

## Indian Pharmaceutical Industry - Affordable Access to Healthcare for all

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There has been little news in the Information Technology (IT) sector around the world where, in some manner or form, India is not mentioned and as a result, India is now well known for its IT prowess. Thirty years ago, it was hard for most of us to imagine this.

The story of the Indian pharma sector could well have been like the IT sector if only enough attention was paid to its achievements and the huge impact it has had on healthcare around the world. Unlike other manufacturing or heavy industries in India, the pharma sector is innovative, widely acknowledged as making a global impact in the treatment of diseases like HIV AIDS<sup>2</sup> and also able to support the healthcare needs of the world<sup>3</sup>.

The fact that Indian factories are licensed to produce 3,685 drugs compared with 3,815 made within the UK suggests that Indian factories meet global quality standards and are able to produce complex drugs.<sup>4</sup> While news of regulators visiting Indian manufacturing facilities and finding fault with processes is widely reported, very little is said about how routine this is. Gerald Heddell, director of inspections, enforcement and standards at the MHRA, stressed that the number of problems identified by regulators in India was in proportion to the volume of medicines they produced. "When we look back over 110 inspections we conducted over the last two years in India, we had significant concerns with 9 or 10 companies," he said. "That does not represent a statistically higher proportion than in other parts of the world. India stands out because it is just such a big supplier."<sup>5</sup> The Indian pharma industry produces about 20%<sup>6</sup> of the global generic drugs with the US accounting for nearly 28 per cent of Indian pharmaceutical exports<sup>7</sup>, followed by the European Union at 18 per cent and Africa at over 17 per cent.<sup>8</sup> This should be a clear acknowledgement of the global leadership that Indian pharma industry has achieved which would have been impossible without following global quality standards.

Another popular criticism of Indian pharma has been that there is insufficient investment in innovation and R&D. Despite over 500 new drugs being discovered by Indian pharma companies during 1985 – 2005, there seems a perception that India thrives on copying foreign products<sup>9</sup>. A

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<sup>1</sup> With research assistance from Prajna Mohapatra and Anushree Kunhambu.

<sup>2</sup> At US\$ 10 billion, India's pharmaceutical industry ranks 4th in the world in volume of production and 13th in value: Grace (2005). See Department for International Development, Health Resource Centre, London, "A Briefing Paper for DFID: Update on China and India and Access to Medicines." [www.dfidhealthrc.org/what\\_new/Final\\_percent20India\\_percent20China\\_percent20Report.pdf](http://www.dfidhealthrc.org/what_new/Final_percent20India_percent20China_percent20Report.pdf), as cited in Mark A. Dutz (ed), UNLEASHING INDIA'S INNOVATION, The World Bank, at 112.

<sup>3</sup> Trends in India's Trade in Pharmaceutical Sector: Some insights, Centre for WTO WTO Studies, August, 2012

<sup>4</sup> ft.com > Companies > Health > Pharmaceuticals, January 5, 2014 2:37 pm, Global reach of India drug producers grows -Andrew Jack in London.

<sup>5</sup> ibid

<sup>6</sup> <http://business.mapsofindia.com/india-gdp/industries/pharmaceutical.html>

<sup>7</sup> India is the second largest manufacturer of over the counter and prescription drugs for the US.

<sup>8</sup> <http://www.ibef.org/exports/pharmaceutical-exports-from-india.aspx>

<sup>9</sup> R.D. Lele, "The Prescription that Changed Practice," UNIQUE BENEFITS OF THE PATENTS ACT, 1970, IDMA (Indian Drug manufacturers' Association) Bulletin, 30 October 2005, at 2

recent study by Evaluate<sup>10</sup>, a leading independent specialist pharma consultancy, reports that there is little difference in the investment by “innovators” and “generics” and it is just a myth that “innovators” invest heavily in research while “generics” don’t.

Despite well publicised claims of the Western world, there seems to be a marked decrease in R&D investments<sup>11</sup> and this trend is expected to continue.<sup>12</sup> When one realises that almost 50% of the European pharma patents are either lying dormant or filed in order to block competitors<sup>13</sup> one wonders how innovation is being defined and encouraged. Is it innovation if the effect is stifling further innovation and competition and creating barriers for improvements?

Indian pharma industry has clearly demonstrated that it has the potential to be a part of the solution for universal access to healthcare. India’s strength is innovating to improve global access to medicines as opposed to developing more and more “me too” drugs which have been traditionally defined by the West as innovation. There is now a growing acknowledgment that the existing IPR regime that is being touted by the West doesn’t foster innovation.

As such, the current patent system is itself reeling from the ill effects of patent assertion entities (trolls) that do not produce anything of value but merely hold patents with a view to threatening businesses with infringement actions to obtain licensing revenue. Patents have other flaws that relate to monopoly power, both because it harms consumers who have to pay high prices and because it can hinder improvements and subsequent innovations.<sup>14</sup> Static distortions, too little incentive for original research, and wasteful duplication of research are some of the most serious problems of the patent system.<sup>15</sup> In addition to TRIPs - compliant patent regimes which ostensibly promote innovation and discourage copying, the next generation of barriers to competition seems to be set up as global standards. Just as IPR was addressed by the WTO in TRIPs, the more recent barriers are likely to be in the form of harmonised regulations. Patent linkage<sup>16</sup> (in Canada and the US for example) denies access to markets on a mere allegation of patent infringement. Despite the US Supreme Court<sup>17</sup> indicating that patent linkage needs to be reconsidered and access to medicines should not be denied on allegation of patent infringement and recent attempts by Italy to introduce a system of patent linkage resulted in a notice from the European Commission asking for the

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<sup>10</sup> Evaluate Pharma, “World Preview 2013 - Outlook to 2018 (Returning to Growth)”, 2013

<sup>11</sup> Evaluate Pharma, “World Preview 2014 - Outlook to 2020 (Returning to Growth)”, 2014 Data 2006-2014.

<sup>12</sup> Evaluate Pharma, “World Preview 2014 - Outlook to 2020 (Returning to Growth)”, 2014 Data up to 2020

<sup>13</sup> The Value Of Patents For Today’s Economy And Society, “Study on evaluating the knowledge economy - What are patents actually worth”, 9 May 2005,

[http://ec.europa.eu/internal\\_market/indprop/docs/patent/studies/patentstudy-report\\_en.pdf](http://ec.europa.eu/internal_market/indprop/docs/patent/studies/patentstudy-report_en.pdf)

<sup>14</sup> Shavell and van Ypersele, 2001, p. 526, Rewards versus intellectual property rights. *Journal of Law and Economics* 44 (2), 525–547 as cited in Earl L. Grinols and Hwan C. Lin, “Patent Replacement And Welfare Gains,” 35 *JOURNAL OF ECONOMIC DYNAMICS AND CONTROL* 1586-1604, 1586 (2011)

<sup>15</sup> Kremer (1998), Patent buyouts: a mechanism for encouraging innovation. *Quarterly Journal of Economics* 113 (4), 1137–1167 as cited in Earl L. Grinols and Hwan C. Lin, “Patent Replacement And Welfare Gains,” 35 *JOURNAL OF ECONOMIC DYNAMICS AND CONTROL* 1586-1604, 1586 (2011)

<sup>16</sup> Monopolies for patent holders are extended through the drug regulatory authorities rather than the patent system.

<sup>17</sup> *Teva v. Mylan*, US Supreme Court (2014), Andrew Zajac, “Teva Loses Suit Against FDA Over Generic of Copaxone”, 15 May 2014 <http://www.bloomberg.com/news/2014-05-14/teva-loses-suit-against-fda-over-generic-of-copaxone.html>

removal of these provisions from Italian law,<sup>18</sup> patent linkage is a real barrier to competition in healthcare which is beset with unaffordable drugs.

Data exclusivity extends the term of monopoly enjoyed by patent holders and keeps out competition and innovation without any benefits to society. This concept does not exist in sectors other than pharma and there seems to be no real rationale for pharma to get special treatment. In fact, data exclusivity raises several ethical and moral issues.

Countries have always been allowed to customise their IP policy and regulation based on their unique local conditions. Some countries are more technologically proficient than others, and this distinction may warrant separate norms in areas of technology that they are strong in.<sup>19</sup> Even where harmonisation has been accepted as a concept, like the EU for example, it has been implemented in a manner that is sympathetic to the local conditions of individual countries. India's strength and expertise lies in developing drugs which are accessible for patients across the globe. India's stand on IPR regime acknowledges that diverse countries cannot be forced to one uniform regulatory system. This principled stand was recently demonstrated during the Bali round of talks on the Trade Facilitation Agreement.<sup>20</sup>

In the background of the Trans Pacific and Trans Atlantic Partnerships being negotiated, India has the opportunity to demonstrate leadership in the global market place by pioneering the opposition to using harmonisation as a proxy for barriers to competition. While the US and its allies may officially oppose India's view of the IPR regime they have realised that the key to their sustainable development is the ability of government to ensure that healthcare is accessible to everyone, not just the rich. Cost of healthcare has increased significantly causing an alarming number of patients to go off treatment, risk importing counterfeits<sup>21</sup> or in many cases, declare bankruptcy<sup>22</sup>.

The issue of access to healthcare in the developing world has, despite some efforts by the UN, The Global Fund, PEPFAR and other aid institutions, not had the impact that it should have. There is a realisation, albeit unarticulated, that Indian Pharma companies have the potential to be, like Indian technology companies averted the y2K crisis, a key element of the solution to world's healthcare crisis. Now is a great opportunity for India to demonstrate leadership in IPR regimes as more and more countries like South Africa and Brazil are following India's example.

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<sup>18</sup> Commission calls on Italy to comply with EU rules on marketing authorisation of generic drugs. Press release. European Commission, 2012 ([http://europa.eu/rapid/press-release\\_IP-12-48\\_en.htm?locale=en](http://europa.eu/rapid/press-release_IP-12-48_en.htm?locale=en), accessed 29 January 2012). The European Union does not accept the system of patent linkage.

<sup>19</sup> Shamnad Basheer & Annalisa Primi "The WIPO Development Agenda: Factoring in the "Technologically Proficient" Developing Countries," <http://ssrn.com/abstract=1289288>, at 110

<sup>20</sup> "WTO fails to reach an agreement on \$1 trillion customs deal as India remains firm on its demand", Reuters, 1 August 2014, [http://articles.economictimes.indiatimes.com/2014-08-01/news/52327495\\_1\\_trade-facilitation-agreement-wto-michael-punke-world-trade-organization](http://articles.economictimes.indiatimes.com/2014-08-01/news/52327495_1_trade-facilitation-agreement-wto-michael-punke-world-trade-organization)

<sup>21</sup> <http://www.nytimes.com/2013/10/23/health/as-drug-costs-rise-bending-the-law-is-one-remedy.html>

<sup>22</sup> National Health Interview Survey report (2014).