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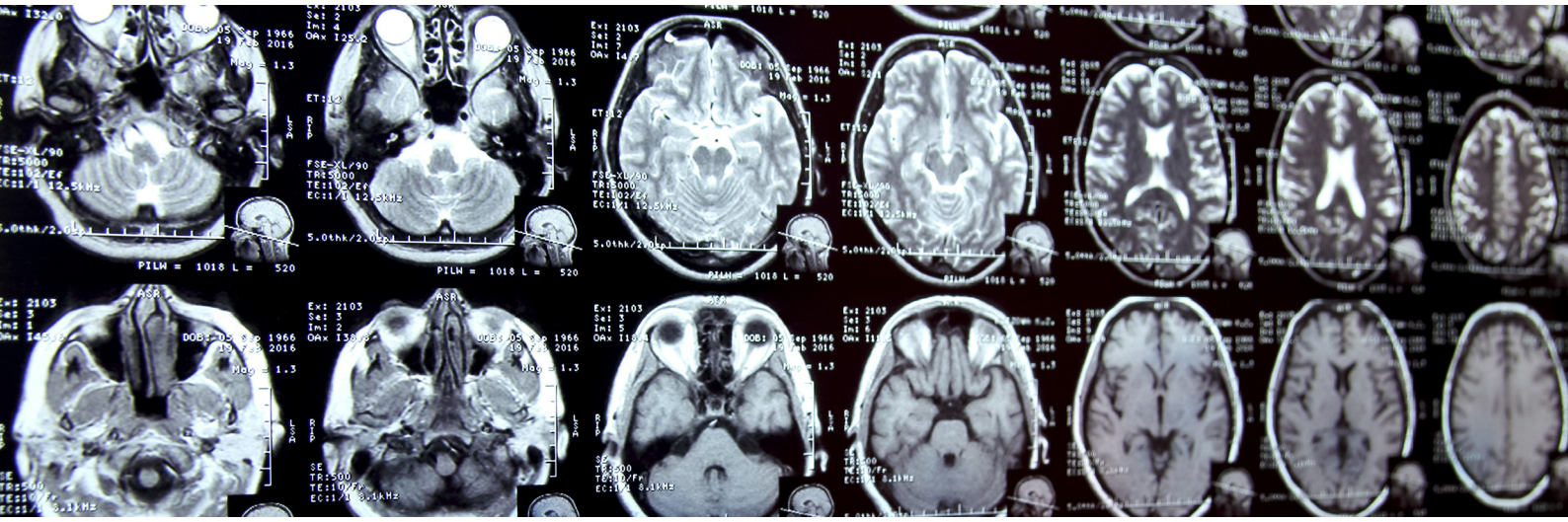

Rethinking intellectual property in an era of personalised health

The traditional business model of the pharmaceutical industry has long relied heavily on intellectual property, and particularly patents, to protect the significant investments required to bring any new drug to market. At its heart, it's a simple proposition: develop a new drug, formulation or use of a drug; secure patent protection; supply to patients around the world; recover the investment on R&D during the period of exclusivity provided by the patent.

However, the new health paradigm of personalised health makes things just a bit more complicated when it comes to IP, as we discuss below.

Diversity of players

Delivery of personalised health solutions relies heavily on diagnostic tools that provide the information necessary to tailor treatment options for individual patients. Diagnostic tools are not just being developed by pharmaceutical companies, they are being developed by tech companies from big through to small, and being implemented on all sorts of devices, including existing, multifunctional devices such as smart phones. The diagnostic tools and devices may be protected by patents held by tech companies. They will incorporate software that might be owned by a tech company, or by another third party (or even be derived from open source software). There may also be a significant amount of confidential information (for example, in complex and proprietary algorithms) embedded within the devices. Therefore the range of IP, and the players who are relying on that IP, will be greatly diversified.

Availability of patent protection

In recent years, courts around the world have also been increasingly reluctant to grant patents for things that are seen to be in the nature of discoveries or rules of nature, such as genes and genetic information. This has meant patents seeking broad protection for methods of diagnosis have had a difficult time of late, with the US Supreme Court taking the view that many of them are not patentable subject matter. In a similar camp are computer

implemented methods, which have come under significant scrutiny from courts and patent offices around the world. As pharmaceutical companies begin to focus more on diagnostics as a significant part of their business, their ability to secure patent protection that covers all aspects of a product may be more constrained than it has been in relation to traditional pharmaceutical products.

Platform technologies

As personalised treatment options become increasingly bespoke, many of them will be based on a particular technology platform, such as CRISPR or CAR-T. Similarly, some diagnostic approaches will rely on platform technologies relating to, for example, DNA sequencing. In order to ensure that these platform technologies continue to be available for the public good, a time may well come when the pharmaceutical industry looks to the precedent set by the telecommunications industry with respect to Standard Essential Patents and FRAND licensing.

Data ownership

Data is no longer collected through conventional channels, such as long and complex clinical trials, which generate data that is held closely by pharmaceutical companies, and is often relied on to extend market exclusivity. Vast quantities of data are being collected in a great variety of ways, including by national health authorities, through smart phones and similar devices, and via social media. The diversification of data collection and ownership would be expected to substantially change the dynamics within the pharma industry, and to give rise to complex questions around data ownership and access, and the use of real world data in the approval process for new products.

So what does this mean for the pharmaceutical industry?

Patents will of course continue to be extremely important for the industry. But it does mean that the pharmaceutical industry will need to diversify its thinking when it comes to its intellectual property strategies. Just a few key considerations are likely to be:

- If patent protection is not available, what other forms of IP are available to help incentivise and recover the significant investments made in developing new personalised approaches and diagnostic tools: can copyright or confidential information be relied on?
- Given the different players that might contribute to a single product, how do those players work together or at least co-exist? Pharmaceutical companies are used to collaborating but as they increasingly collaborate with different stakeholders – tech companies, start-ups, not-for-profits – the expectations as to how that collaboration is going to work, and how the spoils are to be shared, are unlikely to be as clear cut or as mutually understood. New rules of engagement need to be developed.
- Can and should lessons be learnt from the tech sector in terms of how and what IP is used to protect investments into R&D? Should pharma companies be thinking more like tech companies when it comes to IP?
- How do pharmaceutical companies take advantage of the vast amounts of data that are going to be available over time? Does it matter that a company might not have exclusive access to that data, and how does the regulatory landscape cope with the use of data that is not collected through traditional sources?

The pharmaceutical industry is entering a very exciting but also increasingly uncertain time. Intellectual property is just one of the legal and regulatory areas that will need to be reassessed as the industry explores the opportunities presented by personalised medicine. Having worked closely with the sector for many years, particularly in relation to IP issues, Herbert Smith Freehills will be sharing its insights, and lessons learned from other sectors, as to how the sector can navigate those challenges in this new era for the sector.

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