it is not clear to me that the research exemption will necessarily be embraced by the developing world, at least that part of the developing world concerned with exploitation of traditional knowledge who will see the research exemption as a modern European form of gene piracy.

Mrs. Karla Tatiana Ornelas Loera, Third Secretary, Permanent Mission of Mexico, Geneva: I also would like to thank all the speakers, because it has been a very interesting day, especially for those of us who are not experts in plant breeding and I am very glad that Prof. Straus and Prof. McManis have referred to the current negotiations going on in intellectual property. I would like to say that one of the reasons why the United States may not be interested in reviewing the TRIPS Agreement, in relation to this subject of the expansion and increase of patentable material, is because this is now an ongoing discussions in the draft Substantive Patent Law Treaty at WIPO. It is on this that I want to raise my question because the United States has stated that they want to eliminate the exceptions under Article 27.3 of TRIPS and that they want animals and plants to be subject to patenting, as well as other things that currently are not patentable subject matter. This is a major source of concern. Most countries agree on the need to maintain breeders' rights and the exceptions under Article 27.3. Therefore, I would like to know what would the speakers think about the very remote possibility to eliminate these exceptions, because there is a lot of opposition to this?

Mr Peter Lange: Do we have any response to this? Perhaps from the American Delegation? Not so easy. But I think we have heard your message and of course this will be discussed internationally and I hope that an adequate solution will be found, especially for the least developing and developing countries. So may I now, at the end of this discussion, conclude. And of course, this is not very easy, we have heard a lot of different views and statements, but I think there was a general agreement on some major issues. I have written down something which I would now like to present as a first conclusion of this very interesting Symposium. I have divided these conclusions into the three different issues which we had discussed during this meeting.

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