Structural Changes to the Pharmaceutical Industry and Impacts on IP Strategy

Changes Driven by Large Pharmaceutical Companies Affect the need for Smaller Companies and their Advisers to Manage their IP Portfolios.

Astra-Zeneca's recent formation of a Science and Technology Integration Office specifically to develop collaborations with others in the pharmaceutical sector reflects a major structural change which is occurring in the industry. This presents a great opportunity for well-prepared smaller companies but they will need both innovation and sound IP management to take best advantage.

The "patent cliff" faced by major pharmaceutical companies is forcing them to reconsider their approach to all aspects of drug research, development and commercialisation. The "blockbuster" model which held good twenty years ago is no longer affordable and approaches that were tried a decade ago to combat this problem haven't bridged the gap. Add in the mounting regulatory burden on new drugs, pressure for "value" in mature healthcare markets and the increasing importance of emerging markets and the result is unprecedented pressure on all companies within the pharmaceutical sector.

Big Pharma are being forced together for economies of scale in late development but at the same time speed and cost require a light-footed, entrepreneurial attitude to discovery and early development. This encourages collaborations with smaller companies at all stages of development. Flexibility of approach is becoming essential in the area and smaller firms must be ready to take advantage of the opportunities presented by this. A key aspect of that will be having an IP portfolio that is managed appropriately for the types of technology and products to which it relates and which is ready for the new forms of collaboration. This in turn requires that IP professionals understand the needs of the business as well as the merits of an individual case.

The Patent Cliff

In the 5-year period between 2010 and 2015, drugs having an annual revenue of $90 billion will go off-patent. This is in addition to a similar drop over the previous 5 years and all the signs are that this really does mark the end of the "blockbuster" age of pharmaceutical manufacturing. When huge-selling drugs, such as the $11 billion a year Lipitor, lose their exclusivity, we see the so-called "patent cliff". This is caused by generic equivalents entering the market and causing a precipitous drop in the market share and selling price of the branded drugs. This drop can amount to 70% in a few months and cannot be matched by the new therapeutics currently in the pipeline. Although there are new drugs emerging, ever fewer are truly revolutionary and their markets are ever more specialised. This comes as no surprise to the manufactures but in spite of their efforts to invest in further research and development, a simple fact remains: The low-hanging fruit of drug discovery has been taken and the business model in which years of research by huge in-house teams could be supported on the prospect of the next big-seller can no longer be afforded.

Markets in Flux

The balance of healthcare markets is a further factor catalysing change in the sector. Made more pressing by the economic downturn, the squeeze on healthcare budgets in the mature markets of the US, Europe and Japan had already begun to manifest as price cuts, value analysis and hard-bargaining by authorities and regulators. Incentives for prescribers to switch to generics accelerate the patent cliff and mean an ever smaller premium on branded medicines. Most conditions with large patient populations that can be treated at the primary care stage will soon be open to competition from generic medicines and overall the size of the pharmaceutical market in these developed countries is barely growing at present. The revenue from new products is largely offset by discounts on existing drugs.

The current drivers for growth in the global pharmaceutical market are undoubtedly the emerging markets and of those China stands head-and-shoulders above all others. Brazil, Russia and India collectively account for perhaps a third of China's market growth which is fuelled by increasing demand and aggressive Government policy. These emerging markets, however, have often unreliable IP protection systems with prosecution sometimes unpredictable, enforcement difficult and counterfeit products common.

Buying in Innovation

It is evident that the primary-care branded blockbuster is no longer a viable model. Not only has in-house R&D failed to keep pace but research-based Pharma face ever increasing competition from generics and the emergence of a significant market in areas where protection of the brand is hard to guarantee. As a result, pharmaceutical companies have been forced over the last few years to look for alternative strategies to supplement their existing research efforts. These changes started gradually but are becoming increasingly fundamental both in nature and importance.

The first alternative to the in-house development of primary-care blockbuster drugs was in-sourcing from small pharmaceutical companies and biotechs. Historically these externally sourced projects have represented excellent value, particularly in terms of their success rate. This is perhaps because the process of buying in a product or technology involves the type of in-depth analysis of the technology and IP due diligence that is politically difficult for internal projects. Thus a disproportionately large proportion of bought-in projects became successful. A small drug development company having an innovative technology or product line which passed this scrutiny would potentially be bought outright to avoid having to share this benefit in a time when revenue was still plentiful and competition between rival Big Pharma was as great a driver as the search for new leads.

In the climate of 10 or 15 years ago it was often the aim of a start-up in the pharmaceutical sector to make itself an attractive acquisition as quickly as possible. In such times, the IP strategy was relatively straightforward since the company was likely to have one key product or technology and required a portfolio that would provide sufficient coverage when acquired wholesale. A relatively short lifespan for a company also meant that the portfolio was relatively immature by the time it was acquired. In such cases, there was little need for the IP professionals involved to consider how the IP portfolio would be used in the longer term.

A New Model

Even the in-sourcing of lead compounds from smaller companies has not, however, been able to keep pace with the loss of the major blockbusters. Furthermore, the increasing burden on new products imposed by regulatory authorities such as the FDA makes it ever slower and more expensive to bring a drug to the market. A budget of $200 million is not unusual for bringing a drug from lead optimisation to market and the attrition rate is high at every stage. To sustain enough programs in parallel to ensure that a few reach the market requires a large organisation and goes some way to explaining the recent mergers of large companies in the sector. However, large organisations tend to be less innovative and slower to react to new technology and without these attributes the R&D pipeline will never keep pace.

The recent announcements of increasing and more purposeful collaboration between Big Pharma and smaller pharmaceutical companies, biotechs and academia reflects the more active and aggressive approach to sourcing externally now being adopted in an attempt to find a new model. Ideally this would combine the light-footed, small organisation, approach to research with the financial muscle required to push leads through the development and regulatory process. This is one manifestation of the general move to greater flexibility in all aspects of research, development and collaboration which has seen drugs companies diversify into generics, vaccines and devices while new drug products have shifted from primary care to less price-conscious areas in secondary care.

Being Ready for New Collaborations

The more flexible approach now being adopted by large drugs companies has a knock-on effect on everyone in the sector. In particular it requires that smaller companies wanting to harness that muscle to push through their own products, or develop their technology, must be ready to be equally flexible. One key aspect of this should be management of an IP portfolio that will provide the features sought by a large company without requiring that the smaller entity be bought up or give up all control over its technology.

Where a small pharmaceutical or technology company was bought outright its IP portfolio would go with it and would protect the products of that one manufacturer. The major manufacturer buys all of the rights and with them buys complete control over strategy, prosecution, and enforcement. However, in the newer climate of flexibility and collaboration at all stages, conflicts can easily arise regarding both new and existing IP.

Taking the case of drug discovery company founded to apply a new method or technique in the search for novel active compounds, it is not unlikely that a successful project will be of interest to a larger company at the early clinical-testing stage. This may well be the stage when the smaller company will question whether they have the budget to take the project further and the financial clout of the multinational will be attractive. If the whole company were simply being bought then the issue is straightforward but in these more flexible times it could be that a license or even simply the option of a license is all that the large company seeks initially. The heavyweight licensee is likely to want control over litigation and perhaps also prosecution of patents covering the project they are interested in. However, if this represents only an exclusive option to a license on a single product there may be plenty of other projects being worked upon. Furthermore, it may not be desirable to give up control over litigation in particular if they wish to license the same core patents to another party for a different product.

The prospect of multiple licenses to more than one licensee emphasises the need for what would have been good practice in any case: Trying to segregate the core technology IP from the product IP. A small company who can offer up a family of product-directed applications to a potential licensee for prosecution and enforcement is in a much stronger position to retain control over patents to their core technology than one who has all aspects in the same cases. Since it is the core technology that will be utilised in the other projects they are then left able to enter future negotiations relatively unencumbered by existing contracts. It may be possible to unravel applications having both aspects by amendments and divisional filings but this situation is messy and unlikely to inspire confidence.

The temptation to cover all possible products in the first product-directed case is similarly unhelpful since a "laundry-list" of possible actives stands a good chance of mixing coverage of a future product in with the case to be licensed. Only by filing at the stage when some idea of the actual product can be discerned and by having the discipline to limit an application to this area can one project be licensed with minimal impact on the others.

A similar issue applies with collaborative agreements at the lead identification or optimisation stage. A well thought out contract should be able to allow even a small pharmaceutical company to retain any new IP to its own core area even while product-specific inventions go to the larger company or are held jointly.

To achieve any of these advantages, however, the IP professional must be more than a simple tool slavishly carrying out a client's instructions. Few scientists or managers have a detailed understanding of the subtleties of IP law but a scientifically trained patent attorney can achieve enough understanding of the law, science and business to bridge this gap. An understanding by patent counsel of the company's core technology and where the prospective product areas lie is thus vital. This allows filings that ensure the core areas are protected broadly at an early stage and that product cases are appropriate in timing, nature and scope.

Scientists, managers and patent attorneys are all busy people and it is tempting to overlook the need for IP advisers, either internal or external, to stay abreast of the direction of the business. However, in a time when collaborations with major Pharma companies could take nearly any form, the need for the most flexible and well-considered portfolio requires that this effort be made on both sides.

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