

# TWEAKING PATENT LAW: PATENT LAW POLICY AND PHARMACEUTICAL PATENTS\*

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He was very suspicious of inventors,  
for they always meant that some rule had to be broken.

P Susskind *Perfume* (2001)

## 1. INTRODUCTION

The Constitution recognises the basic right of access to health care services, including reproductive health care, but the guarantee is subject to an important proviso, namely that it is dependent on the state's 'available resources' (s 27(1) (a) and (2)). The effect of this limitation formed the basis of the judgment in *Soooramoney v Minister of Health (KwaZulu-Natal)*,<sup>1</sup> which held that the state had no duty to provide a particular patient with expensive dialysis treatment, since it would impact negatively on its obligation to supply basic health care services to the general public. As Chaskalson CJ said (at para 11):

What is apparent from these provisions is that the obligations imposed on the state by sections 26 and 27 in regard to access to housing, health care, food, water and social security are dependent upon the resources available for such purposes, and that the corresponding rights themselves are limited by reason of the lack of resources. Given this lack of resources and the significant demands on them that have already been referred to, an unqualified obligation to meet these needs would not presently be capable of being fulfilled.

Since a large proportion of the community does not have the resources to pay for basic health services, the state has to carry more than its reasonable share of the burden. The state has in this regard many challenges, some self-created: limited or inappropriate use of resources; a lack of infrastructure; the uneven spread of available health services; pandemics such as HIV/AIDS, tuberculosis and malaria; limited training facilities; the medical and nursing brain drain; the many claims for medical negligence; and, for present purposes, the cost of pharmaceuticals.

The high cost of pharmaceuticals, especially those at the cutting edge of medical technology, is laid at the door of the pharmaceutical industry and more particularly research-based multinationals. This finger-pointing deflects attention from structural, personal and fiscal failure for which the state and its

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<sup>1</sup> [1997] ZACC 17; 1998 (1) SA 765 (CC); 1997 (12) BCLR 1696.

organs bear responsibility. The industry is also an easy target because it forms part of the global capitalistic, some would say parasitic, world.

Generic companies – companies that do not rely on research but which prefer to concentrate on pharmaceuticals that are no longer under patent or are on licences – are not subjected to the same level of opprobrium even though they are part of the same profit-driven world. The difference is due to pharmaceutical patents and the focus is accordingly on methods to limit the costs of medicines by curtailing patent rights while at the same time seeking to comply with international obligations imposed by the Paris Convention<sup>2</sup> and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement).<sup>3</sup> The recently published Draft National Policy on Intellectual Property<sup>4</sup> purports to seek an appropriate balance, committing the government to reduce the high cost of medicines attributable to patent rights while complying with its international patent obligations.<sup>5</sup>

Patent law has been around for more than 500 years and in all those years the basic character of patents has not undergone fundamental change. No one has been able to devise a more satisfactory system to promote and reward innovation in spite of the fact that the law has some inherent fault lines.<sup>6</sup> The most conspicuous of these is the fact that all inventions are treated equally: they all have the same life span irrespective of merit. This problem is not peculiar to patent law; it also bedevils copyright law. But since no one has been able to conceive of a viable method to determine the Brownie points that any particular invention or copyright work deserves, this aspect of the law appears to be immutable.<sup>7</sup>

Jeremy Phillips, as did many others, pointed to the vast and all-but-unbridgeable gulf between the social, political, moral and economic bases upon which human activity is carried on in China and the West, and the consequent differences in perception as to how the public interest may be defined and applied.<sup>8</sup> The same applies, if not more so, to the gulf between the developed world and the developing world. Agreements such as TRIPS are

2 1883.

3 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement).

4 *Government Gazette* 36816 of 4 September 2013, available at [www.gpwonline.co.za](http://www.gpwonline.co.za).

5 My more general discussion of the policy is available at <http://blogs.sun.ac.za/iplaw/files/2013/09/HARMS-Comment-IP-POLICY.pdf> or at <https://www.dropbox.com/s/jjgtz72oiykhcgl/HARMS-Comment%20IP%20POLICY%20%282%29.pdf> (both viewed on 14 April 2014).

6 D Vaver 'Sprucing up patent law' (2010) 23 *IPJ* 63.

7 The Patents Act 37 of 1952 permitted the extension of the term of a patent on the ground of inadequate remuneration. The only feasible measure was to have regard to the effective term of a particular patent. The provision was mainly used by the pharmaceutical industry because they could show that, due to regulatory requirements, they lost years as they could only be remunerated once all the necessary testing was done and permissions granted. A similar provision would, in the eyes of the Draft Policy, be counterproductive as are the Supplementary Protection Certificates that are available in Europe: Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version).

8 J Phillips 'Eastern delight: Two new titles on IP in Asia', available at [http://groups.google.com/group/ipkat\\_readers/browse\\_thread/thread/74b42bde52bc73d4](http://groups.google.com/group/ipkat_readers/browse_thread/thread/74b42bde52bc73d4) (viewed on 7 April 2014).

based on the illusion that there is no such gulf. TRIPS in particular promised that protection and enforcement of intellectual property rights (IPRs) would contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users, and that it would be conducive to social and economic welfare and a balance of rights and obligations. Whether or not the promise is or can be fulfilled need not be investigated now, given the government's stated objective in the Draft Policy of honouring its TRIPS obligations while using the 'flexibilities' TRIPS permits.<sup>9</sup>

Although the Draft Policy contains no specific proposals as to how the Patents Act 57 of 1978 should be amended to attain its objects, it does mention some areas which appear to be in contemplation. What follows is an attempt to identify those areas and to assess whether or not such amendments would likely have the desired effect. Any change needs to be carefully considered to ensure that it is not only window dressing but instead achieves its object of reducing the costs of pharmaceuticals consistently with TRIPS.

As context, it might be useful first to give an overview of the patent history of the much publicised Hoodia plant's appetite suppressing ability.

## 2. HOODIA

I shall not discuss the rights of the San or Bushmen<sup>10</sup> to inventions that flow from the use of the plant or their indigenous knowledge. Rather, this case history illustrates how precarious pharmaceutical inventions are and what effect any tampering with the present system might have. The time line used is also limited to those dates and facts that are relevant for the present discussion.<sup>11</sup>

It would appear that the first scientific record of the thirst and appetite suppressant uses of the Hoodia plant by the San was in a 1937 publication by White and Sloane dealing with the account of the Dutch ethno-biologist R Marloth of some years earlier. During the period 1963 to 1971, Hoodia was investigated by scientists, initially as part of a project on edible indigenous plants. Laboratory studies at the Council for Scientific and Industrial Research (CSIR) at the time provided evidence of the appetite suppressant properties contained in extracts of Hoodia. The lack of appropriate equipment inhibited further research until 1982 when the National Chemical Research Laboratories

9 For an analysis of the TRIPS flexibilities see *Max Planck Institute for Innovation and Competition* 'Declaration on patent protection regulatory sovereignty under TRIPS' (Version 1.0 of 15 April 2014), available at <http://www.ip.mpg.de/en/pub/news/patentdeclaration.cfm> (viewed on 16 April 2014).

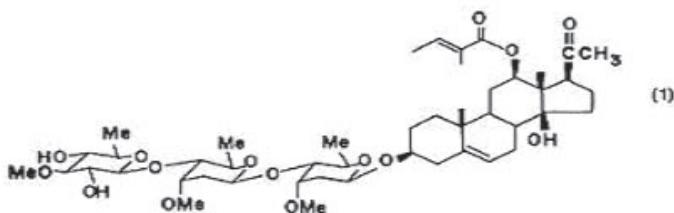
10 D J Stephenson Jr 'The patenting of P57 and the intellectual property rights of the San peoples of southern Africa' (conference paper April 2003) 3 states that the term 'Bushman' is often disdained by the San, because some people in southern Africa consider the term 'Bushman' to refer to backward, unclean, and uncivilized people but that, on the other hand, some San are proud of the name as signifying their heritage, and, consequently, the word 'has been partially rehabilitated', available at [http://doczine.com/bigdata/1/1367403986\\_23f26046\\_11/22002777.pdf](http://doczine.com/bigdata/1/1367403986_23f26046_11/22002777.pdf) (viewed on 4 April 2014).

11 The information prior to 2003 comes from D J Stephenson, Jr (n10).

of CSIR acquired state-of-the-art equipment for isolating and characterising natural products, which enabled it to identify the appetite suppressant agent in Hoodia, which it named P57.

On 4 April 1997 the CSIR filed its SA Patent Application 983170, listing five inventors, and in due course filed Patent Cooperation Treaty (PCT) International Application No PCT/GB98/01100. Patents were subsequently issued in (at least) South Africa, the United Kingdom (patent GB2338235) and the USA (patent 6 376 657). They are all due to lapse on 3 April 2017.

According to the USA patent specification, the invention relates to an appetite suppressant agent consisting of steroidal glycosides being an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia*; a process for synthetically producing the appetite suppressant agent; a process for extracting the appetite suppressant agent from plant material; an appetite suppressant composition containing the appetite suppressant agent; and to a method of suppressing an appetite. It also includes 'a new use for these steroidal glycosides'. This is the chemical structure:



In spite of the exciting invention, its commercialisation came to nought. Large pharmaceutical companies (Pfizer and Johnson & Johnson) terminated their investigations.<sup>12</sup> Even if someone makes a breakthrough before 2017, it will be necessary to proceed to clinical and other tests to satisfy the Medicines Control Council, a body which, according to the Draft Policy, is not functioning as it should.

I use this example to pose the following questions:

- (a) If the P57 problems are now solved, should the patentee be entitled to protection and the San be entitled to share in the profit beyond 2017?
- (b) If P57 is found to be effective against AIDS, would a patent for the new use (as an anti-retroviral) be in order?
- (c) If the P57 molecule is altered to produce another appetite suppressant or another medicine (say, anti-retroviral), would a new patent be in order?

The Draft Policy would have it that the answer in all three cases should be no.

12 Some of this has been related in LTC Harms 'A few negative trends in the field of intellectual property rights' 2009 *THRHR* 175; (2009) 31 *EIPR* 540 and LTC Harms 'Indigenous traditional knowledge and intellectual property law' (2010) 41(5) *IIC* 503.

### 3. EVER-GREENING

Ever-greening is not a legal concept but the term is used to describe legal and business strategies that patentees use to prolong a monopoly after the expiry of the term of a patent.

One such strategy was to prevent a would-be competitor from performing the necessary tests during the life of a patent for approval of a medicine which is to be marketed upon expiry.<sup>13</sup> This practice gave rise to the Bolar exception contained in s 69A of the Act which permits such testing.

Another strategy was and is the use of other IPRs, such as trade marks and copyright, to extend the term of the monopoly in an indirect manner, for instance by trademarking the shape of a tablet<sup>14</sup> or to prevent copying of the prescribed package insert under copyright principles.<sup>15</sup> This is not peculiar to pharmaceuticals. Copyright was used in failed attempts to extend the monopoly in the game *Monopoly*<sup>16</sup> and trade mark and passing-off law to perpetuate the rights in *Lego blocks*.<sup>17</sup>

The use of patent law itself for purposes of ever-greening in the pharmaceutical field is said to take one of two forms: ‘tweaking’ and ‘new use patents’.

#### 3.1 Tweaking

According to news reports the Minister of Health, Dr Aaron Motsoaledi, referred on 13 March 2014 to the practice of tweaking of molecules. Pharmaceutical firms, he allegedly said, just tweak one molecule when a medicine patent is about to expire and then apply for a new patent.

One need not be a rocket scientist (if the mixing of metaphors may be excused) to realise that this statement does not make any scientific sense. Messing around with ‘one molecule’ will probably require the use of the Large Hadron Collider. What the Minister probably had in mind is the replacement of any one of the radicals of a molecule, thereby producing another type of molecule. It is not merely a question of ‘just’ tweaking: as the general formula illustrated above indicates there may be millions of possibilities of tweaking an organic molecule, depending on the specific compound.<sup>18</sup> The problem is that one cannot predict with a reasonable degree of certainty whether the tweaked molecule will have the same or similar efficacy, whether it will be toxic or not, or whether it will be of any use whatsoever.

13 *Stauffer Chemicals Chemical Products Division of Chesebrough-Ponds (Pty) Ltd v Monsanto Co* 1988 (3) All SA 279 (T); 1988 (1) SA 805 (T).

14 *Beecham Group Plc and another v Triomed (Pty) Ltd* [2002] ZASCA 109; 2002 (4) All SA 193 (SCA).

15 *Biotech Laboratories (Pty) Ltd v Beecham Group Plc and another* [2002] ZASCA 11; 2002 (4) SA 249 (SCA).

16 *John Waddington Ltd v Arthur E Harris (Pty) Ltd* 1968 (1) All SA 174 (T), 1968 (1) SA 38 (T) and on appeal 1968 (3) All SA 360 (T), 1968 (3) SA 405 (T).

17 *Kirkbi AG v Ritvik Holdings Inc/Gestions Ritvik Inc* (2005) SCC 65 [Canada].

18 *Stauffer Chemical Co and another v Safsan Marketing & Distribution Co (Pty) Ltd and others* 1987 (2) SA 331 (A).

The argument is in any event legally without merit:

- Tweaking a molecule does not extend the life of the original patent on the ‘untweaked’ molecule.
- To be patentable the tweaked molecule must be new and inventive at the time of the application for the new patent, otherwise the patent is invalid.
- If the molecule passes that hurdle and is new and inventive and an otherwise valid patent issues, the ‘old’ molecule covered by the expired patent is nevertheless free for all to use.
- Anyone is in any event free to tweak a molecule covered by a patent to prepare a new molecule during the life of the patent and patent the new molecule if it is inventive.
- However, if the tweaked molecule lacks inventiveness – ie if it is obvious – anyone would be free to use the tweaked molecule during the life of the original patent and thereafter.

A change to the definition of ‘inventive step’ in s 25 of the Patents Act is nevertheless imaginable, in line with the definition contained in s 2(1)(jA) of the Indian Patents Act 39 of 1970 (as amended) and our membership of Brazil, Russia, India, China and South Africa (BRICS), which states that an ‘inventive step’ means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art’.

The first requirement (‘involves technical advance as compared to the existing knowledge or having economic significance or both’) is not in our Act and the question arises whether anything will change if it is incorporated. The answer is no, for two reasons. First, an invention that does not involve a technical advance or has no economic significance will probably be invalid because it is inutile (s 61(1)(d)). Second, no one will patent or seek to infringe something that does not have any economic significance.

### 3.2 New use patents

Section 25(9) of the Act provides that:

[I]n the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art immediately before the priority date of the invention shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date.

It should be read with s 25(11) which states that:

[A]n invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall be deemed not to be capable of being used or applied in trade or industry or agriculture.

What subsec (9) means in simple terms is that if a known medicine (a ‘substance or composition [which] forms part of the state of the art’) is found to be useful for the treatment of another disease, the new use may be patented

provided the new use is not obvious. Subsec (11) does not deal with the same issue. It deals with ‘a method of treatment’ as such, which may not be patented in contradistinction with a ‘substance or composition for use in a method of treatment’, which may.

A neat illustration of the issue covered by subsec (9) is the history of Aspirin. Hippocrates wrote in about 400 BC about the analgesic qualities of willow bark. In 1829 scientists established that salicin in the bark is a pain-killer. It was first synthesised in 1869 but since it is an acid it had serious side-effects. The problem was solved with the invention in 1899 by Hoffmann (Bayer) who found a method to neutralise the acid and the end product, Aspirin, became a standard analgesic. Today we know that Aspirin can be used for the prevention or treatment of heart attacks, strokes, foetal growth retardation, colon cancer, diabetes and dementia. The question from a public policy point of view is whether these new uses should be capable of being patented.

An example closer to home is the hypothetical question posed earlier, namely, if P57 were found to be effective against AIDS, would a patent for the new use as an anti-retroviral be in order? Under the Act as it stands it would be, provided the new use is inventive. Public policy in this case must be the same as in the Aspirin case, even if it would affect the CSIR or the San.

One may only assume that if the provision is removed the intention will be to make patenting impossible – which raises the question why anyone would spend time, effort and money to determine other non-obvious uses for existing medicines. Removal of the provision will not have any effect because it was probably unnecessary and introduced because it was in the European Patent Convention on which the Act was based. A new use of a known thing, process, substance or composition which is not obvious is in principle patentable in a new method claim and the same would apply to subject matter covered by subsec (9).<sup>19</sup>

The Indian Act (s 3(d)) does not allow the patenting of:

[T]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

The provision falls broadly into two parts. The first relates to ‘the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance’. The meaning of ‘known substance’ is affected by an ‘explanation’ which is in these terms:

For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

19 TD Burrell *South African Patent and Design Law* 3 ed (1999) 178–179 where the case law is collected.

The meaning of the ‘enhancement of the known efficacy’ was the subject of a two-judge decision of the Supreme Court of India in *Novartis v Union of India*.<sup>20</sup> It held that the test of efficacy depends upon the function, utility or the purpose of the product under consideration. For a medicine that claims to cure a disease the test of efficacy is therapeutic efficacy, and for a vaccine, prophylactic efficacy.

The new use provision is in the second part of s 3(d). Acting again on the supposition that our legislature could imitate this provision, it is questionable whether its adoption would make any difference because it speaks of the ‘mere discovery’ in contrast to ‘discovery’. Apart from the fact that the use of the word ‘discovery’ in this context is unfortunate because discoveries have never been patentable, the distinction between a ‘mere discovery’ and a ‘discovery’ appears to suggest that the first is one which is not inventive. In other words, if the discovery of the new use were to be more than mere, ie non-obvious, it would be patentable.

#### 4. PARALLEL IMPORTATION

The Patents Act in its original form did not deal with importation as an infringing act, but such a provision was specifically introduced through the 1997 amendment,<sup>21</sup> presumably to comply with art 38 of the TRIPS agreement. Thus, if goods made by or under licence of the patentee of a South African patent in a foreign jurisdiction are imported into this country without the consent of the patentee, the importation is an act of infringement. Patentees often refuse such consent to protect their channels of distribution or to enforce price differentiation. The practice of importing goods which do not infringe in the country of origin, without consent of the rights holder, is colloquially known as ‘parallel importation’ or the importation of ‘grey goods’. What was not considered when the Act was amended was that art 38 of TRIPS is subject to art 6, which provides that the TRIPS agreement may not be used to address the issue of exhaustion of IPRs. Exhaustion remains a matter for domestic law.

The Medicines and Related Substances Act 101 of 1965<sup>22</sup> was, however, amended during 1997 to permit parallel importation of medicines in order to make them more affordable.<sup>23</sup> The Minister of Health may ‘prescribe conditions for the supply of more affordable medicines’ and the Act provides that:

[N]otwithstanding anything to the contrary contained in the Patents Act, [the Minister may] determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent.

20 (2013) Case No. 2706-2716. The court, which is the ultimate court of appeal, sits regularly as a two-judge panel.

21 Intellectual Property Laws Amendment Act 38 of 1997.

22 Section 15C of Act 101 of 1965.

23 Medicines and Related Substances Control Amendment Act 90 of 1997. For a detailed discussion see Adams & Adams *Practitioner’s Guide to Intellectual Property Law* (2011) 104–107.

The subsequent regulations<sup>24</sup> allow the importation under a permit issued by the Minister for a period of 24 months into South Africa of a medicine protected under patent and/or registered in South Africa that has been put on the market outside the country by or with the consent of the patentee, provided it is registered as a medicine in South Africa under the Act.

The important limitation is the requirement that the medicine must have been put on the market outside the country 'by or with the consent of the patentee'. This means that if the patent for the same invention is held by different owners<sup>25</sup> in different countries it is not possible to parallel import. The reason for this limitation flows from art 4*bis* of the Paris Convention, incorporated by reference into the TRIPS agreement, which recognises the independence of patents.<sup>26</sup>

No reason therefore appears for a change to the Patents Act in relation to the parallel importation of pharmaceuticals. The fact that, according to available information, no one has applied for a permit in more than 10 years must be because of commercial considerations and not legal impediments.

## 5. COMPULSORY LICENCES

The TRIPS agreement permits countries to grant compulsory licences on such grounds as they wish.<sup>27</sup> There are, however, two important restrictions, namely (a) the right holder must be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation, and (b) a licence may only be granted if the licensee intends predominantly to supply the domestic market.

The second requirement (b) was waived pursuant to the Doha Declaration, subject to conditions.<sup>28</sup> In summary and as an example, if Lesotho does not have the necessary manufacturing capacity, a local company may apply for the grant of a compulsory licence for the manufacture of a particular pharmaceutical in South Africa for export to Lesotho. This requires the necessary ground in our Act for such grant. There is no reason why legislation cannot be adopted for this purpose, although experience in countries that have adopted such legislation is that it is not used to any significant extent.<sup>29</sup> Since a licence under such a provision is for export purposes only it cannot affect the price of the particular medicine in this country.

24 Reg 7 of the *General Regulations* GNR 510 of 10 April 2003.

25 In view of the recognition of separate legal personality this would probably hold true even if they are part of the same multinational group.

26 Compare the position in respect of trade marks in *Frank & Hirsch (Pty) Ltd v A Roopanand Brothers (Pty) Ltd* 1993 (4) SA 279 (A); [1993] 2 All SA 521 (A).

27 Art 31. Confirmed in the Doha Declaration (*Ministerial Declaration on the TRIPS agreement and public health* adopted on 14 November 2001) art 5(b), available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) (viewed on 7 April 2014).

28 *Decision of the General Council of the WTO of 30 August 2003 regarding the implementation of paragraph 6 of the Doha Declaration on the TRIPS agreement and public health*, available at [http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm) (viewed on 7 April 2014).

29 R Elliot on the Canadian experience, available at <http://www.ip-watch.org/2012/11/18/fixing-canadas-access-to-medicines-regime-bill-c-398/> (viewed on 7 April 2014).

Another aspect of the Doha Declaration relates to compulsory licences and public health crises. It reads:

Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

Like most documents that make political statements, this one added nothing to the TRIPS agreement save for spelling out the names of three epidemics. The TRIPS agreement, as mentioned, has always allowed countries the freedom to determine the grounds on which compulsory licences may be granted. What this highlights is that our grounds for compulsory licences have not been reconsidered in the light of the TRIPS agreement, but are still based on the grounds set out in the Paris Convention. Some tweaking may be appropriate, but whether it will change the general landscape is open to serious doubt.

The reason why no attention has been given to the compulsory licence provisions in the Act may be because they are not used. The cause has not been empirically established, but it has been suggested that it may be due to the time-consuming procedure and the fact that until the licence is eventually confirmed or granted by the higher courts, parties may have lost interest.

The Patents Amendment Act 76 of 1988 introduced two relevant provisions to counteract the effect of possible delays.<sup>30</sup> The first was that pending the final determination of an application for a compulsory licence a court could not interdict the infringer except under special circumstances (s 56(1A)). The second was that a compulsory licence may be back-dated to the date of application (s 56(7A)).

The first was repealed,<sup>31</sup> presumably because it was thought to be in conflict with TRIPS (which is doubtful), but the second remains in the statute book. This means that until a licence is granted with a back-date, the applicant will be infringing and may be prevented by an interdict. The Draft Policy did not suggest a reintroduction of the repealed provision but it may be that something along those lines may be contemplated.<sup>32</sup>

## 6. EXAMINATION SYSTEM

South Africa has a deposit system, which means that patents are not examined for merit. This has given rise to the belief that we have an unduly high number of invalid patents on the register and that invalid pharmaceutical patents inhibit the supply of more affordable medicines. An examination system is the preferred system, but sometimes preference must yield to practicality. Issues that have not been addressed include capacity, cost, delay, the effect of the period of uncertainty and the like.

30 Subsecs (1A) and (7A) were inserted by s 2(a) and (b) of the Patents Amendment Act 76 of 1988.

31 Section 45(b) of the Intellectual Property Laws Amendment Act 38 of 1997.

32 Disclosure: the author was responsible for the drafting of the 1988 bill.

More important, the underlying assumption for the change may be based on a misconception. It is known that the USA has an examination system which, with our limited resources, we will not be able to emulate. Professors Mark A. Lemley and Carl Shapiro indicated that although about 200 000 US patents are granted annually most have little or no commercial value. Only 1.5 per cent of these are litigated at all and 0.1 per cent litigated to trial – and roughly half of these are found to be invalid.<sup>33</sup> Furthermore, according to a 2012 review by the United States Patent and Trademark Office (USPTO) of 9 328 ex-parte re-examinations of US patents from 1918 to 2012, 11 per cent had all claims cancelled, 67 per cent of the patents had some claims changed and only 22 per cent of re-examined patents had all claims confirmed as valid.<sup>34</sup>

It is reasonable to ask whether there is any reason why things will be different with the few thousand patents granted annually in South Africa. If South Africa were to introduce an examination system it must be fact-based and realistic, not based on assumption drawn on urban legend.

## 7. CONCLUSION

The cost of pharmaceuticals in general and patented pharmaceuticals in particular remains a concern, especially in a country where a large part of the population depends on the government to supply it with the basics required for a dignified existence.

There might be a lesson to be learnt from the history of the polio vaccine. Jonas Salk, who discovered the vaccine in 1954 (its success was established in 1955), was once asked why he did not patent the vaccine and he responded by saying that ‘there is no patent. Could you patent the sun?’<sup>35</sup> The reason he gave for not patenting was nonsensical. He could not patent it because his invention was made in the course of his employment at the School of Medicine, University of Pittsburgh. In addition, the patent attorneys considered applying for a patent but concluded that they would not succeed: why is not known. Importantly, the research was funded by the National Foundation for Infantile Paralysis (now the March of Dimes), a non-profit, centralised research and development operation. Some 80 million people contributed funds for the research in what was regarded as a national emergency in the USA. It was, in fact, an international emergency also affecting South Africa. ‘There was near unanimity within the organization that the public had already paid for the polio vaccine through their donations, and patenting it for profit would have represented double charging.’<sup>36</sup>

33 MA Lemley & C Shapiro ‘Probalistic patents’ (Spring 2005) 19 (2) *Journal of Economic Perspectives* 75.

34 Available at <http://www.ambercite.com/index.php/amber/entry/how-many-granted-patents-contain-invalid-claims> (viewed on 7 April 2014).

35 Based primarily on B Palmer ‘Jonas Salk: Good at virology, bad at economics’ in *Slate*, available at [http://www.slate.com/articles/technology/history\\_of\\_innovation/2014/04/the\\_real\\_reasons\\_jonas\\_salk\\_didn\\_t\\_patent\\_the\\_polio\\_vaccine.html](http://www.slate.com/articles/technology/history_of_innovation/2014/04/the_real_reasons_jonas_salk_didn_t_patent_the_polio_vaccine.html) (viewed on 16 April 2014). The article used J Smith *Patenting the Sun: Polio and the Salk Vaccine* 1 ed (1990) as a reference source.

36 B Palmer (n35).

There is a lesson from this. Instead of relying on the industry to bear the burden of finding medicines for epidemics, the burden should rather rest on government and the public. Research organisations, universities and others who are state funded are investing money and time in searching for and inventing pharmaceuticals. Although they have a statutory and material interest in appropriate patent protection, it will be in their hands to decide how to deal with their patent rights.<sup>37</sup>

Changes to the law should not demotivate research-based companies. There are signs that some of them, knowing that only a miniscule percentage of their profits come from Africa, and feeling threatened by bad publicity and attacks on the patent system, tend to focus on lifestyle medicines. One, for example, announced in January 2014 that it is to simplify its research and development (R&D) footprint and intends to focus resources on three core therapy areas of oncology, cardiovascular and metabolic diseases and respiratory, inflammation and autoimmunity, and it is stopping early-stage research into tropical diseases, tuberculosis and malaria.

Modifications to the Act should seek to fulfil the TRIPS promises by contributing to the promotion of technological innovation and the transfer and dissemination of technology to the mutual advantage of producers and users, be conducive to social and economic welfare and balance rights and obligations.

37 Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008.