Intellectual Property Challenges for Life Sciences Firms – Through COVID-19 and Beyond

Published on Alvarez & Marsal | Management Consulting | Professional Services (https://www.alvarezandmarsal.com)

June 24, 2020

An industry with unique pressures

The role of a life sciences company is to develop drugs and treatments. Some treatments will prove successful and improve the lives of potentially millions of people, while others will never make it to market. This is a business model filled with uncertainty.

When the costs of research and development are so high ($1.36 trillion was invested in pharmaceutical research and development (R&D) between 2007 and 2016), [1] any life sciences business would expect outsize chunks of total revenues to come from a few successful R&D efforts. IP protection helps companies recover their research investments through the treatments that do make it to market, but there are no defences against the losses incurred through inevitable failures.

Risks for life sciences firms are complicated further by ethical scrutiny of companies' activities. The long-running and passionate debate over the extent to which healthcare businesses should serve shareholders' interests or a broader public good is not slowing down. Indeed, it has only been brought into sharper focus by the coronavirus pandemic.

Because healthcare is a necessity for consumers and governments alike, the pharmaceutical and life sciences space has long been regarded as a fairly sure bet through recessions and crises. In some ways, this is true in the present pandemic: the pace at which pharmaceutical companies are responding has drawn praise from industry bodies and governments. The work being done to develop vaccines at record speed may save thousands, even millions of lives over the next few years.

Despite this success, ethical debates are once again coming to the forefront. The expectation that companies should forgo thoughts of revenues and profits to focus on public health has been more apparent than ever over the past three months. Coronavirus did not start the debate, but it has undoubtedly made the conversation more urgent.

In this context, how companies approach IP has never been more important. In this article, we examine some models for new IP structures that can respond to the many pressures impacting life sciences firms from competitors, governments and people.

The state of IP

Countries are putting increased pressure on pharmaceutical companies to scale back patent protection and open up IP for public benefit. Gilead rescinded the 'orphan' status of its potential COVID-19 treatment remdesivir after pressure relating to the extended exclusivity period and tax incentives that came with its new designation. Public opinion criticising Gilead for profiting from the pandemic may have played a part in this decision.

Developed markets have responded to public pressure and lobbying from healthcare bodies to make rapid changes to established IP protocols. Israel overrode IP protections to mandate the generic production of AbbVie's drug Kaletra, for instance, and countries

including Germany and Canada have sought to implement similar compulsory licensing programmes.

As corporations and governments continue to battle COVID-19 at pace, new solutions are being proposed. Costa Rica has lobbied the World Health Organization (WHO) for a global COVID-19 technology pool to share IP. The idea has secured support from other countries and from health bodies like Unitaid, which has temporarily expanded its mandate with the Medicines Patent Pool clearinghouse to include any health technologies that could contribute to the COVID-19 relief effort. Patent holders like Gilead, Pfizer and Johns Hopkins University have licensed IP to the MPP in order to create sublicenses for generics manufacturers.

These developments make it clear that substantive changes to the way IP is handled are necessary. Any changes should respond to the COVID-19 emergency but also lay the groundwork to make sure that the patent system works as intended for all stakeholders. Below, we briefly discuss several potential alternatives for a 'new normal' in IP.

1. Preserving the patent system

Leaders like Roche CEO Severin Schwan have argued that waiving IP would remove incentives for innovation. R&D costs for pharmaceutical companies are a significant expenditure, and it may be a challenge to recreate previous market dynamics once the coronavirus pandemic is over. If IP is not sufficiently protected now, future drug development could be restricted and more limited in scope.

In contrast, governments and other non-corporate stakeholders argue that patents can preclude competition and create artificially high prices. In addition, research has demonstrated the scale of public contributions to drug development, with the US Food and Drug Administration (FDA) having committed $100 billion to R&D between 2010 and 2016.[2]

2. Compulsory generic licensing

Many important markets around the world practice compulsory licensing already, and others have introduced it to better combat coronavirus. This model allows the relevant patent office or health ministry to grant licenses to third parties to promote generics manufacturing, with an appropriate fee to the patent holder as compensation.

Compulsory licensing is deployed when there is public interest in broad availability of a given product. In the last couple of months major markets like France have made legislative provisions to potentially invoke compulsory licensing should there be a requirement in the present context. If the situation is deemed absolutely critical, this can even be done without the patent holder's consent.

Even if governments technically have the ability to impose licensing on manufacturers, trust is still a critical component of the patent system. Governmental overreach in the form of excessive compulsory licensing may restrict future investment in new treatments, not just related to COVID-19. Coronavirus is straining many aspects of pharmaceutical and life sciences firms' business models. Overzealous commitment to generics may inhibit innovation down the line and interfere with market-driven valuations.

3. Clearinghouses

As IP undergoes systemic changes, third parties that can foster innovation could be vitally important. Clearinghouses enable increased flexibility for patent holders by sublicensing IP from willing participants to generics manufacturers. IP can be licensed with royalties or royalty-free, potentially enabling a more efficient response in genuine global crises.

A global clearinghouse with international authority to administer agreements between drugmakers, governments, medical institutions and patients could foster more trust in the system and deliver treatments to more people.

The barrier to this kind of mutual effort is the speed at which institutions can move. Do international bodies like the WHO have the foresight and bandwidth to set up a global clearinghouse right now? COVID-19 has forced governments to engage on a national level and international priorities have become secondary. The example of Europe's proposed unified patent court, which is being delayed by courts in Germany and the UK's government, [3] shows that transferring sovereign rights over to international authorities may not be an easy sell at this time.

Elements of this dynamic are also true for private companies: although major medical and tech companies have signed voluntary agreements like the Open Covid Pledge which covers IP sharing, persuading pharmaceutical companies to consent to a more

structured clearinghouse model may pose an additional challenge.

4. Patent pooling

Patent pools let participating organisations use other participants' patent rights and license pooled patents to third parties. The effectiveness of patent pools lies in better consolidation of patent IP across markets, which creates more efficient commercialisation opportunities for participants.

Pools are already active in several other industries, including manufacturing and aerospace. A global patent pool would have the hypothetical advantage of focusing on developing innovations as well as existing treatments, both for COVID-19 and for other future treatments as required.

Patent pooling may allow national and international bodies to purchase COVID-19 IP and set up a publicly-owned patent pool. (The EU has expressed a willingness to explore this option.) As well as potentially speeding up the pace at which a vaccine could be rolled out to market as and when one is developed, it could be a template for other treatments that may come to market in the future.

Summary: difficult conversations – and incredible opportunities – ahead

No matter how much innovation is currently coming from life sciences companies, it seems likely that the unique pressures of coronavirus will speed up changes to the way IP is handled. Finding a solution that works for all parties over the long term, beyond the current pandemic, may be very difficult.

Pandemics make unusual or unexpected solutions seem achievable, even necessary. But all the same, it is unlikely that any one model will provide the perfect framework for a new global IP structure. Instead, we may see elements of the current patent system, patent pools, clearinghouses and compulsory licensing blending together to work in practice.

In this environment, there may be significant disputes as to how different component parts should and could interact. Life sciences companies must continue to demonstrate the value they contribute to the healthcare ecosystem in order for the industry's voice to be heard.

How A&M can help

A&M's Disputes and Investigations practice combines deep experience in life sciences with specialist litigation and disputes support, covering economics and quantum calculations among other areas of expertise.

If you have any questions regarding the content covered in this article, please contact one of our experts:

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