

**WIPO-UPOV SYMPOSIUM ON THE CO-EXISTENCE OF PATENTS
AND PLANT BREEDERS' RIGHTS IN THE PROMOTION OF
BIOTECHNOLOGICAL DEVELOPMENTS**

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Session II: Accessibility of protected inventions and plant varieties for further innovations

Moderator:

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DISCUSSION

Mr. Qiao Dexi opened the discussions.

Mr. Jean-Luc Gal, National Expert detached within the Industrial Property Unit of the General Direction of the Internal Market, European Commission, Brussels:

I should like to thank the different speakers for the quality of their presentations. I should like simply and very quickly to refer to the presentation by Mrs. Henson-Apollonio concerning the European Patent Law on the question of plant variety protection. It is perhaps not completely correct to say that there was a difference between the practice of the European Patent Office (EPO) and the Directive No. 98/44 since it is made very clear in the Directive that plants can only be the subject of a patent if they are new, involve an inventive step and are capable of industrial application, but that plant varieties are excluded from patent protection. Furthermore, the decision of the Court of Appeals (*Grande Chambre de recours*) to which reference is made, takes on, in a more detailed and complete manner, these exact terms. Therefore, there is no difference, as such, between this Directive, the European Patent Convention and the practice of the Court of Appeals of the EPO.

Mrs. Henson-Apollonio: I think that that's what I said except that perhaps in a way in which it was practiced prior to that Decision there was confusion about exactly what the Directive meant. Maybe I misstated that, but I think we have a clear understanding now of what the Directive means.

Mr. Tim Roberts: The interesting thing, from a legal point of view, about the decision of the Enlarged Board was that it based itself entirely on existing law and did not rely on the Directive No. 98/44. So it is a confirmation that, in that instance at least, Directive No. 98/44 was not making new law, but simply harmonizing existing law.

Mr. Huib Ghijsen Global Manager Germplasm Protection, Bayer BioScience N.V., Astene: I have a question on a subject which has been touched on by three of the speakers about the obviousness or non-obviousness requirement. I am referring to the plant patent, there is a quite good description of what is obviousness in the plant patent system and I wonder whether that could also be applied to other varieties. The instruction in the plant patent system says that techniques are obvious using mutants, chimeric plants and doubling chromosomes. Some speakers say that plant varieties as such are questionable whether they are non-obvious. In the United States, they use utility patents and the definition is that, while a plant variety is the unexpected outcome of a systematic breeding process, it is non-obvious. I have the feeling that it is somewhat a meaningless definition so that every plant variety, whether it is protectable under the PVP system or under utility patent meets, in fact, the same requirements. Maybe this is a somewhat complicated subject for a few minutes, but this afternoon we could perhaps proceed on this subject.

Mr. Tim Roberts: This is a fascinating topic and one which we could easily get carried out by. One thing I would say is that, because a technique is obvious, it does not mean that the product you obtain using the technique is obvious. If you take an analogy, if you like, from copyright, anybody can type, it's what they type that is of interest. And the same can apply. The product may not be obvious, although the process is. If it is obvious to apply the process, and when you apply the process you inevitably get a particular product, then that may mean that the product is obvious, but there are some steps, if you like, to be finessed there. This is not an easy question. I personally, and this is a personal opinion, cannot believe that the US Patent Office is right in regarding all plant varieties as automatically patentable simply because not all their features could have been predicted. If that applies for plant varieties, I do not see why it should not apply to other things as well, and that can hardly be right.

Mrs. Henson-Apollonio: My quick comment would be that very often it is the implementation level in which this sort of thing comes into play and that the individual examiner is making a certain judgement or, his examination unit is making a certain judgement. There are certain guidelines of course that are followed in all of the examination Offices in terms of interpreting this language, and so there are several levels of complication.

Mr. Mark Shillito, Partner, Agribio Law Practice, Herbert Smith, London: This is a question for both speakers. Given that the patent research exemption is wider in some countries, but narrower in others, and the fact that in virtually all of them, if you do something for commercial purposes, you are in trouble as far as that exemption is concerned. I would like to ask both speakers what level of success they would expect if they lobbied the patent authorities in their respective jurisdictions to change the research exemption for plant varieties to look more like Article 15(1) of UPOV Convention.

Mrs. Henson-Apollonio: I think, it is of course very much country-dependent and I think it is the sort of thing where you would have to have industrial lobbies that would exert pressure to have something that was legislated so that it was more clear and more stable than the judicial interpretation. So I think, a lot of it has to do with the industry and what the industry can muster in terms of trying to have something that is

workable. But I just brought up the Bolar Amendment in the sense that it is possible to do that, but you would have to go back and look at the history of how that amendment was actually amended in order get a clue.

Mr. Tim Roberts: We were asked to comment on our respective countries. But I can not resist a quick comment on the Bolar Amendment. The fact that it was necessary to find a specific statutory exemption for that situation perhaps suggests that there is something not quite satisfactory with the US law in this question and maybe there should not be a specific exemption for the Bolar situation, and I note that the Bolar exemption goes further than the current European law in fact, and indeed there have been objections to it as not conforming to TRIPS. The fact that there is this specific statutory exemption for this specific situation in the United States may suggest that the broad law needs further attention, particularly with this new case. As regards, Europe and the United Kingdom, certainly as regards lobbying in the United Kingdom Government for changes in this respect, experience suggests that it will not be too easy to get any change. There is, of course, the question as to whether a change is required, and we shall be hearing more about this. But many small companies are not satisfied with a situation where they are almost certainly right when they are faced with powerful opponents who think they are wrong and have the money to back it up with.

Prof. Joseph Straus: In order to prevent mixing up things which do not go together. The Bolar exception is something which is really only allowing an early entry on the market, by permitting tests/clinical trials aimed at proving that the drug of the generic producer, the so-called “me to” drug, has the same properties as the drug, the marketing of which had been already approved. If you are talking about the breeder’s exemption, to my understanding, breeding is involved, not only proving that what you have is exactly the same as that of your competitors, i.e. what the so-called “ethical drug producer” has. So please be careful on that.

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