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Cost-Effective Healthcare – How Patent Framework Can be Re-designed to Help Fulfil this Objective

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Introduction

Governments all over the world are being pressurised to address the issue of providing better healthcare to every citizen. In order to address this issue the payers are becoming more and more cost conscious and we have seen establishment of cost watch dogs (NICE in the UK) in the healthcare sector and similar developments are being made across the globe. Moreover, recently it was announced that pharmaceutical policy in the new European Commission will no longer be the responsibility of DG Enterprise and Industry but will move to the Health and Consumer Policy directorate, DG Sanco. This shift of pharmaceutical policy to DG Sanco highlights the changing priorities of policy makers to handle the healthcare sector from the social and economic perspective instead of industrial and business. The issue of prices of medicinal products is not only limited to third world countries alone and it is now becoming relevant in developed nations too. However, this issue has been looked at in isolation and various associated factors and stakeholders are not being considered and consulted in order to create a well integrated healthcare provision framework. We need to explore as to how we can readjust the whole healthcare system with the ultimate objective of providing quality healthcare to our citizens. All stakeholders and all applicable regulatory and legal frameworks need to be appraised in order to address the requirements of 21st century healthcare.

From stained glass to biotechnology – why the patent framework is not evolving:

The current patent protection framework is not ideal for the pharmaceutical industry and other stakeholders. In many other technology-based industries it is possible to keep the inventions secret until or very close to market launch, which enables them to maximize the effect of the 20 year patent term. In contrast, in the pharmaceuticals sector, it is not possible
to delay the submission of patents. In fact, a patent application is filed soon after discovery and it takes 10-12 years of extensive R&D before it reaches the market as medicinal product. Therefore, there is a lengthy time period between patent filing and placing a product on the market, which means that pharmaceutical manufacturers receive far shorter periods of patent exclusivity than is the case for other patent dependent industries.

We have not seen any industry friendly developments in the legislative and business framework in which pharmaceuticals operate. Instead, the framework in which pharmaceuticals operate is becoming more complex, lengthy and costly. It seems vital that the framework in which industry operates needs to be aligned with this changing paradigm to ensure that we are not stifling the industry to save the cost. Patent framework for Pharmaceutical industry needs to be compared against other industry sectors to create a level-playing field. Like for any other industry, the patents should give financial benefits for the full patent terms of 20 years to the pharmaceutical industry too. This article intends to discuss the patent framework and asks key questions and proposes ideas which can be further explored to better align the patent framework to meet the ultimate objective of providing cost-effective healthcare globally.

New Class of Pharmaceutical Patents – Development and Medicinal:

The patent framework for the pharmaceuticals needs to be aligned with other legislations governing the major functions of pharmaceutical businesses – R&D, registrations and marketing. Therefore, it seems logical to divide the pharmaceutical patents into two separate classes accordingly - a Development Compound Patent (DCP) and a Medicinal Product Patent (MPP). A DCP would be granted when the new compound or the biotech product is
discovered. For this type of patent, the patent holder would have the rights to produce and develop the compound into a medicinal product – early testing in lab and animal, clinical trials, manufacturing and formulation developments and the like. Second class of patent - MPP, would be granted when the development compound is granted marketing authorisation by the regulators – EMEA, FDA etc. This MPP would claim the compound itself and salts if any, the actual medicinal product, all pharmaceutical forms, its manufacturing process, and indications/usage. MPP should be allowed to claim the established therapeutic benefits/usage, as approved in their labels – SPC, USPI etc. Once a new indication is developed there should a scheme of updating the claims to protect any additional indication for that medicinal product.

Please see fig 1 which summarises the overall pharmaceutical patents scheme proposed here and is discussed below under various headings.

**Affordable and Rational Pricing**

Let’s move on to the second important aspect of patent protection – pricing – and discuss how this new system could help alleviate these concerns.

These MPP would be subject to 5-yearly renewal during their 20 year period. As part of first renewal (at year 5) the MA holder would reduce the price by 5%. At next renewal (year 10) the MA holder will reduce the price further 10% and at the last renewal (year 15) a further 10% reduction. This would be the scheme for developed countries (EU, USA, Canada, Japan etc). A list of countries for this group can be drawn and agreed upon by the members of WTO. We can call this region, Group A.
For developing and third world countries, this scheme would be different. Since, the initial registration applications in these countries rely upon prior registration in group A countries, the price would have been established in Group A countries when the application for medicinal product patent is filed in this Group; Let’s call this region Group B. As opposed to the price reduction at renewal stages as proposed for Group A countries, for this group of countries the applicant would be required to submit initial application with a price which is 30% less than the price of the product in the country of origin (the country/region which is being used as reference for initial registration). The renewal scheme and associated price reductions would be applicable for this Group too, as mentioned above for Group A. Therefore, by third renewal application in this region, the prices would be 50% less than those in Group A countries.

In addition to the two groups mentioned above, there would be another price reduction scheme for Group B region. This will cover those medicines which are part of WHO’s essential medicines list and for those diseases areas which are more relevant to this group B region – HIV, TB, Malaria etc. A list of diseases areas and essential medicines list can be drawn and agreed upon by the members of WTO. For this group of countries the applicant would be required to submit initial application with a price which is 40% less than the price of the product in the country of origin (the country/region which is being used as reference for initial registration). The renewal scheme and associated price reductions would be applicable for this Group too, as mentioned above for Group A and B.
In the meantime, for existing patents for marketed products patent extension schemes can be introduced subject to cost conditions. For instance, 10% price reduction for 1st year of extension and a further 10% for 2nd year of extension.

**Revenues for the State**

This proposed framework would be subject to different fee structures and would generate additional revenues for the state. The development patent applications would be subject to current fee structure for initial applications and annual maintenance fee. However, the medicinal product patents would be subject to premium fee compared to development patent fee. The initial application and annual maintenance fee for a medicinal product patent would be the double the fee of a development patent application. In addition, the medicinal product patent would be subject to 5-yearly renewal fee (which would be 75% of the initial application fee). Additionally, when the MA holder would develop the product in a new indication, this would be submitted as an addendum to update the claim and the fee would be 50% of the initial application fee. Additionally, MPP could be subject to certain taxes, which again would generate revenues for the state. The details can be worked out but the idea is to have premium fees in order to generate additional revenues for the state.

**Advancement of Science and Knowledge Base**

In order to fulfil the major objective of patent philosophy – advancement of science and knowledge base, the DCPs would be revoked once a MPP is granted. Since, the medicinal compounds can be developed for use in multiple disease areas; therefore, upon revocation the DCP would be open to public to further develop in any other indications not covered by
the respective MPP. This scheme would ensure a quick transfer of knowledge to the public domain – within 10-12 years as opposed to conventional 20 years.

**Helping Developing Countries in Health and Economy Sectors**

We cannot dismiss the fact that many patients in the world cannot pay for patented drugs and do not have access to them. However, this is not the result of the patent system; it is the result of lack of sources and non-existence of integrated healthcare framework in these poor countries where people do not have money to purchase these drugs themselves. Provision of healthcare is State’s responsibility. However, industry plays an important part in provision of quality healthcare, but the bill shouldn’t be picked up by the industry alone. Governments need to work with the industry to design frameworks, which ensure provision of quality healthcare to every citizen without exceptions. Therefore, a patent scheme of extended exclusivity – tied with price structures – can help fulfil objective of healthcare provision in developing countries.

**Conclusion**

Contributions made by pharmaceutical industry - in economic terms, in terms of high quality employment, investment in the science base and in terms of public health – cannot be ignored. Pharmaceutical industry is one of the largest contributor to global economy and the largest contributor to research and development (R&D). Around 20% of global business expenditure on R&D is accounted by the pharmaceutical industry worldwide and it generates revenue of more than $700 billion. It invests an average of 16.1% of net sales in R&D - more than any other industry. Another not as well known fact is the important role the
pharmaceutical industry plays in the global efforts to fight diseases and improve public health in the developing world. It is estimated that industry’s contributions are over $2 billions. Industry’s partnerships with academic, governmental, non-governmental, multilateral, and community-based organization exceed or rival in total size the annual budgets of the World Health Organization and World’s Bank’s health programs. These contributions by pharmaceutical industry in developing world cannot be sustained if the industry cannot generate sufficient revenues from developed world. Therefore, in order to maintain and further develop these philanthropic contributions, the governments/payers/policy makers in developed world need to work in close collaboration with the industry to design a framework which creates a conducive environment for the industry.

In order to keep this industry flourishing and keep playing a vital role in making people and economy healthy, we need to understand the requirements of this industry and design appropriate frameworks. Drug development is very risky, costly and lengthy process and inventors and investor deserve financial gains for their efforts. We need to design a framework which addresses all stakeholders’ needs, i.e., industry (return on investment to spend it back in development), payers (cost) and patients (superior quality, innovative and effective products). Additionally, the framework should allow quickly transition of knowledge into public domain to ensure advancement of knowledge and science base. Moreover, the framework should be less complicated for better use of time, money and resources at both industry and patent offices.

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2nd 5 year renewal
10% price reduction

3rd 5 year renewal
10% price reduction

1st 5 year renewal
10% price reduction

Grant of MAA
by EMEA/FDA
for indication A, B, C

Revocation of D.P and open to development for any other indications other than those covered by the M.P.P

Fig.1