

## CHAPTER IV AVAILABLE LEGAL OPTIONS- A CRITICAL ANALYSIS

There are multiple legal and policy options, which may be utilised to deal with anti-competitive practices in the pharmaceutical industry and the health delivery system. These options are to be considered in light of facilitating access to medicines and healthcare by the poor. Competition law apart, patent law and drug price control are crucial for efficacious elimination of competition violations in the health sector.

### COMPETITION LAW

The competition law regime in India has a rather convoluted history. The Monopolies and Restrictive Trade Practices Act was the first competition related legislation in India<sup>110</sup> and was enacted in 1969. The Act was framed to deter and also dismantle any concentration of economic power to the common detriment, for the control of monopolies, for the prohibition of monopolistic and restrictive trade practices and for related matters<sup>111</sup>. The Act provided for the formation of a MRTP Commission. This Commission dealt with the functional aspects of the Act and implemented its provisions. The MRTP Act was periodically amended as and how deemed appropriate.

In the course of time however, finding the ambit of the MRTP Act inadequate for fostering competition in the market and eliminating anti-competitive practices in national and international trade, the Government of India in October 1999 appointed a high level committee on Competition Policy and Law (the Raghavan Committee) to advise on the competition law.<sup>112</sup> The Raghavan Committee concluded that there was a need for new competition legislation, whereafter the MRTP Act would be repealed and the MRTP Commission wound up. The Committee recommended that the new competition law would not cover unfair practices as its predecessor did, since such practices came under the purview of the Consumer Protection Act, 1986. A commission was to be formed under the new Competition law and was to be denominated as the Competition Commission of India. All monopolistic trade

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<sup>110</sup> Atul Chitale, *India: Overview and Recent Developments*, available at [http://www.globalcompetitionreview.com/apar/ind\\_overview.cfm](http://www.globalcompetitionreview.com/apar/ind_overview.cfm)

<sup>111</sup> See generally, Preamble of The Monopolies and Restrictive Trade Practices Act, 1969.

<sup>112</sup> Debashree Dutta, *New Competition Regime in India* available at <http://www.legalserviceindia.com/articles/new.htm>

practices and restrictive trade practices cases pending before the MRTP Commission would be taken up by this new Commission.

The new law, entitled the Competition Act, 2002 received presidential assent on January 13<sup>th</sup>, 2003. However, the entire Act has still not come into force<sup>113</sup>. The implementation of the Act was stalled by public interest litigation (Mr. Brahm Dutt v. Union of India<sup>114</sup>) relating to certain issues concerning the Competition Commission of India. The Supreme Court has ruled on the matter and given recommendations which need to be suitably incorporated in the Act, before it may be deemed enforceable.

At present, the MRTP Act is still in operation. Interestingly, the Competition Commission of India has been established under the Competition Act 2002 and exists alongside the MRTP Commission. However, till date it is the MRTP Commission, which passes orders, the Competition Commission being handicapped in that respect due to the Supreme Court case. The Competition Act, 2002 (hereafter referred to as the Act), being the law of the immediate future, shall be focused on extensively henceforth.

### ***Regulating the Pharmaceutical Industry***

#### ***1. Prevalent Anti-competitive Practices and Competition Law***

The three focal areas of anti-competitive conduct covered by the Act relate to anti-competitive agreements, abuse of dominance and combinations, all three of which give rise to competition concerns in the pharmaceutical industry and the health delivery system, as is evident from the previous chapter.

#### ***Anti-Competitive Agreements***

The main provisions dealing with anti-competitive agreements are as follows:

- Section 3, which prohibits such agreements.
- Section 19, which provides for inquiry into anti-competitive agreements.
- Section 27, which concerns orders, passed by the Commission after inquiry into agreements or abuse of dominant position.

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<sup>113</sup> Anurag K. Agarwal, *Competition Law in India: Need to go Slow and Steady* at [www.iimahd.ernet.in](http://www.iimahd.ernet.in)

<sup>114</sup> WP(C) No. 490 of 2003 decided on 20.1.2005

The specific anti-competitive practices of the pharmaceutical system and the health delivery system, which are covered by Section 3 of the Act are collusive agreements including cartels, tied selling, exclusive supply agreements, exclusive distribution agreements, refusal to deal and resale price maintenance. Matters relating to two such practices are considered below in more detail.

The prohibition of cartel agreements (price fixing, output restricting, market sharing or bid rigging) between enterprises is considered to be the strongest provision in the Act.<sup>115</sup> The Act mandates that cartels would be presumed to be anti-competitive, but also provides for an efficiency defence, namely that nothing in the relevant subsection shall apply to any agreement, if such agreement increases efficiency in production, supply, distribution, storage, acquisition or control of goods or provision of services.

However, while cartels may translate into increased efficiency, they may also result in increased prices, which would be detrimental to consumers. The provision may be allowing far too wide an exception. While the efficiency defence is certainly justifiable, perhaps it might be prudent to have a safeguard ensuring that the increased efficiency envisaged does not impose a burden on consumers.

Surprisingly, while anti-competitive practices in the areas of combinations and abuse of dominance may be condoned on ‘development’ considerations, this latitude has not been allowed for cartels.<sup>116</sup>

However, the law seems to be too generous to agreements that are related to enforcement of IPR but can have anti-competitive effects. Though the law says that an IPR-holder can impose reasonable conditions, as may be necessary for protecting any of his rights, it is not defined what is reasonable. Moreover, the Act does not specifically provide for any remedies if the conditions imposed are unreasonable. IPR related licensing agreements can contain anti-competitive provisions which are purely unreasonable and hence they should have been made clear instead of creating

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<sup>115</sup> Aditya Bhattacharjea, *Do away with flaws before enforcement*, Financial Express, January 28<sup>th</sup>, 2005

<sup>116</sup> Ibid

confusion by using terms like “reasonable restrictions”. If a licensing agreement contains conditions like tie-in arrangement to buy other products or technology, fixing of minimum price for licensed products, restriction on buying products or technology from others or if the firms in a manufacturing industry decide to pool their patents and agree not to grant licenses to third parties, at the same time fixing quotas and prices, then the practices are simply anti-competitive and there is no point in engaging in a debate if they reasonable or unreasonable. Such situation may exist when firms decide to make joint R&D efforts and invent something jointly. It seems that the Act has not taken the advantage of flexibilities allowed under Article 40 of TRIPS.

The provisions relating to anti-competitive agreements, except probably the one on exemption on IPR-related agreements, are for the most part well framed. However collusive conduct, especially if cross-border, in cases such as international cartels, need very adept investigative skills and only time will tell whether the Commission can do justice to the framing of the law.

#### *Abuse of Dominance*

The main provisions dealing with abuse of dominance are as follows:

- Section 4, which prohibits the abuse of dominant position.
- Section 19, which provides for the procedural aspect of inquiry into the dominant position of an enterprise.
- Section 27, which mentions the orders, which may be passed by the Commission after inquiry into the practice of abuse of dominant position.
- Section 28, which concerns division of enterprise enjoying dominant position.

As has been discussed in Chapter Three, patents confer a monopoly status on patent owners and there might be abuse of such monopoly status. Such abuse of dominance is one of the major competition concerns, which may well beset our pharmaceutical industry with the introduction of our new patent regime.

#### **Box 4.1: Explicit embargo on Excessive Pricing-the case of South Africa**

In South Africa, the pharmaceutical companies, GSK and Boehringer, patent owners of ARV (HIV/AIDS) drugs set unjustifiably high prices of these drugs in South African markets. AZT (300 mg) sold at US\$0.92 as compared to the WHO generic price US\$0.25. Compulsory licensing negotiation under their patent Act proved futile as the companies demanded 25 percent royalty on sales as compared to the international rate of 4-5 percent. The Competition Commission took action under Section 8 of the SA Competition Act, which prohibits ‘a dominant firm to charge an excessive price to the detriment of the consumers’, ordering the issuance of licenses to market generic versions of the patented ARV drugs in return for the

payment of reasonable royalty to be decided by the Competition Tribunal. (See generally, Mr. Anand Grover, *Anti-competitive practices in Patent Licensing Arrangements and the scope of competition law/policy in dealing with them*, AMTC, National Workshop on Patent & Public Health, Ministry of Health, April 11th, 2005.)

This case reflects that however much power is exercised by TNCS, a clearly articulated legislation and an effective competition authority can efficiently protect the interests of the consumers and facilitate access to health. Although the Indian Act does not mention excessive pricing expressly, it prohibits unfair or discriminatory prices, which may be construed to include overpricing within its ambit. Given the prevalent fears that prices of medicines will rise, this provision assumes significance in the access to health issue.

The Act prohibits abuse of dominance in Section 4. If, therefore, pharmaceutical companies do engage in overpricing patented products or are unreasonable with respect to licensing terms and so on, our competition law may be resorted to for redressal. It is interesting to note that while intellectual property rights are expressly excluded from the purview of anti-competitive agreements in sec 3 (with the qualification that conditions imposed as a result of such rights are to be reasonable), there is no such exclusion provided in sections dealing with abuse of dominant position and combinations.

#### **Box 4.2: Drug Pricing and the MRTP Commission**

The Director General (Investigation & Research) [investigation authority under the MRTP Act] brought to the notice of the MRTP Commission that pricing of certain drugs manufactured by Stangen Pharmaceutical Ltd was unreasonable and unjustified and that the pricing pattern of the respondent did not appear to have any relationship with the cost of the inputs. The DG asserted that this unreasonable increase in the prices of drugs imposed unjustified costs on the consumers. The DG however failed to establish in the Commission's opinion that such a trade practice has the effect of preventing, distorting or restricting competition in the market, which the wording of the relevant provision mandated.

It was held in Director general (I&R) v. Jagson Pal Pharma Ltd. [2002 CTJ 151 (MRTP)] as well that excessive pricing or pricing pattern having no relationship with the cost of the input not anti-competitive if such a trade practice does not have the effect of preventing, distorting or restricting competition in the market. Increasing prices of drugs per se is therefore not an anti-competitive practice. The new Act maintains this position. This position however may perhaps be reviewed in light of the peculiarity of the pharmaceutical market as discussed in the previous chapters and the fact that consumers are not free to choose the lowest price medicines For instance, say that there is a drug on the market and there are generic substitutes of the same. If the former drug was overpriced, it can be assumed that because of the substitutes there would be no major effect on competition. However given the powerful marketing strategies of large pharmaceutical companies, say that the company marketing the former drug, managed to convince a number of doctors of the superiority of their product and the doctors prescribed accordingly. Although market statistics would not indicate that the pricing was affecting the market in any way, the manufacturers of the former drug would be in a monopoly position with respect to those patients whose doctors they had successfully influenced. This is how increased pricing can have anti-competitive effects even if such effects are not overtly apparent.

Another point to consider is why a company would overprice its products when there is fair

and free competition, given that it would only lose business. Were factors such as the patent status of the drugs concerned, market share of the drug in question in context of the relevant therapeutic segment, the existence of a sufficient number of generic substitutes, considered at all? It is of course difficult to ascertain these questions from the judgment. In case the DG cannot establish a case satisfactorily, is a summary dismissal the extent to which the Commission will deign to act in the matter?

*See generally:* Director General (I&R) versus Stangen Pharmaceutical Ltd. [2005 CTJ 82 (MRTP)] and also Director general (I & R) v. Jagson Pal Pharma Ltd. [2002 CTJ 151 (MRTP)]

Whether it would be correct to consider that this silence is intentional and designed to make it easier for the Competition Commission to deal with IPR related anti-competitive practices in the particular areas of dominance abuse and combinations is a question to be considered. However, there is enough justification to empower the competition authority to grant compulsory licence or take any other appropriate action in case of abuse of IPR right through explicit provisions.

While Section 4 of the Act prevents an enterprise from abusing its dominant position by imposing unfair or discriminatory conditions of purchase or pricing, an exception clarifies that if such practices are adopted “to meet competition”, they will not qualify as abuse. The significant fallout of this is that a dominant enterprise will not be subjected to unfair disadvantage while competing with smaller enterprises.<sup>117</sup> Where does one draw the line though, when deciding what is meant by meeting the competition? The exception allows for a broad defence and may be used as a loophole by enterprises strategising to drive out competition. In the pharmaceutical sector and the health care system, because of the entire access to health issue, this is a matter of special concern.

The Act enumerates several factors to be taken into account while ascertaining whether a firm enjoys a dominant position. One such criterion reads as follows: “Relative advantage, by way of contribution to the economic development, by the enterprise enjoying a dominant position having or likely to have an appreciable adverse effect on competition”. A similar criterion is listed for the purpose of determining whether a merger or acquisition would have an adverse effect on competition.<sup>118</sup> These clauses are pointless and may even be potentially dangerous.<sup>119</sup>

<sup>117</sup> Hemant Sahai and Srinivas Parthasarathy,, *Breathing Space*, The Economic Times, January 18<sup>th</sup>, 2003

<sup>118</sup> Section 19 (4)(l) and Section 20(4)(m), The Competition Act, 2002

The very concept of economic development is questionable because of the inherent difficulty of interpretation. For instance, say a merged entity in the pharmaceutical sector will serve to make our industry more competitive globally and lead to growth in exports. However, the merger may also give rise to serious competition concerns and access to health issue. Its positive and negative repercussions are linked intrinsically to core development concerns. Which then would take precedence over the other and on what criteria would this be decided?

These clauses allow the competition authority, perhaps influenced by the government for whom promoting FDI will be an important consideration, to condone anti-competitive activities by large corporations that purport to be promoting development. Also the wording of the criterion is so broad and lacking in any specificity that it remains open to varying interpretations, based on the subjective understanding of ‘development’, which leads to unnecessary uncertainty in the law.<sup>120</sup>

The aforementioned issues need to be addressed to strengthen the law against abuse of dominance and facilitate thereby the effective restraint or elimination of this kind of practice in the pharmaceutical sector and the health delivery system.

#### *Mergers And Acquisitions:*

The main provisions dealing with mergers and acquisitions are as follows:

- Section 5, which deals with what is denoted by a combination of enterprises and persons, delineating the specific circumstances as per which the acquisition of one or more enterprises by one or more persons or acquiring of control or merger or amalgamation of enterprise
- Section 6, which provides for regulation of combinations.
- Section 20 which concerns inquiry into combinations
- Section 28, which allows for division of enterprises enjoying dominant position.
- Section 29 and Section 30, which lays down the procedure for investigation of combinations
- Section 31, which enumerates the orders of the Commission on certain combinations

The Act provides for merger review beyond a threshold level. As the threshold level is reasonably high, only big deals will come under the scrutiny of the competition

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<sup>119</sup> Supra n. 115.

<sup>120</sup> Ibid

authority. Prior to the new Act, an acquisition or merger that involved a group of companies whose combined turnover exceeded the specified amounts would be a combination. At present, however, only the turnover of the group to which the enterprise would belong to after the completion of the acquisition or merger determines whether the resultant entity is a ‘combination’ or not. The new position appears more in tune with the corporate economic reality and allows for strategic planning.<sup>121</sup>

Regulation of combination is a soft regime under the Act. Merger notification is voluntary<sup>122</sup>, a result probably of the inevitable compromises which are required to be made in creating new legislation. By contrast, most countries favour a compulsory notification regime.

One matter which is giving rise to some anxiety in our domestic pharmaceutical industry, especially in light of the recent spate of mergers and acquisitions is that as the threshold level for regulation is quite high, the Indian industry may become an easy target for MNCs for acquisition. Only those companies with assets more than Rs.1000 crore or a turnover of over Rs.3000 crore would come under the regulatory provision when they either singularly or in combination go for acquisition. Only 100 of the 6000 Indian companies were beyond this threshold limit and the new provisions do not prohibit size of investment.<sup>123</sup>

There is a concern that the Commission may have lack of experience to evaluate mergers. But the Act provides for this by empowering the Commission to draw upon the knowledge of external experts.

**Box 4.3: Incapacity cripples Law**

At the time of the merger of Glaxo Laboratories Pakistan Limited, and Wellcome Pakistan Limited, the Pakistani Monopoly Control Authority (MCA) took initiative to investigate. But the MCA failed to take any action and the case was abandoned halfway. The reason provided by the MCA for this abandonment, is that calculating market shares of individual products with the identification of their substitutes, as required in the case, was a complicated matter, and the MCA did not have qualified and trained staff for this exercise.

*Source: Pulling Up Our Socks: A Study of Competition Regimes of Seven Developing Countries of*

<sup>121</sup> Supra n. 9

<sup>122</sup> Amitabh Kumar, *Creating a culture of competition*, The Financial Express, January 28<sup>th</sup>, 2005.

<sup>123</sup> *Competition Bill passed*, Times News Network, December 17<sup>th</sup>, 2002

The key element in successfully enforcing these provisions is capacity building of the Commission. Without investigative competence the Commission may not be able to efficaciously deal with the complexities of determining the ostensible and the remote possibilities of the combination having an anti-competitive effect on the market. India did not have any provision for merger review in the MRTP Act since 1991, and hence lacks experience in this area. However, considering that many high profile mergers and acquisitions are taking place in the pharmaceutical industry as has been discussed in the previous chapter, it is essential that the Commission does all that it can to overcome this lack of experience and engage in efficient review.

### ***The Functional Aspect of Competition Law***

#### *Jurisdictional Reach*

One important aspect to consider while deliberating on various dimensions of the competition law is the jurisdictional reach granted. The law has extra-territorial jurisdictional reach with respect to anti-competitive agreements, abuse of dominance and combinations (both cross-border and wholly beyond borders) and any other matter or practice or action arising out of such an agreement, dominant position or combination outside India, but having an effect on competition in India. This empowerment has been conferred by the effects doctrine, which has been given expression in section 32 of the Act. The framing of Section 32 gives rise to a contentious issue. The provision ends with empowering the CCI to enquire into an alleged anti-competitive agreement or practice but does not mention explicitly the option to pass an order if such is deemed appropriate in keeping with this Act. This silence is rather inexplicable given that the power to pass orders in domestic matters has been stated clearly in the Act. Of course, it could be interpreted that the power to pass an order is implied, but in matters concerning extra-territorial jurisdiction, it is better not to leave such a crucial area of the legislation unclear.

Given that India's strength lies in its generic markets and that an onslaught of generic competition from China is expected, to just cite one relevant example, matters such as predatory pricing, dumping and injunctions against imports in relation to the powers of the CCI, assume importance. Relevant case law has been taken up which remain

germane to our understanding of the aforementioned matters despite the case being decided under the MRTP Act and not the Competition Act, 2002 which is the principal focus of this study.

In the case of AMAI (Alkali Manufacturers' Association of India) and ANSAC (American Natural Soda Ash Corporation), the MRTP issued orders, which effectively resulted in injunctions against imports. The Supreme Court, however, in its judgment in *Haridas Exports v. All India Float Glass Manufacturers' Association*, which subsumed the ANSAC vs. AMAI case, set aside both the injunctions on the ground that the MRTP Commission lacked jurisdiction. Now the CCI is empowered by law to impose injunctions against imports<sup>124</sup> and therefore there has been a substantial change rendered with respect to this particular matter.<sup>125</sup>

One aspect of this case, which is vital in the context of today, is its reflections on predatory pricing and anti-dumping. In the float glass case, where the question of predatory pricing was central, the importers had contended that the complaint was essentially one of 'dumping' of exports for which there was a specific remedy under the anti-dumping provisions of the Customs Tariff Act. The MRTPC, therefore, had no jurisdiction. The other side contended that the anti-dumping laws did not implicitly repeal the relevant provisions of the MRTPA, to which the SC agreed. Therefore, it was decided that no conflict of jurisdiction as such existed between the MRTPC and the anti-dumping authority.<sup>126</sup> As a sidebar, it may be mentioned here that it is easier to prove anti-dumping cases than predatory pricing and most cases in such situations would probably take recourse to anti-dumping law.

To return now to the present competition authorities being enabled to impose injunctions against imports, the stoppage of imports could be a remedy that strangles competition as such action translates into one less competitor in the market.<sup>127</sup> It may also clash with the WTO commitments and that the provision in question may just be invoked by domestic manufacturers who fear competition from efficient rivals. But

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<sup>124</sup> See Section 33 of the Competition Act 2002.

<sup>125</sup> Aditya Bhattacharjea, *India's Competition Policy: An Assessment*, Economic and Political Weekly, August 23<sup>rd</sup>, 2003

<sup>126</sup> Ibid

<sup>127</sup> Supra n. 126

given that the competition authorities would not pass such an order without heeding the consequences, it does not seem that having such a provision itself would lead to any harm. It would simply have limited applicability.

### *Inter-Agency Linkages*

Another important aspect of the functioning of competition authorities is the linkages they have with other statutory authorities. Section 21 of the Competition Act is vital in this respect, being perhaps the only explicit mention of cross-linkages with other agencies in the Act. This provision provides that when a party objects that any decision which a statutory authority has taken or proposes to take, is or would be, contrary to any of the provisions of the Act, then such statutory authority may make a reference in respect of such issue to the Competition Commission, who after hearing the parties shall give its opinion to such statutory authority which shall thereafter pass such order as it deems fit. An amendment to this section proposed in The Competition (Amendment) Bill, 2005 proposes that this provision shall additionally provide that any statutory authority may *suo moto* also make such a reference to the Commission, without any party before it asking for such a reference.

While this provision is commendable that it establishes a firm connection between agencies, it does not settle the question of precedence and is actually of little use because after all what weight does a reference carry? It may be completely ignored. Competition issues are complex and matters having a substantive competition content, even if comes under the jurisdiction of the Drug Controller or the NPPA or the Patent agency (speaking here only of those statutory authorities which are relevant to the pharmaceutical industry and the health delivery system), should be referred to the Competition Agency whose decision or opinion on competition related issues, for instance say excessive pricing due to abuse of monopoly by the patent holder, should be held binding.

#### **Box 4.4: Jurisdictional Conflict with NPPA?**

In one case<sup>128</sup> before the MRTP a particular company was accused of increasing the prices of its products, namely, Dygiene Tablets, Dygiene Syrup, Cremaffin and Eptoin by 120 percent, 70 percent, 45 percent and 86 percent respectively. The case as such will not be reviewed here, merely a portion of the order shall be highlighted for its relevance to the issue being discussed.

<sup>128</sup> Director General (I & R) v. Knoll Pharmaceuticals Ltd. [2001 CTJ 250 (MRTP)]

This case is rather strange in what it indirectly conveys rather than directly says. It mentions twice, for instance, that the company has contended that the matter of fixation of prices and monitoring of prices of drugs is the function of the NPPA and does not fall within the ambit of the Act, if the essential ingredient of impact on competition is missing. A jurisdictional conflict may have been hinted at since the commission did not respond to this argument. But then nothing explicit was said on the matter. The Commissioner never said that since a separate authority had been created for monitoring the retail prices of drugs, the Commission would not go into that question. They simply left the matter of jurisdiction unaddressed. The case was dismissed on grounds of the accused company having negligible market share. Can the matter of fixation of prices and monitoring of drug prices be considered to be solely under the preview of the NPPA if there is no impact on competition issue involved? But mere increase of prices may have anti-competitive effects, whether such effects are apparent in the market or not. In such a case, the expertise of competition authorities may be required.

While considering inter-agency linkages, it may be mentioned that it is commendable that provisions have been made for the Commission to enter into arrangements with foreign agencies, which is vital for dealing with cross-border anti-competitive activities. Such empowerment is especially important since trans-border anti-competitive activities are likely in the pharmaceutical sector with the significant presence of MNCs and also for that matter in the health delivery system, with the opening up of the hospital sector and the growing popularity of medical tourism.

#### *A Wake Up Call - Likely obstacles to Effective Implementation*

- In the implementation process of the Act, in particular reference to the pharmaceutical sector, MNCs with far greater experience in fighting competition cases in countries across the globe, have a decided advantage over their Indian rivals who will have to hire expensive lawyers and consultants to counter them<sup>129</sup>.
- The following has been mentioned before, but needs reiteration. Various sections lay down multifarious criteria, which the Commission has to take into account. These criteria require proficiency in modern industrial economics as well as statistical analyses of the economic conditions of the industry under consideration. It is crucial to build up the capacity of the Commission and its staff. It should be equipped with multi-disciplinary professionals at senior levels. The required skills would be those of lawyers, managers, economists, statisticians, chartered accountants and even people with a police backgrounds to investigate the conspiracy elements of a cartel. The flaws in the Competition Act if combined with inadequate professional and financial resources in the Commission, will lead to vexatious and costly litigation, inconsistent verdicts, legal uncertainty, and possible retaliation by other WTO members. This, at all costs, should be avoided and concrete measures should be taken to avert such a situation.<sup>130</sup>

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<sup>129</sup> Supra n. 115

<sup>130</sup> Ibid

### *The Patent Regime – A TRIPS Specific Overview*

TRIPS will be examined herein from the perspective of its impact on competition, with specific reference to the pharmaceutical sector and the health delivery system. As has been mentioned previously, product patents as introduced by TRIPS unlike process patents, give a complete monopoly to the patent holder, which in turn may possibly give rise to the abuse of such monopolistic position. Therefore, we will consider those provisions of the TRIPS agreement which award exclusive rights to the patent holder, the extent of such rights, and the flexibilities provided such that the law does not circumscribe too severely the access to health issue afflicting millions.

### *Patents and the Pharmaceutical Sector – An Introduction*

It is necessary, however, to note at the outset that the alarm triggered by the new patent regime and the possible impact on the affordability and the accessibility of medicines ought to be defrayed to some extent by the fact that currently over 95 percent drugs produced in India are off patent and even by 2010, 90 per cent of the drugs trade in India will continue to be in generics<sup>131</sup>. Also, every year, up to forty medicines go off patent.<sup>132</sup> It may, therefore, be concluded that most drugs in current usage are not under patent and thus in case of most medicines there can be no abuse of monopoly to deprive the masses of medicine by overpricing.

Why then is TRIPS such an issue? Is the anxiety engendered by TRIPS on the matter of access to health, unwarranted? Not really. Given that there has been cogent evidence revealing a connection between patents and high prices and that there is growing drug resistance, emerging new diseases and endemic poverty in many of the countries, which are signatories to TRIPS, the agreement may well prove to substantially deprive millions of availing new drugs that are both effective and safe.

It may be borne in mind that industry conduct in the past has revealed that it is not just recovery of costs that concern pharmaceutical companies, but profits on a very large scale. Patents by allowing a monopoly position to be created for a drug block out

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<sup>131</sup> Effect of the new patent regime on prices of medicines, Speech delivered by Mr. ZH Charna, Director, OPPI AT THE national Workshop on Patent and Public Health, New Delhi, 2005

<sup>132</sup> Ibid

competition. Market forces, therefore, can play no part in levelling prices. This is unfortunate since the difference in prices that can be brought about by effective competition from generic competitors is striking. It was only when Cipla, a generic company from India, offered to sell the requisite therapy for AIDS patients at US\$350, that the originator company offered to slash prices from more than US\$10,000 to US\$931 and then further to US\$727. Against this price of US\$727 of the originator company, the therapy is now available from Hetero at \$201.<sup>133</sup>

TRIPS can be easily manipulated to engage in anti-competitive practices in the pharmaceutical sector, impacting the health delivery system as well. Even if the patent regime is deemed justifiable, there should be sufficient flexibilities allowed thereunder to stem any access problem arising in the wake of the Agreement. TRIPS does provide such flexibilities, which shall be considered here later.

## **THE COMPETITION DIMENSIONS**

### *Monopoly Rights to the patent holder*

TRIPS provides that patents shall be available ‘for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.’<sup>134</sup> The term of protection at the most minimum is twenty years. The monopoly position awarded to patent holders is with respect to rights, including the making, using, offering for sale, selling or importing of the invention.

Apart from patents, two other TRIPS related concepts relevant to the present context are those of ‘mailbox’ and ‘exclusive marketing rights’. Although countries like India had till January 1, 2005 to introduce full product patents protection for pharmaceuticals and agricultural chemicals, they were required to introduce ‘mailbox’ and ‘EMR’ provisions from January 1, 1995. The first pertains to putting through applications for grant of patents, the first step to attaining a monopoly position and the second concept confers rights akin to those granted by a patent. EMRs are awarded to the patent applicant in the interim period between patent review and actual grant of a patent.

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<sup>133</sup> Supra n. 16

<sup>134</sup> TRIPS Agreement

### *Mailbox*

Mailbox, at a very simplistic level, would denote a facility to receive and hold product patent applications in the fields of pharmaceuticals and agricultural chemicals till the new patent regime is slated to function. The mailbox has in fact been opened in 2005 to the apprehension of generic manufacturers across the country since many Indian generic companies are producing and marketing a number of drug products for which MNCs have filed mailbox applications.

The question of the moment is that if and when a product patent is granted to any mailbox application, what will happen to the generic companies, which may be producing the product at present? Under the Act of 2005, 'enterprises which have made significant investment and were producing and marketing the product concerned prior to January 1, 2005, need not suspend production. They can continue to produce on payment of reasonable royalty to patent holders. It has not been specified, however, what is meant by the term reasonable. Also if there were no agreement in their interpretation of the term reasonable, then who would intervene? Would that be sufficient to invoke a compulsory license in light of existing provisions? All these questions are matters of uncharted territory, such situations not having arisen as yet.

### *Exclusive Marketing Rights*

Exclusive Marketing Rights can be obtained for an application in the mailbox if a patent has been granted in some other WTO member country and the application has not been rejected in the country as not being an invention.

### *The Saving Grace*

TRIPS in its literal interpretation at least, is not focused solely on the profit concerns of drug manufacturers. However, although development provisions have been incorporated in the agreement, it is doubtful, to what extent they are protective of infringements committed in protection of health concerns. Be that as it may, an examination of these provisions is necessary to examine their utility as legal options to deal with anti-competitive practices in the pharmaceutical sector and facilitate access to health.

The preamble of any agreement embodies the philosophy of an agreement. The preamble of TRIPS recognises the underlying public policy objectives of national systems for the protection of intellectual property.

The objective of the agreement delineated in Article 7 stresses that the protection of intellectual property rights should be to the advantage of both producers and users of technological knowledge and in a manner conducive to social and economic welfare. In practice, however, this altruistic aspect of the objective is more a hollow platitude than a guiding principle for countries and pharmaceutical companies. Government and industry conduct in the cases of Brazil, South Africa and Thailand (see box 4.6 and 4.7) stand testament to this.

Article 8 is more specific in articulating a sense of commitment to development and health issues. Article 8 provides that countries may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development. The scope of this provision is seriously curtailed by the proviso that such measures may be undertaken only in harmony with the provisions of the TRIPS Agreement. The provision further provides that appropriate measures may be taken to prevent the abuse of intellectual property rights by rights holders, but such measures must also be in consonance with the Agreement.

Within the scope of TRIPS, the following are the flexibilities, which developing countries can use<sup>135</sup>:

- Exemptions from grant of patents in certain cases;
- Exceptions to product patent rights in certain cases;
- Limited Data Protection;
- Government use in certain case
- Use by non-patentees in certain cases.

The specific provisions for controlling anti-competitive practices in the pharmaceutical sector are embodied in the following sections of TRIPS:

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<sup>135</sup> Supra n 16 at p. 70

Art 40(1): Understanding that licensing practices or conditions relating to intellectual property may restrain competition and may impede transfer of technology.

Art 40 (2): Legislation may provide for licensing practices and conditions in case of abuse of IPRs having an adverse effect on competition in the relevant market, and for control of such practices

Art. 31(k): Voluntary licensing need not be resorted to in case a practice is judicially or administratively determined to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases.

### ***India's Patent law Regime***

There has been reference to the history of India's patent law in the previous chapters. After signing the TRIPS Agreement, the 1970 Act was accordingly revised to achieve compatibility with WTO requirements. The alterations were made in four stages: The Patents (Amendment) Act, 1999, The Patent (Amendment) Act, 2002, the Indian Patent Ordinance of 2004 and the Indian Patent (Amendment) Act, 2005.

The Patents (Amendment) Act, 1999, introduced the mailbox system and set up a system of exclusive market rights (hereafter, EMRs) to be retrospective from January 1, 1995, in conformity with the TRIPS Agreement. The Patent (Amendment) Act, 2002 introduced 64 changes to the Patent Act of 1970, the most important ones of these being the extension of patent term from 14 to 20 years, and the reversal of burden of proof from patent holder to alleged infringer. The final set of changes to make India's patent regime comply with the TRIPS Agreement *in toto* were first contained in the Indian Patent Ordinance of 2004, that has now been replaced by the Indian Patent (Amendments) Act of 2005.<sup>136</sup>

It is expected that the new patent regime may take about two to three years to be fully implemented.

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<sup>136</sup> Supra n 31 at p. 33

### ***The Competition Aspects of the Indian Patent Act***

The 2005 Act introduced product patents in India, invalidating Section 5 of the Indian Patent Act, which granted only process patents for food, medicines and other drug substances. Under the Indian patent law of today, monopoly status is awarded to patent-holders. However, there are a number of provisions in the Act utilizing the flexibilities allowed by TRIPS.

The general principles in our patent law, both applicable to the working of patented products and relevant to our study are as follows:

- Patents do not impede protection of public health (section 83(d))
- Patents granted do not prohibit Governments to take measures to protect public health [Section 83(e)]
- Patents make the benefit of the invention available at reasonable affordable prices [section 83 (g)]

Certain areas of the Act will be particularly examined for their relevance to this study.

#### **Box 4.5: Encouraging generic competition- The Hatch-Waxman Act**

Under the Hatch-Waxman Act, the first generic firm to file an application for a new drug is granted 180 days of marketing exclusivity if the generic firm certifies that its product does not infringe any of the brand-name company's patents on the drug product or if the generic firm challenges the validity of the brand-name company's patent. During this 180-day exclusivity period the US Food and Drug Administration (FDA) may not approve subsequent generic applications for the same drug. The exclusivity provision has provided increased incentives for a generic firm to be the first to file an application to market its product. As the first to file, a generic has the potential to "reap the reward" of being the only generic product in the market for a set period of time. The provision also provides more incentives for companies to challenge patents and develop alternatives to patented drugs. India may well consider incorporating such a provision in her laws, given that it encourages generic competition and India's strength lies in generics.

Two issues may be highlighted with respect to this 180-day exclusivity provision. Firstly, case laws indicate that it may be manipulated to aid in anti-competitive practices, in particular, collusive agreements. Secondly, in a recent judgment, the US Federal Appeals Court has upheld the FDA's decision to allow pharmaceutical companies to launch 'authorized' generics of their patent stripped drugs during the 'exclusivity period' granted to generic companies which have successfully challenged a patent. The marketing of such authorized generics during the exclusivity period would reduce the financial incentive to undertake patent challenges risking significant litigation costs. The ruling obviously gives the MNCs a huge advantage because creating a generic substitute of a drug to which a company owns a patent is a process they may initiate long before the patent on their drug expires. Thus, the generic competitor does not get the privilege of sole marketing that the period provided earlier. As it is, generic companies are facing major pricing pressure in the US market, with prices of generic drugs dropping by about 80-95 percent within days of ending the 180-day exclusivity period.

*Source:* James Mathew, 'Authorised' generics granted permission, Financial Times, June 8<sup>th</sup>, 2005

### *Patentability Criteria*

Art. 27 (1) of TRIPS mandates that patents shall be granted for any inventions provided such invention is new, involves an inventive step, and is capable of industrial application. None of the terms defining the criteria for awarding a patent have been defined. This provides a leeway, which developing countries can use to their advantage. The terms may be interpreted in a manner, which would restrict the number of patents.

In India, this flexibility afforded by the TRIPS Agreement has been utilized. In this context, it is necessary to understand what ‘primary patents’ and ‘secondary patents’ mean. Primary patents are granted to new chemical entities involved in the new drugs. Secondary patents are awarded to new formulations, new combinations and new uses of existing chemical entities. In the USA, both kinds of patents are granted. A recent research report in the USA has found most of the new products provided have no clinical benefits. Given the strong pharmaceutical lobby in that country, this would be no surprise. The grant of secondary patents where there is no therapeutic benefit is unjustifiable on two grounds: Firstly, it delays generic entry and secondly, patents are granted due to the high cost and effort involved in drug development, but mere tweaking of products usually involves neither cost nor effort to an extent which would warrant monopoly rights. Secondary patents are often used as a tool for evergreening patents<sup>137</sup>.

The Patent Amendment Act of 2005 in its delineation of patentability criteria, takes advantage of the broad wording in the analogous provision of the TRIPS Agreement and has excluded salts, esters, polymorphs, particle size, combinations and other derivatives of known substances from patentable products unless they differ significantly in properties with regard to efficacy (Section 3). There is no scope, therefore, under the law for patentees to be granted secondary patents on frivolous grounds and assume an unwarranted monopoly.

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<sup>137</sup> See generally Supra n 16 at p. 71

### *Pre-Grant and Pos- Grant Opposition*

Given that upon grant of patents, there exists a probability of abuse of exclusive rights and that there may be negative implications on public health concerns, a procedure to properly screen patent applications and eliminate the frivolous ones is essential.

The new patent Act 2005 allows for both pre-grant and post-grant opposition. Any interested person can oppose the grant of patents on specified grounds; and finally a patent is granted only after entertaining such opposition. The advantage of such a procedure is that any wrongful claims can be detected before the patent is granted. For example, in the event of a secondary patent application, which is pertaining to an innovation not therapeutically significant, the pre-grant scrutiny can detect such applications for secondary patents and protection can be denied. The inclusion of post-grant opposition ensures an opportunity to deny a patent after its grant in case of initial oversight of grounds for refusal.

Surprisingly, while detailed procedure has been laid out for the hearing and passing of an appropriate order for post-grant opposition, similar procedure for pre-grant opposition has not been specified, the only reference being that rules may be prescribed in this regard. This may lead to unnecessary confusion and is undesirable. It is important to facilitate pre-grant opposition as much as possible since succeeding in post-grant opposition is difficult and involves more costs, direct and indirect.

### *Exceptions to Rights Conferred*

Article 30 of TRIPS embodies an explicit flexibility in allowing for limited exceptions to the exclusive rights conferred by a patent, but its scope is limited by the necessity that the flexibility must not be used in conflict with the normal exploitation of the patent and must not unreasonably prejudice the legitimate interests of the patent owner. Nevertheless, this provision is certainly useful and justifies practices and policies such as parallel imports, the Bolar provision and usage by non-patentees for research purposes. These practices existed in many countries even before TRIPS came into existence. But the heavy conditionality of Article 30 of TRIPS causes legal uncertainty with respect to the extent this provision allows exceptions to patent rights.

Under TRIPS, the use of exceptions by a country can be contested by any other country and in that case the former cannot use it unless the dispute is resolved in its favour.

### *Parallel Imports*

Under Article 28 of TRIPS, the patent owner has the exclusive right to prevent others not only from making, using or selling the invented product or process in the country, but also importing from other countries. This is, however, subject to Article 6 ‘on exhaustion’. What it basically means is that the patent holders in a country cannot legally stop imports of patented products offered for sale in another country. Such imports of patented products without the consent of the patent holder in the importing country are known as parallel imports. This is very important in the pharmaceutical industry because the same patented medicine is often sold at different prices in different countries and hence parallel imports permit a country to shop around for the lowest price. The underlying justification of allowing parallel imports is that since the innovator has been rewarded through the first sale of the product, its patent rights have been exhausted and hence it should have no say over the subsequent resale. Under Article 6 of TRIPS, as clarified by the Doha Declaration [paragraph 5 (d)], each country is ‘free to establish its own regime for such exhaustion without challenge.’<sup>138</sup>

Under the original 1970 Act, importing was not mentioned as an exclusive right. This has been amended to conform to TRIPS. But unlike Article 28 of TRIPS, Section 48 of India’s amended Patents Act provides no qualification about exhaustion of patent rights. Instead another section (107Ab) has been inserted which says that ‘importation of patented products by a person who is duly authorized under the law to produce and sell or distribute the product shall not be considered as an infringement of patent right.’ This permits parallel imports. In case of abuse of monopoly position by patent holders, this practice may be resorted to for facilitating access to medicines.<sup>139</sup>

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<sup>138</sup> Supra n. 16

<sup>139</sup> Ibid

### *Bolar Provision*

The Bolar provision or early working provision is prevalent in the US. In the US, before 1984, generic producers had to conduct their own studies and submit data about the safety and the efficacy of the product. Generic producers hardly had the resources to undertake such consuming and costly studies. Moreover, under the then existing patent law, they could start the process of testing and submitting data to the Food and Drugs Authority only after the patents had expired. These circumstances made generic entry into the market very difficult. The Hatch-Waxman Act was created to resolve both problems. Under the Bolar provision of the patent Act, non-patentees could start using the patented product for regulatory purposes even before the expiration of the patents. Moreover, generic applicants were no longer required to repeat the clinical studies to prove efficacy and safety of the product. They were permitted to rely on the innovator company's safety and efficacy data and could file only an Abbreviated New Drug Application. This speeds up the process considerably.

It is to be noted that in a recent dispute, the WTO has upheld that the Bolar exemption is in conformity with TRIPS.<sup>140</sup>

The amended Patents Act in India provides for Bolar Exemption. Under Section 107(A), use of a patent for development and submission of information for regulatory approval will not be considered as an infringement of the patent right. Thus, in the new patent regime, as innovator companies introduce new drugs in India and enjoy exclusive patent rights, such Bolar provisions can be used to introduce generics immediately after the expiry of patents.

### *Research and Experimentation*

Section 47 of the Patents Act, 1970, which remains unchanged in the Act of 2005 provides that any patented product may be made or used by any person for experimentation or research including the imparting of instructions to pupils. This is a vital provision for strengthening the research base of our own industry, which will strengthen indigenous capacity in the long run. Having a strong domestic industry is

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<sup>140</sup> Prabodh Malhotra, *TRIPS-plus: Free Trade Agreements jeopardizing Public Health in Developing Nations*, Presented at the conference on Enlarged ASEAN: Issues in Trade, Development and Integration, 24-25<sup>th</sup> November, 2005, p. 11.

mandatory for successfully coping with the new patent regime, the increased presence of MNCs in the market and the increased likelihood of anti-competitive practices. Herein lies the importance of this provision.

#### *Data protection and data exclusivity*

Article 39(3) of the TRIPS Agreement places a requirement upon member countries to provide protection to regulatory data under specific circumstances. Data exclusivity, a relatively new form of protection, is one such form of protection and it refers to the protection of pharmaceutical registration files that contain data submitted by pharmaceutical companies to regulatory agencies, such as the US Food and Drug Administration and the European Agency for the Evaluation of Medicinal Products (EMA), for the purposes of obtaining market approval of patented drugs.

Grant of data exclusivity prevents generic companies from using the test data submitted by the original patent holder to regulatory authorities to prove bioequivalence of the generic version of the products. In practice, data exclusivity terms, since they are granted from the date of introduction of a particular product in a given market, may have the effect of extending the monopoly term of the patent holder beyond the term of the patent and delaying the entry of generics. The general practice in the USA is to grant five years of data exclusivity, whereas the EU grants a ten year data exclusivity period.<sup>141</sup>

Assuming hypothetically that a developing country like India granted data exclusivity of five years, this would mean the following in reality. A product for which a patent was granted in 1995 is valid until 2015. But if this product is introduced in the Indian market in 2013, then data exclusivity in Indian law would protect the regulatory data submitted by the company until 2018 (5 years from introduction), thus delaying the entry of generics (and extending the product monopoly) by three more years than the twenty years granted under the patent. Furthermore, a reading of Article 39(3) of the TRIPS Agreement shows that although there is a requirement to provide protection to regulatory data under specific circumstances, it is not necessary that this protection is granted in the form of data exclusivity.<sup>142</sup>

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<sup>141</sup> Supra n 31 at p. 37

<sup>142</sup> Ibid

The provision gives countries the choice to decide upon the form of protection. India has not had a strict regime that protected secrecy of data submitted by pharmaceutical companies to regulatory agencies. Many MNCs hold the view that this has helped the generics industry immensely to reverse engineer and make cheaper versions of drugs. The general practice amongst Indian generic companies has also been to use the data submitted by the original manufacturer to prove bioequivalence. Presently, a committee set up by the Government of India is examining the extent of data protection that should be afforded to the pharmaceuticals industry.<sup>143</sup>

### *Compulsory licensing*

An invaluable tool to deal with anti-competitive practices in the pharmaceutical sectors, which lead to overpricing, is the issuance of compulsory licensing. Although TRIPS does not specifically use the term, ‘compulsory licensing’, the practice may be deemed to be sanctioned by TRIPS, under Article 31 and Article 40, which provide for use without authorization of the patent-holder.

India did provide for compulsory licensing in the 1970 Act and the 2005 Act also allows for compulsory licensing, although substantial alterations have been made. In India, as per the Section 84 of the Patents Act, any time after the expiry of three years from the date of grant of a patent, any person interested may make an application to the Controller on the basis of specified grounds and request for the grant of a compulsory license to work the patented invention. These grounds are as follows:

- That the reasonable requirements of the public with respect to the patented invention have not been satisfied,
- That the patented invention is not available to the public at a reasonably affordable price
- That the patented invention is not worked in the territory of India

Under similar grounds, the Controller, upon request of the Central Government, may endorse a patent with the words “Licences of Rights” (section 88). Such endorsement will enable any person who is interested in working the patented invention in India may require the patentee to grant him a licence for the purpose on such terms as may be mutually agreed upon, notwithstanding that he is already the holder of a licence under the patent. If the parties are unable to agree on the terms of the licence, the Controller can decide the terms on which the licence shall be granted by the patentee. If the Controller is satisfied that that the reasonable requirements of the public with

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<sup>143</sup> Ibid

respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price, even after granting compulsory licence or licence under the endorsement with the words “Licences of Rights”, the patent concerned may even be revoked after two years from the first compulsory licence or the licence under Section 88.

However, in India’s previous product regime, a lot of problems were faced in implementing the provision providing for issuance of compulsory licensing and it is feared that history might just repeat itself.<sup>144</sup>

**Box 4.6: Hazards of Compulsory Licensing**

Despite elaborate provisions relating to compulsory licensing in the Patents and Designs Act, 1911, patent-holders could take advantage of the cumbersome procedure and frustrate the efforts of interested enterprises to get compulsory licences. A government research institute (Haffkine Institute) applied for compulsory licence. In response to the notice, the patent-holder suggested that they were willing to give the licence voluntarily on the basis of royalties to be fixed through negotiations. They demanded an absurdly high rate of 25 percent. As there was no limit on the time taken, it took more than four years to reduce it to 10 percent, which was still higher than the limit of five percent stipulated by the Reserve Bank of India at that time. By that time, the Institute decided to abandon the project (Joint Committee on Patents Bill, 1969, p. 452).

Similarly, Neo-Pharma Industries Ltd sought a licence from Parke Davis to manufacture a drug. But whereas the subsidiary company in India pointed out that the matter was beyond its jurisdiction, the parent company in the US insisted that the Neo-Pharma should first discuss the matter with local subsidiary. It took more than two years to decide as to who would negotiate. At last, when negotiations started with the parent company, they did not formally refuse to grant the licence but simply sat over the proposal. Finally, when a compulsory licence was sought and granted, Parke Davis went to court and obtained a stay order (Joint Committee on Patents Bill, 1966, p. 493).

Source: Sudip Chaudhuri, *The WTO and India’s Pharmaceuticals Industry*, Oxford University Press, New Delhi, 2005, p. 94

In light of all of the above-mentioned flexibilities which may be used to circumvent the product patent regime, one may now legitimately ask then where lies the problem with TRIPS? Access to health appears to be addressed to some extent at least and

remedies for anti-competitive practices are provided. The truth is that these measures while appearing to be the saving grace of the agreement are actually rather limited in scope, given that they are required to be consistent with the provisions of TRIPS. Thus, there can be no infringement of the Agreement even when public health concerns of a nation may legitimately mandate such violation. Also to be considered is the reality of the global power imbalance and that the pro- intellectual property protection countries are the ones with the leverage in the power game.

One major threat to utilising TRIPS flexibilities is the ‘TRIPS Plus’ provisions, which the TNCs and the US Government seek to impose on nations across the world, notably through regional and bilateral trade agreements. These agreements, while legally enforceable are blatantly anti-competitive in effect, by allowing the creation of rigid monopolistic positions in the market with few, if any exceptions, prohibiting many of the flexibilities provided by TRIPS. A number of complex issues come under the TRIPS Plus heading, including conditions under which compulsory licensing is to be allowed and the issue of data exclusivity. The inherent double standards of the agreements are evident in many instances. To cite just one example, data exclusivity clauses in the agreements so actively entered into by the US, do not provide for the Bolar exemption, but the US law does.<sup>145</sup>

All free trade agreements embodying the agenda to set higher IP standards than required by TRIPS, require an extension of the patent term to offset delays caused by host nations’ regulatory authorities in granting marketing rights for new drugs, some agreements additionally call for extensions to compensate for delaying the granting of patents. (For example, US-Australia, US-Bahrain, US-Chile, US-Morocco and US-Singapore).

These conditions delay the introduction of generics in the market. There are agreements, which even facilitate the evergreening of patents. It is to be noted that such requirements are not mandated by TRIPS. Eminent economist Joseph Stiglitz suggests that in all its bilateral agreements, the US is using its economic muscle to

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<sup>144</sup> Supra n. 16

<sup>145</sup> Supra n. 8 at p. 6

help big drug companies protect their products from generic competitors.<sup>146</sup> A further threat to the flexibilities available under TRIPS is now emerging from the agenda pursued by the US within the World Intellectual Property Organisation with the ultimate objective of global patents that would preclude consideration of national circumstances and do away with the need for most national patent offices.<sup>147</sup>

#### **Box 4.7: Never Practice what you Preach**

There are a number of instances that indicate that the flexibilities afforded by TRIPS may well be defeated by a number of factors such as the imposition of TRIPS Plus provisions and the power imbalance in international affairs. A few such instances have been cited below.

It has already been mentioned that in Korea, after Glivec was awarded a patent, it was priced at a level, which put it beyond the reach of most Koreans. Compulsory Licensing could have been a tool for Korea to alter the situation for public welfare. This, however, was not possible. In face of the US threatening a serious trade dispute over drug pricing, the Korean Government, was compelled to reject the application for compulsory license that would override the patent for Glivec in 2002.

Thailand is another country, which forfeited its right to use certain flexibilities in the TRIPS Agreement upon being pressured by the US Government. A report from the Medecins sans Frontieres details the US Government's pressure on Thailand to reduce its use of parallel imports and compulsory licensing. The Thai Government passed a law banning parallel imports in 1992, under threat from the US to limit textile imports. (Parallel imports are allowed again after amendments to the patent law, which came into force in 1999). Although patent law in Thailand provides for compulsory licensing, MSF reports that the Thai government, this time under threat of high tariffs on imports of wood products and jewellery, passed ministerial regulations in 1998 to restrict the use of compulsory licenses.

Bilateral agreement is another method used to restrict nation's ability to take advantage of TRIPS flexibilities. The US agreements with Australia, Jordan, Singapore and Vietnam restrict compulsory licensing to emergency situations. Except the Vietnam and Jordan agreements, all other agreements prevent marketing approval of generics during the patents protection period without the consent of the patent-holder rendering compulsory licensing ineffective in those countries including Australia and Oman. One of the most shocking instances of arm-twisting through the means of bilateral agreements is the IP Agreement between the US and Sri Lanka.

The Sri Lankan agreement limits the issue of compulsory licensing to the three situations specified below:

- if adjudicated violation of competition law occurred
- during existence of a declared emergency
- to enable compliance with national air pollution standards

Two of these situations are such that their inclusion is a mockery of the rationale of providing flexibilities. Firstly, under the current Sri Lankan Competition Law, intellectual property rights is excluded altogether, there can be no adjudication on IP related matters under competition law. The second exception allowed is far too qualified and rigid to have practical use. Not only will an emergency have to be declared, but the CL will have to be issued within the period of emergency. Therefore, a CL may not be issued in anticipation of an emergency such as bird flu.

<sup>146</sup> Supra n. 140

<sup>147</sup> Nitya Nanda, *WIPO Patent Agenda: As if TRIPS was not Enough*, Economic and Political Weekly, September 25<sup>th</sup>, 2005

It would appear from the above that the US is against the practice of issuing compulsory licensing. However, following a curious “Never practice what you preach” philosophy, the US is one of two countries which have used CL the maximum number of times. The US’ own patent regime is far more liberal than what it is trying to impose on developing countries. Under the US law, if the government wants to use a patent, it can do so without negotiating with the patent-holder. The patent-holder can ask for compensation but has no other rights. In addition, the Bahy Dole Act gives the government wide ranging powers to issue CL.

In India, although the new Patent Act does not take advantage of TRIPS flexibilities as comprehensively as it might have, nevertheless, it does incorporate a number of provisions, which may be utilized as safeguards if patent-holders in the pharmaceutical industry abuse their monopoly position. The capacity of the Patent Office in India, and the awareness of patent examiners of issues concerning the interface between patent law and competition law, will play a key role in determining how these provisions in the Patent Amendments Act of 2005 will be interpreted and enforced and how the flexibilities in the Act may be used to deal with anti-competitive practices in the pharmaceutical industry and health delivery system.

#### **Box 4.8: The Brazilian and South African Experience**

In Brazil, the government decided to take measures to facilitate access to drugs in the context of the HIV/AIDS crisis. This includes, for instance, a strong compulsory licensing regime. The US government objected to the requirement that unless it is economically unfeasible, inventors have the duty to manufacture the product in Brazil. A WTO dispute was initiated by the US in February this year but was withdrawn in June. Interestingly, the US specifically indicated that it was not targeting another section relating to national emergencies. The possibility to provide easier compulsory licensing in case of national emergencies is recognized under TRIPS.

Brazil has, however, gone much further and adopted a decree establishing rules concerning the granting of CL in cases of national emergency and public interest. Public interest includes public health, nutrition, the protection of the environment, and elements of primordial importance for technological, social or economic development. This broad coverage will allow issuance of CL in most situations of need. These grounds are not TRIPS compliant *per se*. Nevertheless, they have been incorporated in the nation’s legislation and are even deemed acceptable by the world community. India also faces health emergencies like Brazil and may draw lessons from the Brazilian experience that laws may be redrafted to take into account the needs of the local population.

In South Africa, the 1997 Medicines and Related Substances Control Amendment Act had created much controversy. This amendment was partly a reaction to the severe HIV/AIDS crisis that the country has been facing and the lack of access to drugs because of their unaffordability. One section in particular was deemed very controversial. It authorizes the government to determine to what extent a specific drug patent will apply. This provision was a direct challenge to the pharmaceutical industry, which reacted by moving the courts, but ultimately the petition was dropped in face of strong public opposition. It is unlikely this provision will be challenged again and it has now been accepted. This goes to show that for the benefit of its population, a nation may, in its adherence to TRIPS, avail of some latitude

even beyond flexibilities allowed, if this is imperative for public welfare.

Source: Patents Bill, TRIPS and Right to Health, Economic and Political Weekly, October 27, 2005

### PRICE CONTROL

Many of the anti-competitive practices in the pharmaceutical sector leads to high drug prices as has been seen in Chapter III. One of the most effective options to deal with such anti-competitive practices is drug price control. Drug price control entails a mechanism or a policy that ensures that essential and life saving medicines are available at reasonable prices.<sup>148</sup>

Control over cost of medicines exists in one form or the other 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. In the UK, there exists the pharmaceutical price regulation scheme (PPRS) - a voluntary agreement between UK's Department of Health and the Association of the British Pharmaceutical Industry, in which companies negotiate profit rates from sales of drugs to the National Health Service (NHS). The PPRS regulates profits to a band of 17 to 21 per cent on historic capital or the initial capital used to begin the venture with a 25 per cent variation on either side. Companies are free to set prices, provided the rate of return is within the band. If the profits are higher, the companies have to reduce profits the next year and if the profits are lower, they can raise prices. In France, Italy and Belgium, prices are set in relation to relative cost, prices elsewhere in the EU and the contribution made to national economy.<sup>149</sup>

Globally, drug companies are being forced to reduce the cost of medicines. Pressure is being mounted by Health Insurance Companies, Health Management Organisations (HMOs) and Governments (in countries like the UK and Canada, where the State provides Health Insurance cover) all over Europe and North America. These pressures have become stronger in recent years, with the realisation that spiralling drug costs are

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<sup>148</sup> *What is drug price control system?* Economic Times, September 26<sup>th</sup>, 2005

<sup>149</sup> Supra n. 10

making health insurance cover (whether state funded or privately managed) unsustainable and obstructing access to medicines.<sup>150</sup>

In India, drugs and formulations have been subjected to price control for more than three decades now, though recently there has been a trend towards decontrol. In fact, significant decontrol was introduced in 1995. Drug prices vary from country to country, for a number of reasons, including patent regulations, government controls, purchasing power, currency exchange fluctuations, etc. Due to the price control and patent regime, drug prices fell considerably, in India, and were among the lowest in the world. The main regulatory mechanism, which enforces price control, is the Drug Price Control Order, which is revised periodically.

### *The History of Price Control in India*

Till 1962, the drug industry was bereft of any price control. In 1962, there was Chinese aggression on India and Emergency was declared. The Government feared that, as a result, drug prices might rise. Accordingly, for the first time, under the Defence of India Act, 1915, statutory control was imposed on the prices of drugs and pharmaceuticals, when the Drugs (Display of Prices) Order, 1962, and the Drugs (Control of Prices) Order, 1963, were promulgated. Under the Drugs Prices (Display and Control) Order of 1966, it was made obligatory for the manufacturers to obtain prior approval from the Government, before increasing the prices of any formulation.<sup>151</sup>

In 1970, the Drug Prices Control Order (DPCO) was passed. The DPCO is an order issued by the Government, under Section 3 of the Essential Commodities Act, 1955<sup>152</sup>, empowering it to fix and regulate the prices of essential bulk drugs and their formulations. The order incorporates a list of bulk drugs whose prices are to be controlled, the procedure for fixation and revision of prices, the procedure for implementation, the procedure for recovery of dues, the penalties for contravention, and various other guidelines and directions. The order is subject to the guidelines of

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<sup>150</sup> Ibid

<sup>151</sup> Ibid

<sup>152</sup> The Essential Commodities Act, 1955 was enacted for the control of production, supply, distribution, trade and commerce in certain commodities that were declared essential by the Central

the Drug Policy and supposedly aims to ensure equitable distribution, increased supply, and cheap availability of bulk drugs.<sup>153</sup>

The DPCO, which aims towards the availability of essential drugs at affordable prices, has played a vital role in directing the pharmaceutical industry's fortunes. The DPCO of 1970 effectively put a ceiling on prices of all mass-usage bulk drugs and their formulations. Its primary objective was to protect the interests of consumers, and ensure a restricted but reasonable return to producers. The order was a landmark regulation and has had several implications in shaping the Indian pharmaceuticals industry.<sup>154</sup>

#### *DPCO, 1970*

The DPCO was first passed in 1970 and then revised in 1979, 1987 and 1995. In its introductory form, DPCO was a direct control on the profitability of a pharmaceutical business, and an indirect control on the prices of pharmaceuticals. It stipulated that a company's pre-tax profit from its pharmaceutical business should not exceed 15 percent of its pharmaceutical sales (net of excise duty and sales tax). In case profits exceeded this sum, the surplus was deposited with the Government. So, a pharmaceutical company had the freedom to decide the prices of its products. Product-wise margins were also flexible, so long as the overall margin did not exceed the stipulated norm. Since individual product prices did not require approval from the Government, bureaucratic hurdles were low.<sup>155</sup>

#### *DPCO, 1979*

In 1974, the Government of India (GOI) appointed a committee under the chairmanship of Rajya Sabha MP, Mr Jaisukhlal Hathi, to inquire into the conditions prevailing in the sphere of pharmaceuticals in the country. The DPCO, 1979 was loosely based on the recommendations of the Hathi committee. The revised DPCO stipulated ceiling prices for controlled categories of bulk drugs and their formulations.

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Government. The Act defines "Essential Commodities" to include drugs since they are considered essential for the health of society.

<sup>153</sup> Supra n 10

<sup>154</sup> Ibid

<sup>155</sup> Ibid

The retail prices of controlled formulations were decided by applying the concept of MAPE (Maximum Allowable Post-manufacturing Expenses).

The pricing formula was: Retail price<sup>156</sup> = (MC+CC+PM+PC) x (1+MAPE/100) + excise duty. MC was the material cost, including cost of bulk drugs/excipients; CC was the conversion cost as per the dosage form; PM was the cost of packing material suitable to dosage form; and PC was the packaging charge calculated in accordance with established costing procedures. The DPCO, 1979 put 370 drugs under price control. These drugs were segregated into three categories, having different MAPE. The most important drugs, including life-saving drugs were put in Category I, which had the least MAPE. Through this DPCO, around 80 percent of the Indian pharmaceutical industry (in value terms) was brought under strict price control. However, 13 TNCs challenged the order and succeeded for some time (see box).<sup>157</sup>

#### **Box 4.9: Drug Price Control in Practice**

Indian consumers were cheated of over Rs.400 crores, which the Supreme Court defined as diabolical profiteering. 13 TNC drug manufacturers, after obtaining a stay on the DPCO, 1979, from our 'convenient' High Courts, had ignored the prices fixed under this. Ultimately, the Government of India had to appeal to the Supreme Court, which upheld the validity of its action and directed the Government to assess and recover the amounts.

In its judgement on April 10, 1987, the Supreme Court made a shocking observation. It discovered that Hoechst India Ltd had fraudulently priced Baralgin Ketone, a non-essential drug. While Hoechst had applied for a price level of Rs. 3,500 per kg. The Government, after analysing the cost, fixed it as Rs. 1,810.20 per kg. Before the DPCO, Hoechst was charging a price of Rs. 24,735.38 per kg. But instead of reducing it to Rs. 1,810.20, or even Rs. 3,500, as requested of them, they continued to sell the drug for Rs. 24,735.38, under the protection of the High Court's stay order.

The angered Supreme Court observed:

“We see that the price, of Rs. 24,735 per kg; at which the manufacturer was previously selling the drug, and at which he continues to market the drug to this day because of the quashing of the order fixing the price by the high court; is so unconscionably high, even compared with the price claimed by itself, that it appears to justify the charge that some manufacturers do indulge in 'profiteering'”.

Little money was recovered, and in spite of various parliamentary interventions, the matter languished in our courts. Whatever little that was recovered, was put into the Drug Price Equalisation Fund to subsidise public sector manufacturers.

Source: All About GATT- A Consumers Perspective, CUTS, February 1983

<sup>156</sup> This retail price is different from the Maximum Retail Price (MRP) as applicable to all other packaged goods. While MRP for other goods are inclusive of all taxes, in case of medicines local taxes are not included in MRP.

<sup>157</sup> Supra n. 10

### *DPCO, 1987*

In 1984, the Kelkar Committee released its report, in which it recommended the exclusion of a number of drugs from the purview of price control. Various suggestions were made for determining the criteria for inclusion and exclusion. The DPCO, 1987 was based on the Drug Policy of 1986, and the Kelkar Committee Report. In the DPCO, 1987, the number of bulk drugs under price control was significantly reduced from 370 to 142. In addition, the categories of control were reduced to two, and higher MAPE was provided for each category of controlled drugs (75% and 100% respectively). However, around 75 percent of the pharmaceutical industry was still under price control.<sup>158</sup>

### *The Drug Policy of 1994*

In September 1994, the New Drug Policy was announced. The New Drug Policy liberalised the criteria for selecting bulk drugs and formulations for price control. In addition, industrial licensing was abolished for all bulk drugs. All hindrances to capacity expansions were removed, and it was expected that, as a result, supply would rise, resulting in higher competitive pressures. Foreign investment up to 51 percent was also permitted in the case of all bulk drugs, their intermediates and formulations. FDI above 51 percent could also be considered on a case to case basis. Nevertheless, five bulk drugs; Vitamin B1, Vitamin B2, Folic Acid, Tetracycline and Oxy-tetracycline were reserved for the public sector till 1998.<sup>159</sup>

**Table 4.1: Market share of drugs under the DPCO, 1979–2004**

<b>Year</b>	<b>Number of drugs</b>	<b>Approximate market share (%)</b>
1979	347	80
1987	142	60
1995	74	> 40
2004	38*	20

\* Not yet effective

Source: Prabodh Malhotra and Hans Lofgren, India's pharmaceutical industry: hype or high tech take-off?, Australian Health Review, Vol. 28, No. 3, 2004

<sup>158</sup> Ibid

<sup>159</sup> Ibid

Currently the Drug Price Control Order, 1995 governs the price control regime in India. For the purpose of implementing the provisions of the DPCO, powers of the Government have been vested in National Pharmaceutical Pricing Authority (NPPA).

#### *DPCO, 1995*

Under the DPCO 1995, just 76 drugs are under price control. Of these, two drugs have been removed from price control and as of today, only 74 drugs are under price control in India.

The Pricing of Bulk Drugs: The methodology, through which prices of DPCO-controlled bulk drugs are fixed, is as follows. While fixing the maximum sale price of a bulk drug, the Government has to provide either a post-tax return of 14 percent on net worth, or a return of 22 percent on capital employed.<sup>160</sup> Each company can choose one of the two methods mentioned above as per its own volition. So, the choice of method is company-specific and not product-specific. Based on the chosen method, each company submits to the Government, a detailed working of the prices of various bulk drugs that it requires. The Government subsequently studies the applications made by the major players for every bulk drug and cost audits reports of manufacturers before arriving at the final price. The price so decided will be binding on all manufacturers irrespective of their actual cost of production.<sup>161</sup>

The Pricing of Formulations: The methodology, through which prices of formulations are fixed, is as follows. In the new system, the retail price of a DPCO formulation is fixed equal to  $(MC+CC+PM+PC) \times 2 + \text{excise duty}$ . In order for the Government to decide the price of a controlled formulation, each manufacturer is supposed to submit to the Government, details of material cost, manufacturing process, etc. For imported drugs and formulations, the landed cost, including customs duty and clearing charges, is the benchmark to fix prices. A margin of 50 percent is allowed to the importer to cover the selling and distribution expenses, including interest and profit.<sup>162</sup>

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<sup>160</sup> In respect of a new plant, an IRR of 12% based on long-term marginal costing is allowed and where production is from basic stage, a post-tax return of 18% on net worth or a return of 26% on capital employed is allowed. (See Supra n. 1)

<sup>161</sup> Supra n.10

<sup>162</sup> Ibid

It is also to be noted that this DPCO grants a uniform MAPE (Maximum Allowable Post-manufacturing Expenses) of 100 percent to all controlled formulations.<sup>163</sup>

#### *National Pharmaceutical Pricing Authority*

NPPA is an organization of the Government of India, which was established to fix/revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country under the Drugs (Prices Control) Order, 1995. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

The functioning of the NPPA is crucial to the effectiveness of the DPCO. However, The NPPA is handicapped in its functioning by a lack of a credible database on market price data. Currently, the determination of the prices of bulk drugs are based on cost studies and techno-economic estimates, market price data obtained from reliable sources and import price data from government agencies. It is felt that price fixation should be based on market price data and not cost and techno-economic studies. Since there is no single source of data for actual price related information, the government needs to work towards evolving a credible system.<sup>164</sup>

#### **Box 4.10: Refunding Illegal Excess to the NPPA**

One of the responsibilities of the NPPA is to recover amounts overcharged by manufacturers for the controlled drugs. In one instance, the drug, Carbamezapine 200 mg, a product of Sun Pharmaceuticals, was being sold under the brand name 'Zeptol' and was excessively priced. However, upon receiving a notification issued by the government of India under the Drug (Price Control) Order, 1995 under the Essential Commodities Act, 1955, Sun Pharmaceuticals reduced the price of Zeptol 200 mg and swore in an affidavit stating therein that the excess amount charged over and above the retail price from January, 1997 to 21<sup>st</sup> May, 1997 would be refunded as soon as the NPPA issues the demand notice. [Source: 2003 CTJ 292 (MRTP)]

At present, there is no penalty as such which the NPPA can impose if companies are caught overcharging. Now companies charging more are simply asked to deposit the over-charged amounts with the NPPA. This is set to change, however, with the new Pharmaceutical Pricing Policy.

[Source: Nithya Subramaniam, *Drug Companies may be allowed to fix prices*, *Business Line*, February 26<sup>th</sup>, 2006]

<sup>163</sup> Ibid

<sup>164</sup> KG Narendranath, '*Pharmaceutical companies must realise that they cannot thrive by not having the government as a friend*', Interview with Mr. Arun Kumar, Chairman of NPPA, available at <http://www.pharmabiz.com>

NPPA has initiated steps to overcome the knowledge lag and has assigned a drug codification project to the National Institute of Pharmaceutical Education and Research. Currently, the codification of drugs in the country is not complete as the drugs are covered under the wider term of fine chemicals. NPPA resorts to the ORG-MARG for the retail price data. However, the chairman of the NPPA feels that there should be a parallel way to collect actual market price data that is crucial for price determination.<sup>165</sup>

**Box 4.11: Patented Medicine Prices Review Board (PMPRB) of Canada**

Created in 1987, under the Patent Act, as an independent quasi-judicial tribunal, the PMPRB limits the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure they are not excessive.

As an independent quasi-judicial body, the PMPRB carries out its mandate independently of other organisations, such as Health Canada, which approves drugs for safety and efficacy; and public drug plans, which approve the listing of drugs on their respective formularies for reimbursement purposes.

The PMPRB has a dual role:

**Regulatory:** To protect consumers, and contribute to Canadian health care, by ensuring that prices charged by manufacturers for patented medicines are not excessive.

**Reporting:** To contribute to informed decisions and policy making, by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees.

This agency is unique in the sense that it was set up exclusively to monitor the prices of patented drugs. Besides it also analyses the therapeutic contribution of the patented drugs and documents the pharmaceutical R&D investment in Canada. Though the data provided by this agency are rich, the PMPRB's area of operation is restricted to the patented medicines marketed or distributed under voluntary licenses. It does not regulate the prices of generic drugs and prices charged by wholesalers or retailers. Thus PMPRB regulates the price of each patented product on the first and last month of every year.

The price of a patented product in Canada can at no time exceed the highest price for the same drug in countries such as France, Germany, Italy, Sweden, Switzerland, the UK and the US. Sale of patented drugs accounted for 67 percent of total sales in 2001 as compared to 43 percent in 1990. Of the 933 patented drugs reviewed by this body till 2001, 827 drugs have been within the price guidelines. This may imply that the PMPRB does keep the prices of patented drugs under control. Lexchin (1997) observes that the prices of drugs, which had voluntarily surrendered patents, were above the prices of patented medicines. Once this was brought to the notice of PMPRB, the rules were changed and now, even if companies voluntarily surrender their patents, such products still come under the scrutiny of PMPRB until the expiry of patents.

Canadian regulators have ordered the local subsidiary of US-based ICN Pharmaceuticals to cut the price of its Virazole, anti-infection, drug by almost 90 percent, and pay a C\$1.2mn (US\$876,000) penalty for excessive pricing. It found ICN had sold Virazole at "an excessive price" since January 1994, and ordered the company to reduce the price of a 12-hour dose from C\$1540 to about C\$200. (SAWTEE newsletter, August-December, 1996)

<sup>165</sup> Ibid

The ruling is the first, since the establishment of the Patented Medicine Prices Review Board in 1987, under reforms to extend patent protection on brand-name pharmaceuticals. However, the Board has reached 100 “voluntary” settlements, which it claims have saved consumers about C\$110mn.

Source: Sawtee newsletter, August- December, 1996

### *The National Pharmaceutical Policy of 2002*

The 1995 DPCO is to be succeeded by the National Pharmaceutical Policy of 2002. The National Pharmaceutical Policy of 2002 contains several important policy changes.

The new Indian Pharmaceutical Policy, 2002, has focused on liberalisation by further reducing the number of drugs, subject to price control, and opening up the market to foreign investment. The new Pharmaceutical Policy, 2002, further reduced the number of drugs under price control to just 38. The key features of the Pharmaceutical Policy, 2002 are:

- Reduction in the number of drugs under price control to 28 percent (19% of the market) from 74 drugs (40% of the market) under the 1995 policy.
- A Drug Development Promotion Foundation (DDPF), and a Pharmaceutical Research & Development support Fund (PRDSF), to be established to boost research and development.
- Foreign investment up to 100 percent to be permitted, subject to stipulations laid down from time to time in the industrial policy.
- Abolition of industrial licensing for all bulk drugs, intermediates and formulations.<sup>166</sup>

The implementation of this policy is presently in a state of limbo. Triggered off by a stay on the application of the 2002 Policy within the state of Karnataka by the State High Court, a petition to investigate the validity of the judgment is pending in the Supreme Court. The ultimate implementation date and effectiveness of the policy when implemented will both be determined by the decision of the Supreme Court in this regard.<sup>167</sup> Meanwhile, the government has come out with the Draft National Pharmaceuticals Policy, 2006. But only Part A of the Policy that contains issues other than statutory price control has been put in the public domain. Nothing is known

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<sup>166</sup> Supra n. 31 at p. 24

<sup>167</sup> Ibid.

about the Part B that might be dealing with statutory price control, presumably due to the pending Supreme Court case.

But a close reading of the Pharmaceutical Policy 2002, gives rise to certain questions. Is decontrol to this extent justified? In an attempt to balance protection of industry efficiency and access to health, is such a liberal regime not tilting the scales towards the industry?

It is necessary to examine this issue more closely by considering the arguments for and against price decontrol.

### ***Dismantling the Decontrol Rationale***

#### *The two main contentions*

Two arguments are primarily put forth to justify price decontrol in relation to the pharmaceutical industry.

1. It is asserted that market forces are best suited to stabilise drug prices. The validity of this argument is suspect. Market forces do tend to be a leveller when it comes to prices in other industries, but given the high concentration in different therapeutic segments and the low elasticity of demand in the pharmaceutical sector, market forces are usually not effective in controlling prices. This reality in conjunction with the fact that the welfare implications of industry conduct is far greater for the pharmaceutical sector than most other industries counters the industry's stand that when price control has been abolished in a large number of industries, it is unfair to continue to stifle the pharmaceutical industry with rigorous price control.

Studies and statistics bolster the assertion that market forces do not control drug prices.<sup>168</sup> This would be illustrated by the pricing patterns of different brands in a particular therapeutic segment. In almost all segments, the brand leader for a particular drug is usually one of the most expensive. That costlier products sell well is inevitable given that because a costlier product can spend more on market promotion and incentives to doctors. It may be mentioned here that for prescription drugs such as these the resistance to price increase must come from prescribers, on whose consultation patients are more often than not blindly reliant. Needless to say the price hike is not influencing to any significant extent the choices made by doctors, which is indicative of the need for more stringent regulation of physician's conduct as well.

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<sup>168</sup> Wishvas Rane, *Prices of Prescription Drugs*, Economic and Political Weekly, August 17<sup>th</sup>, 2002

The IDMA holds that the practice of controlling medicine prices in India has become redundant due to growing competition in the industry. It, in fact, cites statistics that intense competition itself has brought down medicine prices by almost 2-3 percent in the last three years as against the general inflationary growth of 3-4 per cent during the same period.<sup>169</sup> The Indian Pharmaceutical Association points out that a study of price movement for the 12 month period ending March 2003 reveals that the prices of many commonly used medicines such as antibiotics (-9%), antidiabetics (-4%), Tuberculostatics (-8%) etc, have declined during the period<sup>170</sup>.

There exists, however, a wide range of statistical data, which contradicts this contention. Prices have been seen to rise steeply after removal of price control.

According to government authorities, price rise in prices of medicines that are under price control is only one percent, whereas drugs that are not under price control have an average price rise of around seven percent in the past decade.<sup>171</sup>

A recent study shows that the prices of many life saving bulk drugs have gone up steeply. Is decontrol to blame, at least to an extent? Statistics appear to support an affirmative response. Below are the prices of twelve essential drugs before the liberal decontrol of DPCO in 1995 and 1998.

**Table 4.2: Impact of Decontrol of Drug Prices**

Name of the drug	For Treatment	Price 1995	1998	Percentage increase
Diazepam	Depression	3.13	9.50	204
Ampicillin	Antibiotic	12.85	23.15	80
Cephalexin	Antibiotic	45.07	113.15	151
Ethambutol	Anti T.B. drugs	5.92	33.00	457
Rifampicin	-do-	24.00	64.00	167
Pirazinamide	-do-	17.01	46.95	176
Lignocaine Hcl	Anaesthetic	4.16	12.40	198
Promethaxine Hcl	Anti Allergic	1.25	3.23	158
Antacid liq.	Gastritis	13.00	23.00	77
Oxyfedrine Hcl	Angina pectoris	10.44	21.41	105
Discopyramide Phospate	Cardiac problems	16.50	50.46	206
Dipyridamole	Anti angina	2.00	4.73	137

Source: D.P. Dubey, *Globalisation and its impact of the Indian Pharmaceutical Industry-* at <http://revolutionarydemocracy.org>

<sup>169</sup> Remove medicine price control: IDMA, December 18<sup>th</sup>, 2004

<sup>170</sup> P.T Jyothi Data, *Fluctuating Drug Prices*, Business Line, August 10<sup>th</sup>, 2004

<sup>171</sup> Supra n. 31 at 61

It may be noted that the above list is indicative. Hundreds of such examples may be given.

Further telling statistics are provided by a comparative study of drug prices between February 1996 and October 1998 which revealed that the price increase for drugs under price control was negligible, while prices for drugs out of control were up by an average 14.94 per cent. Sporidex was up from Rs 54.25 in 1996 to Rs 61.10 in 1998; Digene was up from Rs 16.55 to Rs 27.10; Crocin went up from Rs 3.89 to Rs 5.88. It may well be inferred that medicine prices are expected to increasingly and silently creep up, as against a one-time escalation.<sup>172</sup>

2. The second justification used to support drug price decontrol is that the industry must be made more profitable in order for it to increase investment on R&D and be globally competitive. A successful drug must pay for its own research, as well as the research on the unsuccessful ones, on which the company also risked money. Citing from the insights of a DSF study post-DPCO (1995), the DSF discounts this theory. "In the past, price controls were slashed from 166 drugs to 74. In the last decade, it was diluted to about 30 per cent of the market to spur R&D activity. But R&D investments in the drug industry is still less than 2 per cent of sales,"<sup>173</sup>. Also even with price control, the pharmaceutical industry remains a highly profitable one. The argument that total price decontrol is necessary so as to have funds ready for R&D, does not hold much water, as a Pharmabiz study finds that pharmaceutical industry in India is the second highest profitable only after IT. The study also mentions, "And a hard truth behind this excellent performance is that a major part of these profits came from overcharging of several drugs by large units."<sup>174</sup> This could happen even in a situation of partial decontrol and hence one can imagine what can happen in a regime of total decontrol.

### *Lowest Prices in the World*

There exists an argument that there are many drugs which are not under price control and which are not overpriced. The pharmaceutical industry emphasised time and again that drug prices in India are amongst the lowest in the world. This may no longer be true. Drugs that are still patent protected are much cheaper in India due to India's earlier Patent Act of 1970. Off-patent drugs (which account for 80-85% of current sales in the country) are not necessarily cheaper in India. In fact, generally drug prices are higher in India than those in neighbouring Sri Lanka and Bangladesh. Even more disturbing is the fact that prices of some top selling drugs are higher, in India, than of those in Canada and the UK. This comparison is on the official foreign

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<sup>172</sup> PT Jyothi Datta, *Few Takers for drug cos' claim on prices*, Hindu Business Line, February 11<sup>th</sup>, 2002

<sup>173</sup> Ibid

exchange conversion rate. If one takes the purchasing power parity (PPP), then the disparity is stark.<sup>175</sup>

**Table 4.3: International Cost Comparison of Select Drugs**

Drug	Dose	Canada	UK	India
Amoxicillin	250 mg	1.75	2.59	2.89
Ampicillin	250 mg	1.75	2.42	3.18
Erythromycin	250 mg	1.25	2.87	3.28 - 4.17
Cephalexin	250 mg	3.00	7.74	4.46
Propranolol	40 mg	1.25	0.25	1.39
Atenolol	50 mg	--	2.65	1.29
Prednisolone	10 mg	1.50	1.09	1.32
Paracetamol	500 mg	1.25	0.32	0.49
Haloperidol	0.25 mg	0.13	1.60	0.55
Phenobarbitone	30 mg	0.25	0.28	0.50

*Note:* Single units, tab/cap/vial, has been taken for all drugs. Prices are in Indian Rupees. Conversion rate is \$1=Rs42.52, 1 Canadian dollar = Rs25, 1 Pound = Rs70. Based on the figures available in British Columbia Children's Hospital Formulary, British National Formulary, No.35, March 1998, MIMS India, March 1998

(Source: Nitya Nanda and Amirullah Khan, *Competition Policy for the Pharmaceutical Sector in India*, in "Towards a Functional Competition Policy for India", Pradeep Mehta (ed), Academic Foundation, New Delhi, 2006.)

### ***Plans on the Anvil***

The government plans to step up monitoring of even small price hikes of drugs and pharmaceutical products. Currently, the NPPA seeks explanations from companies on price hikes of over 20 percent in a year. This cap is likely to be brought further down. The Ministry of Chemicals and Fertilizers clarifies that this would be applicable to drugs outside price control.<sup>176</sup>

It is probable that in the Pricing Policy likely to be introduced, there will be different models to regulate prices of different category drugs. For instance, hospital supply medicines will not be subject to price control although some of the selected drugs will be subject to cost-based price control. For the remaining medicines in the essential drug list, the Government is planning to cap the ceiling prices based on the weighted average of the maximum retail price (MRP) of the top three brands in both volume

<sup>174</sup> <http://www.pharmabiz.com/article/detnews.asp?articleid=12357&sectionid=47>

<sup>175</sup> Supra n. 10

<sup>176</sup> Nithya Subramaniam, *Govt to step up monitoring of small hikes in drug prices*, Business Line, January 1<sup>st</sup>, 2006

terms and value terms. Also prices of drugs for cancer and HIV/AIDS will be kept affordable and those for patented drugs will be pre-negotiated.<sup>177</sup>

Under the new Pharmaceutical Pricing Policy, companies may be given greater flexibility in fixing prices. Instead of the NPPA fixing the prices of certain drugs based on the cost of raw materials, the companies may be allowed to do so. However, they would have to file pricing structure with the Authority. The Authority would then choose a few applications for further inspection. Also the government plans to impose stiff penalties on companies apprehending overcharging and the penalties will increase with every offence. The penalties, however, have not yet been finalized. This would be a marked change from the current liberal regime where companies are merely notified to refund illegal excesses.<sup>178</sup>

Another measure the government is considering is to cap trade margins of drugs not under price control. However, the generic industry is concerned about the margin cap. Big generic players such as Cipla, Ranbaxy and Wockhardt have met to work out a strategy. This policy has the triple effect of price control through restraint on trade margins, curbing the anti-competitive practices engaged in by pharmacists and paving of way for generic prescriptions. The last needs some explaining. One of the policy tools, which will be suggested in the next chapter to deal with the prevalent anti-competitive practices in the pharmaceutical sector and the health delivery system, is enforcing generic prescription for select drugs to address the specific problem of pharmaceutical companies giving incentives to doctors. But the core concern underlying this recommendation is that the focus of the pharmaceutical companies will simply shift to pharmacists and they will offer higher trade margins to pharmacists in return for pushing their drug.

The industry argues that this recent arbitrary imposition of ceiling on trade margins would shift the sales from branded generics to branded products and thus give boost to the sales of leading brands. The action would harm small and medium units in sales with no corresponding benefit to the consumer.

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<sup>177</sup> Ibid

<sup>178</sup> Nithya Subramaniam, *Drug Companies may be allowed to fix prices*, Business Line, February 26<sup>th</sup>, 2006

The Government of India has presently constituted Sandhu Committee that is looking to reinforce accessibility of drugs in the post-2005 scenario by re-defining the categories and basis for price control. Whether or not price control is gradually phased out, there are certain lacunae in the present system, which need urgent attention and this is the mandate of the Sandhu Committee. To illustrate two such problems:

The Price Control Order relies mainly on ORG data to assess prices, which takes into account only retail prices. Institutional sales, such as those to hospital segments are completely left out. Therefore, prices of drugs for very important diseases, such as AIDS and cancer, are left out of the scope of the Order, since most of the drug supply in the case of these diseases is institutional and escapes the economic criteria of the Order.<sup>179</sup> The experiences of South Africa and Brazil in the matter of drug prices and AIDS are indicative that this current weakness in the price control regime be addressed at the soonest.

Secondly, the price control mechanism as it operates today, does not effectively control the prices of imported drugs. The practice under the Order for imported drugs had been to allow a margin over “landed” costs (cost of the drug/ API when it lands on Indian territory). This practice has been problematic in the past because it is hard to monitor price collusions between the Indian importer and exporter of the raw materials/drug. Previously, subsidiaries of MNCs operating in India have used this loophole to claim inflated prices for raw materials imported from their parent companies into India. This problem will become much more acute from 2005 onwards, since patented products do not have to be produced locally.<sup>180</sup> Therefore, solutions need to be created to resolve this oversight of the system.

These and many other issues impinge upon the efficacy of the price control regime and it is to be hoped that the Sandhu Committee is successful in designing effective remedies.

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<sup>179</sup> Supra note 31 at p. 61

<sup>180</sup> Ibid

## OPTIONS IN THE HEALTH DELIVERY SYSTEM

The Competition Act, 2002 can obviously be used to redress violations of competition law committed by doctors, hospitals and pharmacists. The discussion on the competition law provisions in this chapter would apply for the most part to the health delivery system as well, apart from those cases where the anti-competitive conduct is unique to the pharmaceutical industry. But while anti-competitive practices are far more prevalent in the pharmaceutical sector than in the health delivery system, the former is much better regulated as well.

Apart from competition law, there is no concrete regulatory mechanism addressing anti-competitive conduct in the health delivery system. Hospitals are virtually ungoverned in this respect. In some states, there are laws that provide for mandatory registration and technical standards for clinical establishments including hospitals, nursing homes or diagnostic centres. However, the coverage is not comprehensive and even, not to mention about proper implementation. With the hospital industry growing as it is, this gap needs to be addressed. However, as of today and as has been seen in Chapter III, breach of competition principles is committed far more by doctors and pharmacists than by hospitals and legal options to control anti-competitive behaviour will be examined in more detail with specific reference to these two components of the health delivery system.

### **Box 4.12: A Case on the Health Delivery System**

Tabre Treatment Clinic is engaged in providing health services and more especially treatment for arthritis. Consumers desirous of using its services were previously required to endorse certain conditions in writing, the most striking of which is, "I ...agree and undertake not to hold TTC liable in any manner whatsoever, whether for refund, damages or otherwise in respect of this contract or the aforesaid treatment. It was held that this requirement tended to impose unjustified costs on the consumer. The practice being prejudicial to public interest, the respondent was directed by the MRTP Commission to cease the practice by deleting the condition in question and desist from repeating the same in the future. [2000 CTJ 1 (MRTP)]

*See generally Tabre treatment Clinics Madras: In re:*

### ***Regulating Prescribing Doctors***

As has been mentioned many times before in this study, for the purchase of most pharmaceuticals, it is not the health consumer who decides which medicines to consume – a prescribing physician typically makes this choice. The pharmaceutical companies spend large sums in an attempt to influence the prescribing practices of

doctors. Collusion (tied selling) with pharmacies or diagnostic centres is another practice, which is common in the medical profession. Taking commissions on referrals is another practice, which may be interpreted as having anti-competitive effects.

**Box 4.13: Regulating Physicians in the US**

The types of conduct within the health care professions that have been deemed anti-competitive over the decades include agreements on price and price-related terms, agreements to obstruct the entry of innovative forms of health care financing and delivery, and restraints on advertising and other forms of solicitation. Since the 1970s, the Commission has had an active law enforcement program targeting anti-competitive practices among physicians and other health care professionals.

Since 2002, the Commission has entered into 17 consent agreements with physicians, their organizations, or their non-physician consultants and agents, settling charges that the respondents have engaged in unfair methods of competition - primarily different forms of price-fixing.

*Source: Improving Healthcare: A Dose of Competition, A Report by the Federal Trade Commission and the Bureau of Justice, 2004*

Apart from competition law, the only other regulation, which may be resorted to as recourse for anti-competitive conduct, is the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (hereafter termed as the Regulation).

This Regulation strongly emphasises the duty aspect of the medical profession and that the prime object of the medical profession is to render service to humanity and that reward or financial gain is a subordinate consideration. Therefore, accepting incentives to promote particular brands would be against the very philosophy of the code of ethics.

There is a prevalent trend of thought, which will be discussed in more detail in the next chapter, which believes that the practice of pharmaceutical companies giving kickbacks to doctors to push their drugs, might be stemmed by making generic prescriptions mandatory at least in case of selected medicines. The Regulation, in fact, mandates that every physician should, as far as possible, prescribe drugs with generic names and that every physician should ensure that there is a rational prescription and use of drugs. There is explicit mention in the Regulation that drugs

prescribed by a physician or brought from the market for a patient should explicitly state the proprietary formulae as well as generic name of the drug.

Referral on the basis of commission has also been addressed by the Regulation, which provides that a physician shall not give, solicit, or receive, any gift or commission in return for the referring or recommending of any patient for treatment. It further provides that a physician shall not directly or indirectly, participate in or be a party to act of division, transference, assignment, subordination, rebating, splitting or refunding of any fee for medical, surgical or other treatment.

The Regulation stresses on the fact that the practices mentioned as unethical or misconduct under its provisions are not exhaustive and that the Council would consider any other practice which may be construed as professional misconduct. Therefore, other anti-competitive practices for instance tied selling, which are not expressly mentioned by the Regulation may still be redressed by the Medical Council. Does a Regulation have the same weight as legislation? What would be the punishment meted out to a practitioner found guilty? The appropriate Medical Council may award such punishment as deemed necessary or may direct the removal altogether or for a specified period, from the register of the name of the delinquent registered practitioner. Deletion from the Register is widely publicized in local press as well as in the publications of different Medical Associations.

But the Regulation has little effect in practice. That its provisions are not implemented in reality is evident from prevalent practices. Doctors tend to mention the brand name of drugs in prescriptions rather than the generic name of drugs. Doctors, of course, are not always motivated by incentives offered by companies. But this system renders it very difficult to identify doctors who are prescribing on the basis of bribes offered by drug companies among other criteria.

Difficulties in implementation will continue in all probability, as the decision-making authority under the Regulation is the Medical Council, which usually chooses to protect the medical fraternity.

A few countries have evolved a regulatory framework to regulate doctors' prescribing practices. Prescription audit is one method to make a post-facto analysis, which creates an incentive for doctors to be careful. Some countries have sought to create financial incentives for doctors to maintain a high level of rationality and cost-effectiveness in their prescribing behaviour. But to effectively control anti-competitive practices in the health delivery system, it is essential that there be more stringent regulation of physicians' conduct.

### ***Regulating Pharmacists***

Again apart from competition law, there is little governance of this component of the health delivery system. As has been seen in the third chapter, collusive behaviour and arm-twisting drug companies into giving higher margins are practices commonly engaged in by pharmacists. As per the provisions of the new Competition Act 2002, however, only trade unions are allowed to engage in collective bargaining. Hence, the activities of the pharmacists' association to extract higher margins would stand illegal. There is a legislation pertaining specifically to pharmacies, namely The Pharmacy Act, 1948. This, however, is not a useful legal option in controlling anti-competitive practices engaged in by pharmacists. The only provision therein which may possibly be used is that a pharmacist stands to be deregistered if found guilty of any infamous conduct in any professional respect.

The MRTPC, however, has been quite active in controlling anti-competitive practices engaged in by pharmacists. Such cases have been previously discussed. (See Box 3.6).

#### **Box 4.13: The Effect of the MRTPC Commission**

In one case, a pharmaceutical company alleged that a pharmacist association had issued oral instructions to its members not to deal with the complainants and to buy or sell medicines to them. In reply the association not only denied the allegations but also issued a circular to its members mentioning that an allegation has been made that there exists a boycott against the company in question, but that the allegation was untrue and to remove all trace of doubt in the matter, the circular was issued to make clear that there was no such boycott and all members were free to deal with the company and the company with them. Upon this the Commission saw no ground to continue proceedings.

Comments: Now it may very well be that this was exactly what happened. But it may have been that that there was an oral boycott and the complaint served the purpose of getting the boycott turned on its head. [2002 CTJ 124 (MRTP)]

In another case, upon initiation of an enquiry by the Commission into the Utkal Chemists and Druggists Association issuing a circular to boycott the products of Lupin Laboratories, the Chemists and Druggists Association informed the Commission that they had resolved the matter with the company and would not repeat such an action in the future. [(1997) 5 CTJ 350 (MRTPC)]

Most countries have separated the role of physicians and pharmacists to ensure that physicians do not have a financial interest in the pharmaceuticals they prescribe. Japan and Korea are exceptions. Japan has a very high rate of pharmaceutical consumption per capita, even taking into account the high average income. Korea is currently in the process of separating the roles of physician and pharmacist. In some countries, the pharmacist also has some degree of control over the drugs actually consumed. For example, one US study found that 77 percent of physicians asked by a pharmacist, to switch prescriptions, consented to do so. In India, the pharmacist-doctor nexus remains strong and it is to the benefit of the consumer that their relationship be monitored.

### ***Regulating Hospitals and Diagnostic Centres***

As noted above hospitals and diagnostic centres often engage in a range of anti-competitive practices. It has also been observed that the types of market failures are so special that it is not possible to tackle them simply by a competition law. Yet, there is no appropriate law to regulate or monitor the functioning of private hospitals, nursing homes and other medical care establishments in the country in relation to requisite level of facilities, space, equipments, doctors and nurses.

There are state level laws in this regard only in a few states like West Bengal, Maharashtra, Tamil Nadu, Andhra Pradesh and Pondichery, while some states like Kerala and Jammu & Kashmir are considering such a law. The Central Government is also considering a legislation called the Clinical Establishments Regulation Act in consultations with the State Governments with the objective of regulating the establishment of private hospitals/clinics and prescribing uniform minimum standards. As of now, however, in most states, any person can open a nursing home or a hospital or a diagnostic laboratory just by obtaining a trade or a municipal license.<sup>181</sup> Most damaging aspect of the situation is that very little is known about these establishments and people are very often cheated.<sup>182</sup>

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<sup>181</sup> Parliament of India, *Hundred and Twenty Sixth Report on the Petition Seeking Legislative Measures Inter Alia to Provide a Regulatory Mechanism for Private Nursing Homes/Clinics and Stringent Penal Provisions For Production/Distribution*,

Even in states where such a law exists, the provisions are quite rudimentary and implementation is quite poor. Moreover, these laws deal with technical regulations only. On economic regulation front, some laws specify only free treatment to a certain percentage of patients. However, there is no effective mechanism to monitor such provisions. The hospitals in the public sector, however, operate under the regulatory mechanism as may be specified by the Central Government or the State Governments concerned. In practice, however, there are several hospitals and health centres run by governments who do not conform to their own standards. Moreover, though the fees charged by government hospitals are quite reasonable and often free or subsidised, they are also prone to anti-competitive practices.

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*etc. of Spurious Medicines*, Committee on Petitions, Rajya Sabha Secretariat, New Delhi, December 2005.

<sup>182</sup> K V Narayana, *Changing Health Care System*, Economic and Political Weekly, March 22-29, 2003, p. 1230-1241