

**HEALTHCARE AND PATENTS IN INDIA:**  
**PEOPLE'S RIGHT TO AFFORDABLE MEDICINE**  
**VERSUS**  
**A DRUG MAKER'S RIGHT TO INNOVATION**

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It's often quoted that health is wealth. Mathematically this is proven in today's context unequivocally, more so like an arithmetic equation where A equals B, health is cent percent equal to wealth. Simply put, if there is wealth, health is automatically guaranteed. And all it takes is a simple replacement of the first letters. Marred by expensive medicines, disparity with government and the pharmaceutical companies, increased tax slabs, more import duty, threat to pull out of business and growing escalation of unrealistic demands while not bridging the supply chain of essential and affordable drugs is making our mortality rate a number that cannot be ignored or misrepresented for the sake of public relations.

India has made constant efforts to protect the patent regulation and a classic case in point in the *Novartis v. Union of India & Others*<sup>1</sup> by a two judge-bench of the Supreme Court of India on the issue of evergreening of pharmaceutical patents. While this paper examines this case in detail, it's imperative to note that this landmark decision has caused a major eye-opener to people across the nation, and more so to all the international companies in the healthcare industry to take note of Indian laws and its relevant applications. A precedent forms the classic example of our medical jurisprudence in this case and is an overturning moment in the history of patent regulations. While it becomes essential that for all seekers of information, a brief understanding of the Indian Patents Act, 1970<sup>2</sup> is crucial to assimilate and understand the words – invention, innovation and public interest. Under section 3 clause (a) and (b) of this Act read here as under the heading 'Inventions Not Patentable' being: the following are not inventions within the meaning of this Act,—(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws; (b) an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment. In realistic terms, it draws a line between research and responsibility as against profit and business development. This is the real challenge that companies and lawmakers have tried to create a tussle with the higher threshold of inventiveness.

A 2012 WHO study ranks India third — behind Myanmar and Bangladesh — among countries that fail to provide health cover to people. A 2011 study reported in The Lancet on 'Healthcare and equity' confirms this: every year, at least 39 million people here fall into poverty due to private out-of-pocket health expenditure. A vast majority of Indians do not have access to healthcare or essential drugs. By the government's own admission, medicines constitute 74 per cent of out of pocket expenditure on health. Waking up to the crisis, the Centre recently announced measures to bring about alterations to the system — free drugs starting October at state hospitals and price control for patented drugs. Both long-pending proposals require a four-fold increase in public spending on medicines, from 0.1 to 0.5 per cent of the Gross Domestic

<sup>1</sup> 1 (Civil Appeal No. 2706-2716 of 2013)

<sup>2</sup> e-version on www.ipindia.nic.in containing all amendments in the Patents Act, 1970 and the Patent Rules, 2003

Product (GDP), as recommended by the High Level Expert Group (HLEG) on Universal Health Coverage. Today, when patients across the country purchase medicines, a substantial portion of the cost includes price margins for drug manufacturers, and numerous middlemen, including wholesalers, retailers, stockists and pharmacists<sup>3</sup> that being the case, the road to an affordable tomorrow seems to be a distant dream of sorts for the needy admitted in a state hospital.

National Sample Survey data<sup>4</sup> indicate that free drugs supplied during hospitalisation declined from 31.20 per cent in 1986-87 to 8.99 per cent in 2004. The high cost of medicines from the mid-1990s resulted in out-patients not receiving drugs in one-fourth of all cases by 2004, up from 12.11 per cent in the base year. It is important therefore that the central government acts urgently on the expert group's suggestion to move to a system where essential medicines are available free of cost to everyone. It is estimated that this can be achieved through a four-fold increase in public spending on drugs. Such a programme should rely mainly on quality generic drugs produced by a revitalised public sector and compulsory licensing under the TRIPS Agreement of WTO. It is worth pointing out that in the absence of social health insurance, several patented medicines are beyond the reach of the majority of Indians. More households will come under calamitous pressure, if enhanced patent provisions forming part of bilateral agreements (such as those with the European Union and Japan) lead to higher drug prices. Rising India with its hundreds of millions of desperately poor people can ill afford to go down that path. Creating a system of standard treatment, pooled procurement, and decentralised distribution by the government, which will lead to massive savings, brooks no delay.

These solutions are rather arbitrary in a setup that is fuelled by corruption right from the bottom of the pyramid to the top, owing to blind agreements being signed, while rising speculations are confounded with 'adjustments' in the form of helping out in 'kind'. This process of adaptation in our country has been seen and recorded for decades and leads to lesser transparency, while maintaining ambiguous controls on an industry that is open to more criticism and the effect of phase 4 testing<sup>5</sup> on humans. To examine the root causes of the patent verification and regulation, it's important to read this article **Big Pharma At War With Copycats**<sup>6</sup> - Why don't you sell it for Rs 5? Rs 1.2 lakh per month is too high." On September 11, Supreme Court Justices Aftab Alam and Ranjana Desai posed that question to Swiss drugmaker Novartis AG, fighting to patent its expensive cancer drug Glivec. The question wasn't just judicial speculation or indeed wit. It brought out the fundamental issue at the heart of a new war raging in the pharma world. The case, Novartis vs Union of India, is ostensibly about pharma patents: The drugmaker has been locked in a legal battle with India for the last six years, with its patent application for Glivec being rejected repeatedly on the ground that it was not a new drug. But the case is tapping into a much broader conversation about people's right to affordable medicine versus a drugmaker's right to innovation. It also raises questions about India's seven-year-old patent laws, especially Section 3(d), which prohibits patenting new forms of known drugs unless there is significant increase in efficacy, the interpretation of which is now being contested.

The case has a classic David vs Goliath plotline: Multi-billion dollar global pharma vs domestic firms that sell copycat generic drugs. A patent allows exclusive marketing rights to a firm and stops local competitors from selling cheaper copies. But India's patent laws protect access to

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<sup>3</sup> Patients Lose Out To Patents & Profits, The Hindu, September 2, 2012

<sup>4</sup> Medicines For All, The Hindu, Editorial, December 29, 2011

<sup>5</sup> Phases of Clinical Research, www.ncbi.nlm.nih.gov/pubmed/19616703

<sup>6</sup> India Today, Health, October 8, 2012

medicine for all, making it difficult for big pharma with high-priced medicines to break into the market. A series of recent lawsuits prove the point: In March, India asked Germany's Bayer to license its patented cancer drug Nexavar to Indian firm Natco. In May, Cipla got a favourable court ruling in a patent infringement case by Swiss firm Roche over cancer drug Erlotinib. The Glivec verdict, expected in about two months, will seal the fate or secure the future of India's new patent regime. If Novartis wins, big pharma will get millions of new customers. "But the domestic industry will lose early mover advantage and face a slowdown in future," says D.G. Shah, secretary-general of the Indian Pharmaceutical Alliance. "Many patients will suffer or die for want of affordable medicines that India supplies to 80 per cent of the developing world." Affordability<sup>7</sup> is a big issue. Consider Glivec. For the last 20 years, since Novartis launched it, Glivec has been hailed as the gold standard for chronic myeloid leukaemia. Though it does not cure, it raises survival rates from three to 10 years. But Novartis sells Glivec at Rs 120,000 for 30 tablets a month in India. Generic versions cost Rs 8,000 to Rs12,000. India's advantage is that it produces 60,000 affordable drugs in 60 key areas, explains Lanka Srinivas, a Hyderabad-based pharmaceutical expert and an adviser to the Government of India. "From raw materials, profit margins, manpower and cost of bulk production, everything is cheaper here." Over 50 per cent of India's \$12 billion (Rs 64,032 crore) annual production is supplied around the world: European Union to Africa, US to Japan. "That itself speaks for the quality of our medicines." The origin of the case goes back to November 2001. The Doha Declaration of the World Trade Organisation (WTO) spelt out the agreement on trade-related aspects of intellectual property rights (TRIPS). But it also allowed some flexibility to member countries to protect the right to health of their citizens. "Until 2005, India did not recognise pharmaceutical patents, but as a WTO member, it was forced to bring its patent regime into compliance with TRIPS," says lawyer Pratibha Singh of Delhi-based IP law firm Singh & Singh. India made use of the flexibilities to amend the Indian Patent Act, 1970, and include Section 3(d), which is now being challenged by big pharma.

"Section 3(d) is India's invention," points out Singh. "It achieves a great balance between the TRIPS mandate and protects access to medicine for the poor. And this has made India a global leader in pharma patent law." From<sup>8</sup> Philippines, Argentina, Thailand to China, patent laws are being amended to include similar provisions. The battle over Section 3(d) rests on a few fundamental principles. For instance, a patent cannot be granted for any "incremental innovation" if a molecule is known already. The other is "significant enhancement of efficacy". These two are often used by big pharma companies to keep patents alive and retain monopoly over blockbuster drugs they invented, a strategy known as "ever-greening" that Section 3(d) discourages. This year is a significant one for the \$1.2 trillion (Rs 6,403,200 crore) global pharma industry. A "patent cliff", or impending patent expiry of many blockbuster drugs, is approaching. The first patent for Glivec, for instance, will expire in July 2015 in the US. And it's happening at a time when research and development costs are rising, new drugs are urgently needed to replace the lost income and generics are rapidly expanding business. Big pharma needs to reboot its direction. "The wheel of innovation should continue to move with the fuel of intellectual property rights," says Tapan J. Ray, the director general of the Organisation of Pharmaceutical Producers of India. "The purpose of this case is not money but the vindication of honour," Novartis counsel Gopal Subramaniam told the court. Glivec has been granted patents in 35 countries around the world. Why not India? As Justice Alam observed on September 11, "This is a difficult country."

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<sup>7</sup> Ibid

<sup>8</sup> Ibid

But in contrast, a difficult country has achieved rare feats in several different areas, mostly inventions spurred at home labs with Indian intellect and R&D. This calls for a major debate on having solutions and driving it through case studies as we observe in a classic case in the south of India. While it's true that every state is unique and one common model is not applicable, with most questions in a case study do not have a single right answer, although assessing different but equally valid ways of approaching an issue, and then bringing back to the particular line of inquiry that the drug maker wants to pursue is a careful line of medicinal control. While for now Indian companies have won the case against Novartis for a cancer drug, it's essential to look at the reading of **A Sturdy Model**<sup>9</sup> - Tamil Nadu attempted to make drugs affordable to everyone nearly 20 years ago when it set up the Tamil Nadu Medical Services Corporation (TNMSC). Following a serious spurious drugs bust in 1994, the State decided to set those stables in order, and the resultant company, the TNMSC, set out to ensure that essential drugs were available to the public without disruption. The Corporation adopted the World Health Organisation's concept of an essential drug list (EDL). The WHO defines essential medicines as those that satisfy the priority healthcare needs of the population, and intended to be available at all times, in adequate amounts, in the appropriate dosage forms, with assured quality and at a price the individual and the community can afford.

Consultations among expert groups yielded an EDL that seemed adequate for the needs of the population then. "This is a dynamic list, it is being modified every year and will meet 90 per cent of the requirements of those coming to government hospitals," says R. Poornalingam, a retired IAS officer, who was among the architects of the TNMSC. The initial allotment was Rs. 80 crore, and this has been hiked by 5-10 per cent every year since.

For the rest, there is a specialised drug list. District and teaching hospitals are provided 10 per cent of their allotment in cash to procure drugs locally, depending on the need. Subsequently, successive governments started offering health insurance (with income criteria) to cover treatment for certain conditions, including cancer. "The three big advantages that the creation of the TNMSC immediately facilitated were: buying generics under the EDL; the freedom to go in for local purchases for specialty drugs (generics only); and reducing the prices of drugs procured by the State," explains Health Secretary J. Radhakrishnan. The market prices, too, came crashing down, once the government started buying generics in bulk for the EDL. For instance, the price of ciprofloxacin which was then being sold for over Rs. 500 dropped well below Rs.100, adds M. Bhaskaran, retired director, State Drugs Control.

A sturdy warehousing<sup>10</sup> infrastructure was put in place in the districts for efficient distribution of the drugs which were quality tested initially, and subsequently at random. "Warehousing and Information Technology [to take care of the supply chain] were the key game changers," Mr. Poornalingam says. The model clicked. The High Level Expert Group on Universal Health Coverage, in its recent report, posited the TNMSC as a model for the rest of the country. The report said: "The procurement model of the TNMSC has stood the test of time over the past 15 years, and has been hailed as the most efficient, reliable, transparent and replicable model." The possibilities of stock-out are technically low. And yet, a serious stock-out occurred last year, putting the essential diabetes drugs, such as metformin, out of stock. A health researcher says the error occurred owing to an interpretation of the Tender Act. About 30 drugs were sourced from one supplier, and when he failed a quality test, none of the drugs could be used. Clearly, while

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<sup>9</sup> The Hindu, April 7, 2013

<sup>10</sup> Ibid

the model is replicable, one needs to keep watching and fine-tuning systems within the TNMSC to ensure that it runs without disruption, according to Mr. Bhaskaran. “In the Indian context, the TNMSC is a benchmark, but we need to reinvent ourselves constantly in order to address even minor challenges,” Mr. Radhakrishnan adds.

However, the need of the hour calls for<sup>11</sup> greater public investment on drugs, an expanded official list of essential medicines, effective price controls for essential drugs, and a pooled procurement system that leverages the benefits of scale to drive costs down. The substantial cost benefits of centralised procurement for the government system have been convincingly demonstrated in Tamil Nadu, encouraging Kerala to adopt the same model; Bihar, Madhya Pradesh, and Orissa are in the process of replicating it.

To bring in summation, it’s not just the fine print, blue print or the correlative legalese approach given to the industry but effective policy<sup>12</sup> measures are critical, in order to improve access to life-saving medicines, as households in India are known to pay nearly 70 per cent of their health care spending on medicines. This is the dream and promise of achieving safe livelihood, increased security and the ability of the poorest of the poor to combat diseases through affordable buying of life-saving drugs that are essential to keep the last breath from stopping. This is a long way to go, and the country needs a greater responsive measure and seeks for action that yields results which are truly transformative, for you and me.

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<sup>11</sup> Medicines For All, The Hindu, Editorial, December 29,2011

<sup>12</sup> Patent Justice, The Hindu, April 7, 2013