Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement

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1. INTRODUCTION

Concerns on the effect of product patents on the prices of medicines have been acute in many developing countries which, up to the entry into force of the World Trade Organisation (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) in 1995, could and did disallow such patenting in their national patent laws. With TRIPS, all Members of (and those seeking accession to) the WTO, have to make available, with limited exceptions, both product and process patents in every sector, including pharmaceuticals. More specifically, TRIPS provides that all WTO members have to receive product patent applications for pharmaceuticals from the date of establishment of the WTO, i.e. January, 1995.\(^1\) It is important to note that even under the TRIPS regime, patents are to be granted only on applications received from 1995 onwards for new, patentable pharmaceutical inventions. Thus, prices of existing pharmaceuticals already on the market, or even those covered by patent

\(^1\) The maximum time given to developing countries for the formal introduction of product patents is up to the year 2005. However, countries that choose this delayed period have to grant EMRs, which are very similar to product patent rights, to patent applicants for pharmaceuticals (and agricultural chemicals), for a maximum period of five years before the grant or rejection of product patents, upon the fulfilment of certain eligibility conditions.
applications prior to 1994 anywhere in the world,\(^2\) should not be affected, as these markets could continue to be as contestable as before.

India, one of the leading opponents to TRIPS in the Uruguay Round, recently lost WTO disputes with the United States and the European Union on this issue and has now passed the required legislation in March 1998. India now provides, with effect from 1995, a ‘mailbox’ and exclusive marketing rights (EMRs) for eligible pharmaceutical products. The opposition to these provisions of the TRIPS Agreement in India, cutting across political affiliations, stems in the main from the perception that the prices of medicines will rise sharply with the introduction of product patents for pharmaceuticals. The current Indian patent law, the Patents Act 1970, excludes the patenting of pharmaceutical products, allowing only process patents for a grossly inadequate term of just seven years from the date of application. It is this virtual absence of patents in the pharmaceutical sector that is widely credited in India with having created competition in the new pharmaceutical markets and with having brought down prices to amongst the lowest levels in the world.

The question that requires an answer is by how much will the prices of the basket of new, patented pharmaceutical products differ from the existing basket of ‘patentable’\(^3\) pharmaceuticals. Such a comparison is not strictly meaningful as the characteristics of the pharmaceuticals in the two baskets may differ widely. Some use simple inter-country comparisons of the prices of medicines but these can be inaccurate and even deceptive. It would be more meaningful to study\(^4\) the effects of generic entry on prices in patent-expired pharmaceutical markets in India from the year 2015 onwards.\(^5\) Alternatively, it is possible to simulate patent monopoly and identify the key factors on which this price change would depend, based on the current, pre-patent market structures.

The objective of this paper is to first simulate the maximum likely increase in pharmaceutical prices and decrease in welfare in India with the instantaneous introduction of product patents in the existing 22 patentable pharmaceutical markets, using data pertaining to the eve of TRIPS implementation, i.e. 1994.\(^6\) In moving from current competitive conditions in a pre-patent scenario to a monopoly over the specific new chemical entity with the grant of product patents, prices of new pharmaceuticals in the patented segment should, in the standard

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\(^2\) There is a one-year grace period from the date of filing for patents in the home country to filing elsewhere granted under the Paris Convention for the Protection of Industrial Property, 1967. This treaty is now substantively part of TRIPS.

\(^3\) Patentable pharmaceuticals are defined throughout this paper as pharmaceuticals that are on product patents elsewhere where such patents are allowed.

\(^4\) As, for instance, Caves et al. (1991) or Frank and Salkever (1997) did for the US.

\(^5\) TRIPS prescribes a patent term of 20 years from the date of filing (Article 33).

\(^6\) The data used in this study is taken from Operations Research Group (1994), improving upon the methodology first used in Watal (1996). The 22 patentable pharmaceutical markets were identified by Redwood (1994) using the same database.
partial equilibrium exercise, increase with monopoly. The question is, by how much *at most* and upon what factors would this depend? There has been some work on this subject assuming linear demand functions and using inaccurate, macro-level data put out by the US pharmaceutical industry.\(^7\)

This paper improves upon past work, including that done by the author, by using more detailed data on pre-patent market structures, extending the analysis beyond linear demand and analysing to what extent policy measures such as price controls and compulsory licences help in attenuating the adverse effects of patent monopoly. The paper does not attempt to study the possible dynamic benefits of the introduction of effective patent protection for pharmaceutical products in India, such as, for instance, increased domestic R&D and the consequent spin-offs, or the increased benefits from foreign direct investment or transfer of technology.

The rest of this paper is organised in three sections describing, in turn, the effect of the introduction of product patents on prices and welfare losses; the effects of the use of policy options permissible under TRIPS, and the conclusions. The methodology used is briefly described in a technical Appendix.

### 2. CHANGES IN PRICE AND WELFARE WITH PRODUCT PATENTS

The data for 1994 shown in Table 1 confirms the finding in Watal (1996) that patentable pharmaceutical markets in India are already oligopolistic/monopolistic, with the top four firms holding an average of over 75 per cent of the market share. It also shows, amongst other interesting descriptive statistics, that the average share of multinational enterprises (MNEs) in patentable markets was just 18 per cent overall and that, on an average, patentable drugs were introduced in India nine years before patent expiry.\(^8\)

Using the methodology given in the Appendix, Table 2 shows that overall maximum weighted price increase for the entire patentable pharmaceutical segment would be a mean of 26 per cent with linear demand\(^9\) and 242 per cent\(^10\)

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\(^7\) See Watal (1996) and Fink (1998) for a summary of past work.

\(^8\) In half the cases this was 10–12 years before patent expiry. Only in five of the 22 cases was the first introduction by an MNE. It is not clear if there were any important patentable drugs that were not introduced in India during this period, but it is not likely as pharmaceutical technologies are not difficult to copy – precisely why patents are important in this sector.

\(^9\) Lower than the maximum price increase of 67 per cent for India indicated by both Subramanian (1994) and Maskus and Konan (1994) who also assume linearity of demand but assume pre-patent perfect competition and a price elasticity of \(-0.75\).

\(^10\) In the same range as Fink (1998) where, with a constant elasticity demand function, the reported results on price increase are 182 per cent and 225 per cent, under different assumptions, for two important therapeutic sub-groups. Watal (1996) predicted a lower price rise of only 50 per cent with constant elasticity on account of errors in calculation.
### TABLE 1
Characteristics of Patentable Drug Markets In India, 1994

<table>
<thead>
<tr>
<th>Name of the Patentable Drug</th>
<th>Group/Sub-group</th>
<th>European Patent Expiry</th>
<th>Date of Introduction in India</th>
<th>Number of Firms</th>
<th>CR4</th>
<th>CR1</th>
<th>H-Index</th>
<th>MNE Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Cefuroxime sodium</td>
<td>Cephalosporins (injectables)</td>
<td>1994 7/89 3</td>
<td>1.0 0.94 0.9 0.94</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Cefaclor</td>
<td>Cephalosporins, oral solids (o.s.)</td>
<td>1994 6/91 2</td>
<td>1.0 0.57 0.51 0.43</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Netilmicin</td>
<td>All other antibiotics (others)</td>
<td>1995 5/91 1</td>
<td>1.0 1.0 1.0 1.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Albenadazole</td>
<td>Antihelmintics</td>
<td>1995 4/86 15</td>
<td>0.82 0.48 0.28 0.47</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Fluoxetine</td>
<td>Antidepressants, Thymoana</td>
<td>1995 6/90 11</td>
<td>0.77 0.36 0.21 0.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Aciclovir</td>
<td>Antivirals, excluding vaccines</td>
<td>1995 5/88 3</td>
<td>1.0 0.41 0.36 0.41</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 Domperidone</td>
<td>Antiemetics</td>
<td>1995 6/88 8</td>
<td>0.98 0.60 0.40 0.11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 Ranitidine</td>
<td>Antipeptic ulcerants</td>
<td>1997 9/85 30</td>
<td>0.80 0.41 0.23 0.44</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 Cefotaxime sodium</td>
<td>Cephalosporins (injectables)</td>
<td>1997 11/87 12</td>
<td>0.84 0.48 0.28 0.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 Ketorolac</td>
<td>Antipyretics, Non-norcotics, o.s.</td>
<td>1997 4/92 11</td>
<td>0.82 0.40 0.24 0.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 Captopril</td>
<td>Hypotensives, Ace Inhibitors (A.I.)</td>
<td>1997 10/85 3</td>
<td>1.0 0.83 0.71 0.00</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>12 Norfloxacin</td>
<td>Quinolones, o.s.</td>
<td>1998 3/88 24</td>
<td>0.69 0.39 0.18 0.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 Pefloxacin</td>
<td>Quinolones, o.s.</td>
<td>1998 6/91 15</td>
<td>0.84 0.39 0.24 0.02</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14 Ketoconazole</td>
<td>Antifungals, Tablets/injectables</td>
<td>1998 10/86 4</td>
<td>1.0 0.39 0.34 0.39</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15 Famotidine</td>
<td>Antipeptic ulcerants</td>
<td>1999 5/89 29</td>
<td>0.55 0.23 0.09 0.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 Enalpril Maleate</td>
<td>Hypotensives, A.I.</td>
<td>1999 10/89 17</td>
<td>0.84 0.43 0.26 0.15</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>17 Omeprazole</td>
<td>Antipeptic ulcerants</td>
<td>1999 4/91 18</td>
<td>0.73 0.28 0.18 0.06</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>18 Astemizole</td>
<td>Antihistamines, Plain solids</td>
<td>1999 3/88 13</td>
<td>0.75 0.35 0.21 0.12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 Ceftazidime</td>
<td>Cephalosporins (injectables)</td>
<td>2000 4/89 1</td>
<td>1.0 1.0 1.0 1.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 Ciproflaxacin</td>
<td>Quinolones, o.s.</td>
<td>2001 10/89 51</td>
<td>0.60 0.20 0.11 0.07</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 Ofloxacin</td>
<td>Antibiotics, Quinolones, o.s.</td>
<td>2001 4/90 2</td>
<td>1.0 0.50 0.50 0.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22 Roxithromycin</td>
<td>Antibiotics, Macrolides, oral solids</td>
<td>2001 4/92 6</td>
<td>0.94 0.66 0.47 0.15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Weighted average | 27 | 0.76 0.38 0.23 0.18 |
<table>
<thead>
<tr>
<th>Name of the Drug</th>
<th>Group/ Sub-group</th>
<th>D/G</th>
<th>Weighted Average Current Unit Price, Rs.</th>
<th>Weighted Standard Deviation in Prices</th>
<th>Current Profit Margins</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Cefuroxime sodium</td>
<td>Cephalosporins (injectables)</td>
<td>0.06</td>
<td>112.92</td>
<td>3.92</td>
<td>0.2</td>
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<tr>
<td>2 Cefaclor</td>
<td>Cephalosporins, oral solids (o.s.)</td>
<td>0.01</td>
<td>12.62</td>
<td>2.23</td>
<td>0.12</td>
</tr>
<tr>
<td>3 Netilmicin</td>
<td>All other antibiotics (others)</td>
<td>0.20</td>
<td>16.56</td>
<td>–</td>
<td>0.26</td>
</tr>
<tr>
<td>4 Albendazole</td>
<td>Antihelmintics</td>
<td>0.37</td>
<td>7.22</td>
<td>1.46</td>
<td>0.18</td>
</tr>
<tr>
<td>5 Fluoxetine</td>
<td>Antidepressants, Thymoana</td>
<td>0.21</td>
<td>1.98</td>
<td>0.86</td>
<td>0.55</td>
</tr>
<tr>
<td>6 Aciclovir</td>
<td>Antivirals, excluding vaccines</td>
<td>0.78</td>
<td>19.83</td>
<td>3.35</td>
<td>0.12</td>
</tr>
<tr>
<td>7 Domperidone</td>
<td>Antiemetics</td>
<td>0.19</td>
<td>1.40</td>
<td>0.18</td>
<td>0.23</td>
</tr>
<tr>
<td>8 Ranitidine</td>
<td>Antipeptic ulcerants</td>
<td>0.50</td>
<td>1.34</td>
<td>0.19</td>
<td>0.17</td>
</tr>
<tr>
<td>9 Cefotaxime sodium</td>
<td>Cephalosporins (injectables)</td>
<td>0.49</td>
<td>22.87</td>
<td>5.34</td>
<td>0.20</td>
</tr>
<tr>
<td>11 Ketorolac</td>
<td>Antipyretics, Non-norcotics, o.s.</td>
<td>0.07</td>
<td>1.40</td>
<td>0.21</td>
<td>0.46</td>
</tr>
<tr>
<td>11 Captopril</td>
<td>Hypotensives, Ace Inhibitors (A.I.)</td>
<td>0.10</td>
<td>2.66</td>
<td>0.17</td>
<td>0.36</td>
</tr>
<tr>
<td>12 Norfloxacin</td>
<td>Quinolones, o.s.</td>
<td>0.27</td>
<td>3.56</td>
<td>1.46</td>
<td>0.11</td>
</tr>
<tr>
<td>13 Pefloxacin</td>
<td>Quinolones, o.s.</td>
<td>0.14</td>
<td>4.28</td>
<td>1.72</td>
<td>0.13</td>
</tr>
<tr>
<td>14 Ketoconazole</td>
<td>Antifungals, Tablets/injectables</td>
<td>0.24</td>
<td>9.64</td>
<td>0.8</td>
<td>0.20</td>
</tr>
<tr>
<td>15 Famotidine</td>
<td>Antipeptic ulcerants</td>
<td>0.24</td>
<td>1.66</td>
<td>0.48</td>
<td>0.05</td>
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<td>16 Enalpril Maleate</td>
<td>Hypotensives, A.I.</td>
<td>0.61</td>
<td>1.26</td>
<td>0.14</td>
<td>0.21</td>
</tr>
<tr>
<td>17 Omeprazole</td>
<td>Antipeptic ulcerants</td>
<td>0.20</td>
<td>3.41</td>
<td>1.89</td>
<td>0.10</td>
</tr>
<tr>
<td>18 Astemizole</td>
<td>Antihistamines, Plain solids</td>
<td>0.10</td>
<td>1.25</td>
<td>0.13</td>
<td>0.11</td>
</tr>
<tr>
<td>19 Ceftazidime</td>
<td>Cephalosporins (injectables)</td>
<td>0.08</td>
<td>268.20</td>
<td>–</td>
<td>0.52</td>
</tr>
<tr>
<td>20 Ciprofloxacin</td>
<td>Quinolones, o.s.</td>
<td>0.52</td>
<td>7.31</td>
<td>2.72</td>
<td>0.08</td>
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<tr>
<td>21 Ofloxacin</td>
<td>Antibiotics, Quinolones, o.s.</td>
<td>0.03</td>
<td>17.81</td>
<td>0.52</td>
<td>0.25</td>
</tr>
<tr>
<td>22 Roxithromycin</td>
<td>Antibiotics, Macrolides, oral solids</td>
<td>0.18</td>
<td>9.51</td>
<td>1.34</td>
<td>0.25</td>
</tr>
<tr>
<td>Weighted average</td>
<td></td>
<td>0.37</td>
<td>1.62</td>
<td>0.14</td>
<td></td>
</tr>
</tbody>
</table>

Source: Compiled by the author from ORG data except for columns 2 and 4 where source is Redwood (1994). D/G in column 11 is the ratio of the sales of drug to sales of therapeutic group/sub-group.
with constant elasticity of demand. Additional welfare losses in moving from the current largely oligopolistic markets to patent monopoly would be $50 million with linear demand and $141 million with constant-elasticity-type demand function. These sums amount to about three and eight per cent of the total pharmaceutical market respectively. Consumers would lose, in terms of consumers’ surplus, anything between $11 and $67 million at the maximum, depending on the type of demand function assumed.

Calculations available with the author show that price increases are the highest for the product where price elasticity is the least, i.e. for the pharmaceutical, aciclovir, an anti-herpes medicine that has almost no substitutes. Further, there is no change in price (or welfare losses) where a pre-patent monopoly already exists, irrespective of elasticity, as is the case in two of the 22 patentable pharmaceutical markets and there are minimal changes in a third market where pre-patent $H = 0.9$ (see Table 1). However, there are significant differences in the results based on the type of demand function assumed. This is because under linear demand the monopolist moves to a more elastic point on the demand curve, unlike in the constant elasticity case where, by definition, both pre- and post-monopoly elasticity is the same.

<table>
<thead>
<tr>
<th>Demand Function</th>
<th>Weighted Average Price Difference Over Current Prices, % (Range %)</th>
<th>Additional Welfare Loss $ mn. (% Change Over Current)</th>
<th>Monopoly Foreign Profits $ mn. (% Change Over Current)</th>
<th>Additional Consumer Surplus Loss $ mn. (% Change Over Current)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear</td>
<td>26.20 (0 to +33%)</td>
<td>50.46 (+606%)</td>
<td>39.19 (+787%)</td>
<td>11.18 (+334%)</td>
</tr>
<tr>
<td>Constant Elasticity</td>
<td>241.82 (0 to +6400%)</td>
<td>141.06 (+1442%)</td>
<td>66.12 (+1259%)</td>
<td>66.81 (+1475%)</td>
</tr>
</tbody>
</table>

Source: Compiled by the author from ORG data for 1994.

11 Throughout this paper the exchange rate of $1 = Rs. 31.374 in 1994 is used, as taken from International Financial Statistics, International Monetary Fund (May, 1998).

12 These estimates are much lower than the maximum welfare losses predicted for India under the assumption of perfectly competitive pre-patent markets by Nogues (1993) of $3055 million and both Subramanian (1994) and Maskus and Konan (1994) of $1279 million. Even if the additional loss of exports of $18 million is added to national welfare losses, these figures will be $68 million under linear and $159 million under constant elasticity demand functions.

13 No account is taken of losses due to lack of variation in brands as, by assumption, patentable drug markets consist of a perfectly homogeneous product. In practice, the top few firms that hold most of the patentable drug market, whether foreign or Indian, have little difference in quality (see Watal, 1995).
A large proportion of this addition to welfare losses from existing levels of oligopoly consists of pre-tax foreign profits: as high as 78 per cent in the linear case and 47 per cent in the constant elasticity case.\(^\text{14}\) However, the profit margin is higher in the constant elasticity case, increasing from a weighted mean of 0.14 in the pre-patent period to 0.67\(^\text{15}\) in the post-patent period. In the linear case, with higher values of elasticity in the post-patent period, the margin rises to only 0.33. MNEs, which would gain control of the patented segment (by assumption), would collectively profit by an additional $40–66 million per year at the maximum, depending on the type of demand function.\(^\text{16}\) Assuming realistically that most patents are owned by different MNEs, these profits would be shared by, say, 20 MNEs, each earning a maximum of about $2–3 million only in one of the largest developing countries. It may be noted that the costs of R&D for developing a new chemical entity is placed anywhere between $200 and $500 million in the US (CBO, 1998; and BCG, 1996), making R&D for pharmaceuticals relevant only to a few developing countries less likely to take place, even with full TRIPS implementation.

3. POLICY OPTIONS FOR REDUCING WELFARE LOSSES

Given the results of high prices, particularly for patented pharmaceuticals with relatively inelastic demand, it would be interesting to analyse the policy options open to India for reducing welfare losses from the introduction of product patents. Judging by the current political antagonism to the WTO TRIPS Agreement, India is one country where such options are likely to be actively used. This paper examines two options that are widely recommended and are permissible under TRIPS: administered prices or cost-based price controls\(^\text{17}\) and compulsory licences. The third policy option of parallel imports is not explored in this paper.

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\(^\text{14}\) It is assumed in this study that patent owners are 100 per cent foreign-owned entities. As pointed out by an anonymous referee, foreign profits will be lower in the case of joint ventures and high taxes. However, transfer pricing mechanisms could be used by MNEs to counter high marginal tax rates.

\(^\text{15}\) These margins, which range from 50 to 99 per cent, are fairly close to those reported for prescription pharmaceuticals in the US. The *Wall Street Journal* (16 November, 1998) places the gross profit margin for some pharmaceuticals, which includes manufacturing cost but exclude research, promotional and other expenditures, at 90 per cent or even 98 per cent. However, gross and net profit margins *at the industry level* are reported to be 70 per cent and 18 per cent respectively.

\(^\text{16}\) The figures on welfare losses, profits and consumers’ surplus may increase marginally if all dosage forms of the same pharmaceutical in other sub-groups excluded in this study are taken into account.

\(^\text{17}\) Other methods of pharmaceutical price regulation practised in developed countries (see Danzon, 1997) are not analysed here.
as it is not evident that India would find sources for lower priced patented pharmaceuticals and as comparable data was not readily available to test this.

a. Price Controls

India had one of the most extensive regimes of pharmaceutical price controls where until the recent changes in 1995, over 70 per cent of the total pharmaceutical market was under price control (Redwood, 1994, p. 4). Even after the Drugs (Prices Control) Order (DPCO) 1995, 50 per cent of the market is under price control (Lanjouw, 1998). Prices are fixed for each presentation of dosage form and pack size for the bulk drugs selected by the government for price control.18 Under Section 7 of the DPCO 1995 the maximum retail price calculation for a pharmaceutical formulation of the cost-plus method is as follows:

\[
\text{Retail Price} = (MC + CC + PM + PC) \times (1 + MAPE/100) + ED
\]

- MC = Material cost including bulk pharmaceuticals used and allowance for wastage,
- CC = Conversion cost — labour, energy, R&D etc.
- PM and PC = Packing materials and packing charges,
- MAPE = Maximum allowable post-manufacturing expenses, including distribution and retail margins (100 per cent at present19)
- ED = Excise duty

Under the current Drug Policy (1994), a drug is subject to price control if annual turnover in the audited retail market (based on ORG data) is more than Rs. 40 million. A turnover above this minimum revenue level may be exempted if there are at least five bulk producers and at least ten formulators, none with more than 40 per cent of the audited retail market. Any bulk drug with a turnover above Rs. 10 million with a single formulator with 90 per cent or more of the market is also subject to price control. Given this last criterion, all patented pharmaceuticals would be subject to price control, unless they are widely licensed, a highly unlikely scenario20 (see next sub-section below).

---

18 In addition to price ceilings, maximum returns are also fixed at 18 per cent on net worth or 26 per cent on capital employed, where production is from the basic stage. This part of the DPCO has not come into operation as no firm comes close to these limits (Lanjouw, 1998). Since in this study, it is assumed that there is no change in costs, it is assumed that there are no changes in capital employed or net worth.
19 The 1986 Pharmaceutical Policy allowed only 75 per cent for essential pharmaceuticals required under national health programmes listed under Category 1.
20 Although there is a possibility that patent owners may license several small formulating units which are forced to buy the bulk pharmaceutical from them, thus effectively controlling the final sale price while defeating the purpose of the DPCO.
Price control prices are obtained by increasing current marginal cost for each pharmaceutical, 21 by 75 per cent (deducting 25 per cent 22 of the MAPE towards retailers’ margins as we compare wholesale prices). Table 3 shows the results if price controls were to be imposed on the entire patentable pharmaceutical segment, following the criteria laid down by the DPCO 1995, and if such ceiling prices were adopted in lieu of the profit-maximisation prices only when ceiling prices were lower. There would be relatively little relief to consumers in the linear case as such prices are adopted only in four of the 22 pharmaceutical markets. 23 In the constant elasticity case, price ceilings are effective in all 22 pharmaceutical markets. Overall there is a relief of less than one per cent in the linear case and by about 41 per cent over monopoly prices (from the increase over current prices of 242 per cent over current prices) in the constant elasticity case. The range of price reduction under constant elasticity is from 13 to 98 per cent, with just two pharmaceuticals, ciproflaxacin and ranitidine, accounting for over half the overall reduction. Significantly, monopoly profits fall overall only by two per cent relative to patent monopoly in the linear case and by only 13 per cent in the constant elasticity case. Consumers gain a surplus of only one per cent in the linear case but about 54 per cent in the constant elasticity case. There are no losses in any market, and hence availability of patented medicines may not suffer on account of price controls alone.

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<table>
<thead>
<tr>
<th>Demand Function</th>
<th>Weighted Price Difference Over Monopoly prices, % (Range, %)</th>
<th>Change Over Monopoly Welfare Loss $ mn. (%)</th>
<th>Change Over Monopoly Foreign Profits $ mn. (%)</th>
<th>Change in Monopoly Consumers’ Surplus Loss $ mn. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear</td>
<td>(0 to −22%)</td>
<td>−1.06</td>
<td>−0.66</td>
<td>−0.40</td>
</tr>
<tr>
<td>Constant Elasticity</td>
<td>(−13 to −98%)</td>
<td>−44.43</td>
<td>−8.57</td>
<td>−35.86</td>
</tr>
</tbody>
</table>

Source: Calculated by author from ORG data, 1994. Note ceiling prices taken only where these are lower than monopoly profit-maximisation prices, otherwise patent monopoly prices retained.

21 Assuming that this includes material, conversion and packing costs and that R&D costs are zero.
22 Drug Today gives some idea of wholesale and retail prices and a random sampling showed that these generally ranged between 20 and 30 per cent. The margin allowed by each firm seems to depend on whether the brand was established, whether the competition is intense, size of the firm etc. For the purposes of this analysis 25 per cent is taken as a reasonable approximation of retailers’ margins in both pre-patent and patent periods.
23 Interestingly, the Economic Times of 12 November, 1998, reported an inquiry by the Government of India into pharmaceutical companies adopting prices lower than DPCO prices. See www.economictimes.com.

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The point to be noted is that after introducing a patent monopoly, the government of India cannot ensure prices as low as the current prices (i.e. without patent monopoly) even by exercising the option of price controls for all patented pharmaceuticals under the current DPCO with the current MAPE of 100 per cent.

Lanjouw (1998) has briefly outlined the ongoing disputes between the government and the industry on DPCO criteria, outdated data, definition of wastage etc. and points to the general lack of cooperation by industry in the price control exercises. In these circumstances, reduction of MAPE is not a realistic option. In addition, in the case where the drug is not produced domestically and is wholly imported, the c.i.f. price is taken as the initial cost, leading to problems if transfer pricing mechanisms are used by MNEs.

Clearly, a strict price control regime with powers to ascertain costs of production may scare away potential manufacture of patentable pharmaceuticals within the country or even make the availability through imports difficult. The alternative reference pricing method may be ineffective for a developing country with low costs of production and high elasticity of demand, particularly in a world where almost all countries subscribe to the TRIPS regime and therefore have product patents. Even assuming that costs could be correctly ascertained and prices fixed on a cost-plus basis, experience in India in monitoring and enforcing such prices has been notoriously poor (India Today, 1998). Certainly, the costs of establishing and maintaining an effective price control regime over all patented pharmaceuticals may outweigh the benefits.

However, such controls, where effective, do leave consumers better off while leaving patent owners only negligibly worse off. In these circumstances there seems to be a case for selective use of price controls as price decreases (and consumers’ surplus increases) significantly for widely used patentable pharmaceuticals where there are fewer effective therapeutic substitutes. This argument rests on the premise that selective price controls in a small pharmaceutical market like India will not jeopardise the introduction or availability of newer, more efficacious pharmaceuticals in the world or in India, particularly as losses compared to patent monopoly levels are relatively low.

b. Compulsory Licences

Compulsory licences are licences authorised by national authorities to third parties to make, use or sell the patented product for a fixed time period during the life of the patent, even without the consent of the patent owner, upon the payment

24 A more likely scenario as TRIPS now obliges non-discrimination on patent rights between imported and locally produced products.

25 It is for this reason that under the DPCO (1995), in the case of an imported formulation, the maximum price shall be the landed cost plus 50 per cent but this may not be an effective way to counter transfer pricing.
of a reasonable remuneration. The authorities could also issue such an
authorisation to a government department, undertaking or organisation for public
non-commercial purposes. Although the TRIPS Agreement lists out a number of
conditions under which such use could be authorised, these are not as stringent as
they seem, making the issuance of such licences a real possibility permissible
under TRIPS (see Watal, 1998). In developing countries where there is an active,
skilled local pharmaceutical industry, as in India, local companies would be
willing to apply for such compulsory licences, especially where the potential
market is large.

As Scherer (1977) points out there may be no need for compulsory licences if
patent owners voluntarily license their patented products at reasonable rates of
royalty. However, Temin (1979) in documenting the early strategies of
innovating, large US pharmaceutical companies notes their reluctance to licence
their important patents.26 While these firms could theoretically have obtained
monopoly profits through royalty payments, Temin notes that in the
pharmaceutical industry characterised by constant costs and inelastic demand,
the required royalty for such voluntary licences would be very high.

Scherer (1977), however, records that in at least two cases in the UK,
compulsory licensees captured insignificant market shares, despite significantly
lower prices, on account of the reputation and dominant presence of the patent
owner in the market. In India this can be partially offset if compulsory licences
were granted to large Indian companies that have built up a reputation for quality
and timeliness in introducing new pharmaceuticals over the pre-patent period.27

Clearly, the ability to price below the patent owner’s price would depend upon
the royalty rates set by the authorities. According to the TRIPS Agreement,
Article 31, ‘adequate remuneration, taking into account the economic value of
such authorization’ has to be paid to the patent owner. Scherer (1977) shows that
authorities in specific cases in the UK set the royalty in the pharmaceutical sector
at about 18 per cent of sales but in Canada these rates were considerably lower at
ten per cent or more often at four per cent.

The ability to gain market share would also depend upon the timing of entry. In
general, the shorter the market exclusivity period of the innovator drug, the
higher are the chances of the competitor licensee gaining market share. Even in
the absence of product patents in the Indian market, the first-mover-advantage is
significant in gaining market share (Watal, 1995). Therefore, if compulsory
licensing has to be used, early entry for licensees should be ensured, if necessary
by short-circuiting approval procedures.

26 In this paper, the patent owner is equated with the sole licensee, say, a local subsidiary of the
innovator pharmaceutical firm.
27 However, given the resistance by patent owners and the current collaborative arrangements of
large Indian firms with MNEs, many may prefer to keep out of these patented drug markets.
Given the intense opposition by patent owners (and technology exporting countries) to compulsory licences, it is unlikely that such licences are successfully granted in more than one or two patented drug markets. Moreover, granting compulsory licences judiciously to pharmaceuticals that have few or no substitutes in the therapeutic group can be more easily justified under current international law and practice. Going by past experience, market share gained by licensees may be small and royalty payments higher than in the past.

Given this background information, a simple exercise on compulsory licences was done which reveals that the welfare gains from this policy option would depend crucially on the market share gained by the licensee, royalty payments and the elasticity of demand. The following assumptions have been made in the exercise on the effects of compulsory licences on prices and welfare as given in Tables 4A and 4B:

1. One compulsory licence is granted in two pharmaceutical markets, aciclovir and ciproflaxacin, chosen for the reason that the first has the highest price change under patent monopoly and the second is the most profitable pharmaceutical amongst patented pharmaceuticals;
2. There are two alternative scenarios: (i) licensees gain five per cent of the market, pay 20 per cent as royalty and take only ten per cent as profit and (ii) licensees gain ten per cent of the market, pay ten per cent as royalty and take only ten per cent as profit;28
3. Again since changes in market structure are instantaneous, licensees can produce under the same marginal cost conditions; and
4. Licensees set price at marginal cost plus 30 per cent under the first scenario and 20 per cent under the second scenario, forcing patent owners to lower price and profit margins according to the new average market price.

Table 4A shows that there would be a noticeable reduction in prices and in consumer surplus losses from patent monopoly levels in the constant elasticity case only and a significant reduction in welfare losses in both cases, on account of the addition of domestic licensees’ profits. Note that domestic licensees’ profits are larger with a larger market share and would be even larger if a profit margin of more than ten per cent were to be taken with, say, lower royalty payments, or if larger market shares could be taken. In taking these low margins it is presumed here that the national authorities would ensure that the benefit of compulsory licences is passed on to the consumer. Even so, the average market prices, with one compulsory licence, under both market share scenarios, are

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28 We ignore the fact that under the current DPCO these pharmaceutical markets would still fall under price controls as the patent owner has 90 per cent or more of the market. Clearly, prices would fall even more sharply if both options were used in the same drug market.
higher than current pre-patent prices. However, significantly, the welfare gains from just two compulsory licences with an assumption of 10 per cent market share for the licensee could be higher than price controls on all patented pharmaceuticals.

Table 4B shows that the differences between patent monopoly prices and average market prices with compulsory licences, with details of prices set by the licensee and the patent owner. The reduction in average market price from patent monopoly levels is higher under constant elasticity than under linear demand. In both cases this reduction is more significant the higher the market share gained by the licensee. In both cases this reduction is sharper for aciclovir, where demand is relatively less elastic, than for ciprofloxacin.

The low market shares for licensees despite significantly lower prices can occur due to brand goodwill of the patent owner. Caves et al. (1991) and others have observed that patent owners actually increase branded pharmaceutical prices over patent monopoly prices in order to maintain revenue shares after patent expiry in the US market. Similar strategies could be followed in the case of compulsory licences, thus reducing their effect on lowering mean market prices. It would be important for the licensees to enter the market as soon as possible in order to attenuate the effect of the patent owner’s first-mover advantage.

The more important lesson from this simple exercise is that it is possible to achieve comparable levels of price reduction and higher levels of welfare, with possibly lower administrative costs, by using compulsory licences as against price controls. The gains would evidently be higher with more licensees in the same markets or with more drug markets targeted. Clearly, compulsory licences are the superior policy option in attenuating possible adverse effects of patent monopoly as compared to price controls.

Source: Compiled by author from ORG data. Results are shown for two alternative scenarios: (1) licensees gain 5% of the market, pay 20% as royalty and take only 10% as profit and (2) licensees gain 10% of the market, pay 10% as royalty and take only 10% as profit.
<table>
<thead>
<tr>
<th>Demand Name of Pharmaceutical</th>
<th>Monopoly Price</th>
<th>Average CL Price (% Change from Monopoly)</th>
<th>Patent Owner’s Price (% Change from Monopoly)</th>
<th>Licensee’s Price (% Change from Monopoly)</th>
<th>Average CL Price (% Change from Monopoly)</th>
<th>Patent Owner’s Price (% Change from Monopoly)</th>
<th>Licensee’s Price (% Change from Monopoly)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear, Ciproflaxacin</td>
<td>9.73</td>
<td>9.57 (−1.6%)</td>
<td>9.61 (−1.2%)</td>
<td>8.82 (−9.4%)</td>
<td>9.43 (−3%)</td>
<td>9.58 (−1.5%)</td>
<td>8.05 (−17%)</td>
</tr>
<tr>
<td>Linear, Aciclovir</td>
<td>26.11</td>
<td>25.41 (−2.7%)</td>
<td>25.87 (−0.9%)</td>
<td>16.59 (−36%)</td>
<td>24.79 (−5%)</td>
<td>25.84 (−1%)</td>
<td>15.31 (−57%)</td>
</tr>
<tr>
<td>Constant Elasticity Ciproflaxacin</td>
<td>26.21</td>
<td>20.31 (−22.5%)</td>
<td>20.92 (−20%)</td>
<td>8.72 (−67%)</td>
<td>17.21 (−34%)</td>
<td>18.23 (−30.4%)</td>
<td>8.05 (−69%)</td>
</tr>
<tr>
<td>Constant Elasticity Aciclovir</td>
<td>1289</td>
<td>117.18 (−90.9%)</td>
<td>122.47 (−90.5%)</td>
<td>16.59 (−98.7%)</td>
<td>67.84 (−94.7%)</td>
<td>73.68 (−94.3%)</td>
<td>15.31 (−98.8%)</td>
</tr>
</tbody>
</table>

Source: Compiled by author from ORG data. Results are shown for two alternative scenarios: (1) licensees gain 5% of the market, pay 20% as royalty and take only 10% as profit and (2) licensees gain 10% of the market, pay 10% as royalty and take only 10% as profit.
A simulation done, using actual data on the largely oligopolistic, patentable pharmaceutical markets in India on the eve of the application of the WTO TRIPS Agreement, shows that prices are likely to increase and welfare is likely to decrease, in moving from current market structure to patent monopoly. The extent of simulated price increase over the patented pharmaceutical segment differs widely, depending upon the assumption made on demand functions. The maximum weighted mean price increase of 26 per cent for a linear demand function is lower than that shown in past work. However, this price rise could be as high as 242 per cent with a constant-elasticity-type demand function. Similarly, welfare loss changes in moving from current market structures to patent monopoly could be as different as $50 million or $140 million per annum, depending on the demand function. Within each function, price increases depend crucially on the values of demand elasticity at the pre-patent stage and, by assumption, on the availability of credible and effective substitute pharmaceuticals in each therapeutic category. Significantly, simulated changes in pre-patent market structures do not change the results as much as do changes in values of pre-patent elasticity. Even without any a priori knowledge, consumers’ willingness to pay, at least for some life-saving patented medicines, can be assumed to be very high and hence a constant elasticity type of demand function with low price elasticity may not be very unrealistic.

Price controls and compulsory licences can be effective in reducing prices and welfare losses and if used judiciously for pharmaceuticals where there are few or no therapeutic substitutes and/or that are widely used, can be justifiable and acceptable under current international law. The benefits from price controls over the entire patented segment under the current Indian formula, however, are not likely to outweigh the administrative and enforcement costs and there is a strong case for their selective use. Indeed, plausibly lower administrative costs and higher welfare gains make the use of compulsory licences a superior policy instrument as compared with price controls in post-patent India. However, neither of these policy options is likely to result in prices or welfare losses as low as under current pre-patent market structures.

The usefulness of this study, like all such simulation exercises, is limited by the assumptions on which it is based. In particular, the assumptions of Cournot-type oligopolistic behaviour, of arbitrary pegging of values of pre-patent elasticity to a sales ratio of the patentable pharmaceutical to therapeutic group, of the use of the Herfindahl index to predict price and welfare changes, and of ignoring the effects of product differentiation, can be questioned. A model that derives the values of elasticity of demand and substitution more accurately, would arrive at more realistic results. Only empirical studies of price competition
in specific product markets after patent expiry, 20 years from now, would reveal
the accuracy or otherwise of the predictions made with any simulation. Nevertheless, this study makes a contribution to the growing literature on price and welfare changes that can be expected with product patents in the pharmaceutical sector by extending the analysis to different demand conditions and by evaluating policy options available to governments in developing countries like India under the WTO TRIPS Agreement.

APPENDIX

Methodology

In order to simulate the maximum changes in prices, foreign profits and welfare with the introduction of product patents, this study uses the same static, partial equilibrium framework as used in past studies and makes the following assumptions:

1. Each patentable pharmaceutical market consists of a perfectly homogeneous good and all firms in the market face a common, downward-sloping industry demand curve.
2. The hypothetical introduction of product patents instantaneously converts the existing patentable pharmaceutical markets into foreign-owned monopolies, i.e. only one firm, an MNE, operates in the market.
3. There are constant average and marginal costs of production facing each firm. Costs remain unchanged between the pre-patent and post-patent periods.
4. Own (uncompensated) price elasticity of demand of each pharmaceutical depends essentially on the proportion of credible substitutes available for the treatment of the same disease condition, as represented by the ratio of the sales of the patentable drug to the sale of all drugs used to treat a particular disease condition, called the D/G ratio. In this simple model cross-price elasticities are ignored. Finally:
5. Equilibrium in the pre-patent scenario is set by Nash-Cournot behaviour, where each firm in the market believes that the other firms will not alter their quantity sold in response to its own changes in quantity sold.

These assumptions are applied to two distinct demand functions: the constant-elasticity demand function and the linear demand function in such a way as to make the two results comparable. In both cases, it can be shown (Cowling and Waterson, 1976) that at the pre-patent equilibrium, with the above assumptions,
\[ H/e = (p - c)/p, \]

where the Herfindahl index of concentration, \( H = \sum s_i^2 \) is the sum of each firm’s squared market shares in the patentable pharmaceutical market, \( e \) is own price elasticity of demand, \( p \) is the industry price and \( c \) is the weighted industry marginal cost. Using this, the current price-cost margins can be calculated after obtaining \( H \) from the data on market shares and assuming a value for price elasticity. At patent monopoly, in the post-TRIPS period, \( H \) equals unity by definition and hence, with unchanged costs, the new monopoly price with product patents can be found for a pre-determined value of pre-patent price elasticity.

The determination of price elasticity for each patentable pharmaceutical market follows from assumption 4 using the logic that the pharmaceutical with the least substitutes, in terms of D/G, has the lowest demand elasticity and vice versa. The objective is to simulate the maximum price and welfare changes that can be reasonably expected with a changeover to product patents. Given the expectation that drugs with the least elastic demand would show the highest price increases, it was important to assume the lowest pre-patent value of price elasticity possible. The value of 1.0 is chosen as it is the lowest value of pre-patent elasticity at which the results obtained under these two different demand functions would be comparable, since theoretically, a monopolist would not produce at values of elasticity less than unity and this would have caused problems in the constant-elasticity case. The highest D/G (0.78 in 1994) found for aciclovir, an anti-herpes pharmaceutical that has almost no substitutes, is linked to a price elasticity of \(-1.0\). At the upper end of the scale lies the pharmaceutical, cefaclor, a new generation cephalosporin, which has a large number of substitutes in the same group and which has the lowest D/G (0.01 in 1994). The ceiling elasticity for the upper end, where the demand is characterised as elastic, is placed at \(-2.0\). All the remaining 20 patentable pharmaceuticals are pegged according to their D/G ratios to elasticities between \(-1.0\) and \(-2.0\). This maximum can, of course, be extended to higher absolute values of elasticity, resulting in lower price increases and welfare losses.

The analysis is extended to calculate welfare changes, taking the difference between current welfare losses (loss in consumers’ surplus and foreign producers’ surplus) and monopoly welfare losses (loss in consumers’ surplus and the entire producers’ surplus, under assumption 2 of foreign patent monopolies). The results on welfare losses, foreign profits and consumers’ surplus are adjusted by 0.76, the ratio of sales revenue of the most popular dosage form used in the calculations to all dosage forms of the patentable pharmaceuticals, to obtain the total for the entire patented pharmaceuticals segment.

(i) Linear demand function

In the case of the linear demand, the demand function takes the following general form:
\[ p = a - bQ \text{ or inversely,} \\
Q = a/b - p/b. \]

In such a case, elasticity of demand:
\[ e = p/(a - p), \]
\[ a = p(1 + e)/e \text{ and} \]
\[ b = (a - p)/Q. \]

Given that \( H/e = p - c/p \), it follows that:
\[ p = \{H(a + c)\}/1 + H. \]

With data on current prices and quantities, setting \( H = 1 \) at monopoly and leaving \( c \) unchanged, one can obtain the monopoly price and quantity for different values of elasticity:
\[ p^m = \{1(a + c)\}/1 + 1. \]

Note that in the linear case different values of elasticity are generated by the data at monopoly outcome for each patentable pharmaceutical market.

Welfare losses are easy to calculate in the case where demand is linear over the relevant range and the assumptions made earlier hold. It can be shown that in such a case:
\[ W = 1/2(H \Pi_c), \]
where \( W \) is the welfare loss and \( \Pi_c \) is current industry profit. At monopoly, welfare losses are simply:
\[ W_m = 1/2(\Pi_m), \]
or one-half of monopoly profit.

Dixit and Stern (1982) have shown us that, with the assumptions made:
\[ \Pi = (R/e)H, \]
where \( R \) is revenue. Further, that:
\[ \Pi_f = (R/e)\Sigma_f si, \]
where \( \Pi_f \) is profit of foreign firms in the pharmaceutical market and \( \Sigma_f si \) is the sum of the shares of these firms. To the monopoly additional dead-weight losses have to be added the entire profit of MNEs, which is simply \( R/e \) where \( \Sigma_f si = 1 \). The difference in welfare losses is given by the difference between the current total welfare loss and the welfare loss at monopoly.

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(ii) Constant elasticity demand function

In this case it is assumed that the demand function is of the form:

$$Q = Ap^{-e}$$

Or inversely:

$$p = (Q/A)^{-1/e}$$

where $p$ is industry price, $Q$ is quantity demanded and $e$ is own price elasticity of demand. In this case, monopoly price at $H = 1$ is:

$$p^m = c/(1 - 1/e).$$

Welfare losses are also calculated for the same range of elasticity. From the identity:

$$H/e = (p - c)/p,$$

we know that marginal cost:

$$c = p(1 - H/e).$$

This is also the price at perfect competition. Both monopoly and competitive outputs can be obtained by substitution into the relevant demand function and both current and monopoly dead-weight welfare losses can be obtained by integration over the relevant area under the inverse demand function. To the current dead-weight loss has to be added the foreign producers’ surplus. Profit and foreign profit can be estimated by the method given in the above sub-section.

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