

PRESENTATION:

**THE HATCH-WAXMAN ACT AND
ABBREVIATED NEW DRUG APPLICATIONS**

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This is a particularly timely topic for me because I am actually involved in one of these ANDA lawsuits under the Hatch-Waxman Act.¹ I will leave it to you to figure out which side I am on – you might be surprised. For many practitioners from across the world, experimental use raises a policy question that needs answering. It stems from the collision that Judge Rader has talked about, between how we allocate what patent rights we ought to have and, particularly for the pharmaceutical industry, the other statutory scheme that exists to greater and lesser extents around the world with regard to getting market approval.

In the United States, we receive market approval through the Food and Drug Administration. There are analogs to that system in most of the developed world. It is a little more complicated in Europe. There has been a great deal of harmonization in the European sphere in regard to getting pharmaceutical drug approval. There is a similar governing body in Japan, which does not have the difficulties of having to work through multiple countries the way the European system does.

One of the difficulties, over time, is that there have not been legislative answers to these questions. Initially, Judges tried to answer the question of what is and is not infringement when it involves something that we would like to speak of as experimental. In the United States we had a legislative answer – and I really like Judge Rader's view that it was a remedy trying to solve a collision. Would everybody, who thinks they understand Hatch-Waxman, raise their hands? No takers? Let me suggest to my colleagues around the world, who are also looking for solutions to the collision between their patent systems and their drug regulatory systems, not to look to the Hatch-Waxman Act as a model. I am a big proponent of the harmonization of patent laws around the world, and from my perspective the United States Hatch-Waxman Act really stands out as a sore thumb.

I would like to briefly describe why it stands out as a sore thumb; this relates to the filing of ANDAs, to which Judge Rader has alluded. By way of background, the predecessor to an Abbreviated New Drug Application in the United States is a New Drug

Edited for publication by Kraig Hill, Toshiko Takenaka and/or Kevin Takeuchi, CASRIP.

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¹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 1984 Stat. 1538 (codified as amended in scattered sections of 21 & 35 U.S.C.).

Application, or an NDA. For a pharmaceutical company that wants marketing permission for a new drug, massive amounts of clinical studies are required. These studies can take several years. If I want to produce a generic and market that same drug, because previous clinical studies have already been done it might seem irrational from society's perspective to reduplicate those studies. So I can file what is called an "ANDA," an Abbreviated New Drug Application.

Let me discuss a particular area of major controversy in the United States between big pharmaceuticals and generic companies. The Hatch-Waxman Act allows an NDA holder, purportedly the original pharmaceutical company that invents the drug, to list its patent in what is called "the Orange Book." The Orange Book is something that the Food and Drug Administration keeps. Once those patents are listed in the Orange Book, a generic company that would like to market the same drug must assert that those patents in the Orange Book are somehow invalid or not infringed by what the ANDA filer plans to do. Once the ANDA holder makes that assertion, the patent holder or NDA filer has forty-five days to file suit. Upon filing suit, there is an automatic thirty-month stay of FDA approval of the ANDA, until there is a court decision in the ANDA filer's favor. If that already sounds complicated, then let me suggest that our colleagues from elsewhere around the world may not want to follow this system.

This is where some of the pressures and difficulties with these two conflicting regulatory schemes arise. The NDA filer, the original drug holder, lists patents with the FDA. You might think that the FDA examines these patents; however, they do not. A generic company that thinks a patent should not have been listed, and does not want to go through a lawsuit with a thirty-month stay, can tell the FDA that the patent was improperly listed. The FDA, not being a patent office, will not make any determination on whether a patent was properly listed in the FDA Orange Book. All it will do is send a letter to the original lister asking whether they properly listed their patent. The answer always invariably comes back "yes." This is one of the difficulties in trying to have a statutory patent scheme work with a regulatory drug approval scheme. The patent expertise is in the patent office and drug approval expertise lies with the drug approval agency. The drug approval agency does not want to look at patents. This Orange Book and ANDA filing system has spawned a great deal of litigation in the United States – which my foreign colleagues may conclude is reason enough not to follow the Hatch-Waxman Act.

Another difficulty that Hatch-Waxman has spawned, and that a lot of corporations in the United States are dealing with, involves certain anti-competitive consequences. Presently, there is a massive Federal Trade Commission investigation of the major components of the pharmaceutical industry, as well as the generic drug industry, in the United States. Having our antitrust organization taking serious looks at what is going on in a particular industry involving patents and drug approvals, alone might suggest that there is something wrong with the system; there may be something askew here.

In conclusion, I suggest that having no parallel to the Hatch-Waxman Act in the rest of the world may be a good thing for our colleagues outside of the United States.

Thank you very much.