

## ‘Efficacy’ Factors under Section 3(d): A ‘Law and Economics’ Perspective

Aditya Kant†

Institute for Law & Economics, Universitat Hamburg, 36 Rothenbaumchaussee, 20148 Hamburg, Germany

Received 26 October 2012, revised 11 March 2013

The undefined status of ‘efficacy’ under Section 3(d) results in a lot of legal uncertainty due to the possibility of its misinterpretation and misapplication. It may have huge social welfare implications. This policy research paper attempts to analyse various aspects of ‘efficacy’ from the ‘law & economics’ perspective. It calls for a reform imperative, i.e. legal-institutional reform and harmonization, not only at the national level but also at the international level.

**Keywords:** Efficacy, law and economics, L&E, pharmaceuticals, patentability, patent eligibility, cost externalization, externality, innovation, welfare gain, efficacy matrix, Pareto, dead weight loss, incentives, Game Theory, Prisoners’ Dilemma, TRIPS, tragedy of the commons, free riding, tragedy of the anti-commons, moral hazard, adverse selection, path dependence, regulatory capture, rent-seeking, market failure

Global pharmaceutical patent battles are being fought on the Indian judicial and politico-economic turfs in recent years. Many of those battles are directly or indirectly linked to the concept of ‘efficacy’, as embodied in Section 3(d) of the Indian Patents Act, 1970, amended by the Indian Patents (Amendment) Act, 2005.

‘Efficacy’ factor represents both - symptom as well as outcome of an imbalanced incentive structure under the extant patent regime. The uncertainty in its definition, scope, use and applicability creates a lot of *ex post* cost, e.g. high post-grant litigation cost. It lowers the validity of the eventually granted patent. It also has an *ex ante* effect because of the huge inefficient and skewed incentive structure that it fosters. The protection accorded to a few stakeholders, while neglecting others, leads to negative expectations and signaling, thereby adversely affecting the innovation-rate.

The almost undefined status of the concept of ‘efficacy’ leaves wide discretion in its application in the hands of the patent authorities/courts, has welfare-reducing effects-misapplication, arbitrariness, legal uncertainty and corruption. This research paper attempts to analyse the ‘efficacy’ aspect from the law and economics (L&E) perspective. As a solution to the problem, the current author has already proposed a mathematical model, in another research paper.<sup>1</sup> It has

been proposed therein that some legal-institutional reforms, especially the application of the current author’s Efficacy Matrix (based on the wider interpretation of the term ‘efficacy’) and threshold/cut-off model for patentability of pharmaceutical products under Section 3(d), shall bring in legal certainty, thereby making it Pareto-superior. Without going into the details of the proposed mathematical model, but relying thereon, the current author attempts to examine the basis and rationale of such a mathematical model, from the law and economics perspective in the current paper.

### Law & Economics of IPR, Patents, Section 3(d) and ‘Efficacy’

#### Some Theoretical Constructs Applicable to Pharmaceutical Patents

It is essential to understand a few concepts, applicable to the pharmaceutical patents.

#### War of Positions & Incentives

The adversarial patenting posturing (North vs South, developed vs developing, nationalism vs multi-nationalism, TRIPS vs TRIPS plus, etc.) can often be understood in terms of the Gramscian concept of ‘war of positions’<sup>2</sup>, which sits well with the economic view that everyone tries to maximize their current position, the unrestricted practice thereof creates inequilibrium / instability. This is true of the current pharmaceutical patenting scene wherein

†Email: aditya@adityakant.com

predatorily skewed incentive-structures prevail. But now, the time has come to balance/harmonize the various stakeholders' interests, whereby there should not be prohibitive disincentives for any stakeholder; otherwise, the negotiation/exchange process will fail. The balanced solution lies in treating pharmaceutical products as neither purely 'private goods', nor purely 'public goods'.

#### **Non-cooperative Bargaining Game**

Applying Schelling<sup>3</sup>, the pharmaceutical patenting negotiation is a case of multi-party non-cooperative (distributive) bargaining game where none of the stakeholders can gain the whole pie, without adversely affecting the others, thereby making it a 'zero-sum' game. Also, since the power to constrain the adversary depends upon the power to bind oneself, a better strategy for anyone is to concede some voluntary but irreversible concessions, in order to get a bargain from the other, if long-term stability is the aim.

#### **Bargaining Model**

Ideally, the First Best World is characterized by the co-operative (efficiency) game, but that is not achievable in reality, which is characterized by the non-cooperative game of the Second Best World. Under Rubinstein' model<sup>4</sup>, a stakeholder can win its share of the pie only at the expense of the other. After bargaining between the two negotiating parties, 1 & 2, a pie can be shared (in terms of perfect equilibrium partitions, PEP) in the following ways:

- (a) Case 1: Fixed bargaining costs ( $c_1$  and  $c_2$ ):
- (i) If  $c_1 > c_2$ , then  $c_2$  is the only PEP
  - (ii) If  $c_1 = c_2$ , then every  $c_1 \leq x \leq c_2$  is a PEP
  - (iii) If  $c_1 < c_2$ , then 1 is the only PEP
- (b) Case 2: Fixed discount factors ( $\delta_1$  and  $\delta_2$ ):
- (i) If  $\delta_1 < 1$  and/or  $\delta_2 < 1$  and
  - (ii) If either  $\delta_1 > 1$  and/or  $\delta_2 > 1$

=>then the only PEP is given by the expression

$$M = \frac{(1 - \delta_2)}{1 - \delta_1 \times \delta_2}$$

In the above model, one can easily substitute USA (representing the North) and India (representing the South) as two bargaining parties in patent negotiation. At present, India is the hotbed of action regarding

'efficacy'-related pharmaceutical patenting issues and there is an ongoing tacit bargaining, currently taking place through the judiciary but soon likely to reach the political arena. Since there is no likelihood of an ideal Pareto-optimal agreement that can satisfy both parties, the real issue is regarding its Pareto-inferiority/Pareto-superiority. Both parties must concede a little to gain a little because having some agreement is better than having no agreement.

Non-cooperative bargaining has its ill-effects, which can be partially mitigated by balancing the stakeholders' incentives. The TRIPS<sup>5</sup> Agreement's *de minimis* standard is its apt example, but this balanced act is now threatened by the following recent trends:

- (1) Attempt at TRIPS plus and
- (2) Trend towards regional/bilateral trade agreements and blocs, e.g. TPP<sup>6</sup> (Trans-Pacific Partnership Agreement).

#### **Two-level Game Theory**

The incentives-balancing has to be simultaneously initiated at two levels – international and national. Here, Putnam's Two-Level General Equilibrium (Interactive) Game Theory and the concept of 'win-sets' become relevant.<sup>7</sup> If there are no sufficient incentives for all the negotiating parties, then the disadvantaged party has an incentive to deviate/defect/withdraw from the bargaining process. Thus, there is a need for incentives-balancing.

#### **Balancing Imperative**

##### **National-Level Balancing**

On the national/domestic level [Putnam's level-II], the government must provide the politico-economic-legal 'nudge' through reforms in the relevant institutions and infrastructure. The current enquiry is restricted to the legal-institutional reforms within the pharmaceutical patenting field wherein the 'efficacy'-factor is pivotal.

##### **International-Level Balancing**

For easy acceptability, it would be better if the international level incentives-harmonization effort is perceived to be spearheaded by an apparently non-partisan entity, instead of by any particular country or bloc.

##### **Prisoners' Dilemma and other Game Theoretic Models**

Although international bargaining is generally marked by a noisy continuous choice Prisoners'

Dilemma (PD) where ‘international co-operation.....(is) maintained by conditioning future co-operation upon past behaviour’<sup>8</sup>, yet this PD with its single Nash equilibrium model fails to explain many instances of co-operation. There are many other game theoretic models<sup>9</sup> [viz. divergent preferences games (battle of sexes game) with its multiple Nash equilibria, in-essential games (zero-sum game and positive sum game)] that can explain different international bargaining situations. They apply to patents bargaining, too.

#### *Reciprocity*

Although Parisi and Gheihold that ‘despite the occasional failure,...reciprocity is a meta-rule in international’ bargaining, yet the ‘reciprocal’ international IPR negotiations are not truly reciprocal, because the parties differ in their relative bargaining strengths. There is not only the ‘specific’ versus ‘diffused’ reciprocity<sup>10</sup>, but also the absence of ‘level-playing field’, which renders it non-reciprocal exchange.

#### *Level-playing Field*

In this North-South bargaining, the concept of ‘level-playing field’ (maxim of equality among equals) assumes importance. North has more bargaining advantages, while South has more bargaining disadvantages and, hence, a fair Pareto-optimal outcome is not a possibility. Unequal bargains provide incentives for *ex post* defection (e.g. Brazil’s threat of TRIPS-defiance for malaria and AIDS drugs<sup>11</sup>) and this applies to the international bargaining over ‘efficacy’ under Section 3(d), too. There is a need to strike a balance between the North’s ‘proprietary’ and BRIC’s ‘access’ interests.<sup>12</sup>

#### *Catching-up Period*

A valid Northern argument is that in order to ensure a level-playing field, the developing countries, including India, were already given some catching-up time before enforcing full TRIPS compliance. Developing countries counter-argue that the given period was not sufficient to bring developing/underdeveloped countries at par with the developed nations in terms of knowledge, resources and power. A balanced approach could be to replace the special and differential (S&D) treatment of developing countries with gradual, step-wise, progressive regulation, rather than the current one-shot transition period system.<sup>13</sup> It will facilitate

level-field bargaining, leading to more stable outcomes, under the Schelling<sup>3</sup> and/or the Rubinstein<sup>4</sup> and/or Putnam’s<sup>7</sup> non-cooperative bargaining games/processes.

#### *International Incentive-Structure Harmonization*

Scotchmer<sup>14</sup> sees an inter-linkage between the (1) domestic, (2) international and (3) truly global incentive mechanisms. The domestic level patent policy is determined by the summation of the maximized benefits of consumers and innovators, but it is influenced by the international-level profit flows because a stronger domestic patent protection leads to increased profit flow to foreigners, while a stronger patent protection abroad leads to increased profit flow to domestic innovators. These profit flows are determined by (1) the domestic market size and (2) the domestic innovative capacity, but they determine the patent bargaining at the international level. Although these profit flows are merely welfare transfers, yet they are important because they influence domestic patent policy. At yet higher level, a truly global patent policy harmonization attempt must take these national-international negotiation dynamics into account. This global harmonization strengthens patent protection<sup>14</sup>, but this increased legalization helps the developing countries more<sup>15</sup>, if they exploit the TRIPS flexibilities, like India has done.<sup>16</sup>

#### *Public-Private Partnership*

Public-private partnership should be encouraged in pharmaceutical research/patenting. But the current international incentive structure is heavily tilted towards privatization because international system allows for spillover transfer to the innovating countries, which discourages public-private partnership.<sup>14</sup> To correct this distorted incentive-structure, the domestic patent policy must step in. The ‘efficacy’ criterion under a reformed Section 3(d) is one way of attempting this incentive re-balancing.

#### **‘Efficacy’ in Actual Operation in India**

‘Efficacy’ holds a pivotal position under Section 3(d). The undefined ‘efficacy’ is a questionable regulatory import from the drug-marketing approval regime into the patent system.<sup>17-19</sup> Efficacy is not definable because (1) no two pharmaceutical products can ever be compared due to the lack of any ‘efficacy’-standard and (2) there can be no ‘efficacy’-standard, as each case is different. This circularity poses challenges. Uncertainty creates externalities – the

government/patent authority abdicates its responsibility of ensuring *ex ante* certainty in law and passes it (i.e. risk-shifting) onto the patentee who has to *ex post* defend its patent from post-grant infringement/invalidity challenges. Had the government ensured *ex ante* certainty through certainty in the efficacy test at the pre-grant stage itself, then this *ex post* externality of huge post-grant litigation costs would have been reduced drastically. The uncertainty creates and inflates transaction costs. In the Coasean<sup>20</sup> world, in the absence of no transaction cost, any property naturally/ultimately goes to the person who values it most, irrespective of the legal regime or the original assignment of property rights. But in the present case, the crucial Coasean pre-condition is distorted. In the presence of huge transaction costs, *ex ante* and *ex post*, the legal regime's nature and the original assignment of property rights become relevant, as they distort the outcome/incentives. This necessitates regulatory intervention.

#### Incentives Analysis

The following analysis examines the economic incentives-structure.

#### Innovation-Productivity Paradox

The massive profits, which piggy-ride on the blockbuster drugs-wave, are history now.<sup>21</sup> The blockbuster introduction-rate has drastically declined in the last decade because of the 'Innovation-Productivity Paradox', now faced by the innovators.<sup>22</sup> It has been shown that the global R&D spending-rate has outpaced the new drug approval-rate. The R&D performance of major innovators is sub-optimal nowadays.<sup>23</sup> The number of NME-approvals by FDA drastically declined from 53 to 29 during 1996-2006 (ref. 22). Only one out of 10,000 candidate substances finally hit the market and only 30 per cent commercialized drugs become profitable where the generated revenue is greater than or equal to the R&D cost.<sup>24</sup> Clearly, there is a 'Blockbuster Imperative'.<sup>22</sup>

#### Exaggerated R&D Costing vs Price Under-cutting

Without venturing into the twin debates regarding (1) the claim of extremely high cost, productivity-gap and attrition rates in pharmaceutical R&D (e.g. Boldrin & Levine<sup>25</sup>, citing the Center for Economic and Policy Research Report<sup>26</sup>), and (2) the deliberate non-disclosure/exaggeration of costs involved, it is fair to assume that there seems to be some truth<sup>27</sup>

behind the claim of high (R&D) cost of new drug-introduction to market. It appears that an erstwhile extremely profitable (cash cow) innovator's market has lately degenerated into a substitution market because of the generics whose massively erosive power-source<sup>28</sup> lies in the absence of any R&D cost for them, as their cost function comprises mainly the production, marketing, administrative and tax-related costs only.

#### Information Problem/Asymmetry

In the international patent bargaining where Buchanan's<sup>29</sup> 'veil of uncertainty' prevails, there are various types/levels of information problems/asymmetries (*ex ante* and/or *ex post*) - big innovators vs smaller generics, primary vs secondary inventors<sup>30</sup>, patent office vs patent applicants, patent office vs public, patents vs petty patents, drug-manufacturers vs public, etc. For instance, Leung *et al.*<sup>31</sup>, found that 'the informationally disadvantaged incumbent always suffers from loss in its real option value of investment since it tends to act more aggressively in competing for the patent. On the other hand, the real option value of investment of the informationally advantaged entrant may be undermined or enhanced. The incumbent's aggressive response under information asymmetry may lead to reversal of winner in the patent race.' This is just one example of how information asymmetry can determine the direction of the pharmaceutical market, through the R&D investment.

Even the patent offices (USPTO, EPO, JPO, IPO) work in a non-transparent and non-public-friendly way. Multitude of information problems result in 'blind policy decisions when implementing patent laws', mainly because the 'modern patent social contract.....disproportionately favours patent holders'.<sup>32</sup> So, howsoever impossible does it seem to achieve an 'informationally efficient market'<sup>33</sup>, it is still worthwhile to attempt at a Pareto-superior rationalization.

#### Tragedy of the Commons and Free-riding

For a Pareto-superior incentives' design, the innovator's exaggerated cost-claims have to be counter-balanced against the generics' unfair advantage and free-riding.<sup>34</sup> Public goods are mostly under-produced and common properties are over-exploited.<sup>35</sup> It reflects the 'tragedy of the commons' and also the free-riding by the generics.

### *Tragedy of the Anti-commons*

This innovators' tragedy involves multi-level multiplicity of smaller/related/secondary/component-level patents, whereby each component acquires the blocking power, if negotiations fail, e.g. gene patenting. As per the National Research Council (NRC)<sup>36</sup>, the practice of granting research tool patents undermines the patent's innovative effect on the drugs itself.<sup>37</sup> Since innovation is often a cumulative process, the 'self-interested use' of even one patent can act as a blocking patent.<sup>38</sup>

While private responses to this blocking problem include some working solutions, viz. licensing, inventing around, ignoring patents, seeking informal research exemption, going offshore, creating public database, challenging patent in courts, etc., the institutional responses include creation of a public or quasi-public database and raising the standard of patentability of patent research tools, etc.<sup>39</sup> These private and institutional responses depend upon the policy levers/instruments availability and the nature of the drug (i.e. clinical profile) involved.

### *Incentive Problem*

Although the presence of a strong patent system indicates more innovative activity and vice versa<sup>40</sup>, yet the (1) high complexity, (2) risk-proneness and (3) less-rewarding nature of the current pharmaceutical industry lessen the incentives for the potential entrants due to the following factors<sup>22</sup>:

- (1) Force 1: Bargaining power of suppliers,
- (2) Force 2: Bargaining power of buyers,
- (3) Force 3: Risk of entry from potential competitors,
- (4) Force 4: Threat of substitute products,
- (5) Force 5: Rivalry among established companies,
- (6) Force 6: Regulators:
  - (a) R&D regulation and product registration
  - (b) Price regulation and national healthcare systems and
  - (c) IPR

Any balanced patent policy must factorize these six forces in, as they affect the bargaining process. The sixth force, regulator, plays a crucial role through three policy instruments– (1) patent laws, (2) drug-marketing approval and (3) drug-price control. All of this involves balancing between the 'private good' and 'public good' aspects, but the extent of regulatory intervention is a problematic issue. For example, a USA Government study<sup>41</sup> found that lesser drug-price

control leads to more R&D investment, resulting into higher new drug introduction-rate. But the EU<sup>42</sup> countries favour a little more price regulation. Thus, failure in striking a balance will result in more instances of 'voluntary defection'<sup>7</sup> from TRIPS-compliance (e.g. Brazil *vis-à-vis* malaria and AIDS drugs), which are symptoms of the 'incentive imbalance'. Also, since a patent protection regime is extremely important for the existence of pharmaceutical industry (reflected by the statistics, '65 percent of pharmaceutical inventions would not have been introduced without patent protection'<sup>43</sup>), there is a clear need for undertaking a reform at national and international levels.

### **Innovation Analysis**

The first-ever WIPO's World Intellectual Property Report<sup>44</sup>, emphasizes the critical role of patents in innovation-promotion.

### *Short-term vs Long-term Effects*

Innovation is the key, for the pharmaceutical industry and the public, both. Pharmaceutical innovations result from (1) knowledge-enhancement, (2) better application, (3) serendipity and (4) R&D.<sup>45</sup> Hoyle<sup>46</sup> proposes the 'MII Cycle' (maintenance-improvement-innovation) (see Fig. 1) for best innovation-results.

Innovation provides the real competitive advantage<sup>47</sup> whose ultimate beneficiary is the consumer.<sup>48</sup> The 'efficacy' under Section 3(d) is geared towards innovation-promotion<sup>49</sup>, albeit of the primary kind only. Boldrin and Levine<sup>50</sup> hold that Section 3(d) will stifle both- imitation and innovation. But this argument is fallacious. Firstly, there is no total embargo over patenting of all incremental

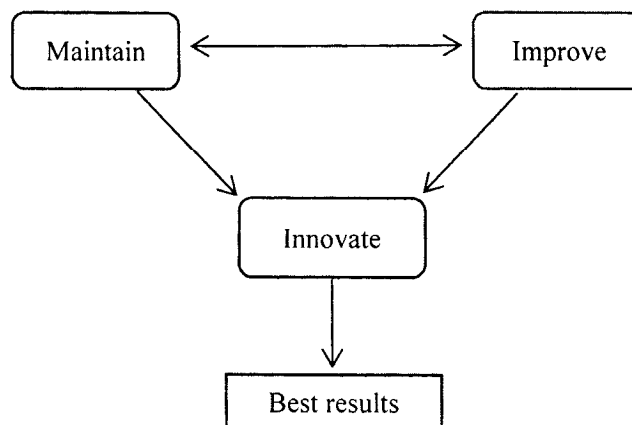


Fig. 1 – MII cycle

innovations. Also, such a limited embargo may actually promote innovation, especially in the long-term. It will force pharmaceutical companies to focus more on new innovations (NCE/NME). The short-term stifling effect (on imitation) of the raised efficacy-standard will be nullified by the long-term gain in innovation-rate. The copy-cats will have no option but to either move up the value-chain and become innovation-oriented, or exit. Most importantly, it is a policy imperative to discourage the current focus on secondary innovation and, instead, incentivize primary innovation. The pharmaceutical industry might witness a consolidation-phase<sup>51-54</sup> in the short-run (e.g. the 2008 Daiichi-Sankyo's acquisition of Ranbaxy, India<sup>55</sup>) and then it is likely to move on to increased innovation-orientation. It will also raise the competition level, which is good for free market economy. The Romanian pharmaceutical industry also is undergoing such a change.<sup>56</sup>

#### ***Increased Innovation-orientation***

The process of increased innovation-orientation has already begun in India (see Chaudhuri<sup>57</sup> and Thomas<sup>58</sup>, both cited by Eger<sup>59</sup>). Kiran<sup>60</sup> finds a positive correlation between the new patents regime and innovation/R&D investment. But Bhaduri<sup>61</sup> sees a decline in R&D investment due to the complacency effect of long duration (20 years) of patent monopoly. An impartial analysis of all such studies reveals that most of them suffer from either reliability/validity problems, or the partisan 'war of positions' posturing.

#### ***Technology Transfer***

Theoretically, a balanced patents regime should result in greater technology transfer, but there are some indications of actually very slow rate of pharmaceutical technology transfer, either from the innovators to the generics<sup>62</sup>, or from the Indian public-funded research bodies to the industry<sup>63</sup> and this acts as a dis-incentive for some of the stakeholders. Thus, there is a clear need for the restructuring of the extant weak policies/mechanisms regarding pharmaceutical technology transfer.<sup>64</sup>

#### ***Innovation as a Process of Creative Destruction***

Without venturing into the debate, if it is assumed that at least to some extent and under some circumstances, patents might lead to more innovation, then one of the ways in which it is achieved is through the process of 'creative destruction'<sup>65</sup> and 'creative accumulation'.<sup>66</sup> The two basic types of innovations –

truly innovative drugs (i.e. NMEs, having priority status) and less innovative drugs – are distinguishable from another type, i.e. 'me-too' drugs that do not qualify for patenting.<sup>67</sup> The first and second type may qualify, if they satisfy the triple patentability criteria of (1) novelty, (2) inventiveness (i.e. non-obviousness) and (3) utility (i.e. industrial applicability/use).

#### ***Social Welfare Effect of New Drugs Introduction Rate***

Gifford's social costs and benefits analysis concludes that since the pharmaceutical market provided both, incentives as well as rewards, the patent monopoly was the best system for increased innovation-rate.<sup>68</sup> Also, the problem of social costs (especially for poorer countries) thereof can be partly mitigated by price-discrimination, provided arbitrage in pharmaceuticals (i.e. re-importation of drugs) is prevented.<sup>69</sup>

It has been found, on the other hand, that the patent monopoly enables the patentee to build-up such a high reputation and brand-awareness that even after the patent-expiry, 'the first mover advantage gives the innovator continuing price-setting power' in the absence of generics competition.<sup>70</sup> Here, Wolf suggests shifting from the current reference pricing (RP) model (based on co-payments, e.g. in Germany) to a new free market-based medical savings account (MSA) model (based on individual's obligation to make deposits for medical contingencies, e.g. in Singapore) for achieving more efficiency in drug provision. This expenditure responsibility transference (onto the patients) (1) reduces moral hazard-induced welfare losses, (2) makes the demand more elastic and (3) enhances competition.

The finding<sup>66</sup> of a significant and positive correlation between the introduction of priority drugs and the rise in the 'mean death age' highlights the important big role of the new priority drugs introduction-rate *vis-à-vis* the public health. Hence, the current trend of declining introduction-rate of new priority drugs is a matter of concern from the social welfare viewpoint, which has two aspects- (i) the efficiency aspect and (ii) the distributive/re-distributive aspect. While the 'public good' votaries argue for a Pareto-optimal improvement, the 'private good' votaries would argue for a Kaldor-Hicks improvement<sup>71</sup> whereby the affected party may be at least theoretically compensable. Actually, this posturing has a political economy component of 'war

of positions'. But also, a purely economic efficiency criterion should not be the only consideration. Its distributive/re-distributive effect, too, must be considered. From the welfare angle, all welfare-reducing distributive exercises involving mere transfer of benefits from one segment to the other, without any efficiency gain, must be discarded. But this general principle concerning private goods, gets complicated by the presence of public good character in pharmaceuticals where the public health requirement calls for equity. Sometimes, even a slightly net welfare-reducing arrangement has to be accepted because of its Pareto-superiority rather than Pareto-optimality.

#### *Innovation vs Public Interest*

Villarreal<sup>72</sup> sees conflict of goals between promoting innovation and access to public health. This innovation-access dichotomy is because of the 'time inconsistency problem', whereby the incentives are misaligned, cross-directional and cross-purposive. According to him, economic incentives demand strong patent protection, while political incentives demand action in favour of public, viz. parallel imports, compulsory licensing, etc. This political economy approach calls for balancing of two sides (innovation and access). One generalized solution is to lessen the political content by providing the long-term political incentives.

#### *Private vs Public R&D Incentives and Externalities*

Scotchmer<sup>14</sup> opines that there is no incentive to make more public R&D investment in pharmaceuticals because it cannot recover the 'cross-border benefits' generated by the public R&D investment. One solution to this externality (i.e. cross-border benefit created outside) is public-private partnership in R&D. It requires international co-operation which unfortunately so far, has remained only in the private domain and not in the public domain. Despite pharmaceuticals having perhaps the highest pay-off potential, there is not much international public-private cooperation and it has largely remained in private hands.

#### *Nature of State Intervention*

WIPO's World Intellectual Property Report<sup>44</sup> promotes collaborative licensing or patent-sharing, but '(f)ears of free riding, risk shifting and other forms of opportunistic behaviour may lead firms to forgo mutually beneficial cooperation' and engage in

anti-competitive collaborations. This market failure provides the rationale for State intervention. Unfortunately, there is no guidance for the policymakers regarding the level/depth of intervention. It is here that some argue that Section 3(d) is an un-necessary/excessive State intervention in the free market functioning. Its counter-argument is that the presence of partial market failure<sup>73</sup> in the form of no cheap public access to drugs, especially the life-saving ones, necessitates state intervention in public interest. If this intervention is used subtly and prudently as per the suggested reforms in this paper, then it may be a welfare-enhancing Kaldor-Hicks improvement in the long-term because not only the common masses will benefit from the cheaper drugs, but also the pharmaceutical companies will be compensable (assuming Scitovsky Paradox<sup>74</sup> does not apply). However, this State intervention will be Pareto-superior and successful only if it is in the nature of a gentle policy push (following the 'nudging' and 'expressive function of law'<sup>75</sup> concepts), rather than an extensive interference with the market forces. Historically, State interventions have tended to have welfare-reducing (Pareto-inferior) outcomes, as per the Public Choice Theory.<sup>76</sup> The only way in which the State intervention can be welfare-enhancing (Pareto-superior) is when all the stakeholders agree to the intervention, or when there is a clear-cut case of technological (allocational) market failure.<sup>77</sup>

In the case of public healthcare in most parts of the world, there appears to be a case for at least a partial (allocational) market failure<sup>78</sup>, which requires some sort of regulatory intervention, e.g. US President Obama had to intervene through an extensive overhaul of the healthcare system through a path-breaking Patient Protection and Affordable Care Act<sup>79</sup>, which was upheld even by the US Supreme Court, vide its decision on 28 June 2012. In the developing and underdeveloped countries, the extent of market failure in healthcare is even deeper.

#### *Partial Market Failure in India*

Indian healthcare system is a case of partial technological market failure, whose nature is allocational. It requires only a gentle policy push type of intervention. The patent monopolist's high prices discourage the productive use of information by the general public.<sup>80</sup> Coupled with high information cost, they discourage the public from being able to use the

information at a very low cost, equal to its marginal cost. In the context of new drug introduction into the market, either the cost-effectiveness or the cost-utility method is used for cost benefit analysis. It is here that another/third party, i.e. the health insurer, assumes an important role at the institutional level – instead of being just passive 'price-takers', the insurers do their own cost-effectiveness analysis of the drug and negotiate to bring down the drug-price. This is under perfect market conditions. But in reality, the distortions/collusions/information-asymmetries in the inefficient market do not allow the drug-price to go sufficiently down to their true intrinsic worth. These are only some, *inter alia*, symptoms of market failure.

#### *Expressive Function of Law*

The behavioural law and economics concept of 'nudge' and 'expressive function of law'<sup>81</sup> is a preference-shaping effect of law where law acts as a signal to the public about what direction to take on an issue. It can be very helpful in providing gentle policy 'pushes', instead of 'shoves'. When push becomes shove, it engenders far greater resistance/dissent<sup>82</sup> and it distorts incentives.

#### *Nudging and Choice Architecture*

As per Thaler & Sunstein<sup>83</sup>, a well-designed 'choice architecture'<sup>84</sup> can 'nudge' the public towards the desired direction, without violating free will. The decision-makers should design their policies not only in accordance with economic compulsions, but also keeping in mind the human psychology.

#### *Policy Levers/Instruments*

In the Indian pharmaceutical patenting context, the regulators have two policy instruments: (i) legislative reform of 'law in books' to clear the ambiguous wordings of Section 3(d)<sup>17</sup> and (ii) judicative reform of 'law in motion', e.g. by widening the interpretation of 'efficacy' from the current narrow interpretation as mere 'therapeutic efficacy', thereby bringing clarity/certainty in its application, which is the main research purpose of this research.

#### *Signaling<sup>85</sup> and Free-riding*

The aforementioned reforms have a big signaling value. The current Section 3(d), acting through its central concept 'efficacy', (i) gives a strong signal to the generics to remain in the generics-production mode, while simultaneously (ii) giving a negative signal to the innovators. Both signals are incentive-

distorting, either actual or perceived, which has a negative impact on the Indian pharmaceutical industry-growth. Strong protection provided by the 'enhanced efficacy' standard encourages excessive/perverse incentive to free-riding, complacency, X-inefficiency<sup>86</sup>, non-competitiveness and non-innovativeness on the part of generics.

#### *Systemic Opportunistic Behaviour and Moral Hazard*

This free riding is the systemic opportunistic behaviour kind and involves moral hazard<sup>87</sup>, too, because monitoring is impossible. Any reform for mitigation/overcoming of this systemic opportunistic behaviour/moral hazard requires some inducement to rationalize the post-reform incentives of the stakeholders and to internalize the current negative externalities and efficiently distribute it amongst all stakeholders.

Reform is also necessary because the nature of a patent regime significantly determines the innovation (i) rate, (ii) direction and (iii) distributive (welfare) effects.<sup>88</sup> The new drug discovery-rate has been found to be positively related to past R&D investment.<sup>89</sup> Lichtenberg<sup>66</sup> points out how the short-term consumer benefit (in terms of short-term populist policies, viz. lowered prices of the existing drugs) may get neutralized by the long-term consumer harm (in terms of lowered new drug introduction-rate) because the price control measures reduce R&D investment by lowering the expected return on investment, thus resulting in fewer new drug-introductions in the long-term. This is why Lichtenberg still advocates for retention of the higher and slightly inefficient patent monopolistic prices, despite the short-term static welfare loss involved in patent monopoly. He cites the very existence of the patent system as an evidence that the 'society recognizes that the (dynamic) welfare gains from innovation outweigh the (static) welfare losses from monopoly'. He also hypothesizes that 'government policy events that significantly reduce market value also tend to reduce R&D investment'.

#### *Externalities*

The grant of patent monopoly has lots of collateral costs, which are basically the externalities imposed on the society.<sup>25</sup> Since grant of patent monopoly results in externalities, which may be welfare-enhancing<sup>90</sup>, any patent policy must keep this factor in mind.

The current Section 3(d) simultaneously creates some, while reduces other externalities. The



externality creation effect will be seen in the case of already granted 'weak patents', e.g. Novartis' Glivec. The externality reduction effect will be seen in future patent grants that will carry more certainty/validity and will be a strong deterrence for potential infringers/challengers. A reformed Section 3(d) will have even more potential for *ex post* externality-reduction. It will reduce even the perception-based (rather than facts-based) externalities. Incremental innovations fall in a grey area *vis-à-vis* patent clarity/certainty/validity. By raising the efficacy standard for incremental innovations, Section 3(d) drastically reduces future expenses involved in patent infringement/validity challenges.

#### ***Trade in Licence and Competition***

The Indian pharmaceutical industry is yet to witness the phenomenon of a substantial free market trade in licences at a significant level. But the Section 3(d)-induced greater certainty in patent validity, coupled with strict enforcement of infringement laws, will encourage greater licensing/cross-licensing activities (especially in cases of tragedy of the anti-commons for secondary innovations) and foster competition, thereby obviating the need for State intervention through such mechanisms, as compulsory licensing, *ex ante* licensing<sup>38</sup> mechanism as a solution to the problem of tragedy of the anti-commons in pharmaceuticals. WIPO's World Intellectual Property Report, 2011 also promotes collaborative licensing or patent-sharing.

#### ***Ex post Certainty and Burden of proof***

Though the Indian Patents Act (IPA) does not officially attach any presumption of validity to the grant of patent, yet Section 3(d) fulfills that function implicitly/indirectly, especially if viewed from the long-term perspective. This implicit measure imparts certainty and greater validity, thereby reducing the *ex post* weight of burden of proof in future legal disputes regarding patent's validity. It certainly will save lots of *ex post* (litigation) expenses and transaction costs in the long-term.

#### ***Moral Hazard and Challenge by Infringement***

The current situation involves moral hazard as far as the generics' tendency towards taking risk (of launching the products even 'at risk') and externalizing the cost onto the innovators is concerned, e.g. the current trend of 'challenge by infringement'<sup>91</sup> (e.g. by Cipla, Natco, etc.). It has a big

negative signaling and incentive-distortion value, which have to be checked, by balancing the cost and incentive-structure. The transaction costs for the generics will have to be upwardly adjusted. Simultaneously, it is a clarion call for the innovators, too, to be careful about technical/scientific data/procedures during the patent prosecution.

#### ***Path Dependency***

One may argue that the 'efficacy' under Section 3(d) serves the purpose of perpetuating the path dependency<sup>92</sup> of the extant pharmaceutical business/patent regime revolving around generics, which may have a negative effect in the long-term. A reformed application of 'efficacy' will cure this defect.

#### ***Adverse Selection***

The current system is resulting in adverse selection<sup>93</sup> through the path dependency mechanism. The patents regime is so much skewed that it adversely selects/promotes only the generics. This lack of positive incentives for innovation will be a costly trade-off in the long-term.

#### ***Risk-shifting***

Innovators face too much of uncertainty costs (*vis-à-vis* generics), which does not get compensated under the current regime whose current 'efficacy' requirement is not helping much in uncertainty-reduction. The policymakers do not want to change the current risk-structure. But, an efficient patents regime requires some re-distribution of risk among all the stakeholders. However, depending upon the price elasticity of demand, it has to be taken care that only 'some' of the resultant (of risk-shifting) costs gets passed on to the public in the form of a little higher market price. Nevertheless, this trade-off has to be effected, if long-term benefit (through increased innovation effect) to the public is to be ensured.

#### ***Welfare Analysis***

##### ***Welfare Analysis of Primary Invention***

The real subject-matter involved in the primary inventions and incremental innovations is 'information'.<sup>59</sup> Inadequately protected information gives no incentive, either for further innovation, or for disclosure of the currently-held information. This ultimately harms the general public because it defeats the twin purposes of the patent system – (1) prevention of expropriation and (2) facilitation of

bargaining and market exchange.<sup>94</sup> It also discourages further innovation. Patent protection accounts for at least 30 per cent of inventions in the pharmaceutical industry.<sup>95</sup> However, the socially efficient patent monopoly has a 'static welfare loss' due to (1) the mark-up over the marginal cost of production, (2) resource wasted on patent-race and (3) rise in secondary innovation cost.<sup>59</sup>

#### *Efficiency Effects and Encouragement Trade-off*

The following developments have serious efficiency effects: (1) primary invention-rates have fallen; (2) secondary innovations have risen sharply; (3) primary inventions are often results of cumulative processes.<sup>96</sup> From the policy angle, there is always a trade-off between various stakeholders, regarding whom to provide encouragement for investment; e.g., trade-off between primary inventor and secondary innovator.

#### *Strength and Length of Patent Protection vs Innovation*

On a different note, Vallée<sup>97</sup> observes greater welfare under milder patent protection regimes. Similarly, James<sup>98</sup> finds that strong IP protection is not essential for innovation because primary inventions are often a result of accumulation of incremental developments. As per his data, the Indian pharmaceutical industry is flourishing under Section 3(d). Gallini<sup>99</sup> finds that the current length (20 years) of patent protection is just right and any increase therein would only result in more incentive to the generics/'me-too' drugs, than to the innovative drugs.

#### *Role of Third Parties, e.g. Doctors, Insurers*

A partisan state intervention (in public interest) is needed in Indian pharmaceutical patenting because of the distortion created by the presence of a third party, i.e. doctor, who makes the actual drug-buying decision on behalf of the consumer/patient.<sup>98</sup> The individual consumer/patient does not actually make the drug-buying decision on account of the *ex ante* information asymmetry. Even if not 'captured' by the innovator companies, the doctor works under a distorted incentive-matrix of its own, e.g. (1) to prescribe the most effective drug, (2) to prescribe the latest drug, (3) to safeguard itself from future liability on account of possible civil or criminal negligence/malpractice charges, etc. Gonzalez<sup>100</sup>, too, captures the role of physician's prescriptions in the context of pricing strategy of the innovators. Schweitzer<sup>69</sup> points out how insurers influence pharmaceutical/healthcare policy.

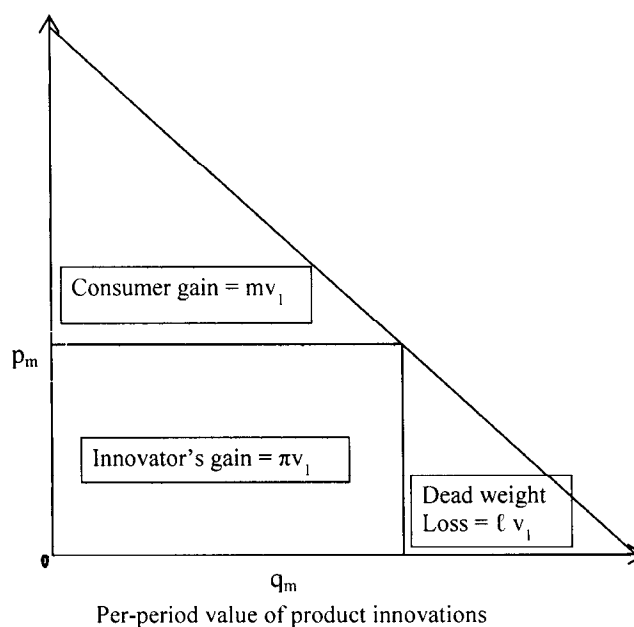


Fig. 2 – Consumer, producer and welfare gain/loss

#### *Static Welfare Loss and Welfare-overtaking*

Patent monopolies are inefficiency-producing and hence, have a 'deadweight burden'.<sup>59</sup> It is a static welfare loss, involved in the monopoly transfer of benefits not only from the consumers, but also from other producers.<sup>101</sup> Cooter does not believe much in the welfare analysis from pure economic angle; instead, he proposes the real policy concern should be 'welfare-overtaking', i.e. law and policy for IP should maximize the rate of sustained growth, rather than attempt to balance the growth against other values.

#### *Consumer-, Producer- and welfare- Gain/Loss*

The simplistic graph<sup>59</sup> (depicted in Fig. 2) explains the consumers'-, producers'- and patentees' welfare-gains/losses (before the entry of the secondary innovator).

Here,  $m + \pi + l = 1$

Consumer surplus =  $m v_1$

Producer (patentee) surplus =  $\pi v_1$

Net effect (dead weight loss) =  $l v_1$

#### *Welfare Analysis of Secondary Innovation*

A perfectly discriminating patentee-monopolist would like to grab the whole pie, '1'. If a secondary innovator has to enter the scene, then the new entrant's incentive would be to appropriate all the extra social value generated out of its improvement upon the original invention. But this comes into conflict with the incentives of the original inventor

who would like to capture at least some share of the newly-created extra social value.

#### *Division of Spillover*

The secondary innovation can happen only if the original invention occurs. So hypothetically, the secondary innovator has to incentivize the original inventor to invent in the first place. On the other hand, the original inventor will have the incentive to invent in the first place only if it could grab the 'stand-alone value' of the original invention, plus some share in the additional social value created by the secondary innovation, if any, which Eger calls 'spill-over  $\max \{0, v_2/r - c_2\}$ ', where  $c_2$  denotes the secondary innovator's cost. Thus, there arises a bargaining within a 'bargaining range' whose boundaries are determined by the extra social value created by the secondary innovator, minus the secondary innovator's cost. This bargaining process involves a very delicate incentive matrix, which no patent policy can ever efficiently divide Pareto-optimally among these two inventors.<sup>59</sup>

#### *Current Author's Division of Spillover*

So, a Pareto-superior regime should strive to divide the spillover into perfect equilibrium partitions (as per Rubinstein's PEP model). For instance, one can divide it in Pareto-superior way in the ratio of their respective R&D costs, as follows:

$$\text{Inventor 1's share} = \left( \frac{\text{R\&D cost of inventor 1}}{\text{R\&D cost of inventors (1+2)}} \right) \times$$

Extra social value generated by innovator 2

$$\text{Inventor 2's share} = \left( \frac{\text{R\&D cost of inventor 2}}{\text{R\&D cost of inventors (1+2)}} \right) \times$$

Extra social value generated by innovator 2

#### *Multi-dimensional Balancing of Incentive*

Another aspect of this balancing act is that a Pareto-superior patent regime should strive not to distort the investment incentives-structure not only between the primary inventor and the secondary innovators, but also amongst other stakeholders, especially involving consumers. Only this multi-dimensional balancing can make it a Pareto-superior patent regime. Eger's analyses neglects the consumers' distortion aspect.<sup>59</sup>

#### *Independent vs Dependent Secondary Innovation*

As per Eger, the nature of the secondary patents [i.e. whether independent (competing), or dependent (subservient)] also affects the bargaining outcome. Depending upon the use of the two available policy levers [i.e. (1) breadth/scope of the primary invention/patent and (2) patentability standard for secondary innovation], the following matrix (shown in Table 1) will represent the possible incentive structures of these two parties<sup>59</sup>:

Although each of these four cases has its own merits and demerits, yet some major generalizations are the following:

Case 1 requires *ex ante* licensing solution. Case 2 may lead to the tragedy of the anti-commons due to the multiplicity/chain of patents.<sup>37</sup> Case 3 is most disincentivizing for the secondary innovator whose best strategy would be to hide the information until situation improves. It ultimately leads to lowered R&D investments even by the primary inventor because there is no spillover gains to be cornered. The Case 4 may lead the innovator 2 to (i) either hide the information and wait for the opportune time, (ii) or to commercialize the product, with infringement. The latter eventuality (ii) is a disincentive for the inventor 1.

Table 1 – Incentive structure			
		Innovator 2	
		Patent to be granted	Patent to be refused (e.g. Section 3(d) in India)
Inventor 1	Broad protection	Broad protection for Inventor 1 + Patent grant to Innovator 2 (Case 1)	Broad protection for Inventor 1 + Patent refusal to Innovator 2 (Case 3)
	Narrow protection	Narrow protection for Inventor 1 + Patent grant to Innovator 2 (Case 2)	Narrow protection for Inventor 1 + Patent refusal to Innovator 2 (Case 4)

*Critique of Eger's Matrix*

(1) Eger has wrongly categorized Section 3(d) under a class 'where secondary innovations are not patentable' because instead of totally barring the patentability of secondary innovations, the Section merely raises the bar of the efficacy test (regarding obviousness / inventive step).

(2) Eger cites only two circumstances in which the evergreening can possibly take place, despite the fact that there are many circumstances when the incentive to engage in evergreening is present. In fact, evergreening incentive can be present in any of the four cases of Eger. The evergreening incentive is independent of both, the secondary innovation's nature and the two policy levers of Eger's four cases. However, except for these demerits, Eger provides an excellent incentives analysis of the incremental innovations' patenting.

Contrary to James<sup>98</sup> however, Eger<sup>59</sup> observes the harmful effect of the excessive protectionism accorded by the 'enhanced efficacy' standard under Section 3(d). The restrictive interpretation of the term 'efficacy' to mean only 'therapeutic efficacy' is legally challengeable and has negative incentive- and signaling-effects. But while analysing the incentive and welfare effects of Section 3(d) and 'efficacy', one should bear in mind the difference between the 'restrictive interpretation of the term efficacy' and the 'restrictive interpretation of the whole Section 3(d)'. Only the former has occurred. There is no 'restrictive interpretation of the whole Section 3(d)'. The Indian patent authorities/courts are merely strictly applying the 'enhanced efficacy' (patentability) requirements.

Scotchmer<sup>101</sup> too, opines that there will be greater incentives for innovation if the primary inventor has greater share in profits from the secondary innovation. Also, the primary inventor appropriates a greater share of the whole profit, if the secondary innovations are not patentable. This contradicts Eger's views.

As per Denicolo<sup>103</sup>, in a two-stage race, the relative incentives for the primary inventors and the secondary innovators depend upon the following three categories to which the secondary innovation belongs - (1) unpatentable and infringing (UI), (2) patentable and infringing (PI) and (3) patentable and non-infringing (PN). He finds as follows:

- (i) Forward protection is lowest in PN and highest in UI;
- (ii) UI has the inefficiency of underinvestment in secondary innovation;

- (iii) '...strong forward protection becomes less attractive as the relative profitability of the first innovation increases and the relative difficulty of obtaining it decreases.'

Denicolo<sup>104</sup> observes that in order to stop fragmentation of IP in a tragedy of the anti-commons-like situation with multiple complimentary/competing/blocking patents, the patentability standard should be higher for secondary innovations than the stand-alone patent. But it comes with a social cost, i.e. dis-incentive to secondary innovators. In order to cure this, the strength of the patent protection (once and if granted to secondary innovations), should be made stronger than the protection granted to the stand-alone patent. Thus, Denicolo commends *ex ante* higher patentability standard and *ex post* stronger protection for secondary innovations, *vis-à-vis* stand-alone patents.

In Denicolo's simplistic baseline model<sup>105</sup> for stand-alone inventions, the sole determinant of optimal level of patent protection is the elasticity of supply of inventions. By comparing the actual level with this benchmark level of elasticity, he infers whether the patent protection is optimal or not. Theoretically, the baseline model predicts that since profit-ratio exceeds the elasticity of the supply of inventions, the innovators are over-compensated. But Denicolo's empirical testing<sup>105</sup> found no empirical evidence that innovators were being over-compensated.

Analysing the four main approaches towards non-obviousness for patentability requirement, Denicolo<sup>90</sup> advocated for denial of patent protection in cases of welfare-reducing sequential and complimentary innovations.

Cooter<sup>101</sup> points towards another welfare-reducing aspect - when the secondary inventor enters, the monopoly transfer from one innovator to the other (in any direction) raises the cost of production. All these aspects have to be kept in mind while formulating a Pareto-superior policy.

**Contra-IPR School of Thought**

There exists a big school of thought, which finds no evidence for the traditional view that patent monopoly leads to increased innovation-rate, or increased welfare. A few such scholars argue for even a negative relationship between them.

### ***Collateral Costs and Moral Hazard***

As per Boldrin and Levine<sup>25</sup>, patent monopoly has two components - (1) right to first sale and (2) right to control after sale (downstream licensing). Patent monopoly-imposed collateral costs (which are externalities on the society) often exceed the value of the (intellectual) property, sometimes because of 'regulatory capture', which is a moral hazard on the part of the legislature/government.<sup>106</sup>

### ***Welfare-reducing Rent-seeking and Redundancy***<sup>25</sup>

The downstream licensing is welfare-reducing. However, more than its welfare-reduction effect, it is the rent-seeking behaviour (which is used to perpetuate that monopoly), which is dangerous. Boldrin and Levine<sup>50</sup> root the welfare-reducing rent-seeking problem in the redundancy phenomenon, i.e. the pre-dominance of redundant research in pharmaceuticals. For example, during 1989-2000, they found that upto 77 per cent of all FDA drug approvals were for medically redundant, and not for innovative/new drugs. The high redundancy reflects socially inefficient rent-seeking, which bolsters monopoly, reduces social welfare and promotes corruption. All of these are artificial creations of the patent system, which may be dispensed with altogether.

### ***Monopoly, Innovation-rate, Exaggerated Costs & Weak Moral Ground***

Boldrin and Levine<sup>50</sup> do not find any linkage between patent monopoly and increased innovation-rate. To the contrary, they find:

RoI for legal tactics > RoI for R&D

where RoI (return on investment) reflects the moral hazard problem, *inter alia*, on the part of the lawyers, too. They cite the Center for Economic and Policy Research Report<sup>26</sup> to find that in addition to the highly exaggerated R&D cost, the only other major costs of innovators are (1) legal cost and (2) advertising (to doctors) cost, all of which are unjustified and, hence, renders the patent monopoly's moral ground weak. They suggest that since 'the cost of eliminating the patenting in pharmaceuticals is outweighed by the benefits thereof, they could well be eliminated'. Whether one subscribes to this contra-IPR approach or not, but this approach reflects some of the welfare-reducing effects of the imperfect patent monopoly, especially in cases of 'regulatory capture'.

## **Conclusion**

### **Reform Imperative in India**

The contra-IPR approach may be partially applied to the Indian pharmaceutical patenting scene, where redundancy, rent-seeking, research-redundancy, corruption, inaccessibility, high prices, R&D cost exaggeration, moral hazard, free-riding, incentive problem, information asymmetry, etc., are present. Their presence makes a thorough law and economic analysis necessary before any reform in 'efficacy' and Section 3 (d); otherwise, it may actually end up stifling both, imitation and innovation.<sup>50</sup> Also, it will not only fail to strike a balanced incentive structure for all stakeholders, but it will also have negative signaling and high *ex post* costs (externalities). This paper has attempted to undertake a preliminary L&E analysis and pure legal analysis is left to another research, as it is in itself a subject-matter of an independent inquiry. However, it is strongly suggested to read this L&E analysis in conjunction with the current author's legal analysis.<sup>1</sup>

### **Policy Implications**

Without going into its details, but still relying upon the mathematical model proposed therein, the current author finds many policy implications, as a resultant of his analyses of the efficacy factor.

### **Domestic Policy Level**

Foremost, the national government shall have to aim at balancing the incentive structure for all stakeholders, if Pareto-superiority is to be achieved. The national government will basically have two policy instruments for its carrot-and-stick policy, (1) economic measures (the 'carrot') and (2) regulatory measures (the 'stick'), each of which will have proscriptive (constraining) and prescriptive (enabling) aspects.<sup>107</sup> Although the enabling policies are generally faster-acting and having lesser monitoring and enforcement costs, yet their positive impact on innovation depends more on the extent/appropriateness of its product-discrimination ability and less on its enabling or constraining nature. Applying this to Indian context, the current author discerns two components of Section 3(d) - its proscriptive component constrains certain new forms/uses of the known substance/processes, while the prescribing component enables patenting for even such new forms/uses of the known substance/processes which meet the enhanced

efficacy standard. Thus, rationale of the carrot-and-stick policy under Section 3(d) appears to be sound, as long as it seeks to weed out only the frivolous patents, by raising the efficacy standard. However, due to the ambiguities on account of (i) the wordings in the Section and (ii) the restricted judicial interpretation of 'efficacy' as mere 'therapeutic efficacy', the resultant legal uncertainty imposes huge *ex post* costs on some stakeholders, especially the innovators, in the short-run. This cost-externalization onto only some stakeholders, is unfair and Pareto-inferior. It is imperative to make it Pareto-superior, by adjusting the incentive structures of all stakeholders. Instead of cost-externalization onto only one stakeholder, the policy should aim at cost-internalization and distribution amongst all stakeholders. Unfortunately at present, there is no political will to internalize the externalities/costs. But the Indian patents law/policy needs to be reformed accordingly, if India has to send positive signal to the international community. Moreover, such a reform is also necessary because it may be the first step in the direction of the current author's proposed transformation of the Indian pharmaceutical industry from its current generics-orientation to innovation-orientation.

#### *International Policy Level*

A concomitant international level incentive-structure adjustment must accompany the domestic reform. IPR is a big instrument of globalization and it often acts as super-tariffs by raising the investment cost for those countries that have (1) neither abundant cheap labour, (2) nor high amounts of intellectual property.<sup>108</sup> Economic globalization has led to a huge rise in IPR-related trade in goods/services and national economies are increasingly getting integrated into a global economy.<sup>109</sup> But this IPR-led global economy has a flawed institutional (patent) mechanics. Often, the choice of a patent system is not totally out of national free will because of some patents-related ill effects of globalization, e.g. the way/manner in which the international patent systems are sought to be applied, often pushes the nation states to make extreme choices.<sup>40</sup> After all, the patent system is ultimately a function of geo-politics, which is primarily driven by economic considerations. So, the patent system must be used carefully, strategically, beneficially and fairly even at the global level. India will have to walk a tightrope in this international bargaining game of patent harmonization.

#### *Harmonization of IPR Systems*

IPR is a system of incentives, which has a differential impact on different regions, depending upon the level of development.<sup>110</sup> This fact simultaneously argues for and against the international harmonization of IPR systems<sup>111</sup>, thereby making it a very difficult task for the policymakers - Indian or international.

#### *Public-Private Partnership in Pharmaceutical Research*

Public-private collaboration should be encouraged, if public has to be served, without discouraging the innovators. Even WIPO's World Intellectual Property Report (2011), calls for 'harnessing of public research for innovation'-promotion.<sup>112</sup>

#### *Future Research*

##### *Empirical Testing of the Proposed Model*

The legal analysis contained in the other paper is merely a theoretical one and it needs to be empirically tested.

##### *Application of Model to Non-Pharmaceuticals*

The mathematical model proposed in the legal analytical paper is scalable/flexible/refinable enough to be applied to even non-pharmaceutical patents.

##### *Gentle Policy Push vs Full State Intervention in Patent Regime*

The reforms have been proposed on the 'nudge' approach. But for a proper comparison of the entire dynamics, counterfactual researches, on the line of 'full state intervention', are also required.

##### *Transformation of Indian Generics Industry into Innovators*

The author holds that a mere 'nudge' by the political leadership/legislature will embolden the corporate culture<sup>113</sup>/leadership to take the quantum 'leap of faith' from generics to innovation. But, this is not to argue that India should leave its generics' core competence. Instead, the argument is to diversify and put primary focus on innovation, but retain the generics strength. There are many examples<sup>114</sup> of innovative companies acquiring the generic companies (or vice versa<sup>115</sup>). There is no reason why India, too, cannot pursue both strategies simultaneously.

##### *Public-Private Partnership in Pharmaceutical Research*

This is an area worth exploring, if public interest factor has to be ensured.

##### *Problematic Gene Patenting*

Very soon, all patent regimes will have to grapple with gene-patenting, which will seriously

challenge/dilute the traditional ‘efficacy’-standard, e.g. BT cotton controversy<sup>116</sup> (India). Orsi<sup>117</sup>, finds that the American allowance of even gene upstream patent (with a very ‘wide’ scope) has resulted in a (1) research-stifling extreme monopoly, which is (2) radically dismantling the standard/classical doctrines governing patents [Myriad Genetics (USA)<sup>118</sup>]. EPO generally follows the same line<sup>119</sup>, albeit with the limitation that the protection granted to the particular gene is not available to its processed products/derivatives.<sup>120</sup> The prohibitively high co-ordination cost involved in a chain of patents results in the tragedy of the anti-commons, which prevents further innovation in genetics, especially in the life-saving drugs category.<sup>37</sup> However, as per Regibeau’s survey<sup>121</sup> research on GM food, gene research will occur even if no gene-patents are allowed because the presence (or absence) of a gene patent does not determine the direction of gene-research through the reward function. The IPA, 1970, classifies genes under non-patentable subject-matters. But sooner or later, the Indian patent regime also will have to make gene patent-eligible. Then it will be left with the only tool of ‘efficacy’ under Section 3(d) to determine gene-patentability, which only time will tell how well it performs under those challenges.

## References

- Kant A, An attempt at quantification of ‘efficacy’ factors under Section 3(d) of the Indian Patents Act, *Journal of Intellectual Property Rights* (in press).
- <http://www.theory.org.uk/ctr-gram.htm#hege> (3 August 2012).
- Schelling T C, An essay on bargaining, *The American Economic Review*, 46 (3) (1956) 281-306.
- Rubinstein A, Perfect equilibrium in a bargaining model, *Econometrica*, 50 (1) (1982) 97-109.
- [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.doc](http://www.wto.org/english/docs_e/legal_e/27-trips.doc) (13 July 2012).
- Kılıç B, Comparative Analysis of the United States’ TPPA Intellectual Property Proposal and Australian Law, *Public Citizen*, August, 2011.
- Putnam R D, Diplomacy and domestic politics: The logic of two-level games, *International Organization*, 42 (3) (1988) 427-460.
- McGillivray F & Smith A, The impact of leadership turnover and domestic institutions on international cooperation in a noisy world, 2003, <http://www.nyu.edu/gsas/dept/politics/faculty/smith/impact.pdf> (3 August 2012).
- Parisi F & Ghei N, The role of reciprocity in international law, *Cornell International Law Journal*, 36 (1) (2003) 93-123.
- Keohane R O, Reciprocity in international relations, *International Organization*, 40 (1) (1986) 1-27.
- Fairman D *et al.*, *Negotiating Public Health in a Globalized World* (Springer, New York), 2012, p. 129-144.
- Dreyfuss R C, The role of India, China, Brazil and other emerging economies in establishing access norms for intellectual property and intellectual property lawmaking, Institute for International Law and Justice, IILJ Working Paper 2009/5.
- Cottier T, From progressive liberalization to progressive regulation in WTO law, *Journal of International Economic Law*, 9 (4) (2009) 779-821.
- Scotchmer S, *Innovation and Incentives* (MIT Press, Cambridge), 2004; as cited by Eger T, Incremental innovation and patent protection for pharmaceutical products in India, in *Economic Analysis of India*, edited by P G Babu (Oxford University Press, USA), 2010, p. 345-347.
- Abbott K W & Snidal D, Hard and soft law in international governance, *International Organization*, 54 (3) (2000) 421-456.
- Kapczynski A, Harmonization and its discontents: A case study of TRIPS implementation in India’s pharmaceutical sector, *California Law Review*, 97 (2009) 1571-1649.
- Basheer S, The efficacy of Indian patent law: Ironing out the creases in Section 3(d), *SCRIPT-ed*, 5 (2) (2008) 232-266.
- Basheer S, ‘Ducking’ TRIPS in India: A saga involving Novartis and the legality of Section 3(d), *National Law School of India Review*, 20 (2) (2008) 131-155.
- Basheer S, The “Glivec” saga: A 3-D perspective on Indian patent policy and TRIPS compliance, 2008.
- Coase R, Problem of social cost, *Journal of Law and Economics*, 3 (1960) 1-44.
- Frost & Sullivan Report, US generic pharmaceuticals market outlook, 30 April 2007, <http://www.frost.com/prod/servlet/report-brochure.pag?id=N135-01-00-00-00> (27 August 2012).
- Gassmann O, Reepmeyer G, Zedtwitz M von, *Leading Pharmaceutical Innovation*, 2<sup>nd</sup> edn (Springer, Heidelberg), 2010.
- The blockbuster drug outlook to 2007 (Reuters Business Insight, Great Britain), 2003.
- Grabowski H, Vernon J & Dimasi L, Returns on research and development for 1990s new drug introductions, *Pharmacoeconomics*, 20 (Suppl 3) (2002) 11-29.
- Boldrin M & Levine D K, The case against intellectual property, *American Economic Review*, 92 (2) (2002) 209-212.
- Center for Economic and Policy Research, Report, 2002, cited by Boldrin M & Levine D K, *Against Intellectual Monopoly* (Cambridge University Press, UK), 2008, Chapter 9, p. 15.
- This does not mean that one should totally ignore the fact that none of the innovative drug companies worldwide ever put the drug development costing information in the public domain. All the costing data are mostly based on indirect estimates, made by third parties. Interestingly, even the regulating authorities have not ever forced them to disclose such data.
- Krikorian G & Kapczynski A, Untangling the web of price reductions: A pricing guide for the purchase of ARVs for developing countries, 9<sup>th</sup> edn, Médecins Sans Frontières, July 2006 (revised), p. 6.
- Buchanan J M & Tullock G, *The Calculus of Consent: Logical Foundations of Constitutional Democracy* (University of Michigan Press, Ann Arbor), 1974 [1962].

- 30 Dewar R D, The adoption of radical and incremental innovations: An empirical analysis, *Management Science*, 32 (11) (1986) 1422-1433.
- 31 Leung *et al.*, Patent-investment games under asymmetric information, [http://www.math.ust.hk/~maykwok/publications/Leung\\_Kwok\\_Asy.pdf](http://www.math.ust.hk/~maykwok/publications/Leung_Kwok_Asy.pdf) (16 July 2012).
- 32 Amin T, Searching for transparency: Improving patent information to increase access to medicines, *ICTSD Bridges*, 14 (4) 2010.
- 33 Grossman S J & Stiglitz J E, On the impossibility of informationally efficient markets, *The American Economic Review*, 70 (3) (1980) 393-408.
- 34 Lemley A M, Property, intellectual property, and free riding, Stanford Law School, Working Paper No 291, 2004.
- 35 Olson M, *The Logic of Collective Action: Public Goods and the Theory of Groups* (Harvard University Press, Cambridge), 1962.
- 36 *Intellectual Property Rights and Research Tools in Molecular Biology*, National Research Council (National Academies Press, Washington D C), 1997.
- 37 Heller M A & Eisenberg R, Can patents deter innovation? The anticommons tragedy in biomedical research, *Science*, 280 (5364) (1998) 698-701.
- 38 Scotchmer S, Standing on the shoulders of giants: Cumulative research and the patent law, *Journal of Economic Perspectives*, 5 (1) (1991) 29-41.
- 39 Walsh J P, Arora A, Cohen W M, The effects of research tool patents and licensing on biomedical innovation, in *Patents in the Knowledge-Based Economy*, edited by W M Cohen & S Merrill (The National Academies Press, Washington D C), 2003, pp. 285-340.
- 40 Falvey R V *et al.*, Trade and the globalization of patent rights, GEP Research Paper No02/21, September 2002.
- 41 Pharmaceutical price controls in OECD countries, 2004, <http://ita.doc.gov/td/health/DrugPricingStudy.pdf> (30 July 2012).
- 42 ECORYS Report: Competitiveness of the EU market and industry for pharmaceuticals, Volume I: Welfare implications of regulation, December 2009, [http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/vol\\_1\\_welfare\\_implications\\_of\\_regulation\\_en.pdf](http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/vol_1_welfare_implications_of_regulation_en.pdf) (30 July 2012).
- 43 Pharmaceutical innovation – An analysis of leading companies and strategies (Reuters Business Insight, Great Britain), 2002.
- 44 World Intellectual Property Report, The changing face of innovation, 2011, WIPO, [http://www.wipo.int/export/sites/www/freepublications/en/intproperty/944/wipo\\_pub\\_944\\_2011.pdf](http://www.wipo.int/export/sites/www/freepublications/en/intproperty/944/wipo_pub_944_2011.pdf). (12 July 2012).
- 45 Sarker D K, *Quality Systems and Controls for Pharmaceuticals* (John Wiley & Sons Ltd, England), 2008.
- 46 Hoyle D, *ISO 9000: Quality Systems Handbook*, 5<sup>th</sup> edn (Butterworth-Heinemann, London), 2006, p. 686; cited by Sarker D K, *Quality Systems and Controls for Pharmaceuticals* (John Wiley & Sons Ltd, England), 2008, p. 13.
- 47 Anik S T, *Pharmaceutical Technology Europe*, October 2002, p. 12-14; cited by Sarker D K, *Quality Systems and Controls for Pharmaceuticals* (John Wiley & Sons Ltd, England), 2008, p. 13.
- 48 Amir-Aslani A, *Technovation*, 26 (2006) 573-582; cited by Sarker D K, *Quality Systems and Controls for Pharmaceuticals* (John Wiley & Sons Ltd, England), 2008, p. 13.
- 49 Scypinski S & Drennen J K, Innovation (Our raison d'être), *Journal of Pharmaceutical Innovation*, 4 (2) (2009) 90-91.
- 50 Boldrin M & Levine D K, *Against Intellectual Monopoly* (Cambridge University Press, UK), 2008, Chapter 9, p.9.
- 51 Indian pharmaceutical sector: Growth drivers strengthen in the near term: Patent expiries in the U.S. & Europe and domestic market are key, ICRA Report, March 2012.
- 52 Consolidation in the pharmaceutical industry, CRISIL Report, <http://crsil.com/Ratings/Commentary/CommentaryDocs/pharma.pdf> (15 July 2012).
- 53 Global pharma looks to India: Prospects for growth, PwC Report, 2010.
- 54 Jayaraman K S, Indian generics companies go on spending spree, *Nature Reviews Drug Discovery*, 4 (2005) 616-617.
- 55 <http://www.daiichi-sankyo.eu/company/global-perspective/global-business-strategy.html> (30 July 2012).
- 56 Ciulu R, Diversification strategy in the pharmaceutical industry, 2008, [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1283129](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1283129) (15 July 2012).
- 57 TRIPS, *Indian generic companies and accessibility of medicines*, paper presented at the Conference on Global Pharmaceuticals, Biotechnology and Health, Institute for Strategic Biotechnology, Health and Training, Mumbai, 6 August 2004.
- 58 *India and China in the knowledge economy: Rivals or allies? Case studies of pharmaceuticals and biotechnology*, paper presented at the Conference on China, India and the International Economic Order, Singapore, 23-24 June 2006.
- 59 Eger T, Incremental innovation and patent protection for pharmaceutical products in India, in *Economic Analysis of India*, edited by P G Babu (Oxford University Press, USA), 2010, p. 129, footnote 2.
- 60 Kiran R, Changing pragmatics of the Indian pharmaceutical industry in the pre and post TRIPS period, *International Journal of Business Management*, 4 (9) (2009) 206-20.
- 61 Bhaduri S, Trips in India: Reasons and rhetorics, *Vidyasagar University Journal of Commerce*, 11 (2006) 28-38.
- 62 WIPO Study on Technology Transfer, Intellectual property and effective university-industry partnerships: The experience of China, India, Japan, Philippines, the Republic of Korea, Singapore and Thailand, 2007.
- 63 Hyndman K G, Technology transfer: What India can learn from the United States, *Journal of Intellectual Property Rights*, 10 (5) (2005) 399-405.
- 64 Agarwal S P, Technology transfer perspectives in globalising India (drugs and pharmaceuticals and biotechnology), *Journal of Technology Transfer*, 32 (4) (2007) 397-423.
- 65 Schumpeter J, *Capitalism, Socialism and Democracy*, 3<sup>rd</sup> edn (Harper Collins, Canada), 1950.
- 66 Lichtenberg F R, Pharmaceutical innovation as a process of creative destruction, in *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech*, edited by M Mazzucato & G Dosi (Cambridge University Press, New York), 2006, p. 61.
- 67 Lichtenberg F R, Pharmaceutical innovation as a process of creative destruction, in *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech*, edited by M Mazzucato & G Dosi (Cambridge University Press, New York), 2006.



- 68 Gifford D J, How do the social benefits and costs of the patent system stack up in pharmaceuticals?, Berkeley Electronic Press Working Paper 209, 23 March 2004.
- 69 Schweitzer S O, *Pharmaceutical Economics and Policy*, 2<sup>nd</sup> edn (Oxford University Press, New York), 2007, p. 274.
- 70 Frank R G & Salkever D S, Pricing, patent loss and the market for pharmaceuticals, *Southern Economic Journal*, 59 (1992) 165-179, cited in *Pharmaceutical Expenditure in Germany: Future Development, Political Influence and Economic Impact*, by Wolf GS, (Nomos Verlagsgesellschaft, Baden-Baden, Germany), 2009, p. 67, 73, 89.
- 71 Stringham E, Kaldor-Hicks efficiency and the problem of central planning, *The Quarterly Journal of Austrian Economics*, 4 (2) (2001).
- 72 Villarreal M, Trips, pharmaceutical innovation and access to medicines, in *Innovation, Employment and Growth Policy Issues in the EU and the US*, edited by P J J Welfens & J T Addison (Springer, Berlin), 2009, Chapter 10.
- 73 Arrow K J, Uncertainty and the welfare economics of medical care, *The American Economic Review*, 53 (5) (1963).
- 74 Scitovsky T, A note on welfare propositions in economics, *Review of Economic Studies*, 9 (1941) 77-88.
- 75 Funk P, Is there an expressive function of law? An empirical analysis of voting laws with symbolic fines, *American Law and Economics Review*, 9 (1) (2007) 135-159.
- 76 Frey B S, The public choice of international organizations, in *Perspectives on Public Choice: A Handbook*, edited by D C Mueller (Cambridge University Press, Cambridge, UK), 1997, pp. 106-123.
- 77 Scitovsky T, Two concepts of external economies, *The Journal of Political Economy*, 62 (2) (1954) 143-151.
- 78 Kuttner R, Market-based failure - A second opinion on US healthcare costs, *The New England Journal of Medicine*, 358 (6) (2008) 549-551.
- 79 [http://www.nytimes.com/2012/06/29/us/supreme-court-lets-health-law-largely-stand.html?\\_r=1](http://www.nytimes.com/2012/06/29/us/supreme-court-lets-health-law-largely-stand.html?_r=1) (4 July 2012).
- 80 Mansfield E, *Microeconomics: Theory and Applications*, 6<sup>th</sup> edn (W W Norton, New York), 1988.
- 81 Feldman Y, The expressive function of the trade secret law: Legality, cost, intrinsic motivation and consensus, *Journal of Empirical Legal Studies*, 6 (1) (2009) 177-212.
- 82 Sunstein CR, Conformity and dissent, Public Law and Legal Theory Working Paper No 34, The Law School, University of Chicago, 2002.
- 83 Thaler R H & Sunstein C R, *Nudge: Improving Decisions About Health, Wealth, and Happiness* (Yale University Press, New Haven), 2008.
- 84 Thaler R H, Sunstein C R & Balz J P, Choice Architecture, [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1583509](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1583509) (12 July 2012).
- 85 Spence A M, Job market signaling, *Quarterly Journal of Economics*, 87 (3) (1973) 355-374.
- 86 Leibenstein H, Allocative efficiency vs. "x-efficiency", *The American Economic Review*, 56 (3) (1966) 392-415.
- 87 Krugman P, *The Return of Depression Economics and the Crisis of 2008* (W W Norton & Company, New York), 2009.
- 88 Mazzucato M and Dosi G, *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech* (Cambridge University Press, New York), 2006, p 12.
- 89 Jensen E, Research expenditures and the discovery of new drugs, *Journal of Industrial Economics*, 36 (1) (1987) 83-95.
- 90 Denicolo V, Economic theories of the non-obviousness requirement for patentability: A survey, *Lewis & Clark Law Review*, 12 (2) (2008) 443-459.
- 91 Kant A, Section 3(d): 'New' Indian perspective, *Journal of Intellectual Property Rights*, 14 (5) (2009) 385-396.
- 92 Page S E, Path dependence, *Quarterly Journal of Political Science*, 1 (2006) 87-115.
- 93 Akerlof G A, The market for "lemons": Quality uncertainty and the market mechanism, *The Quarterly Journal of Economics*, 84 (3) (1970) 488-500.
- 94 Sanders A K, as cited by Eger T, Incremental innovation and patent protection for pharmaceutical products in India, in *Economic Analysis of India*, edited by P G Babu (Oxford University Press, USA), 2010, p. 244.
- 95 Mansfield E, Patents and Innovation: An Empirical Study, *Management Science*, 32 (2) (1986) cited by Eger T, Incremental innovation and patent protection for pharmaceutical products in India, in *Economic Analysis of India*, edited by P G Babu (Oxford University Press, USA), 2010, p. 174.
- 96 Scotchmer S, *Innovation and Incentives* (MIT Press, Cambridge), 2004; as cited by Eger T, Incremental innovation and patent protection for pharmaceutical products in India, in *Economic Analysis of India*, edited by P G Babu (Oxford University Press, USA), 2010.
- 97 Vallée T, Social and technological efficiency of patent systems, *Journal of Evolutionary Economics*, 16 (1) (2006) 189-206.
- 98 James T C, *Patent Protection and Innovation: Section 3(d) of the Patents Act and Indian Pharmaceutical Industry* (Indian Pharmaceutical Alliance, New Delhi), 2009.
- 99 Gallini N T, Patent policy and costly imitation, *RAND Journal of Economics*, 23 (1) (1992) 52-63.
- 100 Gonzalez J, Can branded drugs benefit from generic entry? Switching to non-bioequivalent molecules and the role of physician response to detailing and prices, 2008.
- 101 Cooter R, Lecture titled 'IPRs: should they apply to peasants, professors and students' at the Hamburg Lecture Series, University of Hamburg, 5 September 2011.
- 102 Scotchmer S, Protecting early innovators: Should second-generation products be patentable? *The RAND Journal of Economics*, 27 (2) (1996) 322-331.
- 103 Denicolo V, Two-stage patent races and patent policy, *The RAND Journal of Economics*, 31 (3) (2000) 488-501.
- 104 Denicolo V, Optimal patentability requirements with fragmented property rights, Fondazione ENI Enrico Mattei Working Paper No 134, 2010.
- 105 Denicolo V, Do patents over-compensate innovators?, *Economic Policy (CEPR & CES & MSH)*, 22 (2007) 679-729.
- 106 Boldrin M & Levine D K, The case against intellectual property, *American Economic Review*, 92 (2) (2002) 209-212. The government-enforced intellectual monopoly's regulatory capture 'has extended to the entire U.S. Congress, which has, on numerous occasions, unanimously voted to extend the period of copyright retroactively'.
- 107 Tait J, Governance, policy and industry strategies: Pharmaceuticals and agro-biotechnology, in *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech*, edited by M Mazzucato and G Dosi (Cambridge University Press, Cambridge), 2006, p. 384, 399.

- 108 Ugo P, The crash of the knowledge economy, *Cambridge Journal of Economics*, 33 (4) (2009) 665-683.
- 109 Bossche P Van den, *The Law and Policy of the World Trade Organization* (Cambridge University Press, Cambridge), 2007.
- 110 Correa Carlos, lecture titled International development in IP: How far protectionism can go? at the Hamburg Lecture Series, University of Hamburg, 19 April 2012.
- 111 Mohanty N K, The advantage/disadvantage of the harmonization of the patent system, 2008.
- 112 WIPO World Intellectual Property Report: *The Changing Face of Innovation*, 2011, p. 14-16.
- 113 The global innovation 1000 – Why culture is key, Booz Report, 2011.
- 114 Sandoz to acquire Fougere Pharmaceuticals, becoming the number one generic dermatology medicines company globally and in the US, Media releases, 2 May 2002, <http://www.novartis.com/newsroom/media-releases/en/2012/1608221.shtml> (30 July 2012).
- 115 <http://www.tevapartners.com> (30 July 2012).
- 116 Bharathan G, Bt-cotton in India: Anatomy of a controversy, *Current Science*, 79 (8) (2000) 1067-1075.
- 117 Orsi F, Upstream patents and public health: The case of genetic testing for breast cancer, in *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech*, edited by M Mazzucato and G Dosi (Cambridge University Press, Cambridge), 2006.
- 118 *Association for Molecular Pathology vs US Patent & Trademark Office*, 653 F.3d 1329, 99 U.S.P.Q.2d 1398 (Fed Cir 2011) [2011 BL 197401].
- 119 OECD guidelines for the licensing of genetic inventions, 2006.
- 120 *Monsanto v Cefetra*, 2010, ECJ case no C-428/08.
- 121 Regibeau P, Competition, regulation and intellectual property management in genetically modified foods: Evidence from survey data, in *Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech*, edited by M Mazzucato and Dosi G (Cambridge University Press, Cambridge), 2006.