



Podcast Transcript

“Promoting the Progress of Science. How Clinical Stage Patent Strategies Can Bring New Pharmaceuticals to Market.”

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Kattman: Bringing a new drug to market is a balancing act. Knowing what patents strategies to consider, and at what stage to implement it can make a big difference. I'm Amy Kattman, and you're listening to BakerHosts.

On today's episode, we will discuss clinical stage patent strategies and how to leverage intellectual property assets to minimize risk and maximize opportunity. Our guest is Stephanie Lodise. Stephanie is a partner in BakerHostetler's Intellectual Property Group. She has a PhD in organic chemistry and co-leads our firm's Biotechnology, Chemical and Pharmaceutical Practice team. Welcome to the show Stephanie.

Lodise: Hi, Amy.

Kattman: Hi, Stephanie. We're glad you're here. To begin, could you share with us what is clinical stage development, and how is it different from other stages of pharmaceutical development?

Lodise: Sure. So, for development a product goes through many stages before it actually gets marketed to people to help with disease. Drug development starts at a proof of concept stage, it goes into basic research, drug discovery, then it goes into animals, and that could take many years before it finally goes into clinical development. And clinical development is research involving people. And this research can happen either before the drug is approved or after it's approved, and the marketing applicant wants to determine whether the approved drug can do something better or different.

Kattman: Are there competitive considerations that a marketing applicant should be thinking of during clinical development?

Lodise: Yes. The pharmaceutical field is very competitive. There are large pharmaceutical companies, small pharmaceutical companies, there are generics, there are 505(c)(2) filers, and they all are jockeying for doctors to prescribe their drugs. And they're also jockeying for a position in the FDA's regulatory approval process. So, whenever you're entering into a clinical stage and there's a press release about that, all those competitors are paying attention. They want to see how is your trial going to be run, what findings are you looking for, and how well are you doing in those clinical trials. And competitors are always looking at that information trying to gain an advantage over the marketing applicant.

Kattman: So, let's talk about clinical trial data. Why is it important for the marketing applicant?

Lodise: The clinical trial data is important because it is what will be used to provide to the FDA or another regulatory authority to get the drug approved, either as a first approval or for a new indication or new formulation. It is the culmination of years, possibly even decades, of work. That data, it is truly the holy grail of pharmaceutical development, and it could be used to show so many things that could help the marketing applicant in front of the FDA or another regulatory authority. It can demonstrate that the drug is safe and efficacious, which is the minimum requirement for approval in the United States. It can show that the drug is better than a competitor's, or safer than a competitor's. It can show that a drug has an indication that no one else prior to the marketing applicant doing the study, thought that the drug would be able to help. It could be a study that shows what was done off-label for decades is actually safe and efficacious when done at a particular dosing schedule. So, the clinical trial data is important because it is the drug, it is what the marketing applicant will rely upon in order to get the drug approved and to also sell it after approval.

Kattman: I would say so. That is important. What are some of the potential benefits of intellectual property created during clinical stage development?

Lodise: So, just take a step back and just discuss what is intellectual property and how does it apply to pharmaceuticals specifically. So, the patenting laws allow the patent holder a period of exclusivity for a certain amount of time, and the laws in the U.S. and other countries want to give these incentives because there's the belief that these incentives will spur further innovation. Now, pharmaceutical development is a high-risk venture. The risk that you will fail in bringing your drug to market is extraordinarily high. Not only is that risk palpable, but at the same time you can as a marketing applicant lose billions of dollars before you realize that your drug will never hit the market. So, providing incentives to companies to make those investments and take on that risk I feel are important. So, in pharmaceuticals, much of the time the holy grail of patent protection is seen as the patents that cover the molecule, that cover its general method of use, its formulations, different crystalline forms of it. But, as we know from the research that we see even today, just identifying a molecule does not mean that you will

eventually get onto market with an approved safe and efficacious product. So, developments, discoveries are happening into clinical trials when that drug is first administered to humans and we're given the first opportunity to see what all those decades of pre-clinical research, what happens when it's given to a person in real time. And in many instances, not all but in some, it requires ingenuity, perseverance, lots of thought, group thinking in order to solve problems with a particular molecule in order to bring it to market as a safe and efficacious drug. So, while some drugs, you put them in powder in a capsule, you give them to a patient once a day, wonderful. It works just as it was predicted to, it's safe, a patient can take it for years and years and years, and it helps, for instance, with their cholesterol or with high blood pressure. Then there are other drugs where you try it the first time in people and the first dosing regimen you see incredible adverse events. It's not tolerated well by most of the study population. And it's when the clinicians and the researchers keep thinking about those problems, studying the effects that they're seeing, and come up with alternative ways of perhaps formulating that drug or administering that drug on a certain schedule that take a previously, a molecule that you wouldn't have thought would ever get approved, transforming it into something that's not only approvable but is even better than what was initially sought.

Kattman: Let's switch gears a little bit and talk about risk. How can a marketing applicant minimize its risk of forfeiting intellectual property while also maximizing opportunities for obtaining intellectual property from the clinical stage development?

Lodise: So, I think what's most important for marketing applicants to remember and understand is that inventions can happen at any point in time, even during clinical trials. And one thing that I see marketing applicants do often is that they create tremendous risk to a loss of getting any intellectual property is they publish too soon. They publish things that are too detailed, for instance, in the United States we're required to put a notice on clinicaltrials.gov to let the public and patient populations know that there will be a clinical trial available that might help a particular patient population. That's the purpose of clinicaltrials.gov. What I see lots of applicants doing is posting on clinicaltrials.gov the exact regimen, what endpoints they're looking for, really teeing up what their thought process is as to why they think this new formulation or new dosing regimen will be successful. And a lot of times those are published without first having an application on file, a patent application on file. And the danger of that is, if there's a publication before there is a patent application filing, intellectual property rights can be lost. So, that information, it will generally be considered donated to the public. So, that's one way that marketing applicants can lose exclusivity – they publish too soon, or too much detail on clinicaltrials.gov. The other way that I see potential forfeiture of IP is when the clinicians are getting very excited about their results and what they're seeing. And say phase two ends, they're starting on phase three, and the clinicians are out in the public speaking about what they've seen or observed, or making predictions as to what will happen in the future. And it's wonderful. We want our scientists to share information and that is certainly their nature, but those premature disclosures without having a patent application on file, they can also risk IP. And it could also be, you know, statements they made might be

predictive, but they might be wrong. And those statements might come back during patent prosecution perhaps, and be detrimental to securing protection. So, we don't necessarily want to stifle our clinicians or our researchers from talking about they've found. We want them to tell IP counsel first so that adequate applications can be put on file and the researchers can be tutored on what can be said, should be said, and the impact of their statements on future protection.

Kattman: So, it seems there really is value in following that order. It's, your property is at risk.

Lodise: Yes.

Kattman: Do clinical stage patent strategies reduce patients' access to pharmaceuticals?

Lodise: I know that there will be patient groups who think yes, it does, because there are patient groups who believe that any patent, any effort for a marketing applicant to prevent generics at the same time prevents access. And what I think patients should also keep in mind is that without the patent protection, without these incentives, those drugs wouldn't exist or be available for generic filers to make inexpensively in the future. So, I believe what patent protection during clinical stage development does is it provides incentives for companies to make those risks so that we can have new, better, more improved products being brought to market. And there might be the period of time where patients will have to wait before the prices come down, but I believe that that wait is worth the investments in providing the patent protection.

Kattman: Now, is this evergreening?

Lodise: So, I think evergreening is sort of a bad word. It's generally used to connote where marketing applicants are getting intellectual property in attempts to secure patent protection and exclusivity for longer and longer periods of time to delay competition. But where those efforts aren't, those patents don't provide a therapeutic advantage to patients. I don't want to comment necessarily on whether that's good or bad. It certainly is something that the patent laws provide that you can do because if it's an invention, you can patent it. I'm not talking about clinical stage trials and discoveries that don't necessarily have a therapeutic advantage for patients. I'm talking about those clinical trials, those studies where there is an absolute therapeutic advantage for patients. So I would not consider these strategies to be evergreening.

Kattman: So, one final question for you, Stephanie. When should a marketing applicant start thinking about clinical stage patent strategies?

Lodise: So, as a patent attorney, I would say marketing applicants should think about it as early as possible, because it really is going towards what will you eventually put on the market and be able to provide to patients. So, I believe throughout the whole clinical trial process, usually after one molecule's been identified to move forward into the animal studies, into pre-clinical studies. People should be, the group should be paying attention. What are the findings, what are the

discoveries, what, is this molecule doing things that are surprising or unexpected, is anything new, and share that with IP counsel just to be able to identify inventions when they're there because it's very often the case that the clinicians are so excited to have the drug be working, or so excited to solve a problem that they don't stop to see that they've actually invented something that wasn't there before.

Kattman: Thank you, Stephanie. If you have any questions for Stephanie, her contact information is in the show notes. As always, thanks for listening to BakerHosts.

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