

There cannot be any doubt that it is noble for any country to pursue a policy which stimulates and rewards innovative elements in society, especially when these creations lead to advantages which society as a whole can reap. Although this may provide the originally intended purpose for the intellectual property regime,<sup>4</sup> the ensuing exclusive rights possess the ability to restrict free trade which can, in certain circumstances, even burden society. This negative effect of intellectual property rights can even lead to situations whereby elements of society are hindered from gaining benefits that would relieve their discomfort, illness and/or harm. The intellectual property regime, in particular the patent system, would thus appear to be paradoxical in nature. This however is not the case. The basic tenet of an open market is that free (unencumbered) trade increases economic growth and raises standards of living.<sup>5</sup> Patents form an exception to this rule in that they intentionally restrict trade yet also have the effect that society gains knowledge and efficiency from the invention, thus bringing with it an enrichment to society.<sup>6</sup> The balance between the interest of the society as a whole and that of the inventor rests on the condition that exclusive rights may only be granted for a limited period and when the inventor creates something that is new, non-obvious, useful and discloses the way in which to recreate the invention.<sup>7</sup> This relationship between the patent and the government-granted exclusive rights reflects a type of reciprocal pact in which both parties (the inventor and the government representing society) pay a 'price' in exchange for exclusive rights on the one hand and the creation and diffusion of knowledge and efficiency on the other hand.<sup>8</sup> It is upon this bargain that the patent system is based and justified.<sup>9</sup>

4    *May*, EIPR 1 (2003) p. 2.

5    *Beier*, 11 IIC 5 (1982) p. 548-549.

6    *Templeman*, 1 JIEL 4 (1998) p. 603, *Gervais*, 1 JIPLP 4 (2006) p. 252. *Maskus* makes an analogy between intellectual property rights and exclusive rights to property and notes that both are potentially growth-enhancing. *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 145-146. Early commentators on free trade also did not oppose the patent system. *Beier* also notes that patent rights were, from their beginning, a natural partner of the free market economy. Cf. *Beier*, 11 IIC 5 (1982) p. 549.

7    As early back as 1848 *Mill* was able to make the following clear defence of the patent system: 'Because it leaves nothing to any one's discretion; because the reward conferred by it depends on the invention's being useful, and the greater reward; and because it is paid by the very persons to whom the service is rendered, the consumers of the commodity', Quoted in *Beier*, 94 GRUR 4 (1992) p. 231.

8    *CIPR*, (2002), p. 32, *May*, EIPR 1 (2003) p. 2.

9    An attempt to adequately address either the numerous theories justifying patents or the social, political and legal arguments in favour or against the intellectual property regime would however unnecessarily divert the purpose of this dissertation. As such, the societal justification of

Is the price society pays for the patent too high? This may indeed be the case when one looks at individual patents. Looking at the patent system on a whole it is important to realise that the creation of and the access to knowledge forms the fundamental driving powers behind the development of mankind. Accordingly, the wealth of new and useful information that the patent system brings is, in itself a means whereby society is able to develop.<sup>10</sup> It is almost impossible to quantify the benefit mankind has received through the patent system however patented inventions like the light bulb,<sup>11</sup> the telephone<sup>12</sup> and the four-stroke/Otto cycle engine<sup>13</sup> have themselves brought incalculable benefits to society. This benefit of the patent system was recognised from the very beginning and used as a measure for countries to improve their competitiveness and level of development.<sup>14</sup>

It was also early on in the development of the patent system that governments noticed that exclusive rights could also be abused and misused. As a result and in order that the patent system does not hamper development in an unjustifiable manner, safeguards were introduced to counter the potential misuse or abuse of the patent system.<sup>15</sup> Hence, it can be said that the patent system is there to add to society's wealth – where it fails to do so, the patent system allows society the means to remove the harmful and infringing elements that prevent this. At least in theory, it can therefore be said that there is a balance of rights and obligations within the patent system.

Again from a theoretical perspective, the territorial nature of patent rights further ensures that the benefits can be reaped by all countries, both rich and poor. The reason for this is that the patent exclusivity is limited to the country in which the patent rights are granted. Hence, in each and every country where the inventor acquires patent protection that country has a 'sufficiently clear and complete' description of how the invention works.<sup>16</sup> In other words, in exchange for granting of the patent rights that country has enriched its knowledge base. The countries, in which the inventor decides not (or is not able) to seek patent protection, also benefit because the invention, the existence and operation of which is already fallen into the public do-

intellectual property rights, in particular patent rights, is dealt with briefly and from a current standpoint.

10 *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 150.

11 *Edison* applied for a patent for the 'Improvement in the Electric Lights' in 1878.

12 *Bell* was granted a patent in 1875 for 'Transmitters and Receivers of Electric Telegraphs' (US Patent 161,173).

13 *Barsanti* and *Matteucci* obtained the first patent for the four-stroke/Otto cycle engine in 1854.

14 *Granstand* notes that intellectual property rights are even older than capitalism. Cf. *Granstand*, The Economics and Management of Intellectual Property (Edward Elgar Cheltenham 1999) p. 5, 27-41.

15 The most famous example is the 1623 English Statute of Monopolies. The statute made reference to situations whereby the patented would be rendered void, for example price rises, injury to trade, inconvenience. Cf. *Davenport*, The United Kingdom Patent System: A Brief History (Mason London 1979) p. 20.

16 TRIPS Agreement Art 29.1.

main, can then be freely used by third parties.<sup>17</sup> In practice, however, not all countries are able to reap these rewards. Blaming the patent system for this would be wrong. This inability is due to market factors and insufficient resources; not all countries have the willpower or capacity to produce products domestically – it is often more affordable to import products instead of producing them locally.<sup>18</sup> Regardless of the reason for not making use of the invention (either on or off patent), the ‘blame’ for not doing so is economical or political; rarely is it the patent system itself that can be held responsible for the lack of access.

Criticism of the patent system also originates in the expectations individuals and countries have developed. The patent system is not one that will magically turn all countries adopting it into first-world nations.<sup>19</sup> The patent system only is one of many governmental measures and it alone cannot guarantee a country financial prosperity.<sup>20</sup> It may create an added incentive for an inventor to register its patent but it does not mean that the patent will be successfully exploited in that country, if at all.<sup>21</sup> Despite the neutral effect<sup>22</sup> a patent will *ipso facto* have on a country *Straus* has shown that the adoption of a patent system does not in itself bring less prosperity to a country.<sup>23</sup> In fact, it is a positive indication for a country when inventors increasingly seek patent protection for their inventions. The reason for this is that an inventor will be more willing to apply for a patent, thus paying the application fees and most likely also undertaking a degree of investment in a country that can give the inventor a likelihood of it capitalising on its invention.<sup>24</sup> The more inventors a country is able to attract the more knowledge it is able to accumulate and the more

- 17 A 1997 study of the Indian pharmaceutical market showed that local generic producers were quick to manufacture generic versions of the original product (patented elsewhere). Cf. *Lanjouw* referred to in *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 162.
- 18 *Maskus* provides examples of how open markets were most able to profit, *inter alia*, from intellectual property markets. Cf. *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 169.
- 19 *CIPR*, (2002), p. 39.
- 20 *Kongolo*, 33 IIC 2 (2002) p. 208-209.
- 21 For a discussion on the role of patent rights in national development see *Granstand*, The Economics and Management of Intellectual Property (Edward Elgar Cheltenham 1999) p. 41-45.
- 22 *Blakeney*, A critical analysis of the TRIPS agreement in: *Pugatch* (ed) The Intellectual Property Debate (Edward Elgar Cheltenham 2006) p. 19.
- 23 *Straus*, 6 J. Marshall Rev. Intell. Prop. L 1(2006) p. 1-16. It would however be amiss to draw the conclusion that the intellectual property rights had themselves solely lead to the economic growth in India and China. Such a conclusion ignores the complex macro and micro economic factors that affect the economic growth of a country. Compare *Gervais*, 1 JIPLP 4 (2006) p. 252-253, *Ullrich*, Transformations in IPR, in *Brunn* (ed) Intellectual Property Beyond Rights (WSOY Helsinki 2005) p. 4-5.
- 24 *Abbott*, 1 JIEL 4 (1998) p. 506. *Abbot* also acknowledges other positive factors that may derive from an intellectual property regime, such as added legal security and domestic innovation stimulations.

investment it is also able to count on.<sup>25</sup> This in turn increases market efficiency and competitiveness. The more efficient a country is, the more its wealth is effectively utilised. The sum of all these factors is that the country becomes more attractive for investment and more developed.<sup>26</sup> Innovation has hence become the mainspring of economic growth.<sup>27</sup> Despite this it would be wrong to state that a patent regime would bring short-term benefits.<sup>28</sup> Its true value can only truly be reaped in the long-term; and even then only as one part of a comprehensive domestic strategy.<sup>29</sup>

As mentioned at the beginning of this chapter, critics of the patent system suggest that it could be a barrier to obtaining access to certain essential and life-saving medicines. Critics suggest that patented medicines are higher in cost than similar non-patented medicines (or equivalent generic versions of the patented medicine).<sup>30</sup> This accusation is, in some instances true.<sup>31</sup> Seldom will one find a patented medicine trading at the same or lower price of a generic version thereof. However this accusation has little to do with a misuse or abuse of the patent rights.<sup>32</sup> Quite simply the patent period is a period of exclusivity designed to allow the patent holder the chance to recoup the resources invested into the creation of the pharmaceutical and,

- 25 *Lippoldt*, Can stronger intellectual property rights boost trade, foreign direct investment and licensing in developing countries? in: *Pugatch* (ed) *The Intellectual Property Debate* (Edward Elgar Cheltenham 2006) p. 58-59. Contrast *Blakeney*, A critical analysis of the TRIPS agreement in: *Pugatch* (ed) *The Intellectual Property Debate* (Edward Elgar Cheltenham 2006) p. 23.
- 26 In summing up recent studies on the effect of intellectual property *Gervais* concludes that 'sufficient intellectual property protection is an essential component of increased FDI and trade flows ... for countries above a certain economic development threshold'. Cf. *Gervais*, 1 *JiPLP* 4 (2006) p. 252-253. *Maskus* states that the lack of intellectual property protection hindered research and development and led to poor product quality production. Cf. *Maskus*, *Intellectual Property Rights in the Global Economy* (IIE Washington DC 2000) p. 150. *Imam* also indicates that stronger intellectual property rights could attract FDI to developing countries. Cf. *Imam*, 37 *IIC* 3 (2006) p. 259.
- 27 --, Innovation and the economy: The good, the bad and the ugly, *The Economist* (04.08.2007) p. 29.
- 28 *Imam* notes that development in itself is a gradual process and that intellectual properties can be used as a tool for economic development. Cf. *Imam*, 37 *IIC* 3 (2006) p. 259.
- 29 *Gervais*, 1 *JiPLP* 4 (2006) p. 252, 254-255.
- 30 *CIPR*, (2002), p. 36.
- 31 Although confirming this point, *Maskus* does however note that 'such fears may be overstated'. Notwithstanding this, the higher price for patented pharmaceuticals can and is set-off by: the benefits deriving from increased transfers of technology through trade, FDI and licensing; the improved likelihood of innovative enterprises placing newer products on that market and; a lower price impact where the market is already a competitive market economy. *Maskus*, *Intellectual Property Rights in the Global Economy* (IIE Washington DC 2000) p. 159-160, 162. *Imam* also states that an appropriate intellectual property regime could aid technology transfers and help reduce the academic brain-drain in some countries by giving innovative scientists an economic incentive to remain. Cf. *Imam*, 37 *IIC* 3 (2006) p. 253, 259.
- 32 There are numerous other factors that affect pharmaceutical prices: market structure, demand elasticity, pricing regulations and competition policies. Cf. *Maskus*, *Intellectual Property Rights in the Global Economy* (IIE Washington DC 2000) p. 160-161, *CIPR*, (2002), p. 34-39.

where possible, to make a profit.<sup>33</sup> As pharmaceutical companies and other inventors are principally profit-driven they not only have a right to make money but also a need to do so in order to ensure the health of the company and to invest in new research and development.<sup>34</sup> Expecting pharmaceutical inventors to behave otherwise would be short-sighted and ultimately lead to less research and development and, in turn, to fewer new medicines.

Patents are also accused of creating a monopoly that inhibits subsequent development in this field. It is correct to say that a patent prevents a third party from exploiting the patent for the duration of the patent. It does not, however, prevent the third party from creating an invention which competes with the first patent. More often than not it is the patented invention that competes with existing unencumbered products on the market. Only when the patented invention is able to show that it is better will consumers migrate to the new product – this is especially the case when the patented invention costs more than the existing products on the market. This added competition inspires other producers in the market to update or even develop novel inventions themselves in that field.<sup>35</sup> It is seldom that a patent holder is able to create an invention that corners an entire market and prevents competitors from interacting on the market without its consent. In the past where such patented inventions have indeed cornered a market the result has been that the competition stagnates and, possibly, that the patent holder misuses this situation to its advantage. Where this is the case governments are able to use the safeguards in the patent system to redress the imbalance, allowing, *inter alia*, third parties to exploit the patent without the patent holder's consent by way of a compulsory license. In addition hereto, competition law is also able to provide remedies.<sup>36</sup>

The increasingly global character of patent rights has also been criticised as requiring a common standard of intellectual property rights for countries regardless of their different financial, social and market characteristics. The basis for this criticism stems from the TRIPS Agreement which sets a minimum patent standard for all Member States to implement.<sup>37</sup> Although this is clearly the intention of the TRIPS Agreement, currently one cannot speak of a universal obligation on all WTO Member States.<sup>38</sup> Full implementation for all WTO Member States of the TRIPS obliga-

33 *CIPR*, (2002), p. 34.

34 The *CIPR* correctly reminds critics of the intellectual property regime that pharmaceutical companies are commercially driven. Cf. *CIPR*, (2002), p. 32.

35 *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 147.

36 *Anderson*, 1 JIEL 4 (1998) p. 655-675, for a European perspective *Manley and Wray*, 1 JIPLP 4 (2006) p. 266; for an Italian perspective *Coco and Nebbia*, 2 JIPLP 7 (2007) p. 452-452.

37 It is also interesting to note that the patent system was close to being disbanded in the late 18th to late 19th century in Europe. Objections were raised on the basis of free-trade and anti-monopolistic principles. Cf. *Granstand*, The Economics and Management of Intellectual Property (Edward Elgar Cheltenham 1999) p. 35.

38 *May*, EIPR 1 (2003) p. 2, 4.

tions was initially only required in 2006.<sup>39</sup> This has since been extended to 2016 for pharmaceutical patents<sup>40</sup> and can, by means of an application, be extended on a case-by-case basis.<sup>41</sup> Notwithstanding this, implementing an intellectual property regime in accordance with the TRIPS Agreement need be done in a manner that balances the interests of innovators and those of the society as a whole. It is not only a matter of creating a legal framework but also a social and political awareness on how to use intellectual property rights in a manner that will suit that country itself.<sup>42</sup> No country is the same and neither are the social and welfare pressures on the budget. Each country needs to decide for itself how it is to make effective use of the intellectual property regime.<sup>43</sup>

All taken into account, *Granstand* makes a poignant remark:

‘... although the patent system has often been found to be deficient, it has been better than nothing, and there has been no better incentive system for technical progress in the commercial sector’.<sup>44</sup>

This quote reflects my opinion. The intellectual property regime imposed by the TRIPS Agreement is fundamentally good and has the potential to benefit all countries who subscribe to it.<sup>45</sup> The reason for this lies in the TRIPS Agreement itself. It can be interpreted and implemented in ways that allow Member States to better structure it to suit their own domestic situations.<sup>46</sup> Understanding what the TRIPS Agreement actually requires is thus essential to ensuring the patent system has a positive effect on the country implementing it. This goal, the understanding of the TRIPS Agreement, is critically investigated in this dissertation. Further the effects of

39 TRIPS Agreement Art 65.

40 Public Health Declaration para 7, *Gervais*, 1 JIPLP 4 (2006) p. 250.

41 TRIPS Agreement Art 66.1.

42 *Maskus*, Intellectual Property Rights in the Global Economy (IIE Washington DC 2000) p. 143-170. *Maskus* provides the Japanese patent system between 1960 and 1993 as an example of how the patent system was used to enhance development. Compare *Kongolo*, 33 IIC 2 (2002) p. 208-209.

43 *Straus* and *Hindley* both come to the conclusion that it is not the obligations required by the TRIPS Agreement that require rebalancing but rather that the WTO balance between concessions made in respect to goods, services and intellectual property that requires rebalancing. Cf. *Straus*, 6 J. Marshall Rev. Intell. Prop. L 1(2006) p. 16, *Hindley*, The TRIPS agreement: the damage to the WTO in: *Pugatch* (ed) The Intellectual Property Debate (Edward Elgar Cheltenham 2006) p. 41. *Imam* further notes that countries should adapt the intellectual property regime to suite their own techno-economic development. Cf. *Imam*, 37 IIC 3 (2006) p. 259.

44 *Granstand*, The Economics and Management of Intellectual Property (Edward Elgar Cheltenham 1999) p. 44-45.

45 Other authors have been arguing in favour of a intellectual property regime that can be adjusted according to social needs of the country implementing the regime. Cf. *May*, EIPR 1 (2003) p. 4-5.

46 *Gervais* speaks of the TRIPS Agreement’s ‘built-in normative elasticity’. Cf. *Gervais*, 1 JIPLP 4 (2006) p. 255.

the Public Health Declaration and the subsequent agreements on this understanding are also critically assessed.<sup>47</sup>

47 Interpreting and implementing the TRIPS Agreement will pose difficult policy decisions for countries seeking to adopt or adjust their domestic intellectual property regime. The advantages or disadvantages of such choices or their socio-economic effects are not dealt with here. This dissertation seeks to create a better understanding of what choices are legally tenable under the auspices of the TRIPS Agreement and also addresses the legal effects that the Public Health Declaration may have had on the interpretation of the TRIPS Agreement.