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Tech Advances Trigger Transformation For Pharma

Thought Leadership In Association With Herbert Smith Freehills

by

As the costs of bringing drugs to market continue to rise and pricing pressure bites, pharma is looking for new ways to create value and drive efficiencies, including partnering with tech giants and agile start-ups to create technology solutions that lead to improved and diversified revenue streams. In doing so, pharma companies must self-disrupt to stay ahead in an increasingly competitive and demanding market.

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Artificial intelligence (AI) is being used across sectors to improve business processes and drive efficiencies. Pharma is no exception. With access to vast amounts of data, pharma companies are increasingly adopting AI to process, interpret and use that data to improve efficiency, accelerate the pace of innovation across the product life cycle and personalize health care. There is enormous potential to impact the whole value spectrum, including drug discovery

Authors

Jonathan Turnbull, Partner, Intellectual Property

Rebekah Gay, Partner, Intellectual Property

David Coulling, Partner, Corporate & Commercial – TMT, Data & Sourcing

and development, commercial opportunities, patient diagnosis and outcomes, and pharmacovigilance.

Pharma's use of AI and other technologies (as seen, e.g., in the areas of diabetes and diagnostics) is being backed by regulators. US FDA commissioner Scott Gottlieb has vowed that the agency will be modernized to ensure that its policies are "as scientifically advanced as the products we are being asked to evaluate." Until these regulatory advances are realized, pharma must use technologies within existing regulatory frameworks but with a keen eye on the future, given regulation will inevitably shape pharma's adoption and use of AI and other technologies.

Roche's acquisition of Flatiron, an oncology-focused electronic health records company, provides an example of such forward thinking. Flatiron provides Roche with valuable access to real-world evidence (RWE) that can be used to better design clinical trials and improve prospects for reimbursement. Ahead of the FDA's 2021 target for providing guidance on the use of RWE in regulatory decisions, Roche's acquisition lays down its groundwork for gaining the efficiencies afforded by RWE.

As well as requiring new regulation, the use of emerging AI technologies presents some challenging strategic and legal issues. Here, we explore the new rules of engagement introduced by AI and identify some of the considerations that should be top of mind for pharma leaders as the sector enters what promises to be its most transformative era yet.

Accessing AI Technology: Build, Buy Or Collaborate?

For many, there is a sense that now is the time to be making strategic moves into technology-enabled platforms, products and services, with AI being at the forefront of investment priorities. However, any technology acquisition strategy must be aligned with a pharma business' vision for incorporating the new technology into an integrated offering. Technology acquisitions are therefore less likely to be driven by a single therapeutic area, or a single product, but will stand or fall on their ability to contribute to broader strategic objectives.

An early consideration when shaping strategy is whether it is better to develop and employ technology and expertise in-house, acquire it or form strategic partnerships to access another firm's technology and talent. For technology companies, software developers and data scientists, the cross-sector opportunities for AI make it a very attractive focus for innovation and commercialization, and one that promises significant financial rewards in the medium term. So AI talent and leading-edge AI products and services are in high demand. There are two immediate consequences for pharma: First, any AI assets available for acquisition are hotly competed and command high valuations (at revenue multiples that dwarf those traditionally seen in pharma); and second, hiring technology expertise is difficult, expensive and prone to the risk of future talent departures. This may mean that the best AI strategy is to focus on cross-

sector collaborations. Unusually for the pharma sector, this may also involve engaging in a degree of open innovation. The structure and rules of engagement for these collaborations need to bridge the business models and regulatory environments of two very different sectors (pharma and tech) and there are a variety of legal and behavioral tools that will need to be implemented to foster a successful collaboration.

The Roche/Flatiron deal is a good example of a new approach to collaboration and innovation. Flatiron is only five years old and Roche took an early equity stake, developed the collaboration and then made an outright acquisition. Roche expects the acquisition will keep it at the forefront of oncology drug development, and will deliver tools and benefits that increase its competitive edge. However, Flatiron will maintain the freedom to form partnerships with other pharma companies, which will use Flatiron's RWE to accelerate R&D and to generate evidence on the use of medicines outside of clinical trials. Roche and BMS have agreed to form a joint scientific advisory board to advance the use of RWE for regulatory decision-making. This approach to collaboration between multiple pharma companies will enable Flatiron to accelerate its knowledge and understanding of applications of RWE, and to consolidate learnings from multiple partnerships to the benefit of all its partners. This form of open innovation is a departure from the historical norm for the pharma sector.

To the extent that pharma companies are looking to build up internal capabilities, tech know-how is more critical than ever, and a skill set that the sector knows it needs to import. That, of course, means that pharma is looking to work with a group of professionals who have not traditionally worked with the sector, who are in exceptionally high demand across multiple sectors, and among whom we have seen a high level of mobility within the tech sector. This in turn means that it is essential that robust and enforceable provisions are included in any deal agreements and/or employment contracts. These provisions must include adequate incentives and protections to prevent unauthorized dissemination of expertise and confidential information.

Human Versus AI: Protection Of Innovations

Alongside new models in M&A and collaborations, new IP issues are emerging from the use of AI. Having an understanding of these issues and uncertainties will be critical to assessing the risks/benefits of adopting any AI-based approach, including in the context of M&A due diligence. An example of this relates to ownership of inventions: If a computer generates an invention through the application of a set of human-generated algorithms, who is the inventor and who owns the invention? Is it the person who developed the algorithms? Or is it the person who operated the computer to apply the algorithm to a particular task?

The patent system will also need to decide on the standards that it applies in assessing patentability. Computers will be able to develop innovations that would be extremely

challenging, if not impossible, for humans to develop alone. For example, a start-up can use deep learning to accelerate the process of discovering new drugs – screening more than 10 million compounds each day for potential efficacy, likely toxicity and side effects. This could not be achieved by humans. However, the patent system assesses the validity of a patent according to human standards. The normalization of computer-generated inventions, with little or even no human intervention will surely force a re-examination of those standards and their suitability when it comes to the use of AI in the invention process.

The patent system and the various patent offices around the world are still grappling with arriving at answers to these questions. The heads of the five largest patent offices (the US, European, Japanese, Korean and Chinese offices) identified the impact of AI on the patent system as one of their main strategic priorities at *their last meeting, in June 2018* in New Orleans. It is important that pharma actively engages in these discussions to ensure that emerging practices account for the needs of the sector.

IP issues arising from the use of AI are not limited to patents. Indeed, the increased use of data is likely to result in other IP or related rights (e.g., database rights and trade secrets) being more valuable and more critical for pharma businesses to identify, track and protect. This can be seen in the emergence of digital therapeutics, which includes connected devices, sensors and/or software that employ data to optimize the development and use of medicines and treatment regimens. These data and the insights that can be taken from their aggregation and analysis are extraordinarily valuable, and have the potential to benefit patients both individually and collectively. While the pharma sector is extremely experienced in the collection and use of data through in-house R&D programs and clinical trials, in addition to the prevailing cyber security risks, the decentralized collection of data through third-party digital devices and the management of large data sets with potentially overlapping or competing third-party rights raises novel data rights issues.

The Path To Future-Proofing Value

For pharma companies, developing and implementing an AI strategy means changing focus and behaviors: being more open to sharing data and technology, while learning how to monetize this approach and recognize and protect value across the ecosystem, as well as how to collaborate and compete with a cash-rich and agile tech sector. As pharma and health care businesses embark on this journey, the following checklist provides guidance on just some of the issues that need to be considered.

a. If you can fund a blockbuster acquisition, do your due diligence, craft an attractive offer package and move nimbly and decisively in auctions

b. Consider minority investments, perhaps via a corporate venture program, with a suite of rights

to progress your investment.

c. Identify the tech talent you need, develop appropriate incentive packages and put in place fit-for-purpose employment contracts.

d. Consider alternative approaches to collaboration that are flexible, foster good behaviors and facilitate partnerships with the tech sector

e. Develop a data collection, generation and licensing strategy, and the systems and expertise to implement it.

f. Consider public policy and regulatory angles early when developing strategies for using patient data.

g. Consider whether your patent protection strategy is compatible with the dynamics of the tech sector.

h. Expand your IP protection strategy to accommodate data, copyright and tech-related trade secrets.

These and other legal issues are considered in more detail by Herbert Smith Freehills LLP in their ongoing series, Personalized Health and the Future of Pharma (*www.hsf.com/futureofpharma*).