

DISCUSSION:

THE EXPERIMENTAL USE EXCEPTION

Audience Member: Have any legislatures of the countries we have discussed considered compulsory licensing of experimental use, with perhaps a deferred or continued compensation arrangement as a solution to this problem?

Heinz Goddar: In Germany, obviously not, because experimental use is permitted.

Mark Janis: The TRIPS provision on compulsory licenses is fairly restrictive. You would really have to look and see whether such an approach would violate TRIPS, Article 31.

Audience Member: Regarding the Orange Book, does anybody want to comment about the *Mylan v. Bristol Myers*¹ case? There the generic company sued the pharmaceutical company in district court to pull the patent off of the Orange Book without filing a Paragraph IV certification. They were granted an injunction. Their argument was that the patent did not cover their drug or the drug the pharmaceutical company claimed. It was just appealed and argued last month before the Federal Circuit. It was an interesting tactic. Does anyone know about that case or think that it will stand up?

Panel Member: I do not want to specifically comment on that case, but I think that some courts believe the question of proper Orange Book listing is something that should be addressed by the district court that is going to hear the ANDA infringement action. That case in particular raises the difficulty of putting a patent question in front of ostensibly a Ministry of Health. Many companies go through litigation for two-to-three-year periods to resolve the question of whether the patent was even properly listed. In some ways, it just does not make sense to have a system of that nature.

Martin Adelman: I would like to ask a more basic question. I clearly think that *Clinical Trials II* and the Japanese Supreme Court are wrong. There was no experimental use there. Just trying to get generic drugs on the market faster is not an experiment. They are not experimenting. They are not trying to get any information. They are just trying to say, “look, ours is really a ‘me too’ drug, no use to society at all.” It seems to me that it is plainly wrong. It may even violate TRIPS even though this was tried in Canada and failed. Does anybody agree with me?

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¹ *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

Panel Member: To a great extent that is largely a policy question. You can very easily, as a matter of law – the way the *Roche* court originally did – just state “that is not an experiment.” That kind of experimenting is not the individual scientist or professor in his laboratory just trying to see whether it works. It is an actual act towards getting commercialization. As a policy matter, you can go back to that way of doing it; however, in many places in the world people do not think that is the right policy decision.

Adelman: Because they want to rip off drugs because they think it will get them the drugs cheaper?

Panel Member: I am not sure whether I would agree or disagree with any of the policy decisions. I think that, as Professor Goddar has pointed out, some courts will take the view that it is a decision for the legislature to make regarding what property rights are granted by a patent.

Adelman: The German legislature did not take it; it said “experimental.” That is not experimental. I do not know what the Court said in German – after all they were deciding a German word not an English word there – but how can you say, using English, that the generic companies were doing experiments?

Panel Member: If the choice is between U.S. law versus German law, I would pick the German law because it is in fact a more clearly directed policy than the ambiguous wording of the Hatch-Waxman exemption.

Adelman: Well that may be. I am not arguing for 271(e).

Panel Member: I would never get up and say that the German Supreme Court got German law wrong.

Adelman: I do not know the German word. If the word means “experiment,” then they got it wrong. That was not an experiment. I cannot understand why everybody thought that *Clinical Trials I* was an experiment.

Goddar: The most important consideration, which is what the Japanese Supreme Court said and the Constitutional Court reasoned in *Clinical Trials II*, is that there is no reason to extend the competitive advantage of the patentee beyond the legal duration of the patent. Twenty years, that is it. Anything to extend this period is no good. If you wish to remedy this then you need a different kind of a patent – a thirty-year patent.

Adelman: The German Constitutional Court just allowed the German Supreme Court to cut it down, as a practical matter, to below twenty years, because it is allowing infringement to occur during the twenty-year period. There is nothing the Constitutional Court said that I would disagree with. My disagreement is with the German Supreme Court.

Panel Member: Professor Adelman, I think that you need to take a closer look at the differences between what is required at various stages of clinical trials. Your position that such uses are not experimental does not hold with respect to Phase I or Phase II clinical trials that solely address issues of safety and efficacy. Your argument may have some merit, hypothetically, when you start thinking about Phase III or later trials that have already gone past the issue of efficacy.

Goddard: I would like to make one thing very clear. Except when representing a generic company, I am firmly neutral in this case. I could live with the opposite decision of *Clinical Trials*. It is to me, as a patent scholar, much more logical, but they have decided differently. Now I have to report on that.

Adelman: I understand that, but you do not have to defend it. You can report on it. I do not defend the U.S. decision when the court goes wrong – and usually they do.

Audience Member: I am not a pharmaceutical company. I do electrical work and mechanical work. It seems to me that one issue is behind this debate of Europe and Japan versus the U.S.: We have different medical care systems. In this country, you are pretty much on your own. You had better take care of yourself. You had better plan. In most of the rest of the world there is some kind of national health insurance. So clearly in Germany you are fighting over a predetermined amount of money and about who gets how much of the pie, when it cannot grow. Here, it is up to so-called free enterprise. This is a policy question. To what degree should the patent law determination be based on how people get drug delivery and what the patient has to do?

Robert Blackburn: The upper range cost to develop a product and bring it to market is \$800 million. With research tools, we see tremendous innovation at the front end of the pipeline, which is actually the low cost end of the pipeline. The Phase I, II, III approval process is astronomically expensive. You have different stakeholders now in the process. You have the innovative biotechnology companies at the front end, and the very high end being handled by large pharmaceutical companies. There is more money being spent on clinical trials, but they are getting less and less bang for the buck there. While you have more development possibilities coming in at the front end of the pipeline, the system is being taxed on what it can actually pay for and put through. Perhaps the patent system is just not providing the right incentives for those who are willing to write the check, the big pharmaceuticals. Instead you have this bickering between big pharmaceuticals and biotech. The former are viewing biotech as just a tax on their eventual pay off of development. It is an interesting problem and a policy one, but intellectual property law will be part of it.

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