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For a fool proof patent

Pharma companies employ various strategies while drafting patent claims. ***Viveka Roychowdhury*** *finds out*

It is now about three years since India became a signatory to the TRIPs agreement and recognised product patents. As a consequence, the Indian pharma industry has had to learn new skills and one of these is protecting intellectual property (IP) generated during the process of drug discovery. One of the primary means of doing this is by filing a patent claim/application. "A claim demarcates in words the boundary of the invention which is analogous to a fence around a piece of land property," says Dr Milind Antani, Senior Associate and Head of the pharma, lifescience and healthcare practice group of Nishith Desai Associates. "Claims are very important in the management of the IP resources of a company as it plays significant role during prosecution and litigation and valuation of the company, stronger patent portfolio will add to the growth and valuation of the company," adds Antani.

Claims are very important in the management of the IPR resources of a company and determine the standing of the company in the market and the support received from the investing community. The domestic pharma industry is at a very early stage in drug discovery and therefore filing claims is at a nascent stage. MNCs filing their patents in India are finding out that having a patent for a product in other countries does not imply that their claim will be uncontested in India. "India is a developing country with deep healthcare concerns. As a sovereign nation, India needs to and is rightly expressive of options of flexibility, permissible under TRIPs. This trend is being followed by other developing and Less Developed Countries (LDC). In fact even developed countries are looking forward to strike a proper balance in patent law, between private rights and public good," says Dr Gopakumar Nair, CEO, Gopakumar Nair Associates.

Antani points out that different countries have different guidelines and regulations related to patents. "Section 3 of the Patents Act 1970 of India carves out certain exceptions from the patentable inventions. Different countries (jurisdictions) have different IPR laws governing what is patentable and what is not. A person needs to be watchful of these exceptions while drafting the patent application," advises Antani.

Such differences have given rise to controversies like the Novartis-Glivec case. More recently, Eli Lilly's patent plea for Forteo, its osteoporosis drug, has also been turned down on the same grounds, ie. of prior knowledge, incremental innovation and failure to establish enhancement of known efficacy. This decision was given after hearings held in response to a pre-grant opposition by domestic drug company, USV. A senior official from USV, said that the company had raised three issues-that Lilly had filed a patent for this product in Europe before 1995; its claims on the innovation were only marginal; and there was no substantial efficacy level compared with the known drug.

Dr Gopakumar Nair

Dr Milind Antani

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Different names, same result

Some Indian pharma leaders contend that the strictures imposed by Section 3(d) are unique to the Indian Patent Act and no other jurisdiction has similar restrictions. However, European Patent Law has the hurdle of "inventive step", under which applicants have to show some unexpected effect, some surprising quality, some extra efficacy of the compound. Under the US legal system, the applicant will have to apply similar arguments to prove "non-obviousness". So the result/outcome of this is that in India, applicants will have to show some experimental data to prove that this particular polymorph is better that what is already known from the prior art.

"So ultimately the result of both jurisdictions is the same. It's only that here in India it is called Section 3(d) and in Europe it is called 'inventive step'. So I think that any compound which can overcome Section 3(d) in India will also overcome the hurdle of inventive step and novelty. The result at the end of the day should be very similar. In US, you will have to apply similar arguments when you show 'non-obviousness'," says Dr Markus Engelhard, a European Patent and Trade Mark Attorney and Partner with Germany-based law firm Boehmert and Boehmert.

These court decisions have focused attention on the nitty-gritties of the patent drafting process. How does a company build a patent which is water-tight? "The way to safeguard against this is to build your patent claims like an onion," says Dr Engelhard. "You have an independent claim, which is the broadest claim, that's under attack from the examiner using the prior art claim. And once he's able to find a part piece of prior art that actually anticipates the argument, you peel that layer off like the outer shell of the onion. So you have another shell which is the next shell in the row," he concludes.

There are two basic types of claims; independent claims, which stand on their own and dependent claims, which depend on a single claim or on several claims and generally express particular embodiments. According to Antani, generally, the broadest claim (independent claim) is written first followed by narrower claims (dependent claims). There are various 'best practices' and specific language to be used which make the claim more water-tight.

A good example would be the use of the words 'consist' and 'comprise'. A compound 'comprising' Compound A, B and C, that does not exclude the presence of other compounds, for example D, E and F. Whereas a compound 'consisting' Compound A, B, and C, means that there is nothing else these but these three compounds.

Common errors

Another crucial aspect is defining the patent's scope. The most common error made while drafting patents is that you draft it too narrow, opines Engelhard. Therefore, the claim should be broad enough to cover all aspects of the invention or product.

The other extreme is that the claim is too broad and the applicant can't support it in certain areas. "While a broad independent claim is the best objective, it could also work against the applicant/ inventor. While attempting to broaden the scope of the first independent claim, there is a high element of risk that the claim may encompass 'prior art' or may incorporate 'infringing elements' into the claim. It is therefore imperative that a judicious optimal limit and restraint should be used in claim drafting," recommends Nair.

Engelhard cites a pharma-specific example. In claims where you have a chemical compound, with particular residues, you say a chemical compound, with this formula, and then you list all the different alternatives. This is a Markush claim. The different types of claims filed by pharmacos could focus on various other aspects, like the method or process used, a system claims, utility claims, business method claims, means plus function claim and Jepson claims.

It would seem that certain simple modifications in the claims while drafting applications would help in availing protection in a number of different countries. "Generally, it is seen that the claims are written for a new compound having a number of variable groups resulting in claiming hundreds of compounds with alternate variable groups. However, all these structures are not experimentally proved to exist and possess the desired properties, hence they are not substantially supported in the description. So, such patents are considered very weak in case of infringement analysis involving any of the same compounds," cautions Antani.

Playing safe

If a pharmaco does its homework well, it can find a way around the restrictions. The in-house IPR cells of most pharma companies conduct effective prior art searches to determine the scope of existing patents. This activity may also be outsourced. Antani outlines strategies used by pharmacos to ensure that their patent does not infringe on existing patents:

- In case of a patented multi-component formulation containing a combination of two or more ingredients, one may obtain a patent by changing the non-essential components not covered by the patent
- May play around with the concentrations of different components
- In case of process patent change, the steps involved in the process
- Change the formulation type (drug delivery) resulting in some improvement in efficacy

Patent offices will reject vague terms. Engelhard says: “In a claim directed at a device having a 'thin outer shell', the word 'thin' won’t be accepted by the patent offices, as it does not exactly describe what is 'thin'. So one has to be specific.”

Regulators are also trying to rationalise the patenting process. In Jaunary this year, the US Patent and Trademark Office (USPTO) proposed new laws to improve patent quality, reduce patent litigation costs and harmonise patent laws. After industry protests, the rules were relaxed and are due to come into effect from November 1. The new rules will restrict the number of times patent applications can be re-evaluated and also limit the number of claims contained in any one application. Inventors will be limited to two new continuing applications, through which they can add additional claims to the same patent, and only one request for a continued examination, which an inventor can file after the Patent Office has rejected his or her patent application. The rules also restrict to 25 the number of claims in any single patent submission. Certain multiple applications will be treated as a single application.

The price of patents, from drafting and filing to grant (not including maintenances costs), varies from country to country and as per the chosen patenting strategy. The Patent Cooperation Treaty (PCT) is another option and strategic route which may help to phase out the costs over a few years.

Country	Approx price
India	from Rs 1 lakh to Rs 5 lakhs
US	Rs 5 lakhs to 20 lakhs
E U	Between Rs 10 lakhs to Rs 50 lakhs or more

Source: Gopakumar Nair Associates

Hits and misses

Patent drafting strategies are crucial to enhance the life cycle management of a compound or technology. "Life cycle of an invention is often managed by strategies of progeny patents,

family patents, extension patents and selection patents by incorporating novel inventive elements into the already patented subject matter, so that patentability criteria is met even in later extended patent applications," says Nair. "A successful example, is that of Fexofenadine over Terfenadine or Clarithromycin over Erythromycin. In case of Pfizer Vs Apotex, recently an Amlodipine salt patent was invalidated, due to prior art of another Amlodipine salt," points out Nair.

Drug delivery technologies serve as a strategic marketing tool to differentiate products. This helps in sustaining and increasing the market value of the drug. Developing enhanced version with therapeutic benefits viz. improved efficacy, frequency of dose, and identification of new indications, are two other strategies, though new indications may not be allowed in certain countries.

Patent attorneys are of the opinion that drafting claims for the life science industry has its own complexities. Antani practised as a medical surgeon for 14 years before qualifying as a lawyer and joining Nishith Desai Associates to set up its pharma practice. "The biggest challenge is to understand the invention, complexity and putting it in the most correct form while drafting the patent. Having knowledge of the subject plays a significant role," says Antani.

"Awareness and skills can enhanced by more thrust in providing training on patent laws. Institutes and academies are contributing effectively and productively in this direction," says Nair. In spite of complexities, patent filings will increase and practitioners will have to keep pace. "Indian patent examiners and controllers are also learning fast and are being provided with 'prior art search' tools and training. Global patent laws, including the US and EU, are going through amendments, which are coming into effect and which are intended to 'surprisingly' plug the loopholes in evergreening and frivolous patenting," points out Nair.

Antani sees the country specific patent drafting as an emerging trend. "You try to keep abreast with whatever is happening legally. E.g. for the last 20 years, second medical use claims in Europe have been formulated in a particular manner. Now, with the revision of the European Patent Act—to come into force in December this year—they will have to word it slightly differently," says Englehard giving the EU perspective.

Awareness is no doubt increasing, but it needs to be across all levels of the industry hierarchy. For instance, as India is a hotbed of R&D, IP is generated in research labs by academics and research staff. "Measures should be taken to create awareness of IP and confidentiality at scientist level," says Antani.

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