

Does Intellectual Property Laws in India and China Encourage Innovation?

Parama Sinha Palit (Senior Associate with Corporate Law Group)

Bhaskar Bhattacharya (Senior Associate with Corporate Law Group)

Incremental innovation has become a point of debate the world over. While it is largely believed that 'breakthrough' innovations are important, at the same time it is held that such 'breakthroughs' are rare in medical research. India and China, the two Asian countries are not only joining the international trade as emerging economies but their pharmaceutical industry is also taking big strides. As far as the pharmaceutical industry is concerned, 'minor' but 'essential' steps are considered crucial for the industry to improve medicines and public health. However, there seems to be a dilemma amongst countries over the 'value added' by way of these small incremental changes. This paper attempts to examine both the Indian and the Chinese pharmaceutical industry and analyse the criticality of 'incremental innovation' for the industry in these two specific countries of interest.

■ KEYWORDS Innovation, Incremental, Pharmaceutical, TRIPS, Healthcare, Patent

1. Introduction

The 'Asian Century' seems to have come of age in every sense of the term--strategically, economically and of course pharmaceutically. It is a reality that all action of the 21st century appears to be shifting from the 'West' to the 'East' making Asia the new 'centre of gravity'. As far as the pharmaceutical industry is concerned, the shifting has occurred no doubt. This is vindicated by Dan Bartholomew, senior Managing Director, PricewaterhouseCoopers Pharmaceutical and Life Sciences Practice, who has rightly pointed out that "the pendulum for the pharmaceutical industry is shifting from the West to the East".¹

However, despite the 'shift' and the promising Asian pharmaceutical industry, a lot needs to be done with respect to incentives for innovation—the hallmark of any pharmaceutical industry.

There is little doubt that Intellectual Property Rights in the form of patents not only encourage innovation but also provides an economic incentive to investors to invest risk capital in innovation activity.

While the benefits of patents are getting more and more accepted and acknowledged, there remains an apparent misconception with respect to the nature of inventions to which patent protection must be available. More often, at least in case of India, one comes across the restrictive treatment to adaptive or incremental innovation by the Patent Offices. As a palpable instance of aberration to the universally accepted norms of patentability, in Indian law, patentability of pharmaceutical, biotechnological and chemical inventions has been left open ended to overarching subjective discretion of the Patent Office, needless to state, to the detriment of the applicants. However, it is largely true that any

innovation is incremental in nature and protecting such innovations, therefore, becomes all the more an important responsibility of any Government. Both Charles Darwin (a naturalist) and Alfred Marshall's (an economist) observation that 'nature does nothing in leaps'² can be appropriately applied to understand the role of incremental innovation in the pharmaceutical industry.

Incremental innovation is not confined to nature alone. The invention of the wheel was a breakthrough innovation in transportation. But the subsequent steps (small incremental advances) involved have revolutionized transportation today. Similarly in every other experimentation--drugs in this case--require building on existing knowledge and experience with additional creative/scientific thinking, research and trials which enhances the value of the end-product. There is no denying that efficacy of drugs often increases with small incremental improvements which sometimes are responsible for bringing about tremendous benefits to patients. It has been rightly pointed out that not recognizing incremental innovation in the pharmaceutical industry is like asking medical researchers to reinvent the wheel. Incremental innovation or innovation by steps is essential to pharmaceutical development of new and improved medicines and to public health.

2. Incremental Innovation: A Necessity for Pharmaceutical Industry

Any discussion of healthcare research and development often implies 'major breakthroughs' or 'pioneering advances' such as new classes of chemicals or new compounds that open entirely new therapeutic options. But incremental or adaptive innovations, new dosage forms of

existing products, alternative salt forms or isomers of known substances, or minor changes to existing medical devices, have also been crucial in increasing value to a drug. However, more than often these adaptive/incremental improvements to a given drug have been disapproved of as "minor" or "small" changes that do not deserve any investment. It has been argued that patents granted on small innovations misdirect investments to minor changes and discourage further innovation. But there are still others who counter that though "innovation" may not be synonymous with "major breakthrough" and advances in science and technology, they frequently occur in small steps referred to here as incremental or adaptive innovations. Such advances, they squabble, warrant recognition³ accorded by intellectual property protection and the investment incentives such protection provides.⁴

Breakthroughs have indeed occurred in diagnostic technologies, but incremental or adaptive innovations are required to bring relief to certain diseases which are rampant in poor regions of the world. For instance, most cervical cancers are preventable if detected and treated early. Digene Corporation of Bethesda, Maryland (Digene) is one of the companies responsible for recent technological breakthroughs in cervical cancer screening technology. Products embodying those breakthroughs have been given marketing approval and have contributed to reduced mortality in Western countries.⁵

Worldwide, however, cervical cancer remains a leading cause of cancer deaths among women in some poorer regions. Efforts to diminish the imbalance in availability of cervical cancer diagnostic tools were initiated recently by a partnership between Digene and the Program for

Appropriate Technologies in Health (PATH).⁶ That work would build on the existing basic technology now used in developed countries with strong medical infrastructure. This joint effort could yield low-cost, easy-to-use, culturally acceptable tests for cervical cancer screening, suitable for regions with minimal resources and medical infrastructure. The task is not 'minor': both research and development may take at least five years, if not more. Changes required to adapt existing technology may be incremental, but they definitely are not of a low value to any society. In fact, adapting the existing diagnostic technology to developing country conditions could have significant benefits to women's health in poor regions.⁷

3. India & China Patent Regime: Innovation at Crossroads

With respect to the pharmaceutical industry in India and China, their domestic consumption of medicines is supplied by their respective domestic firms. The US Department of Commerce puts the estimate at 70 per cent.⁸ This clearly indicates that given the low incomes of the Indians and the Chinese, the pharma companies of these two countries supply the low-priced medicines locally for the local population.

While there is no doubt about the growth of Pharmaceutical Industry in the two countries, the countries have not gone far with protecting innovation, despite certain otherwise positive changes taking place in the sector.

Both India and China agreed to go ahead to fulfil the Trade Related Intellectual Property Rights (TRIPS) Agreement. In keeping with the TRIPS Agreement, India introduced product patent in the pharmaceutical sector with effect

from 1st January, 2005 by amending the Patents Act, 1970 in India.

While the pharmaceutical industry in India is undergoing transformation, its inventions have always been treated differently. In the field of pharmaceutical inventions, the IPR issues have always been hijacked by issues of availability and affordability of essential medicines and protection of public health, thus imparting a wrong notion that absence of patents would ensure availability and accessibility of drugs, and thus take care of the public health concerns. The fallacy is evident from the very fact that from 1970 to 2005, there were no pharmaceutical patents and even now a very few patents have been granted. Even in the absence of such patent regime, while the Indian Pharmaceutical Industry grew at a fast rate, the public health scenario remained grim. If one looks deep, the restrictive policy on pharmaceutical innovations in the Indian Patent regime can be actually found in the Industry demography and the public health debate has rather been used as a convenient vehicle for voicing domestic industry concerns.

It is a hard fact that after 1970, Indian pharmaceutical companies especially the more than 22,000 small manufacturers have a stake in a weak patent regime continuing. It must be recognized that most of these manufacturers produce 'generic' drugs. While the larger manufacturers with a strong R&D base favor a TRIPS compliant patent regime, the smaller ones take a reverse stand. As a result, the new patent regime is considerably weaker than the regimes of most other countries. However, in doing so it is promoting a generic market both in India and abroad, which does not offer high value innovative products.

The Indian domestic pharma market, which has consistently grown at 9.5 percent CAGR in the last five years, is poised to accelerate at 13.6 percent between 2006–2010 to touch the market size of \$9.48 billion by 2010 from present level of little over \$ 5.7 billion according to a study undertaken by the Associated Chambers of Commerce and Industry (ASSOCHAM) of India and Cygnus. With such a promising potential, it is imperative for India to take measures to protect inventions, thus making patents more effective.

India has a stake in the global IPR regime in view of the gains being made by its own software and pharmaceutical industry. India, with its vast reservoir of scientific talent and established pharmaceutical industry stands at the threshold of success in biotechnology, after its success in the IT sector and is capable of being part of the next revolution underway. India needs to stoke an innovative culture. In this research driven sector the right legal framework is lacking, which discourages continuation and deepening of international partnerships and expanded research and development in India.

China, on the other hand, primarily thought of as the lowest-cost source of pharmaceutical ingredients and plain vanilla generics, started moving towards protecting intellectual property in 1993 with reform of its patent law. It had also raised bar for entering the pharmaceutical business by passing laws including Drug Management Law and Regulations on Pharmaceutical Manufacturing since 1998. Subsequent to its accession to WTO and TRIPS, it has enacted regulations in 2002 in compliance with TRIPS agreement. Its 2002 regulations extended pharmaceutical patents to twenty years, and data exclusivity for six years.

Although the Chinese firms' advances in biotech and traditional medicines are strong, it is gradually focusing on innovative R&D as a longer-term goal. Even within the innovative products category, Chinese firms seem to focus on opportunities with biotech and traditional medicine primarily, with a lesser emphasis on small molecules, the traditional area of expertise of MNCs and Indian firms.⁹ Incidentally, China's biotech expertise already stands out at the international level with strengths in gene mapping, transgenic technology for animals and plants, gene therapy technology, stem cell research, gene chips and gene research of some major diseases.

However, apart from the fact that China's industrialization of biotechnology still lags behind the Western world, the increased state involvement and lower technological capacity of the Chinese domestic firms have made the Chinese pharmaceutical industry different from countries like India. However, since 2001 China has also made considerable advances in its pharmaceutical-related regulations. It has largely strengthened patent protection but its enforcement is weak. It has also overhauled its Pharmaceutical Management Law, and several other regulations were enacted from 2002-03. It has been observed that although transparency in the approval process is gradually improving, its monitoring needs to be improved further.

With China posing as one of the world's largest market, and expected to grow even more, it is emerging as an attractive market for foreign pharmaceutical investment. However, there are other problem areas too that continue to mar its pharmaceutical industry. Despite international recognition of China's expertise in selected sectors (e.g. biotech), the industrialization of this

expertise is also under-developed.¹⁰ The cooperative relationship between MNCs and Chinese firms are also not comparable to the Indian situation since many factors influence this close collaboration. First and foremost, the language acts as a major barrier. Unlike in India, English is not a popular language in China which unfortunately affects communication and understanding at work. In addition, lower levels of chemistry skills, relatively inferior quality, insecure institutional development for intellectual property protection, long registration approval processes,¹¹ and regulatory favoritism towards local firms act as further deterrents.

Despite the problem areas, things seem to be looking up in the Chinese pharmaceutical industry. The Chinese decision-makers seem keen to work on their problem areas. The recent Pfizer's victory in the Chinese courts (as against the Chennai High Court ruling in the Novartis case) after generic drug makers tried to get its Viagra patent overturned, is indicative of the fact that a stronger legal framework combined with strong skilled scientists and Government incentives are being worked upon to send a positive signal to the international community. The Government seems determined to turn China into a pharma powerhouse. The new regulatory structure that is in place in China also facilitates a court injunction to force the SFDA to withdraw the registration of a rival's license. This ensures that everybody needs to pass through one place in Beijing if they are to legally sell drugs to hospitals and pharmacies in China. This move has led China to surpass US in becoming the world's most litigious country for IP disputes with 13,424 cases filed. This new regulatory system is a big move, as it allows for more creativity in production methods as long as they remain safe.¹²

While China is taking a different approach to deal with patents, India seems to be far behind. It is indeed unfortunate that the Indian law does not allow second use patents and discourages patent protection to salts, esters, ethers, polymorphs and other derivatives of known substances unless it can be shown that they differ significantly in properties with regard to efficacy. With India reluctant to change course, as also evident from the Chennai High Court ruling against Novartis, China's opportunities seem to be gradually increasing in this sector.

4. Future Prospects

On the issue of providing incentives to innovations through a robust patent system, one has to accept that it is difficult to categorise innovations as either 'breakthrough' or 'fundamental' on one hand, or adaptive, cumulative or incremental on the other. Most innovations bring forth some advantages in some form or the other. Innovation implies one step further, specifically crucial in the pharmaceutical industry. Specifically, with respect to the Indian context, considering the stage of development of the Indian Pharmaceutical industry and its capacity to spend on R&D, it is the class of incremental and adaptive innovations that is best suited for the Indian pharmaceutical industry and the same needs to be encouraged by providing adequate and strong IPR protection.

Also, for developing country like India, it is time to understand the importance of patents for a growing pharmaceutical industry and objectively and empirically judge the actual role that patents play in the entire healthcare scenario. Misconceptions based on extrapolated emotive issues are detrimental both for public health and innovations. While superimposing the entire

healthcare access issues on patents make innovations suffer, the same concept results in a flawed approach towards solving the healthcare problems as a policy-maker is prone to overlook the actual drawbacks in the healthcare delivery systems that is the root cause for the grim face of health situation in India.

Talking about improvement in the healthcare scenario, there is an urgent need to come out of the misconceived notions regarding patents alone and look for other mechanisms to strengthen the healthcare system. One of the aspects to be explored in this sector is global public-private partnerships that help distribute the results of experiments in pharmaceuticals worldwide. There are several instances of such global public-private partnerships which have successfully distributed improved derivatives, and bolstered scientific reputation in many developing countries. It was a public-private partnership between Pfizer and the Edna McConnell Clark Foundation that incorporated a multi-faceted public health strategy (SAFE—surgery, antibiotics, face washing and environmental control).¹³ Another example of such partnership is the Novartis Institute for Tropical Diseases (NITD) Singapore Economic Development Board (SEDB) partnership which successfully created increased access to drugs to fight TB and dengue fever by making new drugs available to poor people in developing countries at the lowest possible price.

There is an urgent need for India to get into a similar mode of public-private partnerships in this sector to improve healthcare system in the country. There are a few instances of such public-private partnership in India but we need to have more of these to improve healthcare sector in India and China. An example that comes to the mind is the one between Institute for One World

Health (IOWH), a non-profit pharmaceutical company and Gland Pharma Ltd. of Andhra Pradesh.¹⁴

Patent incentives and public-private partnerships are necessary in the pharmaceutical industry. Without them useful innovative adaptations would not be possible. An invention can often range from manufacturing improvements or modifications to changes in inert or active ingredients. None of these can be considered ‘frivolous’ if the end result satisfies the universally accepted norms of patentability, viz. novelty, non-obviousness and industrial applicability.

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References

- 1 “Asia Pacific to Replace United States and Europe as Pharmaceutical Industry Powerhouse, Finds PricewaterhouseCoopers”, Prime News Wire, <http://www.primenewswire.com/newsroom/news.html?id=124404>
- 2 “Adaptive Innovation, Intellectual Property and the Public Interest: How Patent Extension Leads to More, Better and Safer Medicines”, IFPMA, <http://www.ifpma.org/documents/NR4234/Adapting%20Innovation%20int.pdf>
- 3 Recognition by grant of a patent does not by itself constitute an economic reward. Economic reward flows from products placed in use that embody the patented innovation. This is particularly important in pharmaceutical technologies because patentability is determined long before any product exists from which one could calculate economic value with certainty.
- 4 Bale, Harvey and Azais, Boris “Pharmaceutical Innovation is Evolutionary and Incentive – Driven”, Id. At 788 – 789; Attaran, Amir “Patents do not Strangle Innovation, but Their Quality Must be Improved”, Id at 788. Recognition by grant of a patent is not an economic reward. Economic reward flow only through products placed in use
- 5 See press release and article at: <http://www.path.org/resources/press-release.php?id=3> and <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/02-18-2004/000211586&EDATE=>
- 6 ‘How does the Regulatory Framework Affect Incentives for Research and Development’, Prepared for World Health Organisation’s Commission on Intellectual Property Rights , Innovation and Public Health (CIPIH), November 2005, <http://www.who.int/intellectualproperty/submissions/USPCIPIH.pdf>
- 7 Ibid
- 8 See <http://www.buyusa.gov/china/en/ pharmaceuticals.html>
- 9 Cheri Grace, “The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines”, *DFID Health*

Systems Resource Centre. <http://www.ip-watch.org/weblog/index.php?p=176&res=1280&print=0>.

10 Ibid

11 On July 10, 2007, China's State Food and Drug Administration (SFDA) promulgated the amended Measures on the Administration of Drug Registration (the Amended Measures) which will take effect beginning October 1, 2007. For details see China Reforms Drug Administration, July 2007, http://www.wilmerhale.com/files/Publication/34e4cc44-5ae0-4489-b593-bede2ae1ae/Presentation/PublicationAttachment/c1f42276-2337-475d-a06b-bf7f5134e6f3/ChinaBriefing_July2007.pdf

12 'Drug Makers Challenge India', Business Week, September

24, 2007.

13 'How does the Regulatory Framework Affect Incentives for Research and Development', Prepared for World Health Organisation's Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), November 2005, http://www.who.int/intellectualproperty/submissions/USPCIP_IH.pdf

14 Gland Pharma Limited is an Indian Company with which IOWH worked in preparing the product dossier for 'Paromomycin Injection', and an entity that holds the recently-granted product approval for 'Paromomycin Injection' in India. Gates Foundation had funded the project.
