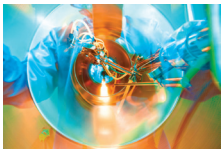
METROPOLITAN
CORPORATE
COUNSEL®

OCTOBER 2015

WWW.METROCORPCOUNSEL.COM



Special Section:

HEALTHCARE & MEDICAL DEVICES

MCC INTERVIEW: Dorothy Whelan / Fish & Richardson

Post-Grant Pushes Forward in Life Sciences

IPRs embraced as a faster and cheaper means of challenging patents

MCC interviews ***Fish & Richardson*** *principal* ***Dorothy Whelan*** *about emerging trends in challenging and defending life sciences, pharmaceutical and biosimilar patents at the USPTO. A leader in the field who has handled over 100 inter partes reviews (IPR) and covered business method matters, Whelan describes how IP litigators are using IPRs to develop successful new strategies.*

MCC: Fish was recently named the #1 most active law firm at the PTAB. Can you share with us the work you are doing generally in the post-grant area, and specifically how you are using IPRs in your patent and litigation strategies for life sciences companies?

Whelan: After the America Invents Act (AIA) introduced new post-grant proceedings in 2011, this became the hot new practice area and every law firm wanted to be part of it. At Fish, we've been the most active firm in both challenging and defending the validity of patent claims for over 30 years. These proceedings were called patent reexamination before the AIA introduced the new inter partes review (IPR), post-grant review, and covered business method proceedings. With all of our expertise – and hundreds of reexamination matters under our belt – we helped shape the AIA rule-making process before it was finalized, and have been helping our clients understand how to use these powerful new tools.

Dorothy Whelan
Co-chair of Fish & Richardson's Post-Grant practice
whelan@fr.com

There isn't another law firm in the country with our level of knowledge and experience, which is why we are the #1 most active law firm at the PTAB. Over the past two years, Fish has handled 284 post-grant proceedings and concluded 169 matters, which is a staggering number.

Specifically in the life sciences, we represent both patent owners and petitioners. Our IPR teams work closely with our litigation teams to provide a comprehensive and coordinated enforcement or defense strategy. For petitioners, part of that strategy involves evaluating whether the PTAB or district court is the appropriate forum for challenging a particular patent. For patent owners, it can mean anticipating an IPR challenge. Our ability to draw upon our firm's deep expertise in both patent prosecution and litigation is a big part of what differentiates us from other firms that do post-grant work, and what makes us so successful.

Many use the patent owner's preliminary response to convince the PTAB to deny institution.

MCC: The number of life sciences IPRs has been steadily increasing. What's behind the growth, and what have you learned from your work in this area?

Whelan: Inter partes review was designed as a cost-effective alternative to litigation for challenging patents. Part of the growth has been spurred by the relative success that petitioners have enjoyed in the electrical and mechanical areas. Our firm has done extensive work in those areas, and many of the lessons learned apply equally to life sciences patents. For example, in each of these technology areas, it is critical for a petitioner to do a lot of legwork upfront to identify the best prior art references and then to present a robust, well-reasoned challenge based on those references – in essence, treating your petition as your trial brief, rather than your invalidity contentions.

For patent owners, a useful strategy involves attacking the sufficiency of the evidence offered to establish, e.g., inherency or a

motivation to combine references. And in all cases, it is important to coordinate IPR and litigation strategy.

MCC: There have not been a lot of IPR petitions yet in the biosimilars and biologics space. Do you expect that to change and why?

Whelan: It is already changing. It is really a question of timing. The patents covering many of the basic drugs are starting to expire, leaving patents covering formulations and dosing regimens. We expect to see the latter being challenged via IPR.

MCC: Tell us more about the biosimilars and biologics IPRs that have been filed – where do those stand and how will the outcome affect other filings?

Whelan: The PTAB recently granted an IPR petition that Boehringer Ingelheim filed against a patent owned by Genentech. This was the first biosimilars-related IPR petition to be granted. Following institution, Celtrion filed a "copy cat" petition seeking to join the proceeding. This illustrates an interesting phenomenon in the biosimilars field. Specifically, we expect to see multiple biosimilars parties challenging a patent or portfolio of patents relating to a particular drug, which creates complex timing and joinder issues. The "patent dance" provisions of the BPCIA governing biosimilars creates additional strategic timing issues.

MCC: Fish is one of the leading firms litigating Hatch-Waxman ANDA cases for big branded pharma companies. What role are IPRs playing in your ANDA litigation strategies?

Whelan: We represent branded companies in Hatch-Waxman cases. Therefore, our clients are the patent owners in IPRs with related Hatch-Waxman litigation. In biopharma, Hatch-Waxman litigation is typically the process for adjudicating patent validity. However, the number of biopharma-based IPR challenges has been steadily increasing. For example, we have seen an increasing number of IPR petitions filed by generic manufacturers, particularly against patents directed towards formulations and methods of use.

With the growing popularity of IPRs, we expect to see even more IPR challenges in the pharma and biotech space, particularly where multiple generic challengers are involved. For branded companies, this highlights the importance of maintaining a deep portfolio. The presence of pending continuation applications can be key. We also encourage the use of "picture claims," which often can be defended more easily against an obviousness challenge compared to broad independent claims.

MCC: Non-practicing entities like hedge fund manager Kyle Bass have come under fire for using IPRs as "weapons" against pharmaceutical patents in what many argue is for personal gain. Do you expect these NPEs to be successful, and what can patent owners do to protect themselves from being targeted by NPEs at the PTAB?

Whelan: NPEs in the life sciences sector are different from the trolls in the tech industry. The latter acquired patents and then sued multiple companies with the objective of extracting a financial settlement. Many of the targeted companies then filed IPR petitions to defend themselves. In the life sciences sector, what we have seen are trolls who file IPR petitions against patents held by pharmaceutical companies with the objective of depressing stock prices and/or extracting a financial settlement.

These NPEs will only be successful if they can convince the PTAB to grant their petitions. While recent PTO statistics show that petitions are granted more often than they are denied, the success of NPEs will ultimately turn on the quality of their petitions. It's interesting to note that two of Kyle Bass' petitions were denied recently on the ground that they failed to establish that the references qualified as printed publications.

There is not much that a patent owner can do to prevent an NPE from targeting it. What patent owners can and must do is concentrate on convincing the PTAB not to grant these petitions. If more and more petitions are denied, IPR becomes less of an attractive tool for an NPE.

MCC: What should a life sciences company do if an NPE files an IPR against them? Can a petition be knocked out prior to institution, and can an NPE petitioner appeal to the Federal Circuit if they lose?

Whelan: Often the best strategy is to use the patent owner's preliminary response to convince the PTAB to deny institution. Most patent owners file preliminary responses. They have been effective, particularly in the life sciences area. Challenges can be based both on procedural grounds, such as failure to name a real party in interest, or substantive grounds, such as failure to provide a well-reasoned rationale for combining references. The PTAB's proposed rule changes may make preliminary responses even more effective tools by permitting patent owners to submit expert testimony with the response. Regarding appeal, decisions on institution are final and non-appealable, providing yet another reason why it is a good strategy to convince the PTAB to deny institution.

If the petition is granted and proceeds all the way to a final written decision, and the NPE loses, the NPE may not have standing to appeal to the Federal Circuit.

MCC: Are the kinds of claims and challenges in life sciences IPRs different than other industry categories?

Whelan: In the life sciences area, many challenges are based on obviousness. Claims often involve drug formulations and dosing protocols. What distinguishes life sciences IPRs from mechanical or electrical IPRs, for example, is that in life sciences the issue of unexpected results frequently arises and often becomes the focal point of the obviousness issue.

MCC: What new rule changes are on the horizon that could directly impact life sciences companies? Are there any that specifically impact biosimilar and biologic companies?

Whelan: Two proposed rule changes come to mind. One is the proposal to allow patent owners to include expert testimony with their preliminary responses. Currently, it is not possible to submit new testimonial evidence with a preliminary response. In contrast, the IPR petition typically includes one or more expert declarations. This proposed change could strengthen preliminary responses and aid patent owners in convincing the PTAB to not grant an IPR petition.

The second proposed change relates to imposing Rule 11-type requirements on practitioners. Coupled with the authority the PTAB already has to grant sanctions, it could deter NPE activity involving petitions filed for improper purposes.

MCC: Looking ahead, how big a role will IPRs play in the life sciences industry one year, three years, and five years from now?

Whelan: I predict that IPRs will play an increasing role in the life sciences industry, particularly in the biosimilars context. They represent a fast and relatively inexpensive means of challenging patents and creating freedom to operate space.