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IP Strategy for Drug Discovery: A Dedicated Research Firm's Perspective

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Even though, dedicated research firms rely heavily on the strength of their intellectual property (IP) to strike a favorable licensing deal, they seldom have the bandwidth to maintain a dedicated IP team to strategize the IP in a fashion which would enable them to reap the maximum value from the IP generated. The article discusses how to approach the issue of designing an IP strategy from a dedicated research firm point of view.

Keywords: IP strategy, dedicated research firm, drug discovery, licensing, knowledge management, IP portfolio

Given the nature of business of a dedicated research firm (DRF) in the pharmaceutical sector, intellectual property (IP), particularly, patents are considered to be the most valued asset. More times than not, the standing of a dedicated research firm, in the market place, is judged by the strength and nature of their intellectual property portfolio in comparison to that of their competitors in the market who incidentally come from the same pool as their prospective partners. The tricky market standing of a DRF requires it to have an IP portfolio that is not only better than that of its competitors but also appealing to the prospective partners. Therefore, ideally a DRF should have both a competing and a complementing patent portfolio when compared to the market.

Considering the complexity of its relationship with the other market players and the possible repercussions its tiniest faulty move could have on its other research handles, it is inevitable for a DRF to put in place an IP strategy not only helps in maximizing the value of their knowledge centric assets but also accommodates the dynamics of the market place. The readers may appreciate that there are multiple effective routes that a DRF can adopt in order to build a robust IP strategy. This article aims at discussing few of the approaches that could be considered by a DRF while building its strategy and shall not be considered to be conclusive. Furthermore, to evolve a best fit strategy for any DRF, significant modifications may have to be made to these approaches based on its business models and research plan.

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A DRF Business Model

A dedicated research firm, as the name suggests is a firm that bases its business model on research alone. The firm may either be founded based on already existing patents which form the crux of the business model or may be founded with a research concept which enables patent generation around it. However, unlike in case of giant pharmaceutical organizations, DRFs mostly do not venture into production and direct commercialization of the products they develop. Being an invention centric business entity, a typical DRF brings out products based on their research and then positions the same for licensing to interested parties who further develop the product and bring it to the market. Today there are several variations to this business model and there exist several DRFs that have a slightly different approach to business. Some DRFs partner with other firms having expertise in commercialization and together aim to bring the product to the market, while some others that have the financial bandwidth and the expertise to actually take at least a few products to the market, would research and license out some products while they decide to themselves take their product to the market for some others. However, most DRFs seen today have multiple business models which differ from programme to programme. For the purpose of this article, the focus would be on DRFs which are exclusively research firms, looking out for licensing partners to take their product forward. However, most aspects discussed here may be applicable to all the above mentioned business models, given that research that translates into money is an inevitable component of a DRF.

Since the main source of revenue generation for a DRF is from the invention which is the outcome of their research, IP is considered as the most valuable asset, arguably only second to the inventors who actually are instrumental in creating the invention.

A dedicated research firm in the drug discovery sector typically has multiple research handles based on the clinical indications the firm specializes in. Such firms are mainly instrumental in research and identification of drug molecules and positioning these for licensing at a desired stage or time during the development cycle of the drug.

As mentioned earlier in this article, the primary source of income of a DRF is constituted of the upfront payment and royalty payments which are outcomes of such licensing deals. These deals can be struck at any stage during the drug discovery process. However, given the indecently high failure rate (more than 70 per cent) during the regulatory process, the royalty for the deal is decided based on the stage at which the deal is struck. For example, in case of an early stage deal, which is usually considered as a high risk deal, the engagement will be valued at a lower price as compared to a late stage deal.

Given that, resource and budget required to take a drug candidate from an early stage to a late stage is significantly high and since a DRF may in most likelihood not have the expertise to take the drug to the clinic, it prefers to engage with the partner at an early stage since it will help in sharing the risk of drug development. However, such deals are most carefully scrutinized by the licensee and hence it is very critical to have a sound portfolio in order to be in a favourable bargaining position during licensing deal negotiations.

To strike a favourable deal with prospective partners, the product on offer should form part of a strong patent portfolio which covers a significant portion of the market space. As mentioned earlier in this article, an IP portfolio should not only be competing with the market but also should complement the market. However, an IP strategy alone may not necessarily be a viable solution to create a portfolio that is complementary and competitive at the same time. For achieving this, a thorough analysis of the market place is called for. Prior to dedicating resources for any programme, it is vital to study the market for which the drug is being developed. This study should be able to provide the various players in the market and the status of their programme. For example, if a firm has interest in focusing on Parkinson's disease as the research area, it should first study the landscape with regard to how many treatment options are available at that point of time, how many are effective, how many are in the pipeline, who are the major market stake holders for the indications, how crowded is the patent space, etc. As a risk lowering strategy, most DRFs prefer to exploit a sparsely crowded research area which will enable one to secure a substantially high market stake on one hand and provide sufficient case studies in the form of existing products being marketed to foresee the possible challenges with the product on the other. If this analysis is carried out prior to committing resources towards any specific area, one would have a clear understanding of who are the competitors and who are the prospective partners. However, to defend itself from competing products and to attract a good licence deal, it is important to have a strong patent portfolio. At this stage, a sound patent strategy will definitely help in improving the market standing of the firm.

In an ideal case, a patent portfolio should be both deep and bulky. In other words, the strength of a patent portfolio is not only judged by the commercial viability of the inventions themselves, but also by the number of patents the firm files relating to the invention. The product or molecule on offer should form part of patents that cover considerably broad chemistry space which will translate into a sizeable market space. Furthermore, apart from patenting the actual invention, a DRF must try to patent several other inventions around the core product space in order to ring fence the core product making it difficult for competitors to penetrate into its proprietary space. Most times, these peripheral inventions or assets are neglected and forgotten since they do not fare as well as the core inventions. Thus, in order to maximize the value of the research and to strengthen the patent portfolio, it is important to mark the assets that the DRF has generated in and around its core products.

Most DRFs have a modest set up and a small team which is mainly dedicated to research. Given their resource and time constrains they pay less attention to developing their overall asset portfolio. The rest of this article focuses on bringing out the best strategy to build a strong asset portfolio.

Creating an Asset Portfolio

Although the ultimate goal of a typical drug discovery programme is to invent a drug candidate that will survive the drug approval process, during the

process of getting to such a molecule, a DRF generates other assets which most of the times are not recognized by the firm, or if at all recognized, are not fully protected and cashed by the DRFs given their budget constrains.

During the course of research, the firm creates assets sometimes intentionally and other times accidentally. In order to derive highest possible value from the asset portfolio, it is important to be able to recognize such assets. The first step is to mark the assets as they get created. This can then be followed by protecting these assets from an IP stand point. Once this is achieved, based on the business dynamics, the DRF will be able to build an IP strategy that can get into a semi autopilot mode which will largely take care of the IP standing of the company. However, it must be appreciated that a considerably high degree of alteration may be required to the IP strategy from time to time to accommodate the market dynamics.

Asset Marking

Drug discovery is an interdisciplinary effort which requires understanding of disease biology, assay development, medicinal chemistry, synthetic chemistry, toxicology to name a few. Some of this information is knowledge that is available in prior art, while some of it gets generated in-house on a need basis and can be considered to be proprietary knowledge. More times than not, such proprietary knowledge is built on the prior art information and hence it becomes critical to differentiate between the two.

A good place to start the process of asset marking is the knowledge database where all the information that is used from prior art for facilitating research and all other information that gets built on such prior art are recorded. However, at this juncture, it is not necessary to evaluate the merit of such information. The information should be entered into the database without analysing whether it may or may not provide monetary benefits or whether it is in line with the firms' research objectives or not. For example, if while looking at literature, a firm with focus on cardiovascular diseases (CVDs) finds two articles: the first one on treatment of arteriosclerosis (subset of CVDs) using NSAIDs and the second one on the use of aspirin which is a commonly known NSAID for pain management, both these articles should find a place in the knowledge database, although use of aspirin in pain management is in no way related to the firm's research goals.

While populating the database, irrespective of its complexity, any information that was picked from prior art for research or was developed in the process of research should be classified based on subject matter and stored in the knowledge database. One must however, keep in mind that this is not a one-time process but a continuous one.

As the data gets populated in the knowledge database, the first level of marking should happen simultaneously. This first level of marking should differentiate the prior art from the proprietary knowledge. By doing this, the first filter to separate the assets from prior knowledge is being created. A simple way of doing this is to mark the prior art with its source or citation and mark the proprietary data as 'confidential' or 'proprietary'. For example, the articles that were found from the literature about the role of NSAIDs in CVD treatment and role of aspirin in pain management, both being pieces of prior art, can be tagged as 'prior art' with reference to the citation. The citation would help in pulling out the prior art at a later point of time. However, an analysis report or presentation created within the firm that relates to the possible role of aspirin in treatment of CVDs can be marked confidential and proprietary. It is important to understand at this point of time that such an analysis report may or may not have value from an asset point of view. For example, the probability of aspirin being effective in CVD risk is equal to the probability of it not being effective and it can be proved only by further research and studies. Hence the tagging at this point is done irrespective of the asset value of the knowledge.

The proprietary data can be diverse. It could be possibly a novel target, a customized assay protocol, a new measurement in an assay or a newly designed molecule. Once the proprietary knowledge is marked confidential, the second level of asset marking should be done. In this level, the confidential assets should be classified based on the type of knowledge. For example, a proprietary data that talks about a gene that can be used in diagnosis of cancer can be tagged as 'diagnostic' whereas data relating to the process of synthesizing a molecule can be tagged as 'synthetic process'. This may be a good time to compare the data with prior art to determine novelty. A detailed prior art search will require dedicated resources to run an extensive search in literature and patent databases to ascertain the novelty of the data.

After meticulously following this process for sometime, a list of novel targets, novel assays, novel molecules, novel procedures and so forth will begin to surface. This can be collectively referred to as the asset platform. With the marking, it would be helpful to tag the data with the programme it was generated under. For example, all targets, assays, molecules, procedures that relate to CVDs can be tagged under the CVD programme. This comes in handy especially when the DRF is looking to license out an entire programme. In case of a DRF who licenses a project (subset of the programme), it will help to tag every information with the project code as well. Some information may be common across programmes for multiple projects. It will definitely help to tag these types of information separately. Such tagging will make it clear during the deal as to which asset shall be licensed on exclusive terms and which should be licensed on non - exclusive terms. For example, if the firm has an asset in the form of a method of diagnosing CVD risk, this can be of value for all the projects which fall within the CVD programme. The special tagging of such an asset will then enable the firm to identify this asset as a subject matter of non - exclusive licence, since it may have to be shared with partners of other projects in the same programme.

As the research develops, the firm may channelize the research into specific disease areas, specific targets and so forth. Once this process is initiated, the asset platform needs to be time and again revisited in order to further tag or mark the asset to the related research programme. By doing so, all the assets related to a single programme/ project would get compiled in a single dossier or folder which shall form an asset portfolio for the said programme/ project.

Asset Protection

Once each component of the asset has been classified into its type of knowledge (assay, molecule, process, etc.), based on the asset marking discussed above, each asset may enjoy a different type and level of protection based on several parameters including kind of asset, its potential value, its alignment to the business, its relevance to the research programme and so on. If the firm believes that any particular asset can add direct or indirect value in terms of financial gains to its business, the assets should be protected as either patents or trade secrets.

Patent Protection

Of all the possible protection routes for inventions, patents are the most sought after. It is a general understanding among firms that any asset that provides direct financial value must be protected by a patent. However, this may not necessarily be true and may be an opinion formed with lack of foresight. Although patents provide very strong protection under the law, they have their share of limitations such as limited protection term, high protection and maintenance cost and most importantly a considerably long list of exceptions to patentable subject matter. Despite these limitations however, patent protection in certain cases are inevitable. For example, a drug molecule or a process of synthesis is best protected through a patent. These being assets that generate direct value, it is very critical to acquire patent protection for these.

While protecting any asset under the patent regime, it must be verified that it is patentable in all jurisdictions of interest. For example, to protect a new use of a known drug may be possible in US and Europe. However, this falls under exception to patentability in India. In such a scenario, the protection strategy in India may have to be different. It is also critical to conduct a patentability analysis and analysis from a freedom to operate point of view for all jurisdictions of interest before validating any asset as patent worthy.

The most critical part of patent protection however, is the drafting of the specification. The specification should be drafted craftily to ensure maximum protection possible. The drafter of a patent should ensure that the patent is drafted to cover the broadest possible scope respecting the scope of other neighbouring patents. A patent claim should be drafted in a way that it is specific enough to cover all the elements of the invention and broad enough to stop others from easily designing around the invention.

Another aspect to be taken into consideration is that every other novel element relating to the invention that is patent worthy should be protected either in the same or a different patent. For example, apart from drafting a claim for novel molecules in the programme, claims should also be drafted for the synthesis process of the molecules, possible compositions, method of treatment, administration routes, etc. This will ensure a bulky patent portfolio which can be used in favour of the DRF during licence negotiations. Although, the focus of this article is not on patent searching or drafting, it must be kept in mind that drafting a good and viable patent application requires special skill set and should be preferably done by professionals.

Further in the process, several strategic decisions are likely to be made at the time of patent filing. Since at the time of patent filing, a DRF is less likely to know the actual jurisdictions in which their licensing partner may wish to commercialize the patent, they have to ensure that the patent is filed in most jurisdictions. One way of approaching this issue is by filing a PCT application which gives the firm more than two years to decide the jurisdictions it would wish to pursue the patent in. These two years is crucial for entering into a licence deal and hence the decision regarding which countries to pursue and which to let go can be a decision that the DRF and its partner can collectively take.

The timing of filing a patent is another important aspect that needs to be taken care of. Typically it would take 7 to 8 years for any drug to hit the market, from the time it enters clinical trials. Hence, the actual term of the patent in the drug discovery sector may be slashed from 20 years to about 12 years. If the patent is filed very early, this 12 year term may further shorten, which is not a desirable prospect for the prospective licensee. On the flip side, if the patent is filed later, even though it would extend the exclusivity term, one runs a risk of losing the patent to other competitors who are researching in the same area simultaneously. Also, as time passes, the prior art relevant to the invention would increase, thus reducing the scope of the prospective patent. Hence it is important for one to study the market, and figure out the best time to file for the patent.

For assets which can be banked on for a longer duration than what the patent protection can provide, alternate protection strategy may be required.

Trade Secret Protection

An alternate strategy would be to maintain assets as trade secrets. This strategy is best fit for assets that are difficult to reverse engineer or assets which have value only because of their secret nature. The main benefit of a trade secret is that it is not limited by term and can be protected so long as the secrecy is maintained. Also, the asset being protected under trade secret regime need not be registered as is required in case of patents. However, the biggest drawback of a trade secret protection is that it can be reverse engineered. For example, if a firm protects its drug molecule as a trade secret, the molecule can be easily reverse engineered by another firm which will bring an end to the protection of the molecule. Hence, it is important to differentiate between inventions which can be reversed engineered and which cannot be, in order to determine its protection strategy. For instance, a biomarker which is useful in assessing the efficiency of a drug molecule three times faster than known markers, can be a valuable tool in drug discovery for lead candidate selection. This tool is most likely an asset that helps in the internal process optimization for the DRF and need not be accessible to the outside world. Furthermore, if protected by patent, it is difficult to enforce such an asset since its use by another firm is difficult to audit. Given this scenario, it is best to maintain such asset as a trade secret. The only flipside to such a protection is that unlike in the United States, Indian laws with regard to trade secret protection are not well developed and the deserving relief for its misappropriation is uncertain. The level of protection to maintain such secrets in India therefore, will have to be stringent.

The three basic ways to ensure protection of trade secrets include legal instruments, notice and physical access controls. Legal instruments such as non-disclosure contracts with employees, consultants, advisors and so on stating clearly the terms of confidentiality is the most critical level of protection. Providing notice with regard to the sensitivity of the information is the second level of protection which includes marking every document that directly or indirectly describes the assets as ‘confidential’. This includes emails, presentations, documents, excel sheets, printouts, etc. It is also important to sensitize the people with regard to the sensitivity of the data. The third and very important measure is to create access controls. Any asset information should be shared (even with employees of the firm) only on a need to know basis. Physical security measures such as monitoring emails, restricting access to storage devices, clean desk policies, etc., are effective access control strategies. Effective implementation of the above stated measures will ensure sufficient trade secret protection.

There are other protection mechanisms through which certain assets can be safeguarded such as designs and utility models. However, such protection strategies are not very relevant in drug discovery set up.

A protection strategy that is determined for a particular category of asset can be implemented when another asset of the same category is created. However, one must bear in mind that certain alterations and modifications may be required on a case to case basis.

Cashing on the Portfolio

A clearly demarcated asset portfolio gives a clear understanding of the actual value of the asset being transferred. Based on the asset portfolio, a valuator will be able to calculate the value of the assets being transferred in a licensing deal. If the assets are aptly marked and sufficiently protected, it facilitates in putting together an asset portfolio for any licensing deal. Unlike in other technical inventions such as a computer program or a mobile device, a licence agreement for a drug molecule can seldom be limited to its patent alone. Although a patent being licenced will form the crux of a licensing deal, a typical licence deal in the drug discovery sector will require the licensor to license out the patent portfolio along with the know how and expertise of the licensor relating to the invention being transferred.

Once the asset portfolio for the programme is put together by the marking process, it not only enables the firm to define the licensing terms more specifically, it also helps in regulating asset transfer to the licensee. It gives the firm a clear idea of what can or cannot be shared with the licensing party. It also enables the firm to determine and distinguish between the assets that can be exclusively transferred to the licensee and the assets that the firm may need to use for its other programmes which may either be kept out of the scope of the licence agreement or be provided on non exclusive terms.

Conclusion

While designing an IP strategy for a DRF, it is important that the IP strategy is closely weaved into the firm's business strategy. One good way to approach this is to ensure that the IP goals are kept in line with the research and business goals of the company. It must also be noted, that asset generation is purely a research initiative and a robust and effective IP strategy should have minimal influence and interference with the asset generation process. However, IP strategy should ensure that management of the generated asset is accounted for in the strategy.

To summarize, asset management can be initiated by asset marking to build a well classified knowledge platform followed by asset protection and demarcation of an asset portfolio. The worth of an asset portfolio is largely dependent on the asset generated and an IP strategy may not be able to ensure high value assets. However, an effective IP strategy enables the firm to realize the value of its assets and communicate the same to the prospective licensee in order to strike a favourable licensing deal with them.