DIRECT PRICE CONTROL ON PATENTED DRUGS IN INDIA: THE PROBABLE EFFECTS ON INNOVATION AND ACCESS TO MEDICINES

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Addressing the growing concern stemming from the issue of access to and affordability of drugs, this article argues for the use of a direct price control mechanism to prevent the abuse of monopoly rights emerging from the patenting of pharmaceutical products. The article also demonstrates the limited utility of compulsory licensing in achieving access to medicines, and explodes the myth of direct price control necessarily hindering innovation, consequently putting forward a persuasive case for reformulating and rigorously implementing India's hitherto impotent price control regime

I. INTRODUCTION

"As we enjoy great advantages from the inventions of others, we should be glad of an opportunity to serve others by any invention of ours; and this we should do freely and generously."

- Benjamin Franklin.

The imposition of price controls on drugs in India has been a topic of much debate, more so after the introduction of product patents for medicines and drugs in 2005. The new patent regime inspired by TRIPS[1] has led to growing concerns

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1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1125, 1197 (1994).

about the accessibility and affordability of patented drugs in India. The government has been dismissing these concerns by citing drug price regulations and compulsory licensing as tools to tackle the problem of high prices.[2] The pharmaceutical industry in India, on the other hand, has been strongly critical of the direct price control mechanisms.[3] It claims that direct price controls hinder research and development, the safeguarding of which is the main object of granting patent protection. However, there is also a strong lobby for the strengthening of the drug price control mechanisms to make them more effective in reducing the high prices of patented drugs. This paper analyses the role of the drug price control mechanism in India as a tool to increase the access to and affordability of medicines while avoiding the adverse effects of price control on Research and Development (R&D). Part I of this paper examines the drug price control mechanism that is prevalent in the country. Part II analyses the effect of direct price control on patented drugs. Part III deals with the effect of price control on R&D and innovation, and Part IV concludes the paper with a brief overview of upcoming laws and policies and suggestions about their functioning.

II. Patent Law and Drug Price Control Mechanisms: An Overview

The law of patents was first introduced in India through the Indian Patents Act, 1856.[4] This Act was subject to many amendments over the years and was finally repealed to give way to the Indian Patents and Designs Act, 1911. After India's independence in 1947, the Government appointed the Tek Chand Committee and the Ayyangar Committee to review patent laws.[5] The reports of these committees recognised the need to strengthen indigenous industries, considering that India ranked high in epidemic disease prevalence, poverty and drug prices.[6] Following this, the Tek Chand Committee recommended the introduction of compulsory licensing to curb the abuse of monopoly by the patent holder.[7] The

2. Kamal Nath, Statement on the Ordinance Relating to Patents (Third) Amendment (Dec. 27, 2004), *available at* http://pib.nic.in/release/ release.asp?relid=6074.

3. *Pharma Industry Opposes Price Control Mechanism*, Bus. Line, Jan. 11, 2007, *available at* http://www.ficci.com/news/viewnews1.asp?news_id=855.

4. *History of Indian Patent System, available at* http://www.patentoffice.nic.in/ipr/patent/history.htm.

5. Raghavan, *The First Ten Years of the TRIPS Agreement: Of the Inequals of The Uruguay Round*, 10 Marq. Intell. Prop. L. Rev. 273, 273-274 (2006).

6. *Id.*

7. Raghavan, *supra* note 5.

Ayyangar Committee recommended that only process patents be granted for medicines and food. The Committee reasoned that these products were essential and steps should be taken to make them available at low and affordable prices.[8] The recommendations of these two committees suited the needs of an under-developed India and were, therefore, extremely influential in the formulation of India's patent policy. They were consequently incorporated in the Indian Patents Act, 1970 which only allowed for the grant of process patents for food, medicines and drugs.[9] This law was in effect until 2005, till India amended the Indian Patents Act, 1970 and allowed product patents for food, medicines and drugs in order to make Indian law TRIPS-compliant. The present patent law is, thus, TRIPS-compliant and provides for product and process patents for all inventions which meet the criteria under the Indian Patents Act, 1970.

Drug price control has existed in India ever since the Third Five Year Plan.[10] The failure of the Third Five Year Plan led to introduction of the Drug Price Control Order of 1970 (DPCO).[11] The DPCO allowed the government control over drug prices, thus complementing the compulsory license provisions.[12] The liberalisation of the economy in 1991 and India's WTO membership led to the Drug Price Control Order, 1995.[13] The Drug Price Control Order, 1995 and the Pharmaceutical Policy, 2002 constitute the current drug price control regime in India.[14]

The Pharmaceutical Policy is under litigation before the Supreme Court for aiming to reduce the number of drugs under the Drug Price Control Order, 1995.

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8. Raghavan, *supra* note 5.
9. Raghavan, *supra* note 5, at 274-275.
10. 1961–1966 PLANNING COMMISSION, THIRD FIVE YEAR PLAN, ch. 32, ¶ 45, *available at* http://planningcommission.nic.in/plans/planrel/fiveyr/ default.html.
11. The Drug Price Control Order, 1970 was passed under The Essential Commodities Act, 1955, *available at* http://indiacode.nic.in/fullact1. asp?tfnm=195510.
12. *See* P. G. Sampath, *Economic Aspects of Access to Medicines After 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry*, COMMISSION INTELL. PROP. RTS. INNOVATION PUB. HEALTH, *available at* http://www.who.int/intellectualproperty/studies/ access_2005/en/index.html.
13. The Drug Price Control Order, 1995 *available at* http://nppaindia.nic.in/ drug_price95/ txt1.html.
14. The Pharmaceutical Policy, 2002, *available at* http://nppaindia.nic.in/may-2002/policy-02.html.The DPCO is the main regulatory mechanism through which the prices of the drugs are fixed and controlled. The National Pharmaceutical Pricing Authority (NPPA) is the regulatory body which monitors and regulates the price of drugs according to the provisions of the DPCO. The Pharmaceutical Policy, 2002 is a policy which aims to amend the DPCO 1995 according to its aims and objectives, thus renewing and amending the list of drugs under the DPCO 1995.

III. Direct Price Control: Effect on Access and Affordability of Patented Drugs

With the introduction of product patents for drugs, the prices of patented drugs have become a contentious issue. Studies estimate that drugs tend to be priced higher when conferred product patents.[17] Of special interest is a study by Yale University and World Bank economists that estimates a rise of about 100% to 400% in prices when product patents are available to foreign firms without any price regulation.[18] Further, on account of exclusive rights granted under the patent, the patent holder may have negligible competition, especially when the drug has no substitutes. This can clearly be seen in the case of Glivec, a life-saving drug that is used in treating cancer.[19] Novartis was granted Exclusive Marketing Rights (EMR) for the drug and it was priced at US $30 per capsule, whereas the generic version of the drug, which only Natco Laboratories was allowed to manufacture, was priced at US $1.5 per capsule, thus providing an affordable substitute for the drug.[20] The removal of other generic substitutes from the market, as a result of the EMR allowed Novartis to set the price at US $2000 for a month's treatment with Glivec, making it unaffordable for the majority of the population.[21] Thus, extreme price rise as a

15. *Centre Adds 75 New Medicines to Essential List*, Times of India, July 11, 2003, *available at* http://timesofindia.indiat imes.com/articleshow/71739.cms.

16. The Pharmaceutical Policy, 2006, Part A, *available at* http://pib.nic.in/archieve/others/2005/documents2005dec/docu ments2005dec_chemfert.pdf.

17. *See* S. Chaudhuri et al., *Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India* (Nat'l Bureau of Econ. Research, Working Paper No. 10159, 2003) *available at* http://ssrn.com/abstract=478668; C. Fink, *How Stronger Patent Protection in India Might Affect The Behavior or Transnational Pharmaceutical Industries* (The World Bank, Working Paper no. 2352, 2000) *available at* http://ssrn.com/abstract=630724.

18. Chaudhuri et al., *supra* note 17, at 6.

19. Glivec (iminatib mesylate) is a drug used to treat chroni myeloid leukemia.

20. Sampath, *supra* note 12.

21. *The Impact of India's Amended Patents Act on Access to Affordable HIV Treatment*, HEALTHGAP, Feb 2005, *available at* www.healthgap.org/press_releases/05/020105_HGAP_FS_INDIA_IPR.pdf.

result of the granting of product patent protection is a cause for concern, especially with regard to the affordability and accessibility of drugs. Direct price control is a tool that can provide an effective solution to these problems. It involves monitoring, regulating and directly fixing the prices of drugs based on fixed criteria such as annual sales turnover, reference pricing, essential medicines, etc.

The Pharmaceutical Policy and the DPCO have a common objective of ensuring that essential drugs are available at reasonable prices.[22] The Doha WTO Ministerial Declaration in 2001 recognised that the exclusivity of patents should not prevent governments from taking measures to protect public health, especially by providing access to and ensuring the affordability of medicines.[23] Thus, the effectiveness of direct price control in India depends on factors like the criteria for price control, the enforcement of these criteria and the concern for R&D while providing for affordable and accessible drugs.

Price control measures are adopted to ensure that the product is available at the lowest price to the public and that the price is not disproportionate to the supply and the cost of production. Studies show that in India, even if a strict price regulation maintains the price of patented drugs at the pre-product patent level, the consumer will lose easy access.[24] This is because the extensive marketing and distribution networks of generic companies allow their products to be more readily available to the consumer. Further, the consumer would also feel the loss of variety.

Direct price regulation, by itself, may not allow for easy access or greater variety, but will still be useful for ensuring affordability.[25] If the patented drug has many substitutes in the market, then price regulation would be more effective if accompanied by compulsory licensing. However, direct price control is more advantageous than issuing compulsory licenses in certain situations. Compulsory licenses are issued to any person interested in working the patented invention and who has made an application to the controller of patents for the grant of such license. Further, compulsory licenses are issued only on the basis of certain fixed grounds[26] and are issued only after three years of granting the patent.[27] Therefore,

22. *See generally* The Drugs Price Control Order, 1995; *See also* The Phamaceutical Policy, 2002.
23. World Trade Organization, Declaration on the TRIPs Agreement and Public Health of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).
24. Chaudhuri, *supra* note 17, at 4.
25. Chaudhuri, *supra* note 17, at 4.
26. Section 84, Patents Act, 1970.
27. Section 24C, Patents Act, 1970.

direct price control is the only tool that maintains the exclusive rights of the patent holder, allowing the holder to optimise profits even while under price control. Further, within the first three years, direct price regulations act as an effective tool in preventing escalation in the prices of the patented drug. Another advantage of direct price control is in respect of patented drugs which do not have many substitutes, such as Anti Retro-Viral (ARV) drugs used for Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) treatment. An ARV drug is the main treatment for HIV/AIDS. Though it is not a cure, it is considered a life-saving treatment as it can help in increasing and maintaining the immunity of a person living with HIV/AIDS, which is very important to counter the effects of the disease. The prices of these drugs can be controlled without the issuance of a compulsory license. Thus, direct price control mechanisms can assist in increasing the affordability and accessibility of essential drugs. However, the price control mechanisms in India have not quite achieved these objectives. This is because of the poor implementation of direct price control through the DPCO and the Pharmaceutical Policy, 2002.

A. De-control of Prices

A look at the drugs under the DPCO clearly shows that pricing, so far, has hardly considered health policies and needs. The main function of the DPCO and the Pharmaceutical Policy has been the de-control of drugs. The effect of de-control on prices of essential drugs is seen in the following table:[28]

Name of the Drug	Treatment for	Price: 1995	Price: 1998	Percentage increase
[illegible]	Depression	3.13	9.5	204
[illegible]	Antibiotic	12.85	23.15	80
[illegible]	Antibiotic	45.07	113.15	151
[illegible]	Anti TB Drug	5.92	33	457
[illegible]	Cardiac Problems	16.5	50.46	206

Further, according to government authorities, the price rise of medicines that are under price control is only 1%, whereas drugs that are not under price control have had an average price rise of around 7% in the past decade.[29]

28 N. Nanda & A. Khan, *Competition Policy for the Pharmaceuticals Sector in India* in Towards A [illegible] Competition Policy For India: An Overview 107 (M.S. Pradeep ed., Academic Foundation in Association with Consumer Unity and Trust Society 2005).

29 *Id.*

B. Criteria for Control

One of the reasons for the inefficiency of the DPCO in achieving its aim of providing affordable and accessible medicines is the criteria on which the price is fixed or controlled.[30] According to the DPCO, the need for price control is based on the minimum or total annual turnover of the medical drug or formulation.[31] The DPCO does not base its criteria on the need for the drug in the country. Due to this, the life-saving drugs for HIV/AIDS and tuberculosis treatment are not on the list. This is of critical importance as HIV/AIDS and tuberculosis patients often need second line and third line treatment.[32] This need arises often when the patient becomes resistant to the drug after its repeated use, which is known as "cross resistance". This necessitates the changing of treatment to include new drugs so that the new drugs are not amongst those to which HIV has become resistant.[33]

In India, only the first line and the second line treatment for HIV/AIDS is freely available in those areas where these diseases are highly prevalent.[34] The third line treatment is out of the scope of price control and is not provided freely by the government. As a result, patients of HIV/AIDS as well as public health at large are disadvantaged. Thus, the focus of drug pricing policies should shift from the existing turnover based criteria to a need based criteria, in order to ensure that the DPCO is successful in achieving the objective of affordability.

C. Price Regulation

With regard to price regulation, the National Pharmaceutical Pricing Authority (NPPA) has the responsibility of tracking down price manipulations by companies on a regular basis. Pharmaceutical companies currently indulge in large scale price dodging by altering the pack sizes of drugs or the strength of formulations. They also market non-standard pack sizes of syrups, tonics and

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30. Sections 3 & 7, DPCO, 1995.

31. According to the DPCO, 'Bulk Drug' means means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation. A 'formulation' means a medicine processed out of, or containing without the use of any one or more bulk drug or drugs without pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention in human beings but only includes allopathic drugs.

32. This is due to factors like non-compliance with the prescribed regime, non-availability of prescribed drug or immunisation to the first line treatment.

33. *AIDS & HIV Antiretroviral Drug Treatment, available at* http://www.avert.org/aidstreatment.htm.

34. The Government provides second line treatment only to those who prove resistant to the first line treatment.

creams for the purpose of escaping price control.[35] However, the NPPA is unable to function effectively as it is not well-equipped or adequately provided with the requisite number of state departments. Thus, it falters in fixing prices of controlled formulations on time and in the detection of any price control violations.

Further, the NPPA cannot regulate the prices of essential medicines, unless they are included in the price control list that is in constant decline and has not been reviewed in the past few years.[36] Presently, under DPCO, 1995, there are 74 bulk drugs and their formulations under price control, that cover approximately 40% of the total market. The following table is illustrative of the decline.[37]

Market share of drugs under the DPCO, 1979-2004

YEAR OF REVIEW	NUMBER OF DRUGS	APPROXIMATE MARKET SHARE (IN PERCENTAGE)
1979	347	80
1987	142	60
1995	74	40
2004	38*	20

* Not yet effective

It is clear that direct price control shall remain a failed system if it is not implemented intelligently. The reason that direct price control has not adequately increased affordability and accessibility of medicines in India is because of the aforementioned flaws in the DPCO and the Pharmaceutical Policy.

IV. DIRECT PRICE CONTROL ON PATENTED DRUGS: EFFECTS ON R&D AND INNOVATION

The pharmaceutical industry has been very vehement in its opposition to the direct price control mechanism for drugs in India.[38] One of the reasons for

35. *Dodging Price Control*, PHARMABIZ, Jan. 30, 2008, *available at* http://www.pharmabiz.com/article/detnews.afsp?articleid=42750&sectionid.

36. *See Functions of NPPA*, *available at* http://nppaindia.nic.in/index1eng.html (last visited Mar. 21, 2008).

37. P. Malhotra and H. Lofgren, *India's Pharmaceutical Industry: Hype Or High Tech Take-off? in* TOWARDS A FUNCTIONAL COMPETITION POLICY FOR INDIA: AN OVERVIEW 107 (M.S. Pradeep ed., Academic Foundation in Association with Consumer Unity and Trust Society 2005).

38. *Pharma Industry Opposes Price Control Mechanism*, *supra* note 3.

opposing the direct price control of drugs is that it leads to lower investment and fewer R&D activities.[39] That there is no correlation between direct price control and R&D activities is evinced by the fact that there was no increase in investment or R&D in the pharmaceutical sector even when the number of drugs subjected to price control was reduced to 74.[40]

Prices have been seen to rise steeply after removing price control. The argument that total price de-control is necessary to ensure funds for R&D is fallacious. A recent study found that the Indian pharmaceutical industry is one of the most profitable industries in India, second only to the IT industry.[41] The study also found that one of the reasons for this excellent performance is that a major part of these profits come from overcharging several drugs. R&D investment in the drug industry continues to be less than 2% of sales.[42]

The only area that needs encouragement is investment in the distribution and marketing of patented drugs by foreign firms to make the drugs more accessible.[43] This can be conveniently done as it causes no harm to the profits or the R&D of the patent holding company. In fact, price control mechanisms are prevalent in many countries around the world – particularly in Europe – that are renowned for R&D activities.[44]

A. Comparison with other Countries

Price Control over medicines exists in some form in most countries. In Australia, since 1993, new drugs with no advantage over existing products are offered at the same price. Where clinical trials show superiority, incremental cost effectiveness is assessed to determine whether a product represents value for money at the price sought.[45] In European countries such as Denmark, Greece, Finland, Ireland, Italy, the Netherlands, Portugal, and Sweden, the maximum price of

39. *Pharma Industry Opposes Price Control Mechanism, supra* note 3.
40. Nanda & Khan, *supra* note 28, at 108.
41. *Supra* note 35.
42. *Supra* note 35.
43. *See generally* Chaudhuri, *supra* note 17. As mentioned above, domestic generic companies are more accessible to the public as a result of wide marketing and distribution networks.
44. *See generally* K.E. Bloor & N. Freemantle, *Lessons from International Experience in Controlling Pharmaceutical Expenditure III: Regulating Industry*, 313, BRIT. MED. J. 1996 33-35 (1996). In Netherlands, Germany, New Zealand and Sweden, reference pricing is followed. In Spain, maximum prices are set for each product, comprising total cost and company profit. France has a system of volume related price cuts.
45. Malhotra and Lofgren, *supra* note 37, at 97.

medicines is set in relation to prices in neighbouring countries. In Belgium, France and Italy, prices are set in relation to prices in the E.U. Spain and the United Kingdom set their prices to ensure a rate of return within a particular profit range.[46]

In Canada, the Patented Medicine Prices Review Board (PMPRB), established in 1987, limits the prices set by manufacturers for all patented medicines, new or existing, sold in Canada, under prescription or over the counter, to ensure they are not excessively priced. The PMPRB, an independent quasi-judicial tribunal, was set up exclusively to monitor the prices of patented drugs. The PMPRB regulates the price of each patented drug in the first and last month of every year.[47] Even in the United States, where there is no official price control, there is a growing demand from special interest groups calling for legislation to make pharmaceutical drugs more affordable, either through legalized re-import from price-regulated markets such as Canada and the E.U., or more directly through government-imposed price controls.[48]

In comparison, the need for a strict price control regime in a developing country such as India can hardly be over-emphasized. Where, unlike in the developed countries, expenditure on medicines constitutes a large proportion (greater than 50%) of total medical expenditure and 90% of this expenditure is out-of-pocket expenditure by the people,[49] exercising control over prices of drugs is of utmost importance. This is accentuated by the absence of basic healthcare and a social security system in the country.

V. The Road Ahead

The Pharmaceutical Policy by aiming to reduce the number of drugs under price control, does not seem to take into account the need for cheap drugs in the country and the effect of de-control on essential drugs. As mentioned above, the Pharmaceutical Policy is under litigation before the Supreme Court of India as a

46. *See generally* A. Maynard and K. Bloor, *Dilemmas In Regulation Of The Market For Pharmaceuticals, available at* http://content.healthaffairs.org/cgi/ content/full/22/3/31.

47. Malhotra and Lofgren, *supra* note 37, at 104.

48. *See generally* R.E. Santerre and J.A. Vernon, *Assessing consumer gains from a drug price control policy in the United States, available at* http://goliath.ecnext.com/coms2/gi_0199-5698626/Assessing-consumer-gains-from-a.html#abstract.

49. S. Narain, *Public Health-A Life Saving Order, available at* http://www.flonnet.com/fl2115/stories/20040730 004110300.htm.

result of a stay order of the High Court of Karnataka on the policy. The High Court of Karnataka had previously decided that the Policy is arbitrary and against Articles 14 and 21 of the Constitution.

The Supreme Court has directed the Central Government to *"consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control"* [50] Accordingly, the Central Government brought out the National List of Essential Medicines, 2003 which contains 354 drugs.[51] The Government announced that these drugs would be under price control but did not implement the same due to the opposition from the pharmaceutical industry.

The Central Government also brought out a part of the Pharmaceutical Policy, 2006, under which mandatory price negotiations for patented drugs are a precondition to market approval.[52] However, these negotiations are truly effective only when performed with the participation of civil society. The Pharmaceutical Policy, 2006 also provides for public-private partnership programmes for anti-cancer and anti-HIV/AIDS drugs.[53] But it is not clear why the programmes are limited to only these diseases. The Pharmaceutical Policy, 2006 is currently under review and has not been enforced.

The Central Government of India has now constituted the Sandhu Committee that is looking to make drugs more accessible in the post-2005 patent regime by re-defining the categories and basis for price control.[54] The government can also look at other solutions, like increasing government grants for R&D activities to companies. The pharmaceutical companies on their part can enter into strategic alliances with foreign firms that can facilitate their use of the foreign players' superior R&D facilities and can also look at strengthening industry-academia linkups.[55]

It is clear that direct price control mechanisms are potential tools to counter the abuse of monopoly on a patented drug. The Ayyangar Committee's view that essential products such as medicines should be available at cheap and affordable prices even with the grant of patents still holds good today.[56] The advantages that

50. The Pharmaceutical Policy, 2006, *supra* note 16, at 1.
51. The Pharmaceutical Policy, 2006, *supra* note 16, at 1.
52. The Pharmaceutical Policy, 2006, *supra* note 16, at 11.
53. The Pharmaceutical Policy, 2006, *supra* note 16, at 9-11.
54. Malhotra and Lofgren, *supra* note 37, at 111.
55. Malhotra and Lofgren, *supra* note 37.
56. Raghavan, *supra* note 5, at 4.

direct price controls offer should be used at the right time, especially when the issuance of compulsory licenses is not possible. At the same time, if the flaws of the DPCO, the Pharmaceutical Policy, 2002 and the NPPA are not corrected, direct price control will prove to be an ineffective tool to ensure affordability and accessibility of medicines. Steps such as reduction of de-control, provision for a need-based criterion and improvement in the functioning of the NPPA will make direct price control a stronger tool in making cheaper drugs available to the public. However, at the same time, it should be ensured that these steps do not adversely impact investment in R & D and innovation.

De-control of drug prices has succeeded in raising the prices of drugs but has hardly resulted in a favourable impact on R&D activities.[57] It is difficult to determine how far direct price control will affect investment in R&D in the pharmaceutical industry in the future. Much will depend on the nature of the drug, the need for it in the country and the actual investment in R&D activities by the patent holding company. Therefore, it becomes important that the law should maintain a balance between the affordability of medicines and encouraging R&D activities.

57. *See* Nanda & Khan, *supra* note 28, at 108.