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Patent Prognosis: Pfizer's Chief IP Counsel On The Year Ahead

by William Looney

For the biopharma industry, nothing is more important than patent protection in preserving that vital license to operate, especially now that IP is a key component of the global supply chain. Pfizer's chief IP counsel Roy F. Waldron provides an overview of industry strengths and vulnerabilities – and what to do about them – as the IP policy front moves forward in 2017.

- Patenting is approaching near universal acceptance as standard business practice in biopharma, with the number of patent applications tripling since the turn of the millennium. Nevertheless, effective – and enforceable – use of the patenting system remains sporadic.
- A contradictory and unpredictable US legal environment for IP is adding to litigation risks for biopharma patent holders, and rulings by the Supreme Court this year may create negative precedents for IP protection in other key markets around the world, from Canada to China.
- Biopharma is finding it harder to cultivate allies in other high-tech sectors, but is moving forward with aggressive investments in evidence-based data to document the positive impact of IP on entrepreneurial businesses in emerging market countries – an important IP constituency whose support can positively shape the future climate for innovation.
- On the advocacy communications front, expect more targeted messaging to confront a revived NGO activist movement opposing IP for restricting medicines access to low- and middle-income patients with unmet medical needs.

If there is one thing that biopharma agrees on, it is that drug patents move markets. With billions in shareholder value turning on a single obscure court decision, patent litigation is the embodiment of what risk means in this industry – just ask *Pfizer Inc.*'s chief IP counsel and senior vice president Roy F. Waldron, PhD. The 54-year-old New York University law graduate with a chemistry PhD from Yale University is responsible for managing one of the industry's largest intellectual property portfolios, consisting of tens of thousands of patents and trademarks

covering technologies from traditional small molecules to advanced biologics, vaccines and diagnostics. He is also one of the lead strategists on industry-wide advocacy for IP protection and enforcement, serving concurrently as head of the Executive Committee of INTERPAT, the IP coordinating body of R&D companies, and as chair of the International IP and Trade Committee of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), which represents R&D-based industry associations in 41 countries.

In a conversation with *In Vivo,* Waldron looks at the year ahead and highlights several big pluses – and not a few minuses – facing industry as it works to convince an increasingly polarized international community of the advantages that patenting brings to the hard slog of turning research into innovative products and services. "I like to call myself an advocate for public health," Waldron says, "because the path to curing disease starts when an inventor files for a patent."

Patenting: It's Popular

There are two ways to look at the environment for IP: short term and long term. An optimist by nature, Waldron points to enormous changes over the past three decades as governments, local business and even academia recognize the benefits attached to IP. Globally, the World Intellectual Property Organization (WIPO) finds the number of patent applications has tripled since the turn of the millennium, which means that more new inventions are being processed through the formal system. More important, use of the patent system is spreading beyond North America, Europe and Japan to key markets of the future such as Latin America, Korea and especially China – with India still the notable outlier. Says Waldron, "the system has been internationalized – and biopharma is a key beneficiary."

According to the Organization for Economic Cooperation and Development (OECD), the pharmaceutical sector leads in the number of patents registered by teams of company inventors located outside a firm's home base. Patents registered in multiple countries account for a very significant proportion of the average biopharma's entire patent portfolio. What this indicates, from a larger policy point of view, is that patented innovations are being brought to all corners of the globe. "This means the world can now see patents at work in local legal systems, a trend that encourages greater acceptance of this tool in promoting more homegrown innovation," Waldron explains.

However, more data demonstrating the way patents, trademarks and other forms of IP are actually put to use in different geographies and industrial sectors are needed to affirm this conclusion. Referencing work underway between IFPMA, INTERPAT and the International Chamber of Commerce (ICC), Waldron offers that "better evidence generation on the link between IP and a dynamic, entrepreneurial business culture is a priority of the industry going forward." Why? Because not everyone agrees. And it's not a narrative that works for some, more ideologically minded stakeholders. Waldron relates that many government officials outside the

US are up front, telling him, “Our country is too small to attract drug innovation and economically we are not in a position to pay for it.” His conclusion? “No one is apologizing for being a ‘free-rider’ anymore – in fact governments now boast about it, making it part of their basic economic policies in the long term.”

The rise of the orphan drug segment is an excellent example, where the FDA’s grant of smaller, expedited trials and review times – which add up to real money for drugmakers – has led to a rush of new medicines for the category's 7,000 rare conditions, most of which still lack approved treatments.

Countering this view requires the industry to push back with a full-throated defense built around the importance of incentives in changing the story line on medicines innovation. The rise of the orphan drug segment is an excellent example, where the FDA’s grant of smaller, expedited trials and review times – which add up to real money for drugmakers – has led to a rush of new medicines for the category's 7,000 rare conditions, most of which still lack approved treatments.

It’s why Waldron feels the industry case for its high-risk business model is bolstered by the excellence of the science now coming from company labs. “Innovation in key areas of unmet need like cancer immunotherapy has gone from the abstract to real. Just a few years ago prominent critics like Martha Angell [MD] of the *New England Journal of Medicine* were claiming our new products were 'me too' imitations of old molecules. ‘Where is the innovation created by patenting?’ she asked. Notice that Angell is no longer posing this question. That’s because of the irrefutable evidence that we are treating – and beating – the very biggest challenges to public health, like hepatitis and cancer.”

Biopharma has also benefited from decades of progress in incorporating recognition of IP in the multilateral trade agenda, beginning with ratification of the World Trade Organization (WTO) Agreement on Trade-Related Intellectual Property Protection (TRIPS) in 1994. Although TRIPS has never fulfilled its potential in enforcing IP rights, it and other agreements since then have laid down the principle that all trading nations must acknowledge IP as a legitimate instrument in guiding commercial activity, trade and economic development, in-country and across borders. Provisional implementation in 2017 of the EU-Canada Comprehensive Economic and Trade Agreement (CETA) represents a new, higher standard in the level of IP protection for Canada, one worth citing in the aftermath of the apparent collapse of the larger Trans-Pacific Partnership

(TPP) accord. Waldron believes the EU-Canada pact could act as the reference point in barring any downgrading of the IP chapters in the 1994 North American Free Trade Agreement (NAFTA), should the latter head back to the negotiating table this year, as promised by the Trump administration.

Among other things, the failure to get the longer protection of biotech products allowed under US law into the TPP text dimmed the industry's enthusiasm for the deal. Multilateral trade negotiations do require some hard choices and trade-offs. "You have to weigh it against evidence that these agreements create a valuable precedent for good governance and rule of law," Waldron says, noting that Article 18.4 of the TPP commits signatory governments to promote innovation, foster competition in open and efficient markets, and respect principles of transparency and due process in the interests of all stakeholders, including rights holders. "It's basically a certification of our license to operate, which makes it vital we get the provisions right. But that's no excuse not to keep trying because well-crafted free trade agreements have on balance been good for this industry."

Headwinds Aplenty

Looking ahead in 2017, the picture for IP looks less rosy. "The industry has to confront some serious short-term risks," acknowledges Waldron.

Chief among these is the continuing conflict with activist NGOs, international organizations and some governments over the perception that IP rights restrict access to essential medicines and limit the economic potential of low- and middle-income countries by keeping people sick. "The United Nations' *High-Level Panel on Access to Medicines*, endorsed by the General Assembly in September 2016, was the most negative, anti-industry report from the international community since the HIV crisis in the 1990s," states Waldron. (Also see "*More Pressure On Pharma: UN Report Backs Compulsory Licensing*" - Pink Sheet, 15 Sep, 2016.) "There was a deliberate effort to de-couple industry's investments in R&D from pricing, which the report claimed was the major barrier to greater access to medicines in developing countries."

To fix this problem, the High-Level Panel advocates a very narrow set of objectives. These include mandated disclosure of confidential business information, on grounds that a patent is itself a non-transparent instrument of control, and denial of protection against infringement on grounds of public health, through compulsory licensing, patent exhaustion and international reference pricing.

Although the industry disputes the conclusions of the report, Waldron says the global debate on drug prices and IP rights has now been re-ignited and will likely be stoked by additional high-level events later this year, including a World Health Organization (WHO) forum in Geneva on fair pricing of medicines. "It's going to set the discussion in a confrontational direction that will be unhelpful for all stakeholders for some time to come," he predicts.

Another problem relates to building the cross-industry coalitions that can drive support for all forms of IP. Highlighting the role of patents in promoting new innovations for unmet medical needs requires outreach to potential allies with independent credibility. But this looks harder than ever, particularly when the interests of biopharma are diverging from other high-tech businesses. "Product cycles for knowledge-based service and information providers are shrinking to the point where the turnaround is so high that patent protection is seen almost entirely through a short-term prism," Waldron claims. "We are a business with a different model, where protection against up-front investment risks based on predictable reliance on patent cover is still measured over a decade – or more."

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Lack of a common stance across all industry sectors torpedoed a long-awaited patent reform bill in Congress last year, and there remains little prospect for introduction of a similar reform bill this year. The momentum of any patent reform that may come forward in the US appears to be toward lengthening discovery and trial procedures to cope with alleged patent litigation abuse by so called patent trolls. Such trends will erode the integrity of the 1984 Hatch-Waxman legislation that promised a speedy resolution of patent disputes to achieve the delicate balance between the interests of innovative and generic producers. Preserving that balance is a key argument underpinning the economic value of the entire IP system.

Supreme Sensitivities

Even the US Supreme Court is developing a reputation for a selective, highly idiosyncratic approach to defining what subject matter is eligible for a patent that has left commercial interests baffled. Recent Supreme Court rulings appear to take a narrowly restrictive view of business method patents, but along with it the court has adopted interpretations of the law that raise issues for the ability of biopharma innovators to obtain patents on diagnostic tools, processes, methods of treatment, vaccines and other advanced medical technologies. Ironically, non-US tribunals are increasingly taking positions in this area that seem much more innovator-friendly than those taken in the US. Also, the US now has an inter partes review regime – a patent challenge process instituted under the 2011 America Invents Act to give third-party petitioners and litigants multiple "bites at the apple" in challenging validity of a patent under

different standards than used in the courts, even after it has been granted and successfully litigated. (Also see "*New Patent Battleground: Inter Partes Reviews Besiege Innovators*" - In Vivo, 14 Dec, 2015.)

> ***"The [Supreme} court is the world's single most prestigious legal forum and is thus being watched closely by foreign governments that might find it desirable to cite court precedents in restricting, in the biophama and diagnostic space, what you can get on a patent as well as raising the barrier on what you must show to keep it." – Roy Waldron, PhD***

Several cases on the Supreme Court docket in 2017 could add to biopharma's worries. It will look at the legal status of international exhaustion, in a ruling that could impede the ability of all US manufacturers to price goods differently in poor countries. The court will also assess the legality of key provisions of the 2010 Biologics Price Competition and Innovation Act affecting the litigation process prior to approval and timing for biosimilar drug launches.

For Waldron, the potential spillover impact of Supreme Court actions is equally worrisome: "The court is the world's single most prestigious legal forum and is thus being watched closely by foreign governments that might find it desirable to cite court precedents in restricting, in the biophama and diagnostic space, what you can get on a patent as well as raising the barrier on what you must show to keep it. Korea, Canada and China are certainly looking at these precedents and attempting to leverage them in their own courts on a closely related theoretical basis."

The new year will also see resumption, albeit on a more modest level than earlier this decade, of the so-called patent cliff of exclusivity expirations. Informa's Pharma Intelligence's *Medtrack*

projects patent losses of $11.1 billion in 2017 in a number of key therapeutic areas, followed by another $20.7 billion in 2018. (*See Exhibit 1*.) Most of these are first-wave specialty biological products that will require IP managers to work more creatively with brand marketers on ways to manage the decline in revenues.

Exhibit 1

US Drug Product Patent Expirations, 2017-2020

Click here to explore this interactive content online

Note: Top 20 companies by revenue

Medtrack | Pharma Intelligence, 2017

2017's Action List

In the end, what all these developments do is create more uncertainty for a business that thrives on predictability for the long term. To address that future, policy leaders like Waldron are focusing on three priorities to shape the external environment and maintain the strong IP frameworks that contribute to the transparency and rule of law that companies depend on to do business globally. These are:

Improving evidence that associates IP protection with broad-based economic development that empowers business creation, especially in small enterprises in middle-income and developing countries. Work is continuing with groups such as the ICC on research to highlight that IP is not biased toward big multinationals – in reality, it is the entrepreneur that gains the most from a system of enforceable patent rights. "Stealing an idea might be survivable for a big pharma enterprise, but for a small biotech start-up in countries with a desperate need for localized health solutions, it's equivalent to an early death," says Waldron. "We want to change that dynamic."

Development of "gold standard" language to drive resolutions on IP issues among the major international organizations. Consensus on such criteria is important in responding consistently and decisively in follow-through to the UN High Level Panel on Access to Medicines, among other anti-industry screeds.

Drafting principles and messaging on patent term extension and the relationship between patents and competition. Both are points of vulnerability for the R&D-based industry. Even in the face of long waits to obtain the marketing authorization necessary to put a medicine out for sale, few stakeholders are interested in extending patent life; in fact, most contend that in biopharma it is too long already, mainly for the argument that patents effectively bar any real competition within a therapy class. Reversing that linked perception is critical as more countries like South Africa work to undermine patents through a classic anti-trust claim. "Messaging is hard on IP given the technicalities, but getting everyone in the industry on the same page is the essential first step toward a dialogue with the outside world that allows us to hold our own," Waldron says.