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Post-Grant Review Roils Patent Litigation Waters

More changes to come as Congress, the courts and the Patent Office weigh in

The America Invents Act (AIA) has had a profound impact on patent litigation, particularly surrounding inter partes and other post-grant proceedings. Below, ***Manish K. Mehta****, who handles patent litigation across an array of key sectors, including pharmaceuticals, discusses both the defensive and offensive strategies that companies can employ in the rapidly evolving patent arena. His remarks have been edited for length and style.*

MCC: As an IP litigator you represent companies ranging across sectors, from life sciences to manufacturing. Are the changes to the patent laws, particularly the introduction of inter partes review proceedings, having different impacts on different sectors?

Mehta: Absolutely. I have been involved in litigation spanning the pharmaceutical, medical device and heavy machinery industries where we have filed or considered filing IPRs. In my experience, the number of competitor IPRs in the pharmaceutical sector is lower than in other industries. I think that is because many pharmaceutical disputes are litigated under the Hatch-Waxman Act, which covers the regulatory approval process for generic versions of a branded drug and provides the statutory requirements that need to be considered in assessing whether to file an IPR. For a company looking to make a generic version of a branded product, it must certify to each of the patents listed in the Orange Book (which is not actually orange or a book; it's on the FDA website). A generic company or Abbreviated New Drug Application (ANDA) filer can submit a Paragraph IV certification that the proposed generic product does not infringe the Orange Book patent(s) or that the Orange Book patent(s) is invalid. This is commonly referred to as a P-IV certification.

Evaluating whether to file an IPR petition is a mandatory consideration when mounting a patent defense.

Once the innovators or NDA applicants receive a P-IV certification, they have a 45-day window to file a lawsuit to secure a 30-month stay of the final approval process for the generic product. P-IV certifications happen quite frequently because the Hatch-Waxman Act incentivizes generic companies to challenge Orange Book patents by granting them a 180-day "first filer" exclusivity, which goes to the first generic or generics to submit a P-IV challenge to a particular product. That means some generic companies may have limited market exclusivity for 180 days, which can be very valuable. However, this exclusivity can be forfeited under certain circumstances. Since the IPR process moves very quickly and a petition can be filed prior to a lawsuit by the patentee, there may be a final decision from the federal circuit prior to the expiration of the 30-month stay, which could trigger the forfeiture of the 180-day exclusivity. The law in this area is still evolving. However, there is this regulatory framework to be careful about when considering an IPR petition in a Paragraph IV litigation. It's not to say that it hasn't been done, but it is definitely something to be mindful of.

Moreover, because Hatch-Waxman litigation frequently involves multiple generic filers, some defendants may not have an incentive to file an IPR petition if they have a unique non-infringement position. They might not want to challenge the patent via the IPR proceeding because that may open the floodgate for all other generics to enter the market around the same time. If a non-infringement position, which hopefully is unique to me, could get me on the market before everyone else, why would I want to challenge the validity of the patent?

MCC: Has your strategy changed for patent litigation defense? What approaches are most likely to lead to a successful outcome, especially given the sensitivity of in-house counsel to what are perceived as out-of-control IP litigation costs?

Mehta: The strategy now is very different. In my opinion, whether to file an IPR petition is a mandatory consideration when mounting a patent infringement defense. In my practice,

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our strategic defense planning includes quickly evaluating whether to file an IPR or some other type of post-grant proceeding. Time is of the essence here because there is a limited window to file an IPR petition if you've been sued on that same patent – the one-year time bar. If you don't file an IPR petition of a patent within a year of being served with a complaint alleging infringement on that patent, you're going to be time-barred from doing so.

The ability to challenge a patent in a more favorable forum is a major shift in the patent litigation defense landscape. For in-house counsel, one primary concern is cost surrounding the substantial work needed to assess filing an IPR petition. You want to find a way to get the work done properly but not blow the in-house litigation budget. In most cases, we use a multistep process. We identify the relevant claims that may be asserted against our accused product. Sometimes it's worthwhile to focus your IPR petition on only the claims that matter as long as you have strong non-infringement defenses with respect to the rest of the claims. Next, we assess the strength of our non-infringement defenses. If they're strong enough to withstand an infringement allegation based on non-infringement – stronger, say, than your invalidity defense – we may not want to file an IPR petition. The burden of proving infringement is on the patentee, and you'd rather put the onus on the patentee in district court litigation if you're confident that you have a strong non-infringement position.

If it's not as strong as you'd like, then you may want to evaluate the strength of the invalidity defense. I tend to do these two steps in parallel with invalidity because you may have equally strong non-infringement and invalidity defenses. You may still want to launch the invalidity attack in the IPR proceeding because of the challenger-friendly aspects of an IPR proceeding: lower burden to prove invalidity, broader claim construction and no presumption of validity. If you use the invalidity defense, you have to remember that it's based on prior art patents and printed publications only. If your defense is based on prior use or sale, you can't raise it in an IPR proceeding. You may need to take the nature of your invalidity defense into account in deciding on whether or not to file an IPR. Lastly, I would look at other defenses, such as failure to claim statutory subject matter under 35 U.S.C.101. This defense has become more popular in light of the *Alice* decision. You may be able to get the case dismissed via a dispositive motion under Rule 12(b)(6) and circumvent the expensive cost of litigation through trial.

As in-house counsel attempt to control costs, I'd recommend asking counsel for a phased approach, assuming the company is not looking to settle based on a nuisance value. In conducting the filing due diligence up front, one option from a business perspective is to ask your outside counsel to execute each of these phases under a "not to exceed" fee cap so you have some cost certainty. Nine times out of 10, this due diligence will be useful even if you don't file an IPR petition.

MCC: Where is the action these days as far as patent litigation goes? Is it pharma or medical devices?

Mehta: Both of those are very litigious sectors. Looking at the pharmaceutical space, according to a study by Lex Machina there were 466 ANDA litigations filed in 2015, up from 434 the prior year. That's a significant number of patent cases and a result of multiple companies seeking to make a generic version of the same branded product. This results in multiple lawsuits involving the same drug. For example, I was recently involved in a pharma case where there were more than seven related litigations over the same drug.

Looking at the medical device industry, while it's less litigious in terms of volume, there are still a sizable number of competitor cases, and some of the largest patent verdicts over the last couple years are in this space. One example is *Stryker v. Zimmer,* in which Zimmer was ordered to pay more than $200 million for willful infringement. The federal circuit reversed the willfulness finding, which slashed the damages award, and now the issue concerning the scope of enhanced damages is before the U.S. Supreme Court and being closely watched by the patent community. While the number of cases in the medical device space is definitely lower, they are very meaningful.

MCC: Some litigators say they are seeing a new type of litigation spawned by the America Invents Act – patent trolls challenging branded pharma patents to move a stock price. Have you seen any of this?

Mehta: I'm not directly involved, but I've been watching this trend closely. It's unclear to me whether they are trading on the stock prices or what the net effect is, but one can make that assumption based on the handful of non-practicing entities filing IPR petitions on Orange Book patents that cover drug products. It's an interesting tactic with significant upside to the petitioner. Non-practicing entities can do this because they do not need standing to file an IPR petition. Anyone can challenge a patent regardless of whether they have a competitive product or not. There has been a movement to create a standing requirement that could potentially curtail or limit these types of challenges, including proposed legislation.

I don't think a standing requirement will be put into place. It would undermine the purpose of IPR proceedings, which was to seek review of patents that may not be patentable or susceptible to challenge because they are not novel or they're obvious in light of the prior art. It would be difficult to draw fair lines of demarcation between which parties are eligible to file an IPR proceeding and which are not. From a practical standpoint, I don't see how we can strike a fair balance.

MCC: What's this issue concerning real parties-in-interest in the IPR context? It seems to be a requirement that is rather benign, but there has been some activity on this front.

Mehta: There are rules in place that require the petitioner to identify all of the real parties-in-interest (RPI) in the petition. There is no bright-line test to determine who is a RPI, but the Patent Trial and Appeal Board (PTAB) has provided guidance. An RPI is a party or parties at whose behest a petition was filed. Typically, an entity is an RPI if it funds, directs or controls the IPR proceeding, or if it could have exercised control over a party's participation in a proceeding.

The RPI requirement in the petition is an important tool to prevent other interested entities from challenging the same patent on the same or similar grounds as long as those folks were related to the original petitioner or were a RPI to the original petitioner. Why is that? In a final written decision in IPRs there is an estoppel provision that bars RPIs from asserting claims the petitioner raised or reasonably could have raised during the inter partes review in litigation. This prevents serial filing. That's why it's important to have all of the RPIs identified in the petition, and the Patent Office and the PTAB have taken this requirement very seriously. There can be serious ramifications if it's later discovered that all of the RPIs were not identified. For example, the board can vacate the original filing date of the petition, which means the petitioners must file a subsequent petition that identifies all of the RPIs and the filing date will be the date of that second petition, which can implicate the one-year time bar if there is a parallel litigation on the same patent. If the new filing date is one year after the date of service of the complaint that alleges infringing of that patent, the petitioner won't be able to file an IPR proceeding on that patent.

MCC: From a litigator's perspective, what are the tricks to building a bulletproof patent portfolio?

Mehta: I have a few strategies. One is maintaining a pending application related to your core technology. It's absolutely critical because it can help mitigate any harm to your patent portfolio if any of the issued patents are subsequently challenged in an IPR proceeding. It might even give you an opportunity to strengthen your portfolio through

what you learn from any ongoing proceeding on a related patent, and it can help you craft claims to overcome any invalidity arguments that were made during those proceedings. It also allows the patent owner to strengthen claims in the related application that can withstand subsequent IPR challenges if the application issues.

The other benefit, and we do this quite frequently, is an opportunity to draft claims that cover the petitioner's technology because you now know that they clearly are interested in your core technology. It shouldn't be very difficult to figure out what they are doing commercially based on publicly available information and to build a set of claims that cover it to provide you with a stronger infringement position.

On the petitioner side – I represent both patent owners and petitioners – one of the first things we do is look at the patent family of any patent that we are looking to challenge in assessing whether to file an IPR petition. The presence of a pending application related to the patent that we're looking to challenge is one relevant factor in assessing whether to file an IPR petition.

The second tactic that I discuss with my clients is creating dependent claims with value, meaning that the dependent claims of any patent application that you draft should include meaningful limitations. In studying patents that are potential IPR candidates, I often see that the dependent claims include meaningless or obvious limitations and do not add additional nuggets of novelty to the invention. This makes it much easier from a petitioner's perspective to invalidate those claims. You also need to build in a series of dependent claims in your claim sets to require the petitioner to link multiple prior references together. This is one of the areas where much can be done to help withstand IPR challenges from a patentee's perspective.

And, finally, bolster your portfolio with design patents, which are a smart and inexpensive way to strengthen your patent portfolio. Design patents are also eligible for IPR proceedings, but there haven't been many challenges to date. One of the benefits of an IPR proceeding for utility patents is that the threshold is lower to demonstrate invalidity. For design patents, it's virtually the same standard as in district court litigation, which inures to the benefit of the patentee. It is also rare to invalidate a design patent based on obviousness grounds. I would definitely recommend including design patents in your portfolio.

MCC: Are there times that it makes sense for companies that are usually on the defensive side on patent litigation to go on the offense? When is an offensive strategy appropriate?

Mehta: There are times when companies should be proactive. One strategy is to challenge a patent or patents owned by a third party that may have a profound impact on your business. For example, there may not be a lawsuit or threat of litigation just yet, but if company A identifies patents owned by a third party that potentially could be problematic for company A's business, that may be a circumstance where you would want to consider looking at an IPR petition to remove the uncertainty that can cloud the business. Instead of taking a wait-and-see approach, you may want to be proactive by removing this risk to your business. And I would make the challenge robust. First, consider challenging all of the patent claims, not just the ones you think you might infringe, because you will eliminate the possibility of a non-challenged claim being asserted in litigation. Also, one of the true benefits of an IPR proceeding is to promote business resolutions by advancing settlement discussions. Essentially, by attacking all of the claims, you're calling into question the entirety of the patent, not just a subset of claims. That can create significant leverage.

I also recommend preparing an IPR petition and providing it to the patent owner prior to filing, and then potentially negotiating an amicable solution. Why is this important? Once you file an IPR petition, you can't unring the bell. The petition will be public and will remain in the public domain even if the parties reach a settlement and the PTAB grants a request to terminate the petition or proceeding. The IPR petition, if done properly, provides a road map to potential invalidity arguments that could be easily incorporated by another party in a subsequent IPR. The patent owner should see value in the non-disclosure, which will give the challenger leverage in negotiating a settlement. And you can always file the petition if the negotiations fall through without the concern of a time bar if there is no parallel litigation.

MCC: Now that we have some experience with post-grant proceedings, where do you see things moving in the months and years ahead?

Mehta: We are going to see a lot of changes coming from three areas: court decisions, the legislature and the Patent Office itself. We can expect the federal circuit to weigh in on the PTAB decisions. We've already been seeing this happen recently. One hotbed is the scope of the estoppel provision that we talked about earlier, where the RPIs, if there is a final decision, will be estopped from raising those grounds that they did or could have raised in the IPR proceeding. In a case decided on March 23, 2016, in *Shaw Industries Group v. Automated Creel Systems*, the federal circuit held that grounds that were not instituted by the PTAB on the basis of redundancy will not be subject to estoppel in later proceedings. As you can see here, the federal circuit is now starting to carve out exceptions to the broad, and what can be seen as overbearing, estoppel provision that was originally enacted in the IPR proceedings.

The Supreme Court is also going to start looking at some of these issues. They've granted review of *Cuozzo Speed Technologies v. Lee*, which was the first IPR decision ever by PTAB, and will consider two issues: the claim construction standard used in IPR proceedings and whether a PTAB decision to institute a trial can be reviewed after the final written decision. These two points will have a profound impact on future proceedings. Oral arguments were held on April 25, 2016, and we are patiently waiting the Court's decision.

Lawmakers are seeking to address such things as the standing issue – which parties can file an IPR petition – and also create a presumption of validity of a patent just like in district court, and then employ a claim standard consistent with the *Phillips* decision.

In terms of the statistics, the IPR was seen as pro-challenger or anti-patentee at its inception, but I think we're starting to see the pendulum begin to swing back in favor of patent owners, which should bring a sigh of relief from innovative companies that are seeking to patent their innovations.

The IPR institution rate has dropped from around 75 percent in 2014 to 68 percent in 2015 and is hovering around the same mark this year. But the institution rates don't tell the entire story. Once the petition has been instituted, the rate at which the claims have been canceled or held to be unpatentable remains very high – around 80 percent. This tells patent owners that the battleground should be focused on preventing the institution of an IPR proceeding, and the patent owner should spend a considerable amount of time and resources filing a preliminary patent owner statement and fighting the institution of the petition instead of being coy and waiting to mount its full defense post-institution.

Those are some areas where I think we're going to see a lot of change. It's an exciting time, and I'm glad to have clients that are active in this space and to be able to continue to represent them in these types of proceedings.