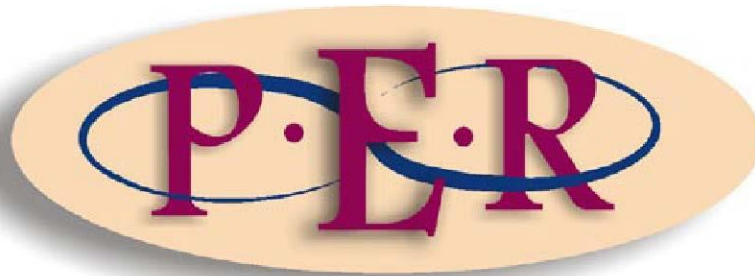


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## LESSONS FOR THE SADC FROM THE INDIAN CASE OF *NOVARTIS AG v UNION OF INDIA*

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### 1 Introduction

The Southern African Development Community (SADC) continues to face health related challenges in the context of HIV/AIDS, tuberculosis, malaria, heart disease, cancer, hepatitis and a host of other ailments. Although regional cooperation has seen the HIV/AIDS infection rate on the decline, the disease burden in other areas, especially in tuberculosis and life-style diseases such as heart disease, is not on the decline.<sup>1</sup>

The SADC region depends largely on imported patented medicines to deal with the burgeoning disease burden, but the medicines are expensive. Although some SADC members such as South Africa, Zimbabwe and Mozambique have limited pharmaceutical manufacturing capacity, the volumes of locally produced drugs are inadequate to deal with the disease burden. As members of the World Trade Organisation (WTO), SADC members can take advantage of the flexibilities introduced by the *Agreement on Trade Related aspects of Intellectual Property Rights* (TRIPS) and override patent rights in some specified instances in order to access affordable essential medicines.

One of the TRIPS flexibilities is the leeway given to WTO members to decide within the confines of their national laws and contexts what amounts to patentable subject matter and to exclude certain inventions, such as diagnostics, methods of treating the human or animal body, and new uses of existing patents from registration as patents.<sup>2</sup>

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<sup>1</sup> Kredo *et al* 2012 *Health Policy and Systems* 2.

<sup>2</sup> For example, in terms of s 25(11) of the *South African Patents Act* 57 of 1978, methods for treating the animal or human body and diagnostics are not patentable since they are deemed to be incapable of application in trade, industry or agriculture. However, the same law provides for new use patents in s 25(9).

One of the major causes of high drug prices, which create affordability barriers, is the notorious practice by pharmaceutical companies of extending patent life spans beyond the mandatory 20 year period by filing for secondary patents.<sup>3</sup> Secondary patents may be granted for minor additions or embellishments to drug formulae, thus extending the life span of the patent, preventing the entry of generic drugs onto the market, and thereby creating monopolistic prices. This notorious practice is called patent evergreening and is one of the reasons why drug prices remain high. Evergreening may be cured by introducing strict requirements for patentability so that only those inventions which are new, involve an inventive step, and are capable of industrial application may be patented.<sup>4</sup>

This paper highlights how the legislative inclusion of TRIPS flexibilities around the requirements for patentability<sup>5</sup> can be effectively used to curb incremental patenting.<sup>6</sup> The paper critically analyses the 2013 Supreme Court of India case of *Novartis AG v Union of India*. Firstly, the paper outlines, albeit briefly, the WTO TRIPS provisions regarding the patentability of new-use patents and contextualises the discussion to South Africa and the SADC region. Secondly, the paper narrates the facts of the relevant case before coming to an analysis that highlights useful lessons for the SADC region in its quest to reform intellectual property (IP) laws in order to curb evergreening. Finally, the paper concludes with a summary of the major highlights of the case and recommendations, urging SADC members to use the decision as a reflection of good law that should inform IP law reforms which might have the consequence of improving access to medicines.

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<sup>3</sup> In terms of A 33 of the *Agreement on Trade Related Aspects of Intellectual Property Rights* (1994) (TRIPS), the term of protection for a patent shall be 20 years counting from the filing date. S 46 of the *South African Patents Act* provides for the same period subject to the payment of renewal fees by the patentee.

<sup>4</sup> These desirable requirements are generally spelt out in A 27 of TRIPS.

<sup>5</sup> A 27(1) of TRIPS.

<sup>6</sup> According to Eisenberg 2005 *Yale J Health Pol'y L & Ethics* 717. Evergreening is a practice consisting in the extension of the commercial life of a patent through the filing of applications for the patenting of new uses of the same product or for marginally improved substances or derivatives. Evergreening is frowned upon because it has anti-competitive effects, delays the entry of generics on the market, and negatively impacts on drug prices.

## 2 The patentability of new uses of patents: a brief contextual overview

The general rule on patentable subject matter under the TRIPS Agreement is that, subject to exceptions set out therein, patents shall be available for all inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application.<sup>7</sup>

However, invention is not defined in the TRIPS Agreement and this leaves WTO members with the flexibility to define the scope of the concept of invention under their national laws.<sup>8</sup> This flexibility may have both positive and negative implications for access to medicines. On the one hand, the absence of a definition may make it possible for WTO members to exclude new uses of drugs from patentability under their national laws.<sup>9</sup> On the other hand, other WTO members may take advantage of the absence of a definition and use it to frustrate access to medicines by granting patents to new and sometimes minimally improved uses of drugs. Standards should, therefore, be set to avoid the granting of patents for "evergreen" or "me-too" drugs that extend patent duration without an improvement to the drugs' efficacy.<sup>10</sup> These types of drugs can be broadly defined as "chemically related to the prototype, or other chemical compounds which have an identical mechanism of action".<sup>11</sup>

The proponents of new use patents justify them on the basis that the discovery of a new use may require the same level of investment as that which obtained with the first patent.<sup>12</sup> According to Musungu, Villanueva and Blasetti,<sup>13</sup> the forms of *innovation*

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<sup>7</sup> A 27(1) of the TRIPS.

<sup>8</sup> S 25 of the *South African Patents Act* 57 of 1978 specifies the requirements for patentability in terms similar to those of the TRIPS Agreement, but on the aspect of industrial application (utility), the law says the patent must be useful in *trade, industry and agriculture* (emphasis added). The *South African Patents Act* does not define an invention.

<sup>9</sup> Musungu, Villanueva and Blasetti *Utilizing TRIPS Flexibilities* 15.

<sup>10</sup> According to Vawda and Baker 2013 *AHRLJ* 72, drug companies extend patent monopolies by making minor variations to existing drugs, thus stifling competition through the development of "me-too drugs" for patentability in terms similar terms to those of the TRIPS Agreement; but on the aspect of industrial application (utility), the law says the patent must useful in *trade, industry and agriculture* (emphasis added). The *South African Patents Act* does not define an invention.

<sup>11</sup> Musungu, Villanueva and Blasetti *Utilizing TRIPS Flexibilities* 15.

<sup>12</sup> Gerattini 1997 *Journal of Nephrology* 283.

<sup>13</sup> However, according to Correa *Guide to Pharmaceutical Patents* 46, a majority of such patents might not have been granted if adequate standards of assessing patentability requirements had been applied.

<sup>14</sup> Musungu, Villanueva and Blasetti *Utilizing TRIPS Flexibilities* 15.

in the pharmaceutical industry for which patents may be claimed vary from breakthrough discoveries to minor modifications of existing medications.<sup>14</sup> The authors cite examples from a study that was conducted by the National Institute of Healthcare Management Research and Educational Foundation which showed that in the 12 year period from 1989 to 2000 in the United States, the market with the largest number of pharmaceutical patents, of the 1035 new drugs approved by the Federal Regulatory Agency only 35 per cent contained a new active ingredient.<sup>15</sup> According to the report cited, during the 12 year period only 15 per cent of the medicines were highly innovative drugs.<sup>16</sup> The logical conclusion which may be drawn from the study, therefore, is that the bulk of new medicines are modified versions of older drugs, which ironically cost more than the original ones on which they are based.

On a related note, India has raised the criteria for patentability so as to prevent evergreen patents from being registered.<sup>17</sup> In the specific Indian context, applicants are made to establish to a high degree of certainty that the medication for which an application for a patent has been made is *more effective than* (emphasis added) those medications already used for the same condition.<sup>18</sup>

In India the relevant law<sup>19</sup> allows members of the public to bring to the attention of the patent controller evidence which may lead to patent rejection.<sup>20</sup> The existence of this remedial measure made it possible for the Indian Network of People living with HIV/AIDS and the Manipur Network of Positive People to successfully oppose GlaxoSmithKline (GSK)'s patent application for the drugs zidovudine and lamivudine in 2006 on the basis that the patent claim in the specific instance was not for a new invention.<sup>21</sup>

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<sup>14</sup> Such claims were held to retard progress and innovation by the US Supreme Court in the case of *KSR International v Teleflex Inc* 550 US 398 15.

<sup>15</sup> Musungu, Villanueva and Blasetti *Utilizing TRIPS Flexibilities* 15, citing from NIHCM 2002 <http://www.nihcm.org/pdf/innovations.pdf> 3.

<sup>16</sup> That is to say, drugs which contain new active ingredients and at the same time provide significant clinical improvement.

<sup>17</sup> See s 3(d) of the *Indian Patent (Amendment) Act* 2005.

<sup>18</sup> Angell *Truth About Drug Companies* 75.

<sup>19</sup> S 3(d) of the *Indian Patent (Amendment) Act* 2005.

<sup>20</sup> Adusei 2011 *JWIP* 12.

<sup>21</sup> Adusei 2011 *JWIP* 12.

It is submitted that the case discussed below demonstrates that at least in the Indian context, having higher patentability requirements in order to prevent weak or evergreen patents does have positive results for access to medicines.

### **3 The case of *Novartis AG v Union of India*<sup>22</sup>**

#### **3.1 Contextual background to the case**

On 1 April 2013 the Indian Supreme Court delivered what it described as a very important judgment in *Novartis AG v Union of India* (hereafter the *Novartis* case)<sup>23</sup> in an appeal that had been brought to it by Novartis, a Swiss-based pharmaceutical company with a business presence in India, against rejection by the Indian Patent Office of a product patent application for a specific compound, the beta crystalline form of Imatinib Mesylate.<sup>24</sup> Novartis lost the case because the Supreme Court ruled that the beta crystalline form of Imatinib Mesylate failed both the tests of invention and patentability.<sup>25</sup>

The crux of the matter was whether or not the appellant was entitled to a patent for the beta crystalline form of the compound Imatinib Mesylate, which is a therapeutic drug for chronic myeloid leukaemia and certain kinds of tumours and is marketed under the name "Glivec" or "Gleevec".<sup>26</sup>

#### **3.2 The Pertinent Facts and other Background Information**

The drug Glivec, manufactured by Novartis Pharmaceuticals, was originally invented by Jurg Zimmerman, a medicinal chemist, who invented a number of derivatives of N-phenyl-2-pyrimidineamine.<sup>27</sup> The name Imatinib was given to one of the derivatives

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<sup>22</sup> *Novartis AG v India* (Supreme Court of India) Civil Appeal No 2706-2716 of 1 April 2013 (*Novartis* case).

<sup>23</sup> The importance of this judgment and the case was highlighted by the Supreme Court's remark at para 22 that, "in the end all agreed that given the importance of the matter, this Court may itself decide the appeals instead of directing the appellant to move the High Court".

<sup>24</sup> Abbott 2013 *Intellectual Property Watch* 1.

<sup>25</sup> *Novartis* case para 195. The tests for invention and patentability are provided for in s 2(1)(j)-(ja) and s 3(d) of the *Patents Act*.

<sup>26</sup> *Novartis* case para 3.

<sup>27</sup> *Novartis* case para 5.

as a non-proprietary name by the World Health Organisation.<sup>28</sup> The derivatives, including Imatinib, are capable of inhibiting certain protein enzymes and have valuable anti-cancer properties, which makes them suitable for the treatment of warm blooded animals.<sup>29</sup> Imatinib and other derivatives were submitted to the United States (US) Patent Office for the registration of a patent therein on 28 April 1994 and the patent sought was granted in 1996.<sup>30</sup>

After further research revealed that the beta crystalline form of Imatinib<sup>31</sup> is more stable, Novartis sought to patent this in the US as well, and after initial opposition from the Patent Office, a patent was granted in the US.<sup>32</sup> Novartis also applied for a patent in India for the same product in 1998,<sup>33</sup> but the application was considered only in 2005, when India became truly compliant with the TRIPS Agreement.<sup>34</sup>

The basis for Novartis' patent application for the beta crystalline form of Imatinib in India was an alleged inventive step that materialised when a two-stage invention process involving the introduction of a specified amount of beta crystals into the base form of Imatinib was embarked upon.<sup>35</sup> Very specifically, the claims in the patent application alleged the following about the Beta crystalline form of Imatinib:

- (a) it had more beneficial flow properties;<sup>36</sup>
- (b) it had better thermodynamic stability;<sup>37</sup> and
- (c) it had lower hygroscopicity than the alpha crystalline form of Imatinib.<sup>38</sup>

It was alleged that these properties made the beta crystalline form of Imatinib "new" and superior due to its ability to store better, be processed more easily, and its having

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<sup>28</sup> *Novartis* case para 5.

<sup>29</sup> *Novartis* case para 5.

<sup>30</sup> The patent was granted under US Patent Number 5 521 184.

<sup>31</sup> Imatinib Mesylate is marketed in India as Glivec.

<sup>32</sup> US Patent Number 6894051.

<sup>33</sup> Application No 1602/MAS/98. Novartis applied for a patent of Imatinib Mesylate in beta crystal form at the Chennai Patent Office on 17 July 1998 (*Novartis* case para 8).

<sup>34</sup> From 1 January 2005, India allowed drug patent protection in order to comply with the requirements under TRIPS. See specifically Chaudhuri 2012 *Economic and Political Weekly* 46.

<sup>35</sup> *Novartis* case para 6-7.

<sup>36</sup> *Novartis* case para 8.

<sup>37</sup> *Novartis* case para 8.

<sup>38</sup> *Novartis* case para 8.

"better processability of the methanesulfonic acid addition of a compound formula I" coupled with the advantage of storing and processing.<sup>39</sup>

Two important developments occurred before the patent application was considered by the Chennai Patents Office. Firstly, the Patents Act was amended and section 3(d)<sup>40</sup> was introduced. Secondly, before the patent application was considered, it had attracted five pre-grant oppositions.<sup>41</sup> The most vocal oppositions came from rival pharmaceutical companies and patient groups, basing their opposition mainly on the fact that the alleged invention had been anticipated, was obvious, and ran afoul of section 3(d) of the *Patents Act*.

The matter relating to the patentability of the beta crystalline form of Imatinib was heard by the Assistant Controller of Patents and Designs and the application was rejected.<sup>42</sup> The Assistant Controller of Patents and Designs rejected the application on the basis that the invention had been anticipated by reason of prior publication,<sup>43</sup> its lack of novelty and its not meeting the acid test of section 3(d).<sup>44</sup>

Novartis appealed the decision of the Assistant Controller of Patents and Designs to the High Court in Madras, in addition to asking for an order that section 3(d) was unconstitutional and also fell afoul of the TRIPS Agreement.<sup>45</sup> At that time the Intellectual Property Appellate Body (IPAB) had not yet been formed. After the IPAB had been formed the matter was remitted to it by the Madras High Court. Despite ruling in favour of Novartis by reversing the findings of the Assistant Controller on novelty and non-obviousness, the IPAB ruled that the patent could not be granted in the light of the provisions of section 3(d) of the Act, which, according to the IPAB,

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<sup>39</sup> *Novartis* case para 8.

<sup>40</sup> S 3(d) excludes from patentability "*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 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*" (my emphasis).

<sup>41</sup> *Novartis* case para 13. Pre-grant opposition is provided for in s 25 of the *Patents Act* of 1970 as amended.

<sup>42</sup> The matter was heard on 15 December 2005.

<sup>43</sup> This was based on the fact that patents for the same subject matter had been granted under the Zimmerman patents.

<sup>44</sup> *Novartis* case para 14.

<sup>45</sup> *Novartis* case para 15.



introduces a higher standard of inventiveness and provides that what is patentable in other countries will not necessarily be patentable in India.<sup>46</sup> The IPAB went a step further and observed that the specific section was particularly targeted at drugs/pharmaceutical substances.<sup>47</sup>

Very peculiarly, the IPAB referred to the pricing policy of Novartis, which had exclusive marketing rights over Glivec, which sold at 120 000 Indian Rupees per month<sup>48</sup> per required dose, and concluded that the patentability of the subject product would fall foul of section 3(b) of the Act, which prohibits the granting of patents on certain inventions the exploitation of which could cause public disorder, among other social ills.<sup>49</sup>

Novartis then appealed the decision of the IPAB to the Supreme Court of India, which was initially reluctant to hear the appeal but was swayed by the public interest in the matter<sup>50</sup> and the delays that had accompanied the finalisation of the matter. Judgment was delivered on 1 April 2013.

### **3.3 The Supreme Court judgment**

Before delivering its judgment, the Supreme Court of India per Aftab Alam J reduced the issues at stake in the case to an enquiry into the true import of section 3(d) of the Act and how it interplays with clauses (j) and (ja) of section 2(1) of the Act.<sup>51</sup> The key question to answer in the opinion of the Court was "does the product which Novartis claims as a patent qualify as a new product?"<sup>52</sup> As a corollary to the question, it was crucial to enquire into whether the product in question had a characteristic feature that *involves a technical advance over existing knowledge that makes the invention not obvious to a person skilled in the art* (emphasis added).<sup>53</sup> After affirming that the

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<sup>46</sup> *Novartis* case para 17.

<sup>47</sup> *Novartis* case para 17.

<sup>48</sup> On the other hand, the price of generic equivalents was about 10 000 Rupees per person per month.

<sup>49</sup> *Novartis* case para 19.

<sup>50</sup> *Novartis* case paras 21-22.

<sup>51</sup> *Novartis* case para 3.

<sup>52</sup> *Novartis* case para 3.

<sup>53</sup> *Novartis* case para 3.

meaning of an invention is delimited by clauses (j) and (ja) of section 2(1) of the *Patents Act*, the Court went further and asked the rhetorical question of whether or not a product qualifying as an invention under the relevant clauses of section 2(1) could have its patentability status questioned under section 3(d).<sup>54</sup> The Court answered the rhetorical question in the course of the judgment.

Clauses (j) and (ja) had deleted section 5 of the previous *Patents Act*, which prohibited product patents in India, and at the same time, amendments were effected to section 3, introducing section 3(d).<sup>55</sup> The Court expressed the opinion that in order to understand the purport and objects of the amendments it was important to identify the mischief parliament wanted to check.<sup>56</sup> The object which section 3(d) sought to achieve was to prevent evergreening, provide easy access to life-saving drugs to citizens, and realise the constitutional obligation to provide good health care to citizens.<sup>57</sup>

After a detailed exposition of India's legislative history<sup>58</sup> relating to intellectual property generally and patents in particular, the Supreme Court concluded that the law had been passed in order to protect India's policy space to afford good health to its citizens while complying with the basic prescripts of the TRIPS Agreement.<sup>59</sup> The Court believed that the patent protection of pharmaceutical and agricultural chemical products might have the effect of putting life-saving medicines beyond the reach of a very large section of the population,<sup>60</sup> and that the amendments were therefore justified.

The Court clarified the pertinent legal provisions as follows:<sup>61</sup> the 1970 *Patents Act* as amended in 2005 requires that inventions must be new (not anticipated), involve an

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<sup>54</sup> *Novartis* case para 3.

<sup>55</sup> *Novartis* case paras 24-26.

<sup>56</sup> *Novartis* case para 26.

<sup>57</sup> The Supreme Court at para 18 cited with approval the object which was spelt out by the Madras High Court in earlier litigation in the matter.

<sup>58</sup> *Novartis* case paras 31-46.

<sup>59</sup> *Novartis* case para 66.

<sup>60</sup> *Novartis* case para 66.

<sup>61</sup> *Novartis* case paras 88-89.

inventive step,<sup>62</sup> and be capable of being made or used in an industry.<sup>63</sup> The requirement that an invention must involve an inventive step implies that there must be a feature that involves a technical advance as compared to existing knowledge or having economic significance or both.<sup>64</sup> Further, this feature should be such that the invention is not obvious to a person skilled in the art.<sup>65</sup>

With specific reference to section 3(d), the Court first of all observed that section three provides for "what are not inventions".

Under section 3(d), the following are not inventions within the meaning of the Act:

*(d) 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 or* (emphasis in the original) *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.*

From the provisions of section 3(d) of the current *Patents Act* cited above, the words in bold were grafted onto the pre-2005 section 3(d) of the *Patents Act* of the 2005 amendment of the law.<sup>66</sup> The new section 3(d) adds the words in bold at the beginning of the provision, deletes the word "mere" before "use" in the old provision,<sup>67</sup> and adds an explanation at the end of the clause.<sup>68</sup> Very importantly, section 3(d) does have a detailed explanation that fully contextualises the extent of the exclusions.<sup>69</sup> Citing Indian Parliamentary Debates, the Supreme Court observed that section 3(d) is targeted 80 per cent at drugs and pharmaceutical products and 20 per cent at agricultural chemicals.<sup>70</sup> This was a bold admission by the Court - that section 3(d)

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<sup>62</sup> S 2(1)(j)(i)-(iii) of the *Patents Act*.

<sup>63</sup> S 2(1)(ac) of the *Patents Act*.

<sup>64</sup> *Novartis* case para 89.

<sup>65</sup> *Novartis* case para 89.

<sup>66</sup> *Novartis* case para 95.

<sup>67</sup> The full text of the old s 3(d) is hereby reproduced verbatim for information as follows: "(d) the mere discovery of any new property or mere 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".

<sup>68</sup> *Novartis* case para 96.

<sup>69</sup> The explanatory clause to s 3(d) provides that "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".

<sup>70</sup> *Novartis* case para 97-98.

targets specific fields of technology (pharmaceuticals and agricultural chemicals) - since nothing had ever arisen in the context of the section in other fields of invention.<sup>71</sup>

It was submitted on behalf of Novartis that section 3(d) was not an exception to patentability. Hence, once a substance satisfies the requirements in section 2(1)(j) and (ja), it satisfies the requirements of patentability. Consequently, section 3(d) did not apply to the Novartis case.<sup>72</sup> This submission was made notwithstanding the concession by counsel for Novartis that the aim of section 3(d) was to prevent trifling change and evergreening while allowing and encouraging incremental patenting.<sup>73</sup> With specific reference to public health and the use of TRIPS flexibilities, Novartis argued that the best route was to make use of compulsory licences,<sup>74</sup> revocation proceedings<sup>75</sup> and multiple stages of patent opposition procedures<sup>76</sup> rather than to make use of section 3(d).<sup>77</sup>

The Supreme Court dismissed the above submissions on a number of grounds.<sup>78</sup>

Firstly, the Court held that section 3(d) is not a provision *ex majorie cautela* (out of abundant caution), as was submitted on behalf of Novartis, when taking into account the totality of the historical development that led to the enactment of the provision.<sup>79</sup> Secondly, the Court cautioned that the relevant provision was enacted to deal with chemical patents and pharmaceuticals by setting additional qualifications for the patentability of such products.<sup>80</sup> Thirdly, and very importantly, the Court clarified the position by stating that the door was wide open for true inventions but closed by

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<sup>71</sup> *Novartis* case para 97-98. There is a likelihood that s 3(d) may be impugned at the WTO dispute settlement level on the ground that it is discriminatory in terms of targeting patents in specific fields of technology contrary to the TRIPS Agreement, which provides in A 27.1 that patents shall be available in all fields of technology, and that patent rights must be enjoyable "without discrimination" as to "the field of technology". However, see for a counter argument Lewis-Lettington and Banda *Survey of Policy and Practice* 19, in which the authors convincingly argue that such discrimination should be characterised as addressing problem areas rather than technical fields.

<sup>72</sup> *Novartis* case para 99.

<sup>73</sup> *Novartis* case para 100.

<sup>74</sup> In terms of Ch XVI of the *Patents Act*.

<sup>75</sup> As provided for in ss 63, 64 and 65 of the *Patents Act*.

<sup>76</sup> In terms of s 25 of the *Patents Act*.

<sup>77</sup> *Novartis* case para 101.

<sup>78</sup> See *Novartis* case paras 102-104.

<sup>79</sup> *Novartis* case para 102.

<sup>80</sup> *Novartis* case para 103.

section 3(d) for repetitive patenting or the extension of patent terms on spurious grounds.<sup>81</sup> In coming to the conclusion that section 3(d) applied to the case, the Court emphasised that different standards are set for things of different classes to qualify as inventions; and for medical drugs and other chemical substances, the invention threshold is set higher.<sup>82</sup>

It was also argued on behalf of Novartis that the production of Imatinib Mesylate from Imatinib in a free base form was a result of a step involving a technical advance when compared to current knowledge, thus bringing into existence a new substance.<sup>83</sup> The Supreme Court rejected this argument and ruled that the production of Imatinib Mesylate did not constitute an invention as contemplated in the current law of India.<sup>84</sup> In dismissing the submission, the Supreme Court remarked thus:

... we firmly reject the appellant's case that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmerman patent.<sup>85</sup>

Therefore, the specific product did not satisfy the test of an "invention" as laid down in section 2(1)(j) and (ja) of the *Patents Act*.<sup>86</sup>

With specific reference to the beta crystalline form of Imatinib, it was submitted on behalf of Novartis that section 3(d) applies if a substance is a new form of a known product having known efficacy, and that "known" in the specific context meant proven and well established while "known efficacy" meant "efficacy established empirically and proven beyond doubt".<sup>87</sup> Citing with approval the case of *Monsanto Company v Caramandel Indag Products (P) Ltd*,<sup>88</sup> the Supreme Court disagreed and rejected the submission on the basis that it was wrong in both fact and law.<sup>89</sup> The court sealed the dismissal of the submission with the powerful observation that the beta crystalline form of Imatinib Mesylate is a new form of a known substance, namely, Imatinib

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<sup>81</sup> *Novartis* case para 103.

<sup>82</sup> *Novartis* case para 104.

<sup>83</sup> *Novartis* case para 106.

<sup>84</sup> *Novartis* case para 133.

<sup>85</sup> *Novartis* case para 157.

<sup>86</sup> *Novartis* case para 157.

<sup>87</sup> *Novartis* case para 158.

<sup>88</sup> *Monsanto Company v Caramandel Indag Products (P) Ltd* (1986) 1 SCC 642.

<sup>89</sup> *Novartis* case para 159.

Mesylate, with well-known efficacy.<sup>90</sup> Therefore, the fact that the beta form of Imatinib was a product that claimed to enhance the form of its old counterpart triggered the application of section 3(d).<sup>91</sup>

Very specifically, the Court observed that in its application for a patent, Novartis averred that all the therapeutic qualities of the beta crystalline form of Imatinib Mesylate were also possessed by Imatinib in a free base form. This, therefore, raised the question of whether an enhanced efficacy over a known substance as demanded by section 3(d) existed.<sup>92</sup> The Court held that the correct "efficacy" to consider in section 3(d) is "therapeutic efficacy" in the specific context of medicines.<sup>93</sup> The Court further noted that the test for enhanced therapeutic efficacy must be applied strictly.<sup>94</sup> The Court, therefore, concluded that the physico-chemical properties of beta crystalline Imatinib Mesylate<sup>95</sup> may be beneficial but do not add anything to therapeutic efficacy.<sup>96</sup> On the contention submitted on behalf of Novartis that the beta crystalline form of Imatinib had increased bioavailability, the Court held that an increased bioavailability, in the absence of compelling proof, may not necessarily lead to an enhancement of therapeutic efficacy;<sup>97</sup> hence Novartis' bid for a patent for the beta crystalline form of Imatinib Mesylate had to fail.<sup>98</sup>

In conclusion, the Court ruled that the impugned form of Imatinib failed the test of invention as provided for in section 2(1) clauses (j) and (ja) and section 3(d), that it did not have enhanced therapeutic efficacy, and that Novartis' appeal had inevitably to fail.<sup>99</sup>

In order to avoid doubt and a possible misinterpretation of its judgment in the light of the overflowing public interest in the matter both in India and internationally, the

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<sup>90</sup> *Novartis* case para 161.

<sup>91</sup> *Novartis* case para 161.

<sup>92</sup> *Novartis* case para 163.

<sup>93</sup> *Novartis* case paras 179-180.

<sup>94</sup> *Novartis* case para 182.

<sup>95</sup> Namely that it has more beneficial flow properties, better thermodynamic stability and lower hygroscopicity.

<sup>96</sup> *Novartis* case para 187.

<sup>97</sup> *Novartis* case para 189.

<sup>98</sup> *Novartis* case para 190.

<sup>99</sup> *Novartis* case para 195.

Supreme Court issued a final note of clarity.<sup>100</sup> It is submitted that the Court held quite correctly that the import of its judgment was not to outlaw incremental inventions of chemical and pharmaceutical patents, but that only those chemical and pharmaceutical inventions that did not lead to the enhancement of therapeutic efficacy were barred by the judgment.<sup>101</sup> This clarification is welcome for jurisprudential certainty and puts Indian patent law on the subject in a positive light.

As anticipated, the decision was warmly welcomed by access to medicines activists and patient organisations in India and beyond. Given India's key role in the global supply of affordable medicines, both patented and generic, there is no gainsaying that the decision has worldwide implications,<sup>102</sup> including in the SADC.

#### **4 An evaluation of the case and lessons for the SADC**

From the above narration of facts and the outline of the decision of the Supreme Court of India, it is important to emphasise what the court said and did not say.<sup>103</sup>

The court did not say that a new form of a known compound could not be patented; neither did it say that improving bioavailability characteristics of a drug may not result in enhanced efficacy.<sup>104</sup> Rather, the court left open the issue of whether enhanced efficacy refers narrowly to the curative effect of the drug or more broadly to the improved safety and reduced toxicity of the drug.<sup>105</sup> This clarity is important for allaying the fears of the US and like-minded countries that almost always conceive the contextual application of TRIPS flexibilities as an affront to IP rights. For example, in 2013, the United States government listed ten developing countries on its priority watch list for various alleged IP violations. The Ukraine was listed as a "priority foreign country", which is a rare listing reserved for the worst offenders.<sup>106</sup>

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<sup>100</sup> *Novartis* case para 191.

<sup>101</sup> *Novartis* case para 191.

<sup>102</sup> Lofgren 2013 *The Conversation* 1.

<sup>103</sup> Abbott 2013 *Intellectual Property Watch* 3.

<sup>104</sup> Abbott 2013 *Intellectual Property Watch* 3.

<sup>105</sup> *Novartis* case para 191.

<sup>106</sup> USTR

<https://ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf>.

For the SADC, the manner in which the Indian Supreme Court dealt with the application of section 3(d) in the specific context should be encouraging. SADC members should be emboldened by this decision and embark on IP law reform that takes into account each member's social and economic needs. This is a general assumption based on the apparently widely accepted view that evergreening is bad and affects developing countries negatively. As previously said, section 3(d) is TRIPS-plus, but it does not follow that TRIPS-plus IP legislative provisions are WTO-illegal.<sup>107</sup> South Africa has taken the lead and has boldly stated in its Draft IP Policy that it will not tolerate incremental patenting and a proliferation of evergreen patents.<sup>108</sup>

Despite the decision in *Novartis* having been characterised in colourful terms by other writers and critics,<sup>109</sup> this writer believes that the decision is relevant to the context obtaining in the SADC for the reasons outlined below.

Although the rejection of *Novartis'* claims was met with criticism from the pharmaceutical industry as shifting the balance too much in favour of the protection of public health,<sup>110</sup> the fact that the decision gave prominence to public health issues over IP must be celebrated as relevant to the current SADC situation in which law reform is still possible. In the judgment itself, in the course of describing the history of IP law in India the Supreme Court said that the Committee under the chairmanship of Justice N Rajagopala Ayyangar "took a fresh look at the law of patents to completely revamp and recast it to best subserve the (contemporary) needs of the country".<sup>111</sup> One of the observations of the Committee, which I don't entirely agree with, was that patent systems are not created in order to satisfy the interests of the inventor but rather to take care of the interests of the economy.<sup>112</sup>

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<sup>107</sup> Abbott 2013 *Intellectual Property Watch* 3 submits that there is nothing wrong with the strict Indian standard and a similar approach was followed by the US Patent Office until the decision in the Court of Appeals for the Federal Circuit, in the case of *In re Brana* 34 USPQ2d 1441 (Fed Cir 1995).

<sup>108</sup> See Draft National Policy on Intellectual Property 2013 in GN 913 in GG 36818 of 29 August 2013 8-9.

<sup>109</sup> For example, Raju 2008 *Indian Journal of Intellectual Property Law* 7 regards the case and its development as a "saga".

<sup>110</sup> Barazza 2013 *JIPLP* 776.

<sup>111</sup> Abbott 2013 *Intellectual Property Watch* 3.

<sup>112</sup> *Novartis* case para 36.



This observation rings very true in the SADC region, which is urged to revamp its patent laws by taking advantage of TRIPS flexibilities in the context of regional priorities. Indeed, the rejection of Novartis' application was regarded by some health activists as a victory for public health.<sup>113</sup>

The debate over the patentability of pharmaceuticals has been intense and in the majority of instances emotionally charged, when the right to patent exclusivity is pitted against the right to public health.<sup>114</sup> The Supreme Court of India displayed sensitivity to the potential conflict, for both social and economic reasons.<sup>115</sup> The Court did, in actual fact, show that it was aware of the conflict when it clearly recognised that the current IP system seeks to promote both innovation and social economic welfare in India, thus making the benefits of the patented invention available at reasonably affordable prices to the public.<sup>116</sup>

The decision in Novartis relating to the interpretation of section 3(d) was well reasoned, since similar decisions have been handed down in other parts of the developed world in similar contexts.<sup>117</sup> The case is however important because it deals with the subject in the context of a less powerful WTO member, India, and this will in all likelihood inspire and embolden other developing countries. The similar decisions referred to in this paragraph and the subsequent references to case law in footnote 118 below are related to developed rather than developing countries.

The main aim of section 3(d), as previously explained, is to prevent evergreening and avoid the issuing of patents that are of a low quality and add only insignificant

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<sup>113</sup> 't Hoen 2013 *J Public Health Policy* 370.

<sup>114</sup> Barazza 2013 *JIPLP* 786.

<sup>115</sup> Barazza 2013 *JIPLP* 786.

<sup>116</sup> Barazza 2013 *JIPLP* 786.

<sup>117</sup> Barazza 2013 *JIPLP* 786-787. The pertinent cited cases are *Pfizer Inc v Apotex Inc* [2007] 480 F 3d 1348; *Takeda Chemical Industries Ltd v Alphapharm Pty Ltd* [2007] 492 F 3d 1350; *SmithKline and French Laboratories v Evans Medical Aid Ltd* [1989] FSR 561; *In re Dillon* [1990] 919 F 2d 688; *In re Deuel* [1995] 51 F 3D 1552; *In re Elli Lilly and Company v Premo Pharmaceutical Laboratories Inc* [1980] 630 F 2d 120; and *Les Laboratoires Servier v Apotex Inc* [2008] EWCA 445.

improvements to the state of the art.<sup>118</sup> The concern about evergreen patents is not unique to India.<sup>119</sup>

It is also important to note that the patent which Novartis sought to register in India was initially rejected by the US patent authorities for lack of novelty and granted only on appeal in May 2005.<sup>120</sup> Evergreening is compounded by weak patent examination systems and chokes technological progress.<sup>121</sup> Some SADC member states do not provide for a patent examination system, hence evergreening is likely to proliferate in such situations.<sup>122</sup>

The problem is well illustrated in South Africa. According to the Treatment Action campaign (TAC) and Médecins Sans Frontiers (MSF), Novartis managed to register in South Africa a patent for a "new use" of Imatinib which does not expire until 2022, even though the original patent was set to expire earlier in 2013.<sup>123</sup> To treat chronic myeloid leukaemia for one year in South Africa using Novartis' Imatinib costs over R387,000, a price out of reach for most South Africans and medical aid schemes. The stark irony is that what Novartis lost in the Supreme Court of India was gained in South Africa through the registration of a secondary new use form of Imatinib. This should be a lesson for fellow SADC members to seriously consider patent law reform that takes care of the loopholes in their laws relating to the requirements for patentability and the absence of a patent examination system. Patent thickets around a single molecule are particularly common in the pharmaceutical drug industry, where "minor modifications such as changes in size, colour, dosage, delivery mechanisms and compositions are either simultaneously or subsequently patented".<sup>124</sup> India should be applauded for nipping this practice in the bud in the Novartis case, as has been described above.

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<sup>118</sup> Roderick and Pollock 2012 *The Lancet* e2.

<sup>119</sup> EU 2010 [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf). The US side of the debate is ably canvassed in Glasgow 2001 *IDEA* 227 while for Australia, Chalmers 2006 *MULR* 29 provides a useful critique.

<sup>120</sup> Coventry 2013 <http://www.hardnewsmedia.com/2013/07/593?page=show>.

<sup>121</sup> Coventry 2013 <http://www.hardnewsmedia.com/2013/07/593?page=show>.

<sup>122</sup> See generally, Ndlovu 2014 *Speculum Juris* 79-81.

<sup>123</sup> See TAC and MSF 2013 <http://www.fixthepatentlaws.org/?p=638>.

<sup>124</sup> Coventry 2013 <http://www.hardnewsmedia.com/2013/07/593?page=show>.

When pharmaceutical companies seek to maximise profits by patenting incrementally despite the obvious lack of novelty and inventive step, such behaviour, as was the case with Novartis in this instance, may fairly be characterised as patent abuse aimed at registering patents over minor insignificant changes in order to extend monopolistic prices.<sup>125</sup> It is submitted that in addition to having robust legislative provisions along similar lines to India's section 3(d), SADC members may react to such forms of abuse through the deployment of compulsory licenses in the event of an abuse of patent rights, as ably provided for in most IP legislations of the member states.<sup>126</sup>

The Novartis judgment delivers the message that the problem of low quality patents continues, aided and abetted by low quality patent examinations in the absence of pre- and post-grant patent opposition. Maybe it is now time to have many third world emulations of India's section 3(d), and such emulation seems to have already started in all earnest in Argentina, China and Thailand.<sup>127</sup> The decision in Novartis must be celebrated, taking into account how it testifies to the "flawed project of global harmonization of intellectual property laws",<sup>128</sup> which currently remains a pipedream which the SADC and the developing world can transform into context-specific reality through what Musungu, Villanueva and Blasetti characterise as "South-South cooperation".<sup>129</sup>

The Novartis decision demonstrates that TRIPS flexibilities are not a paper tiger and can be used despite the pressure from big pharmaceutical companies and the US government.<sup>130</sup> From the precedent set by the Novartis case, it is now possible for governments in developing countries (including the SADC) to set stringent patentability criteria for pharmaceuticals in order to facilitate the early entry of life-

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<sup>125</sup> At least this seems to have been the view of the Supreme Court in the *Novartis* case para 19, wherein the Court expressed the opinion that such high prices are prone to result in the creation of public disorder.

<sup>126</sup> In South Africa, such a "compulsory licence in case of abuse of patent rights" is provided for in s 56 of the *Patents Act* 57 of 1978.

<sup>127</sup> Coventry 2013 <http://www.hardnewsmedia.com/2013/07/593?page=show> 3. The author adds that there were reports soon after the judgment that Australia and Canada were considering provisions similar to s 3(d).

<sup>128</sup> Coventry 2013 <http://www.hardnewsmedia.com/2013/07/593?page=show> 3.

<sup>129</sup> See generally Musungu, Villanueva and Blasetti 2004 *Utilizing TRIPS Flexibilities* 35-79.

<sup>130</sup> Lofgren 2012 *The Conversation* 1-5.

saving, low-cost generics.<sup>131</sup> To raise the patentability standards in the SADC region, patent examiners have to be trained to interpret patentability requirements strictly before granting pharmaceutical patents.<sup>132</sup>

Because countries like India, China, Brazil and Thailand bring political and economic resources to bear on their interactions with multinational pharmaceutical companies and governments in the US and Europe,<sup>133</sup> such strength may be used collaboratively to the benefit of other developing countries through South-South cooperation.<sup>134</sup>

It will be recalled that pharmaceutical product patents were not recognised in India between 1972 and 2005, which is a situation that enabled the generic drug industry to flourish in India.<sup>135</sup> This enabled India to supply the domestic market and external markets (both developed and developing) with affordable generic drugs.<sup>136</sup> For example, it is reported that the entry of Indian firms in the global drug supply market<sup>137</sup> lowered the prices of first-line triple combination antiretrovirals (ARVs), used in the treatment of HIV, from US\$15 000 per person per annum in the year 2000 to less than US\$120 in 2012.<sup>138</sup> While the drug in dispute in the *Novartis* case had nothing to do with HIV/AIDS, this disease is very important in the SADC, and had the Supreme Court interpreted section 3(d) in favour of Novartis or struck it down completely, this would have had a devastating effect on access to medicines generally and HIV/AIDS drugs in particular. The importance of this decision in an HIV/AIDS context is aptly captured by Loon Gangte, president of the New Delhi Network of Positive People (DNP+). Interviewed by William New on the eve of the decision on the *Novartis* case, he said "We rely on the availability of affordable AIDS drugs and other essential medicines made by the Indian generic manufacturers to stay alive and healthy".<sup>139</sup>

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<sup>131</sup> Lofgren 2013 *The Conversation* 1-7.

<sup>132</sup> Musungu, Villanueva and Blasetti *Utilizing TRIPS Flexibilities* 15.

<sup>133</sup> Lofgren 2013 *The Conversation* 5.

<sup>134</sup> Musungu, Villanueva and Blasetti 2004 *Utilizing TRIPS Flexibilities* 46.

<sup>135</sup> Lofgren 2013 *The Conversation* 2.

<sup>136</sup> Lofgren 2013 *The Conversation* 2.

<sup>137</sup> The importance of India as the "pharmacy of the world" was highlighted in the letters from the HIV/AIDS Director of the WHO and the Director of Advocacy, UNAIDS, reproduced by the Supreme Court of India in the *Novartis* case paras 76-77.

<sup>138</sup> Lofgren 2013 *The Conversation* 2.

<sup>139</sup> New 2011 *Intellectual Property Watch* 1.

In concluding the discussion of the lessons to be learnt by the SADC from the Novartis case, it is important to refer to the role that was played by civil society groups to highlight the high stakes and importance of access to medicines. It has been reported that the outcome of the case is consistent with the pattern in the 1990s of a *de facto* coalition between health advocates, NGOs and some governments, including India, which are desirous of limiting the impact of IP on access to medicines.<sup>140</sup>

It needs to be recalled that various advocacy groups, such as Médecins Sans Frontiers, Health Gap in the US, the Delhi Network of Positive People and the Swiss-based Berne Declaration took part in lobbying against the *Novartis* case.<sup>141</sup> In addition, leading up to the Novartis AGM demonstrations were held in a number of US cities such as Boston, New York and Washington, while in India more demonstrations were held as a way of drawing attention to the *Novartis* case.<sup>142</sup> The role of civil society in promoting access to medicines is clear and need not be laboured here, save to say that apart from South Africa, most SADC countries have limited civil society activity, or like in Zimbabwe, they selectively criminalise civil society activities.<sup>143</sup> In the *Novartis* case, there was a coalition of civil society groups from within India and beyond. The success of such a coalition should be an informative lesson for the SADC in the context of regional IP reform to improve access to medicines.

The *Novartis* case is therefore important because it clearly shows that with a government that is sensitive to the peculiar public health needs of its people, it is possible to take full advantage of the TRIPS flexibilities with the aid of an independent judiciary and a robust civil society that works well with its global counterparts. The decision scored a victory for the generic industry in India by arresting incremental patenting and evergreening. The victory was achieved through the deployment of patentability provisions and opposition procedures in the *Indian Patents Act*.

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<sup>140</sup> Lofgren 2013 *The Conversation* 3.

<sup>141</sup> Esalimba 2009 *Intellectual Property Watch* 1.

<sup>142</sup> Hermann 2012 *Intellectual Property Watch* 2.

<sup>143</sup> For example, in 2011 it was reported by the International Centre for Not-for-Profit Law 2012 *IJNL* 20 that Zimbabwean police raided an academic meeting and arrested all civil society activists present for watching a video on the Arab Spring uprisings in Egypt and Tunisia. The activists were charged with treason or attempting to overthrow the government by unconstitutional means.

## 5 Recommendations

Going slightly beyond the facts of the case and the sources consulted, the recommendations outlined below illustrate how the lessons highlighted above may be practically implemented in select SADC countries. The recommendations relate to new use patents, strengthening patent abuse provisions in order to curb evergreening, strengthening patentability requirements for medicines and related substances, and introducing patent searches and examinations in order to ensure that patents rejected in other jurisdictions are not registered in the SADC region.

### 5.1 *New use patents*

The Indian case discussed above was primarily a complaint about Novartis' attempt to register a patent in India for a drug that was already state of the art and therefore not really worthy of registration as a patent. A significant number of SADC members allow patents for new uses of known medicines, mostly through legislation that allows for the grant of patents generally without an express reference to the prohibition of new uses of known substances.<sup>144</sup> Only three countries, namely Malawi,<sup>145</sup> Namibia<sup>146</sup> and Zambia,<sup>147</sup> have provisions in their relevant legislation specifically prohibiting the patenting of new uses of existing substances in the pharmaceutical context. It is therefore recommended that those SADC members that provide for new use patents in their laws should consider revising them in line with the Indian position by imposing conditions on the award of patents such as enhanced efficacy. For those countries that currently do not provide for new use patents in their IP laws, they are hereby urged to maintain the status quo, which is TRIPS compliant.<sup>148</sup>

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<sup>144</sup> See for example s 25(9) of South Africa's *Patents Act* 57 of 1978, which provides for the patentability of such new uses without any further qualification or conditions.

<sup>145</sup> S 18 of *Malawi's Patents Act*, Chapter 49:02 excludes the patenting of inventions "capable of being used as food or medicine" which are "a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients".

<sup>146</sup> Ss 17(1)(j)-(k) and 17(2) of the *Namibia Industrial Property Act* 2012 exclude the patenting of new uses of patents.

<sup>147</sup> The *Zambian Patents Act*, last amended in 1987, generally does not exclude new uses except in cases where the invention is capable of being used as food or medicine in a prohibitory context similar to that provided for in Malawian law (see s 18(1)(c) of the *Zambian Patents Act*).

<sup>148</sup> In terms of A 27 of TRIPS, patents shall be available for inventions of products and processes in all fields of technology as long as the inventions are new, involve an inventive step and are capable

## 5.2 *Strengthening patent law provisions to curb evergreening*

The drug in dispute in the Indian case, Imatinib Mesylate, was patented in South Africa with no litigation ensuing.<sup>149</sup> The most likely reason why this drug and its new use variants have been patented in South Africa since 1993 is the fact that South African patent law does not provide for mandatory patent searches and examinations.<sup>150</sup> The Mesylate version of Imatinib was patented in South Africa in 1997 and the patent is due to expire in 2017, while a new use patent for the same drug was granted in 2002 and is due to expire in 2022.<sup>151</sup> In 2013 and 2014, Novartis applied for and was granted a process patent for the *Process for the Preparation of Alpha Form Imatinib Mesylate*<sup>152</sup> and a product patent for the *Pharmaceutical Granulate Comprising Imatinib Mesylate*.<sup>153</sup>

It is doubtful if such minor additions to Imatinib would have been patented in a legal system with a robust patent examination model. A substantive patent examination system would essentially involve an examination of the quality of the invention.<sup>154</sup> This would entail a consideration of a number of pre-requisites such as the subject matter of the invention, which must be patentable; the industrial applicability aspect of the patent; and the novelty and inventiveness aspects.<sup>155</sup> It is heartening to report that South Africa intends introducing substantive patent examinations in its legal system soon.<sup>156</sup>

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of industrial application. The TRIPS Agreement does not provide for the patenting of new uses of substances as a requirement for patentability.

<sup>149</sup> See CIPC 2015 <http://patentsearch.cipc.co.za/>.

<sup>150</sup> See s 34 of the *Patents Act* 57 of 1978 and Regulations 40 and 41 to the same Act.

<sup>151</sup> According to Cortes *et al* 2009 *Journal of Clinical Oncology* 427 there are no major therapeutic differences between Imatinib Mesylate and its new use counterpart.

<sup>152</sup> South African Patent Number 2013/00872, granted on 30 April 2013.

<sup>153</sup> South African patent Number 2014/06139, granted on 27 May 2015.

<sup>154</sup> Wen and Matsaneng 2013 <http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf> 8.

<sup>155</sup> Wen and Matsaneng 2013 <http://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf> 9.

<sup>156</sup> See De Wet and Wild 2014 <http://mg.co.za/article/2014-10-30-new-drug-policy-is-patently-high-risk> in which Elena Zdravkova, the senior manager for patents and designs in the CIPC, confirmed that South Africa had already set aside a budget for the training of patent examiners by October 2015.

In the SADC region, Botswana's *Industrial Property Act* of 2010 may be regarded as model legislation for patent examinations.<sup>157</sup> The relevant law provides for an examination of the subject of a patent application in order ascertain if it complies with the requirements of the Act,<sup>158</sup> and also grants the Minister responsible for patents the discretion to designate certain patent applications as exempt from an examination covering the requirements for novelty and inventiveness.<sup>159</sup> Although Botswana's law in this specific context could have been drafted better, it is a good example of taking a deliberate step that will limit the abuse of the patent system and curb evergreening. It is therefore recommended that SADC members include patent examination provisions in their laws in order to ensure that only deserving patents are granted.

### **5.3 Patentability requirements for medicines and related substances**

Historically, there was an initial reluctance to allow patents on pharmaceutical products in many jurisdictions.<sup>160</sup> The *French Patent Act* of July 5, 1844 on patents<sup>161</sup> (*Loi du 5 juillet 1844 sur les brevets d'invention*), for example, excluded from protection "[L]es compositions pharmaceutiques ou remedes de toute espece", (my emphasis) that is, pharmaceutical compositions or medicines of all kinds.<sup>162</sup> The Act banned patents on pharmaceutical products and their pharmaceutical composition but not the process of fabrication of a pharmaceutical substance.<sup>163</sup> The ban remained until 1959, when an ordinance was passed providing that patents would be granted for pharmaceutical products, with a possibility of issuing compulsory licences in the case of insufficient quantities and abnormally high prices.<sup>164</sup>

All SADC members have provisions in their laws allowing for the granting of pharmaceutical patents.<sup>165</sup> In addition, more than 50 per cent of the SADC members

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<sup>157</sup> See specifically s 22 of the *Botswana Industrial Property Act* 2010.

<sup>158</sup> S 22(1) of the *Botswana Industrial Property Act* 2010.

<sup>159</sup> S 22(2) of the *Botswana Industrial Property Act* 2010.

<sup>160</sup> See Kropholler and Zweigert *Sources of International Uniform Law* 718.

<sup>161</sup> *French Patent Act*, adopted on 5 July 1844.

<sup>162</sup> See Kropholler J and Zweigert K *Sources of International Uniform Law* 718.

<sup>163</sup> This obviously did not auger well for patent protection, thus leaving the product vulnerable to illegal reproduction with impunity.

<sup>164</sup> Kropholler J and Zweigert K *Sources of International Uniform Law* 719.

<sup>165</sup> This may be by virtue of specific provisions in the pertinent patents legislation or membership of the Patent Cooperation Treaty and the African Regional Intellectual Property Organisation (ARIPO)



are least developed countries (LDCs), which are not obliged in terms of the WTO TRIPS Agreement to enforce patents.<sup>166</sup> All SADC countries are members of the WTO.<sup>167</sup> The ARIPO Harare Protocol provides for the patentability of new inventions that involve an inventive step and are capable of industrial application.<sup>168</sup> While it is not disputed that pharmaceutical products should be patented in order to spur technological innovation in the field, SADC members must consider amending their patent laws in order to provide a special regime for the patentability of pharmaceuticals. Important lessons in this specific regard may be drawn from India and Brazil.

This paper recommends that SADC members adopt either the Indian or the Argentinian approach. In India new forms of known substances (except those that show a significantly enhanced therapeutic effect) may not be patentable.<sup>169</sup> In Argentina, the law provides for a basic exception for patents on new forms of known substances,<sup>170</sup> but details of the exception are spelt out in regulatory guidelines rather than in the text of the relevant legislation.

The foregoing recommendations have been proposed as concrete practical examples of legislative measures that SADC members may adopt, after contextualising the lessons learned from *Novartis v India* to the region.

## 6 Conclusions

Although Indian law does not apply to the SADC region, the lessons discussed in this paper are generalisable to the SADC context. The case provides a good example of

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Harare Protocol with 19 members, namely Botswana, The Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Liberia, Rwanda, São Tomé and Príncipe, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

<sup>166</sup> See A 66.1 of the TRIPS Agreement. LDCs in the SADC region are Lesotho, Swaziland, Mozambique, Democratic Republic of the Congo, Malawi, Tanzania, Seychelles and Zambia.

<sup>167</sup> WTO 2015 [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm).

<sup>168</sup> A 10(a) of the *Harare Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organisation* (ARIPO) text entered into force on April 25, 1984, and amended by the Administrative Council of ARIPO on April 27, 1994, November 27, 1998, November 24, 2000, November 21, 2003, November 24, 2006, November 30, 2011 and November 25, 2013.

<sup>169</sup> S 3(d) of the *Indian Patents Act* as amended in 2005.

<sup>170</sup> See Ignacio 2012 <https://www.aippi.org/enews/2012/edition25/Ignacio.html>.

how to take maximum advantage of one of the TRIPS flexibilities, namely setting national criteria for patentability. In identifying the source of lessons for SADC from outside the region, it is important to select lessons from countries with socio-economic conditions similar to those that prevail in the SADC. India is therefore appropriate as a source of the lessons, based on the fact that it is a developing WTO member which most SADC members are likely to use as a source of generic drugs.

While the Indian legislative inclusion of the relevant TRIPS flexibility may be regarded as going slightly beyond the minimum prescribed by the TRIPS Agreement ie TRIPS-plus, such inclusions are TRIPS-compliant. It is therefore recommended that SADC members embark on IP legislative reforms along similar lines to the Indian.

For example, South Africa, a SADC member with one of the highest HIV/AIDS infection rates in the world, does not have provisions in its patent laws dealing with pre-grant opposition to patents as a condition precedent to the granting of a patent. Such an omission does not augur well for access to medicines and deserves a legal administrative rethink. Patent offices must therefore push for high standards of disclosure in order to discourage the filing of bogus patent applications meant to serve a gate-keeping function to the entry of generics in the market. SADC member states may, therefore, consider dealing with this problem by requesting technical assistance from the WTO<sup>171</sup> and the World Intellectual Property Organisation (WIPO) to amend their laws so that patent examination becomes mandatory.

One of the most important lessons for SADC members is that the TRIPS Agreement does not prevent them from denying the patentability of new uses of drugs for lack of novelty, the involvement of an inventive step and the lack of industrial applicability. Developing countries and SADC member states would be within their rights if they excluded new uses of known products including diagnostic, therapeutic and surgical methods from patentability in order to protect their citizens' right to health and by extension, their access to medicines.

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<sup>171</sup> Article 66 of TRIPS mandates developed WTO members to provide, upon request, financial and technical cooperation to their developing and least developed counterparts on mutually agreed terms and conditions. Such cooperation includes assistance in the preparation of laws and regulations to prevent the abuse of intellectual property rights.

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## LIST OF ABBREVIATIONS

|                        |   |
|------------------------|---|
| ARIPO                  | African Regional Intellectual Property Organisation                                       |
| AHRLJ                  | African Human Rights Law Journal  |
| ARVs                   | Antiretrovirals   |
| BRICS                  | Brazil, Russia, India, China and South Africa   |
| CIPC                   | Companies and Intellectual Property Commission of South Africa                            |
| EU                     | European Union  |
| GSK                    | GlaxoSmithKline   |
| IDEA                   | IDEA: The Journal of Law and Technology   |
| IJNL                   | International Journal of Not-for-Profit Law   |
| IP                     | Intellectual Property   |
| IPAB                   | Intellectual Property Appellate Body  |
| IPR                    | Intellectual Property Rights  |
| J Public Health Policy | Journal of Public Health Policy   |
| JIPLP                  | Journal of Intellectual Property Law and Practice   |
| JWIP                   | Journal of World Intellectual Property  |
| LDCs                   | Least developed countries   |
| MSF                    | Médecins Sans Frontières  |
| MULR                   | Melbourne University Law Review   |
| NIHCM                  | National Institute of Health Care Research Management Research and Educational Foundation |
| SADC                   | Southern African Development Community  |

|                                |   |
|--------------------------------|---|
| TAC                            | Treatment Action Campaign                             |
| TRIPS                          | Trade Related Aspects of Intellectual Property Rights |
| USTR                           | Office of the United States Trade Representative      |
| WTO                            | World Trade Organisation                              |
| Yale J Health Pol'y L & Ethics | Yale Journal of Health Policy, Law, and Ethics        |