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The Structural Changes in the Global Pharmaceutical Marketplace and Their Possible Implications for Intellectual Property

UNCTAD-ICTSD Project on IPRs and Sustainable Development

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Introduction

A number of changes have taken place in the global pharmaceutical marketplace over the last decade that are putting pressure on the large research and development (R&D)-based pharmaceutical transnational corporations (TNCs) to change the way they do business. This policy brief examines how some of these changes interface with intellectual property (IP) policies, and suggests what that may mean for IP issues and pharmaceuticals in the years ahead.

1. The Traditional Pharmaceutical TNC Business Model

Historically, the business model for the R&D-based pharmaceutical TNCs with headquarters in developed countries has been to invest in R&D in order to generate a flow of 'blockbuster' new chemical entities (NCEs) which can be sold at profitable prices around the world. The long gestation period for NCEs, from discovery to regulatory approval, has been used to justify high prices while yielding enormous net profits. It has been well documented that this R&D investment model of the large R&D-based pharmaceutical companies has started to fall apart, with a consequent reduction in the number of NCEs that are produced.[1] Surprisingly, total global R&D expenditures have only marginally declined,[2] in spite of all the comments on downsizing by these companies.[3] However, there has been a rebalancing within the R&D figures through outsourcing to Asia.[4]

The decline in NCE productivity on the part of these companies has in recent times been reflected in the reduced number of successful new drug applications approved by the US Food and Drug Administration (FDA). In 2008, the FDA's approval figure was 24, in 2009 it stayed at 25 and in 2010 it fell to 21. Indeed, the 21 approvals in 2010 included one new drug from a US generic company, Watson.[5] Consequently, as 'blockbuster' patents have expired or are soon expiring, existing R&D has been unable to fill the resulting product flow gap. In parallel, the generic industry has become more effective at challenging patents around the world. This has contributed to the so-called 'patent cliff', which is a term used to show the weakness in the R&D-based TNCs' future sales and profits given the impending expiration of patents in their key markets. Many companies

1 See, for example, Alazraki (2011).

2 According to Hirschler and Kelland (2010), the large R&D-based pharmaceutical TNCs spent more than USD 65 billion in 2009 on R&D.

3 See, for example, http://www.nationmultimedia.com/home/2011/03/25/business/Economic-worries-cast-shadows-over-strategy-30151853.html

4 *Ibid.* China and India are favorite destinations to outsource R&D.

5 See FierceBiotech (2011).

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are facing major patent erosion, with soon-to-expire patents comprising up to 70% of some companies' total sales. Possibly the major exception has been Roche, which seems to have managed its patent pipeline well as a result of its Genentech acquisition, although it too now faces major patent expiries related to some of its larger molecules. The number of new generic companies from India and China is constantly rising, with new names appearing every month in international markets, leading to a highly competitive environment.

Other pressures have also come to bear on the large R&D-based TNCs, including regulatory and antitrust issues. Regulatory hurdles have risen, with more questions being asked by drug regulatory authorities on clinical data submitted with respect to potential 'blockbusters'. The hurdles for access to the European marketplace have also risen. Government authorities have increased their scrutiny of the business practices of the large R&D-based pharmaceutical TNCs. The EU antitrust authorities organised four separate but related antitrust raids on large pharmaceutical companies in 2008/09.[6] In the US, the antitrust pendulum has swung both for and against deals between R&D-based TNCs and generic firms, but today it is probably resisting such deals in spite of the legal uncertainty of patent litigation in the US.[7] Altogether, this has put great pressure on the newly patented product pipeline.

The large R&D-based TNCs may have reached a ceiling on the profitability of developed country markets; there is now a stronger focus on developing country markets. Whilst Indian, Chinese and Brazilian generics are well known, a number of other countries are rapidly developing a robust pharmaceutical sector. IMS Health, a leading information provider on health-related topics, has now generated a new name for this pharma sector called 'pharmerging'.[8] The seven emerging markets of Brazil, China, India, Mexico, Russia, South Korea and Turkey are estimated to have contributed an unprecedented 51% of global pharmaceutical growth in 2009. On the other hand, the conventional mature markets of North America, Western Europe and Japan accounted for just 16% of global growth. This is in sharp contrast to 2001, when these so-called 'pharmerging' markets accounted for only 7% of global growth, compared to a 79% share for the mature markets.[9]

In fact, IMS Health has recently redefined its 'pharmerging' sector as 17 markets divided into 3 tiers. The first tier is comprised of China on its own; the second by India, Russia and Brazil; and the third tier represents 13 other markets, mainly from Southeast Asia.[10]

2. The Response of R&D-based Pharmaceutical Companies

The double-digit growth of the emerging marketplace and the generic sector has attracted the attention of the leadership of the large TNCs. This is slowly percolating down through the middle ranks of these companies and is generating interesting management choices and strategic realignments. For example, Pfizer now calls its generics division the "Established Products Unit", probably because it has to deal with five decades of anti-generic public relations. This active interest can also be seen in the recent Ranbaxy and Piramal acquisitions in India by, respectively, Daichi Sankyo (Japan) and Abbott Laboratories (US). From the perspective of the R&D-based companies, such acquisitions make sense as it gives them a stronger footprint in the developing world and access to the double-digit growth in the generic marketplace. They also make sense for the generic manufacturers, as it hands them an owner with 'deep pockets' in case they lose patent litigation in the US on the launch of an at-risk molecule. In the US, there is always a risk of large damages that could potentially bankrupt a medium-sized generic company.

Alternatively, some large R&D-based TNCs are buying smaller companies with potential new drug pipelines – such as Roche with Genentech, or Sanofi Aventis with Genzyme. In addition, the larger companies are focusing on improving their R&D efficiency. According to the Tufts Center for the Study of Drug Development, actions that will improve R&D productivity include: "greater reliance on translational science to help identify the right disease targets for new molecules; […] greater use of partnering with external service providers to share risks, reduce cycle times, lower costs and improve resource management; […] and greater use of portfolio management techniques."[11] However, the most recent estimate of the cost of developing a new drug is approximately USD 1.3 billion, which again raises the viability of the old R&D business model.

6 For the 2008 raids, see Newman (2008). For the 2009 raids, see Wachman (2009).

7 An interesting case is currently pending before the US Supreme Court: does the patent justify/authorize a patent holder to pay a generic competitor for not entering the market before a certain date ("reverse payment settlements")? See *Louisiana Wholesale Drug Co. v. Bayer AG* (On Petition for a Writ of Certiorari 2011). There is currently a bill tabled in the US Senate to prohibit such deals (January 2011).

8 Campbell and Chui (2010).

9 Hill and Chui (2009).

10 See Campbell and Chui (2010).

11 Taylor (2011b).

At the same time, some corporate headquarters are trying to relocate parts of their manufacturing and R&D operations to Asia, whilst retaining in-house the added value roles like regulatory compliance, clinical trial design, price negotiators and sales/marketing teams.[12] This outsourcing to Asia is leading to an active Contract Research and Manufacturing (CRAMS) business segment, which in turn has led to restructuring in most of the top 20 pharmaceutical companies in recent years, and the consequent loss of jobs in the R&D-based industry continuing through 2010. In September 2010 alone, the US industry lost 6,069 jobs,[13] and by November 2010, worldwide 50,000 jobs had been cut from the industry headcount.[14] In January 2011, nine French unions called on Sanofi workers to strike in opposition to workforce reductions.[15]

Some companies have gone for big mergers and acquisitions to conceal their problems. Others have looked to change their strategic focus towards the emerging world, generics and vaccines. While many of these larger firms remain profitable, it is clearly not 'business as usual'. The examples cited above give a sense of the rapid changes underway in the pharmaceutical industry.

The world's biggest multinationals are becoming increasingly comfortable with undertaking R&D in the emerging world. Companies in the Fortune 500 list have 98 R&D facilities in China and 63 in India.[16] More than 200 international companies have R&D innovation centres in India, with 40% of them located around Bangalore. Each dollar spent per ounce of innovation there is said to make a dramatic difference when different R&D facilities are compared. The CRAMS market size was expected to reach USD 76 billion in 2010. What is surprising is that both India and China represent only a fraction of this marketplace (for example, India itself was forecast to have only a 4% share in 2010).[17] The potential for expanding this share is huge and explains why the investment community sees this sector as a vibrant one.

In the generic space, Indian Drug Master Files (DMFs) continue to represent the largest share of all generic filings in the US, compared to only 15% for the US and 9% for those sourced from China.[18] In addition, Indian Abbreviated New Drug Applications (ANDAs)[19] in the US have now overtaken those originating in the US itself.[20] Chinese labour costs in the industry continue to be lower than in India – although those in Taiwan (Province of China) are under pressure from rising salaries. Chinese energy costs are very competitive and will likely attract investment in fermentation-type facilities.

This policy brief suggests that these structural changes will have an impact on the future of IP policies, including on issues such as compulsory licences (see Section 4 below).

3. What Will Be the Impact of Large R&D-Based Pharmaceutical Companies Buying Generic Companies?

The sale of Ranbaxy (a leading Indian generic manufacturer) to Daichi Sankyo (a leading Japanese R&D-based manufacturer) in 2008 signified the beginning of a number of dramatic changes in India. A merger bringing together the organizational capability of the Japanese company and the intrinsic entrepreneurship of Indian business is thought to be a winning combination. Having gained a new owner with significant financial resources, Ranbaxy should now be able to move to the next level. Those difficult launch decisions should now be easier to make at the Board level when it comes to launching a possible "at risk" highly-profitable generic in the lucrative US marketplace. With hindsight, many Indian promoters can now see the commonsense and opportunity in taking such a strategic move. For example, shortly after the November 2010 expiration of the underlying US patent, Ranbaxy and its parent, Daiichi Sankyo, launched a generic version of Daiichi Sankyo's Japanese competitor Eisai's 'blockbuster' drug Aricept, which is designed to treat Alzheimer's disease, for which Ranbaxy was able to obtain exclusive marketing rights up to the end of May 2011.[21]

12 Personal conversations with CEOs of the large R&D-based pharmaceutical TNCs.

13 FiercePharma (2010c).

14 FiercePharma (2010d).

15 FiercePharma (2011).

16 The Economist (2010).

17 Cygnus (2008).

18 See http://apothecurry.wordpress.com/2010/03/13/dmf-daddy-india-tops-usfda-list-of-drug-master-files/ quoting 2009 data from Pharmexil India.

19 An Abbreviated New Drug Application is an application for marketing approval of a generic equivalent of an existing licensed medication or approved drug in the US.

20 Generics Bulletin (2009).

21 See Nihon Keizai Shimbun (2010), p. 11.

As a consequence of this deal, many promoter families who have heretofore controlled the large generic companies in India are reconsidering their priorities. What is the best way of distributing the family wealth? Younger members of the promoter families are also reviewing their career prospects, as not everybody wants to join the pharmaceutical industry and its complex and technical working environment. What was in the past a taboo that could never be voiced is now a part of the strategic planning for such owner families. In the long run, this should lead to better-balanced decision making within these conglomerates since all the real options for refocusing the family wealth are now fair game for debate. With the positive economic dynamics in India, the availability of a significant cash flow from divesting parts of the family business, including in pharmaceuticals, can lead to a multitude of investment opportunities.

As expected, the new post-2005 IP regime in India resulting from its World Trade Organization (WTO) membership has slowly reduced the generic new product pipeline available to Indian companies on the domestic market. In spite of this, the local Indian market grew at 21.3% in 2010, with 47% of all sales being exported.[22] However, Indian chief executive officers (CEOs) face a new domestic era. There are currently a large number of strategic discussions taking place between CEOs of the large R&D-based TNCs and Indian CEOs, either directly or through lawyers and consultants or via Indian merger and acquisition brokers. As previously mentioned, the limitations of the old R&D model have led many R&D-based companies to reconsider their strategy and widen their vision to the emerging world. So far Pfizer has formed supply arrangements with Cipla, Aurobindo, Claris and Strides Arcolab. GlaxoSmithKline is linking up with Aspen and Dr Reddy's and acquiring assets in Egypt and South Korea, respectively. Sanofi Aventis has acquired 80% of Shanta Biotech and acquired generic assets in Mexico, Brazil, Turkey, Japan and the Czech Republic. Perrigo has bought Vedants, Lonza has acquired Simbiosys Biowares, Lanxess (Germany) has absorbed Gwalior, and Mylan and Pfizer have tied up with Biocon for biosimilars. Abbott has become the leading company in India and the emerging world with the acquisition of India's Piramal. Some of these are very unusual partnerships, given the historical track record of some of the acquiring companies.

Most developing world generic markets are called 'branded' generic markets as the medicines carry a local brand name instead of the scientific generic name. In these markets, the doctors know and like the brand names and are not familiar with the international non-proprietary scientific name. In addition, the doctors prefer to specify what is given to their patients rather than letting the local pharmacy substitute and change what they have prescribed. These branded generic markets are growing strongly around the world and, more importantly, continue to be very profitable.[23] This profit element is part of the reason why the large R&D-based TNCs are placing emphasis on the emerging markets.

4. What Will Be the Impact of Large R&D-Based Pharmaceutical Companies Selling in Developing Countries through Their Generic Company Acquisitions?

The large R&D-based TNCs have increasingly become aware of the fact that 88% of the world's pharmaceuticals are shared between only 18% of the world's population, according to 2005 data.[24] More significantly, this means that 82% of the world's population shares only 12% of the world's pharmaceuticals.[25] Herein lies a business opportunity. The Chinese domestic vaccine market alone is predicted to be worth USD 1 billion in 2012, growing at 25% per annum with over 40 domestic companies.[26] This opportunity is strategically reflected in many ways. Some companies have a generic strategy, some have a developing world strategy, some have an outsourcing strategy and some have all three. In addition, some have a parallel strategy of expanding in vaccines and other biologics, consumer/over-the-counter medicines, animal health, medical devices and/or healthcare venture capital investments.

The large R&D-based TNCs are expanding strongly in Asia and elsewhere in the developing world, and now present an emerging world face alongside their presence in mature developed country markets. With the current generation of global CEOs with open minds, new global developments on IP may be on the horizon. The large R&D-based TNCs are increasingly realizing that in order to be profitable in developing countries, they need to adapt their licensing and pricing policies. Not too far into the future, it could be possible for new chemical entities

22 Corporate Catalyst India (2011).

23 See, for example, Saran *et al.* (2010).

24 IMS, Earth Trend Data Tables.

25 ibid.

26 FierceVaccines (2010).

that are protected by patents to be sold or licensed at different rates: one rate for the mature, developed country markets, one for the Least Developed Countries (LDCs) and one for the emerging world markets. The first signs are already there, with a dual pricing policy that some companies are now following in Africa and Southeast Asia. In May 2010, GSK introduced an allergy treatment in Mexico with a 50% price discount in order to expand local usage and sales volumes. At the time the GSK Emerging Markets Chief said "[t]he old mindset at GSK would have been: come in and launch it and have access to only the top 5% or 10% people who can afford it."[27] In another turn of events that would have been unthinkable a few years ago, and reflects the impact that the changes in the industry are having on IP policies worldwide, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), a worldwide association based in Geneva that represents the global R&D-based pharmaceutical TNCs, announced on 10 February 2011 that it would support a further extension of the deadline for the LDCs to comply with the provisions of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[28]

At least in developing country markets, a future less-restrictive IP regime could, in turn, lead to less of an incentive to 'evergreen'[29] pharmaceutical patents. While in some corners of the industry there is still resistance to changing a business model based on exclusive rights that supported the industry in its heyday, more and more executives of pharmaceutical companies are acknowledging the limits to the 'blockbuster' business model. In a July 2010 interview, the CEO of Sanofi Aventis said "[a]bove all what I am looking for is businesses that are not dependent on patents"[30] – a remarkable but understandable statement. Indeed, a recent survey by the strategic consulting firm Roland Berger showed that 65% of the top executives of pharmaceutical firms considered the pharmaceutical industry to be facing a strategic crisis and 67% saw diversification away from a patent-based business model as a potential solution.[31]

This is particularly so with respect to many developing countries, as the R&D-based pharmaceutical TNCs will be forced to lower their prices to reach consumers there (see Section 5 below). For example, India has 2 million cancer patients and there are 700,000 newly diagnosed patients each year. It is estimated that USD 1.2 billion of medicines will be needed to treat these patients. However, the current sales of oncology drugs in India are only USD 30 million. This big gap indicates the inaccessibility of these oncology medicines. Solutions being considered by the Indian government include compulsory licencing and limitations to the foreign ownership of Indian pharmaceutical companies.[32]

It was these thoughts that led to a Cipla advertisement in the Washington Post a few months ago, which asked "what is the use of developing life-saving medicines if you can't make them affordable to the patient?"[33] Indeed, India has historically been the source of 64% of the medicines that flow into the developing world with the support of the World Health Organization (WHO) pre-qualification system.[34] Consequently, how India's pharmaceutical industry develops will have a large impact on the shape of access to medicines throughout the developing world.

It is, however, yet to be seen how Indian firms will react to the dual role of being the 'pharmacy of the developing world' and the newly-found partners of R&D-based pharmaceutical TNCs. For example, India's sales to Japan are expected to increase following their signing of a Free Trade Agreement (FTA) in February 2011, which will abolish duties on more than 90% of goods traded within 10 years. PharmaTimes (Taylor, 2011a) reports, for example, that Japan is the second largest pharmaceutical market after the US, and while it currently represents only a small market for Indian pharmaceutical firms, the Japanese government is encouraging the use of generics. It is thus forecast that the Japanese market should represent 5% of all India drug exports within the next 3-4 years.[35] It is telling that the FTA actually devotes an article to ensuring the ease of marketing authorization for generic medicines from the other (see Article 54 of the India-Japan FTA, 2011).

27 FiercePharma (2010a).

28 See IFPMA (2011) press release. It should be noted that the press release did not, however, make any specific reference to the waiver on pharmaceutical product patents that is in effect until 2016.

29 'Evergreening' is a term used to describe when, in the absence of any apparent additional therapeutic benefits, patent-holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term. See WHO (2006).

30 FiercePharma (2010b).

31 Jack (2010).

32 Department of Industrial Policy & Promotion of India (2010).

33 The advertisement was published in The Washington Post on 1 December 2010.

34 See WHO website at: http://apps.who.int/prequal/.

35 Taylor (2011a).

5. What Will Happen if Large R&D-Based Pharmaceutical Companies Do Not Change?

Despite the adaptive measures taken by the large R&D-based pharmaceutical TNCs, there are also indications that many of these companies are also trying to maintain as much of their old business model as possible. Novartis, for example, is continuing legal actions to challenge the denial by Indian authorities of a patent over a leukaemia drug that had not been granted because it was considered a minor variation of an existing drug. The company, for its part, claims that not granting a patent in this case is a violation of India's obligations under the TRIPS Agreement.

If these large companies do not change, however, their current failing R&D model will take them to a continuing trend of declining profits and downsizing of their work force. If they try to keep the prices of new drugs highly inflated, then important drugs will be priced beyond the purchasing power of developing country consumers. Access to these important medicines will then become a public health crisis and developing country governments will more likely issue compulsory licences more frequently. What happened in Thailand between 2006 and 2008, where no less than seven compulsory licenses were issued over a two-year period, could therefore be seen as a precursor of things to come if the R&D-based pharmaceutical TNCs do not adjust to new realities.

With increased scrutiny by drug regulatory authorities and decreased investment in basic R&D, there will probably be fewer and fewer new drugs approved in future years – perhaps less than 20, if US FDA approval is taken as a benchmark. This would put further pressure on the firms' bottom line and consolidation would continue amongst these failing companies as their Boards come under pressure to find a way forward. Simply put, those companies that do not adapt to the new climate are unlikely to survive.

6. Conclusions

It is all too clear that the old R&D model is in crisis. A structural change is taking place in the global international pharmaceutical market with future implications in the area of IP. The possible impacts of these changes are summarized below:

- An emerging global strategy and presence is a high priority for most R&D-based pharmaceutical TNCs; this is borne out by the numerous deals and acquisitions of generic drug manufacturers that have taken place in the last 5 to 10 years as a result of the so-called 'patent cliff' and other competitive pressures.

- India promoter families who have heretofore owned the large domestic generic firms as part of conglomerates are reviewing their wealth profiles and considering divesting their companies.

- It is possible that the younger new generation of CEOs will agree to a differentiated approach to IP issues/protection in developed country and emerging markets in a similar way to the dual pricing policies that have recently been introduced.

- Compulsory licences are likely to become more frequent once life saving medicines are manufactured in India but cannot be sold locally at low, generic prices following the introduction of pharmaceutical product patents in that country.

- If the large R&D-based TNCs do not change, they will probably be acquired by those companies that have changed and already moved into the emerging world with tiered pricing. These companies will have to come to accept an open, flexible approach to access to medicines in the developing world.

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