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Biography

Elizabeth Barnhard chairs Leason Ellis' pharma/biotech practice group. As a strategic advisor, she uses her vast legal and corporate knowledge to create robust IP portfolios that protect her clients' intangible assets and add value to their businesses. Ms Barnhard's experience in all phases of litigation, appeals of intellectual property, unfair competition actions and USITC Section 337 proceedings have helped her to resolve academic research companies' and start-ups' IP issues, allowing them focus on their businesses.

As a mentor to law students and young lawyers, what is your most valuable piece of advice for aspiring IP professionals?

Being an IP professional means that you will work with clients on the innovations of the future. Whether you want to prosecute or litigate, you must learn to do both to be an effective lawyer. It is not enough to obtain a granted patent if the claims will not hold up in litigation. Working on invalidity and non-infringement opinions, as well as seeing how claims are attacked in litigation and what happens on appeal gives you the perspective to strengthen the written description and the claims, avoid potentially damaging statements during prosecution and obtain enforceable claims. Similarly, learning patent prosecution teaches litigators the challenges in obtaining a patent and what to look for in its prosecution history.

But it is not enough just to know the law. You need technical knowledge and you must keep up with developments in your subject areas. Be curious. Devote an hour each day to read about something new and expand your knowledge base, stay current on new developments and fuel your creative thinking. Clients will appreciate that you are keeping an eye on future trends that could impact their work.

You have extensive experience in all phases of litigation and Section 337 proceedings before the International Trade Commission (ITC). What are three top tips for an effective portfolio enforcement strategy?

First and foremost, before a Section 337 proceeding is instituted, it is vital to have an independent counsel carry out an analysis. Find foreign counterpart patents to identify any weaknesses in the claims and if possible, eliminate these before filing a complaint. This upfront assessment is necessary to make an informed decision; ITC proceedings move rapidly, and they are expensive and disruptive to businesses.

Ownership and licencing records must also be checked carefully to ensure that the right companies and/or individuals are the petitioners. Are there assignments? Is the chain of title correct? Are there any exclusive licencees that should be petitioners? Is there a parent and/or subsidiary company that should be a petitioner? Respondents will challenge the failure to include all those who should be petitioners, which could result in dismissal of the proceeding - a negative and costly outcome for the petitioner.

The petitioner controls when the complaint is filed and should prepare beforehand for the fast-track demands of ITC litigation, as well as for the impact on budget from compressed legal costs that would be spread out over several years in a typical litigation.

When the ITC issues a notice of institution – bringing about a Section 337 investigation – a series of tight deadlines must be met until the ITC issues a final determination 12 to 16 months later. Within 45 days of the notice, the administrative law judge (ALJ) issues a scheduling order for fact discovery, claim construction and expert discovery, to be completed within six months. This is followed by an evidentiary hearing (equivalent to a trial) two months later, because the ALJ must issue an initial determination of violation at least four months before the ITC's target date for issuance of a final determination of violation.

Let those time frames sink in for a moment. All discovery by both sides must be completed in six months. This is disruptive and expensive for both petitioner's and respondent's businesses, as responses to discovery requests must be produced within 10 days after service of the request. Years ago, a respondent incurred over US$1.5 million in legal fees during the discovery phase - more than its entire net income the previous year.

What, for you, are the most crucial elements of a world-class IP portfolio in the biotech space?

A world-class biotech patent portfolio must protect the owner's manufacture, use and sale of its invention. It should deter competitors and source revenue, whether that be from sales, licensing fees and/or royalties. For biologic therapeutics, the portfolio should protect the biologic, functional derivatives, formulations, uses, delivery vehicles, manufacturing processes (unless trade secret protection is warranted), diagnostic tests, future improvements and new uses.

AI is the hot topic that everyone is talking about. What are some of the biggest threats and opportunities you see in this space?

For attorneys, generative AI has great potential for automating repetitive tasks, creating templates, speeding up search and analysis in litigation and major transactions, and legal research using natural language search queries. Legally focused AI tools with known data sources, confidentiality protection and security are available, and there is more to come. However, using publicly available AI chatbots like ChatGPT, Bing and Bard presents significant ethical risks for lawyers who are obliged to preserve clients' confidential information, provide competent representation, use legal judgment and confirm the accuracy of information in their work product. Issues with data privacy, cybersecurity, bias in

datasets, copyright infringement, regulatory compliance, ownership of AI-generated work, accuracy of AI chatbot-provided information and lack of industry standards raises multiple ethical issues. For now, lawyers must stay current on developments, privacy policies and terms of use before using AI, and get trained on how to use generative AI effectively and ethically.

What has been your proudest professional achievement to date, and why?

One of my proudest professional achievements was prosecuting the family of patent applications that would provide protection for Mylotarg (gemtuzumab ozogamicin), the first FDA approved cytotoxic drug-antibody conjugate. It was approved in May 2000 as an orphan drug for use as a stand-alone treatment for patients with CD33-positive acute myeloid leukaemia who had relapsed. I took over prosecution from the retired in-house attorney who wrote the parent application when I joined AHP/Wyeth in 1995.

I was privileged to work with the inventors and our collaboration partner to successfully obtain patent coverage for Mylotarg and subsequent process and formulation developments. When the new drug application was being prepared, my prosecution work and the patents I obtained were reviewed by external counsel as part of the decision-making process for which patents to include in the application and list in the Orange Book.

In-house patent attorneys write and prosecute many applications for potential drug candidates. Due to the high failure rate, it is rare for an in-house patent attorney to have their work be associated with a successful drug candidate that becomes a product. To be part of the team that advanced the development and launch of Mylotarg taught me many lessons and was a special experience in my professional career.

Your clients span large companies, SMEs, start-ups, solo entrepreneurs, and academic and research institutions. How do you tailor your approach to the type of client that you are dealing with?

My approach with each client, regardless of size, is to first listen and learn what they have developed, their business goals, and near-term plans for growing and commercialising their products or services. I spend time with each client exploring alternative options for protecting their innovations, branding, publication plans, potential partners and licencing/selling opportunities. We work together to create a strategic plan that will address their specific needs. My goal is to utilise my industry and law firm experience to obtain IP protection that adds value to their business and enables society to reap the benefits of their innovations.

How would you characterise the IP transactions space at present?

In the pharma/biotech sphere, it has become much harder for early-stage companies with only drug candidates that are in pre-clinical or Phase 1 testing stages to obtain investments through initial public offerings (IPOs). In the first half of 2023, Biopharma Dive reported that only nine biotech companies have gone public, with five having medicines in Phase 2 studies or later. By contrast, from 2020 to 2022, two-thirds of these companies had preclinical or Phase 1 tested candidates.

The current IPO market is weak and high interest rates are shrinking valuations. This is making the acquisition of publicly traded biotech companies (whose assets will fill product pipelines and provide revenue growth) an attractive option for pharmaceutical and life science companies. These businesses have blockbuster drugs that will currently be losing patent protection, similar to the last patent cliff of 2008 to 2010.

If you could change three things about prosecuting patents in the United States, what would they be and do you think they are likely to happen?

Subject-matter eligibility three times over. Section 101, Chapter 35 of the US Code states that:

> *Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.*

Thanks to the US Supreme Court Bilski, Mayo, Alice and Myriad Genetics decisions andsubsequent conflicting Federal Circuit decisions, subject-matter eligibility determinations that used to be straightforward have become confusing, frustrating and impossible to reconcile for patent examiners, applicants and the courts. We have seen swathes of technology rendered unpatentable by these judicial exceptions, which are swallowing up the whole statute. The Supreme Court has refused to revisit its decisions, denying review of numerous appeals. It will take an act of Congress to overturn this and restore the full scope of subject-matter eligibility provided by the statute. However, with the 2024

election cycle gearing up, it is unlikely that legislation will be passed soon.

What are your top tips for SMEs trying to build a robust IP portfolio, especially in the pharma industry?

To build a robust portfolio, before any applications are drafted, the patent attorney and client must have a clear understanding of all aspects of the invention. They must decipher how it is made and used, the key elements that must be present, the competitive landscape, any anticipated developments that could build on the invention, and what aspects of the invention are most crucial to the business.

SMEs must conduct experiments to provide data in the application, demonstrating that the compounds or biologics and alternatives work, and how they provide support for the entire scope of the claims. In many countries, pharma and biotech claims are limited to what is demonstrated in the examples, with the United States also heading in that direction. The recent US Supreme Court Amgen v Sanofi decision invalidated two Amgen patents claiming antibodies that inhibit the PCSK9 protein (a genus of antibodies performing a specified function): the patents claimed a vast number of antibodies, but only disclosed 26. The Court held that this disclosure required an undue amount of experimentation to make every possible antibody encompassed by the claims.

SMEs should be prepared to either claim less broadly based on the experimental data they have, or to incur the cost of conducting more experiments that provide support for broader patent claims. Having a clear focus on the business objectives that a patent should support at the outset will ensure that only necessary data is obtained to support what is commercially important for the SME.

How do you stay abreast of the latest industry developments both in the United States and internationally?

There are several avenues that I follow to stay up to date. I regularly read a variety of scientific, business and legal newsletters and blogs, as well as published scientific research articles in a variety of fields. The beauty of technology is that it enables me to attend webinars with speakers from around the world on a wide variety of topics, giving me insights on cutting-edge research and businesses. Communications from foreign counsel keep me current on legal and industry developments in their countries. Through LinkedIn, I have been able to engage with thought leaders of different expertise. All of this is a valuable investment of my time and helps me to think strategically about how best to utilise IP rights and protect new technologies.