How Life Sciences and Pharmaceutical Companies Can Harness Opportunity in Their Supply Chains

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In this hoganlovells.com interview, Hogan Lovells counsel Penny Powell talks about disruptive technologies, the increasing trend towards collaboration and joint venture agreements, the opportunities and regulatory burdens associated with working in emerging markets, and related supply chain considerations for the life sciences industry.

How are disruptive technologies like 3-D printing impacting the life sciences and pharmaceutical industry's supply chain?

Powell: When you are advising clients on their supply arrangements, it is important from a strategic perspective to factor in how they can ensure that they are making the most of new technologies being developed. New technologies, and in particular digital disruption technologies, are forcing a move away from traditional supply chain models. We are seeing a continuous increase in the availability of data, in particular patient data, which is in part driven by the more complex products and therapies coming onto the market. Companies are moving towards having data analytics systems in place to take advantage of new data in relation to demand fluctuations (assessment of which can enable enhanced working capital management, increased speed and efficiency of drug development, and targeted pricing), but also to adapt to increasingly sophisticated delivery models. Companies are required to regularly review their supply arrangements, organizational processes, and planning in light of rapid technological developments to assess how these new technologies could be introduced in their supply chain.

We also have this issue at front of mind from an M&A perspective when we are advising a client on a potential target. We need to have an awareness of exactly how potential disruptive technologies may impact the supply chain. If a purchaser is taking into account such developments, it should be looking to assess whether the target's business model and current digital strategy would require an extensive change to capitalize on the market potential that these technologies might unlock. We have seen in the hearing aid and hip replacement space with 3-D printing vehicles entering the market and radically changing the landscape in terms of the speed to market. It is cheaper and faster to generate the products using 3-D printing than it is to go through the traditional manufacturing line. The U.S. hearing aid industry is said to have adopted 100 percent 3-D printing in under 500 days. This is a drastic acceleration of the normal

model for business change. Companies which did not make the conversion were left behind and did not survive. Rather than just improving an existing model by making a process slightly faster, 3-D printing radically altered that market.

The pharmaceutical industry is also likely to be disrupted by 3-D printing. The U.S. Food and Drug Administration (FDA) approved the first 3-D printed drug (Aprecia's Spritam drug for epilepsy) in August 2015. 3-D printing enables customization, may potentially generate less waste; and, with the production of more complex objects in a single process, it potentially enables decentralized manufacturing. We may see 3-D printing of medicines in pharmacies customized according to the patient's characteristics such as age and renal and liver function. Our teams at Hogan Lovells are well set to advise on the regulatory aspects, as there will be issues around product liability (for example, who is the manufacturer?), as well as complex IP issues to consider.

Can a supply chain be optimized through collaboration?

Powell: There is an increasing trend in the life sciences and pharmaceutical industry for collaboration among parties to achieve a more effective supply chain, such as partnerships for the development of new products and collaborative business models sharing resources. A rapid evolution in technologies has created the opportunity for players in the life sciences and pharmaceutical industry to form alliances with key technology specialists. This year Hogan Lovells has assisted the life sciences arm of a major U.S. West Coast technology player on its joint venture with a leading listed UK pharma company, to form an entity to enable the research, development, and commercialization of devices for remote application of bioelectronic medicines, in addition to numerous digital and mobile health initiatives that involve alliances between life sciences and technology players.

We have also seen major pharmaceutical players use more traditional outsourcing models to outsource their manufacturing and distribution needs, increase flexibility in responding to consumer demand, reduce operation costs and capital expenditure while increasing production flexibility and enhancing productivity. This approach requires mitigation of outsourcing risks — i.e. loss of control, risk of decreased quality, risk of IP disputes, and lack of visibility in operations. These can be managed by interconnectivity and transparency within the supply chain.

Care must be taken to determine how the IP generated by such collaborations will be protected and who will own it. Risk and liability apportionment, quality assurance, and supply chain control provisions will need to be agreed upon in commercial agreements.

We expect such collaborations to continue going forward; we see it in relation to the mobile health apps that are hitting the market and the wearable digital technology. The life sciences industry is moving to harness technology and one way to do that efficiently is to marry up with advanced technology companies through collaborative or joint venture arrangements. We are

advising our clients to be aware of this trend and that their competitors may be progressing these sorts of initiatives. It is sensible to consider the potential of a collaboration across all fields and keep an open mind about where to optimize the supply chain and where underlying suppliers and subcontractors can be encouraged to do the same to create an integrated, transparent, and technically advanced system.

How can companies achieve a transparent and technically advanced supply chain?

Powell: Life sciences companies must ensure their products are produced in a way that is compliant with all the stringent, ever-changing regulatory requirements at every level in their supply chain, including quality and labelling provisions and manufacturing standards. At the same time companies want to ensure visibility of the supply chain to improve its management. Certain active ingredients have very long lead times. Given their very high value, companies need to have processes in place to ensure issues in stock availability are identified as soon as possible to mitigate the associated supply chain costs and ensure end-to-end supply chain planning.

Parts of the life sciences sector are moving away from centralized batch manufacturing systems and moving towards decentralized production models using continuous manufacturing (effectively, a highly automated end-to-end production line) which decreases capital and operating costs, enhances quality, and reduces time to market. Supply chain "flow-through" operating models also enable integrated end-to-end supply chain planning, which helps with anticipating and embedding regulatory changes as well as managing day-to-day stock availability issues.

To optimize a successful transformation you need to leverage new technology in a truly integrated way, with IT systems that give you visibility of what's going on at every level, making sure that quality management systems are managed. This involves harnessing whatever tools are at your disposal and making sure that it corresponds to the size of the initiative, product, or batch run. If you are the ultimate manufacturer and vendor of the product, you want to be able to guarantee that the same systems are in place all the way down the supply chain and that you have a full understanding of your control systems at all times. Therefore transparency is key to ensuring an end consumer can get the high quality medicine they need.

How has the rise of biopharmaceutical manufacturing impacted product portfolios and supply chains?

Powell: Biologics are perceived to be the way forward in a lot of key medical areas. There has been a shift towards products manufactured through innovative biopharmaceutical processes. Pharmaceutical companies are investing in large molecule drugs and targeted medicine that are associated with a complex manufacturing process that is high risk, high cost, and has long lead times on production. As the prevalence of complex medicines, orphan drugs, and personalized

medicines increases, we are also seeing a trend shift from high-volume manufacturing of a small number of products sold to mass markets to distributed manufacturing of a range of products in smaller volumes for niche markets. In response, we are seeing investment by our clients in their own plants to carry out this kind of manufacturing or the entry into collaborative relationships to guarantee security of supply in relation to the development of biopharmaceutical products. Given that for many pharmaceutical companies this involves entering a market in which they don't have a long history of experience, collaborations present a good way of overcoming that hurdle.

At Hogan Lovells, we help companies look at their manufacturing arrangements and how they can harmonize their knowledge and know-how with collaboration partners. If companies are entering the field from scratch, we have experience in the market to advise on an efficient supply chain framework to produce these very high-value, complex drugs.

What are some of the opportunities and regulatory challenges posed by emerging markets?

Powell: Markets such as China, India, Southeast Asia, Africa, and South America are an important factor in the global planning for many of our clients. As manufacturers move closer to local consumers they need to restructure and relocate multinational supply chains. Outsourcing manufacturing and supply chain business models requires consideration of a need to mitigate the outsourcing risks. This can be managed by seeking to achieve a level of interconnectivity among all supply chain providers and recipients, both in terms of facilities and processes, as well as information systems to optimize transparency and ensure an integrated process.

The life sciences sector is heavily regulated, and harmonization of regulatory requirements would help life sciences companies. For example, there are issues relating to traceability of drugs coming from supply chains based in certain jurisdictions. However global efforts to harmonize regulation can also add to a company's administrative burdens through the introduction of new requirements that must be complied with, for example the global serialization requirements which will be implemented in the EU by an amendment to the Falsified Medicines Directive. In terms of transparency and traceability throughout the supply chain, being able to trace every ingredient back and understand where and when it has been made increases confidence in the supply chain and quality of the products produced.

New EU legislation on falsified medicines entered into force in 2013 to address the increasing threat to public health from such products. The term "falsified medicines" covers fake medicines that are designed to mimic real, authorized medicines, and are distinguished from "counterfeits" which specifically refers to products that infringe IP rights. Companies need to be aware of the requirements introduced by the Falsified Medicines Directive and the implementation deadlines as well as other developments in the regulatory requirements.

About Penny Powell

Penny Powell is a counsel based in the Hogan Lovells London office. She combines her M&A know-how with significant commercial experience and knowledge of technological developments to advise on complex transformational projects, joint ventures, collaboration and outsourcing projects, as well as strategic service and supply arrangements and governance structures.

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