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## South Africa's Medicines and Related Substances Control Amendment Act: A Spoonful of Sugar or a Bitter Pill to Swallow?

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## COMMENTS

# South Africa's Medicines and Related Substances Control Amendment Act: A Spoonful of Sugar or a Bitter Pill to Swallow?

## I. Introduction

As the lead advocate for the new law, South Africa's Minister of Health, Nkosasana Zuma, faced opposition from the multinational pharmaceutical industry giants and the world's most powerful nations, and yet, for now at least, she has won. South Africa passed the Medicines and Related Substances Control Amendment Act (hereinafter the "Act") in December of 1997 in an effort to lower the cost of medicines and thereby improve access to medical care for many impoverished South Africans.<sup>1</sup>

While primary healthcare has been entitled by law to all citizens of South Africa since 1996, most South Africans are still unable to receive even the most basic medical care.<sup>2</sup> Today, less than one-fifth

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\* This comment is dedicated to my wife Jennifer for it was not the work of one intellect and conscience, but of two, which made it a reality.

1. See *Medicines and Related Substances Control Amendment Bill* (visited Oct. 14, 1998) <<http://www.anc.org.za/as/pubs/whip/whip22.html>>.

2. See Nigel Benetton, *Changes to the Law Promise Less Flexibility for Medical Schemes* (visited Oct. 14, 1998) <<http://www.woza.za.com.>>. Primary health care includes "basic emergency first aid treatment, immuniz[ation], education, especially

of the population “is consuming over half of the healthcare resources.”<sup>3</sup> Many rural clinics still do not have running water or electricity, and even fewer clinics are assured a steady supply of medicines.<sup>4</sup> To further complicate matters, South Africa currently endures over 20,000 cases of malaria and 160,000 cases of tuberculosis each year.<sup>5</sup> Unfortunately, however, there is an even bigger problem facing South Africa: AIDS. South Africa has one of the highest growth rates of HIV in the world, with 2.4 million people infected which represents 6.3 percent of the population.<sup>6</sup> Thus, it is no wonder that Minister of Health Zuma considers the new law to be a desperately needed step in beginning to heal the nation’s ailing health care system.<sup>7</sup>

Critics, however, are quick to point out that the new law is far from being a panacea for the problems currently affecting the nation.<sup>8</sup> Many see the new law as an impending disaster.<sup>9</sup> The Act has been surrounded by controversy because it seeks to lower pharmaceutical prices by changing existing patent laws.<sup>10</sup> The United States Trade Representatives’ 1998 annual report identified the new law as “[the United States’] largest patent rights concern.”<sup>11</sup> Accordingly, United States Trade Representative Charlene Barshefsky announced the placement of South Africa on the Watch List for countries who provide inadequate intellectual property right protection.<sup>12</sup>

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with [regard to] sexually transmitted diseases, disease control and the provision of clean running water, for example.” *Id.*

3. *See id.*

4. *See id.*

5. *See id.*

6. *See* Benetton, *supra* note 2. And as the demand for medicines has increased, so have prices. Figures from the Representative Association of Medical Schemes show that the price of medicines rose 37 percent in 1990, rose 45 percent the subsequent year, and the increased another 14 percent in 1994. Pat Sidley, *Vested Interests Resist Reform in Medicines*, BUSINESS TIMES, visited Oct. 15, 1998, <<http://www.btimes.co.za/97/0504/news/news17.htm>>.

7. *See* Benetton, *supra* note 2.

8. *See* Donald G. McNeil, Jr., *South Africa's Bitter Pill for World's Drug Makers*, N.Y. TIMES, Mar. 29, 1998, at Section 3, Page 1.

9. *See id.*

10. *See id.*

11. Simon Barber, *US Court Decision Holds No Sway Over Battle With SA*, BUS. DAY, Mar. 18, 1998, at 13.

12. *USTR Announces Results of Special 301 Annual Review*, USTR PRESS RELEASE, May 1, 1998, at 6, 21. Under the Special 301 provisions of the Trade Act of 1974, the USTR has the authority to place higher duties and restrictions on imports from countries that provide inadequate intellectual property protection. *See also* Stefan Kirchanski, *Protection of U.S. Patent Rights in Developing Countries:*

The new law has also sparked responses from private industry.<sup>13</sup> One major United States drug manufacturer threatened that if the law were not changed it would halt all operations in South Africa, thereby eliminating thousands of jobs.<sup>14</sup> The pharmaceutical companies claim that in order to lower prices, changes could be made in South Africa's inefficient distribution chain by eliminating extensive price mark-ups by middlemen and by stopping the theft of drugs from public hospitals.<sup>15</sup> Furthermore, the International Federation of Pharmaceutical Manufacturers indicated that companies may retaliate against South Africa by refusing to introduce new drugs, including any new Aids medications, unless the law is changed.<sup>16</sup> Thus, the question remains whether the new law will help ameliorate the condition of many South African people or whether they will end up suffering even greater harms.

This comment examines the potential benefits and problems presented by the Medicines and Related Substances Amendment Act as it relates to pharmaceutical patent rights in South Africa. Part II provides a background on some basic principles of intellectual property law that are relevant to the new law. Part III then looks at the changes made to the laws of South Africa with the passage of the Act. Part IV examines the effect of the Act on South Africa's compliance with the Trade Related Aspects of Intellectual Property Rights Agreement ("TRIPS"). Part V discusses the pros and cons of the new law. Part VI then summarizes and concludes that the new law may be beneficial to South Africa.

## II. Intellectual Property Law Fundamentals

### A. Intellectual Property

Intellectual property is "intangible property that is a product of human creativity, such as books, films or inventions."<sup>17</sup> Intellectual property laws attempt to provide the protections that normally accompany ownership of tangible property to the "intangible

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*U.S. Efforts to Enhance Pharmaceutical Patents in Thailand*, 16 LOY. L.A. INT'L & COMP. L.J. 569, 588 (1994). However, South Africa was only placed on the Watch List of less severe offenders, which means they will be subject to "out-of-cycle reviews," but not be subject to trade sanctions. *Id.*

13. See Mary Braid, *Drug Giants Flex Muscles as SA Tries to Cut Health Bill*, INDEPENDENT (London), Oct. 8, 1997, at 14.

14. See *id.*

15. See *id.*

16. See *id.*

17. See Kirchanski, *supra* note 12, at 570.

products of mental labor.”<sup>18</sup> The primary protection the law seeks to secure for intellectual property is exclusivity. As patent attorney Peter D. Rosenberg explained, “the essence of property is the exclusive right to enjoy it.”<sup>19</sup> While intellectual property undoubtedly has economic value, as it may be bought, sold and otherwise exploited commercially, the product of mental labor has not always been provided legal protection.<sup>20</sup> Indeed, some countries still rely on the free-market, through self-protection, to provide adequate protection for intellectual property.<sup>21</sup>

### B. *The Benefits and Costs of Intellectual Property Laws*

Under a free-market approach, the inventor, author or other creator of intellectual property would still retain the right to make, use or sell his or her invention.<sup>22</sup> However, in the absence of legal protection, there is nothing to prevent someone from copying the invention and using it.<sup>23</sup> Consequently, someone who copies and sells the invention is competing with the original inventor, and therefore, the inventor’s ability to sell and profit from his or her own invention is diminished.<sup>24</sup> The copier also has the advantage of being able to compete without bearing the investment, time or effort necessary for the discovery, and as a result, the copier might make more money from the invention than the inventor.<sup>25</sup> Most countries, however, believe the unfettered use of another person’s inventions is unjust. And as a result, countries have enacted intellectual property laws to provide the inventor the sole benefit of his or her invention by excluding others from enjoying the invention.<sup>26</sup> In other words, the government grants the inventor a monopoly on the sale of his or her invention.<sup>27</sup>

Not only do advocates of intellectual property believe the grant of a monopoly to inventors is fair, but they also believe it improves the “size, quality, and efficiency of both the labor force and the

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18. *See id.*

19. PETER D. ROSENBERG, *PATENT LAW FUNDAMENTALS*, at 1-7 (2d ed. 1980).

20. *See* Kirchanski, *supra* note 12, at 570.

21. *See* Theresa Beeby Lewis, *Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries*, 30 INT’L L. 835, 837 (1996).

22. *See* ROSENBERG, *supra* note 19, at 1-5.

23. *See id.* at 1-5, 1-6.

24. *See id.* at 1-6.

25. *See id.*

26. *See id.* at 1-4.

27. *See* ROSENBERG, *supra* note 19, at 1-6.

capital stock within a country.”<sup>28</sup> They believe that the reduction in competition, due to the grant of the monopoly, increases the profitability of inventions and therefore encourages the search for and, as a result, the discovery of new inventions.<sup>29</sup> Ultimately, advocates of intellectual property rights believe that the increased number of inventions benefits the economy as well as society’s well being.<sup>30</sup> But there is a cost associated with granting an inventor a monopoly.<sup>31</sup> Inventors may charge premium prices, commonly referred to as royalties, for their inventions.<sup>32</sup> Thus, countries that have adopted intellectual property laws have presumably concluded that the cost to society from the royalties due to the monopoly are outweighed by the benefits of the new inventions.<sup>33</sup>

### C. Patent Law

In its most plain sense, a patent is simply a contract entered into by an inventor and a government.<sup>34</sup> The government promises to provide the inventor a monopoly to the enjoyment of his or her invention in return for disclosure of the invention to the public.<sup>35</sup> Indeed, the word “patent” is commonly understood to mean open or obvious.<sup>36</sup>

The justification for disclosure is that it will “catalyze other inventors activity and make possible additional advances in the art”<sup>37</sup> by allowing them “to think and to write about what is covered by the patent.”<sup>38</sup> Otherwise, a discovery could potentially be kept a secret forever.<sup>39</sup> The life of a patent, however, is usually limited to a certain amount of time, such as 20 years in the United States.<sup>40</sup>

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28. See Lewis, *supra* note 21, at 838.

29. See Kirchanski, *supra* note 12, at 572.

30. See *id.*

31. See *id.* One author noted that there is a significant difference between a government granted monopoly in a patent and other monopolies. Rosenberg, *supra* note 19, at 1-7. He noted that “[u]nlike a franchise, a patent deprives the public of nothing that it freely enjoyed prior to the grant of the patent.” See *id.* Nonetheless, prospective costs remain.

32. See Kirchanski, *supra* note 12, at 572.

33. See *id.*

34. See ROSENBERG, *supra* note 19, at 1-4.

35. See *id.*

36. See *id.* at 1-1.

37. See *id.* at 1-4.

38. See *id.* at 1-8.

39. See ROSENBERG, *supra* note 19, at 1-4.

40. See Lewis, *supra* note 21, at 837.

Consequently, the public may use and enjoy the invention after the patent has expired.<sup>41</sup>

Normally, when “an invention is novel, useful, and not obvious, it is patentable if it falls within the patentable categories provided in a particular country.”<sup>42</sup> Countries vary as to which inventions are patentable.<sup>43</sup> There is often international controversy in patent law because some developing countries do not allow patents for certain categories of inventions, such as new medicines or agricultural inventions.<sup>44</sup> Countries refuse to allow patents in these categories because, among other reasons, they believe the cost to their economy would be too great or the prices of important discoveries would be prohibitive for their citizens.<sup>45</sup> The international controversy concerning the existence of a patentable category for pharmaceuticals in South Africa is the matter addressed by this comment.

#### *D. Parallel Imports*

This comment also deals with the allowance of parallel imports in South Africa. Parallel imports are “goods which are bought in a foreign market by an independent third party, and then resold in [another] market to compete with authorized distributors.”<sup>46</sup> Despite many efforts to harmonize and increase intellectual property protection around the world, there still exists a significant number of countries that permit parallel imports.<sup>47</sup> As a result, companies that sell their products abroad may experience increased competition from their own goods.<sup>48</sup> Even multinational companies that only produce goods in countries that do not permit parallel imports, such as the United States, still run the risk of unauthorized dealers buying goods and selling them in other countries in competition with authorized foreign dealers.<sup>49</sup>

The impetus for diverting foreign bound goods from one country to another is usually the potential to profit from different

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41. *See id.*

42. *See id.*

43. *See id.*

44. *See id.* at 837.

45. *See Lewis, supra* note 21, at 835.

46. Hillary A. Kremen, *Caveat Venditor: International Application of the First Sale Doctrine*, 23 SYRACUSE J. INT'L L. & COM. 161 (1997).

47. *See id.*

48. *See id.*

49. *See id.*

prices.<sup>50</sup> Companies often discriminate in pricing between countries for a couple of reasons.<sup>51</sup> First, authorized distributors may pay to promote and advertise the patented product in some countries where other authorized dealers do not.<sup>52</sup> Second, authorized dealers often provide product support and service for their goods.<sup>53</sup> Unauthorized dealers also exploit currency fluctuations, buying in one country when its currency is weak and selling in another where the currency is stronger.<sup>54</sup>

Parallel imports, through increased competition, have obvious potential benefits for consumers.<sup>55</sup> Increased competition will pressure companies to lower the price of their product.<sup>56</sup> Indeed, the price discrimination must be substantial, with prices drastically higher in one country, for the unauthorized dealers to be able to offer a lower price on goods which must be transported between countries.<sup>57</sup> In short, the controversy surrounding parallel imports centers on whether or not patent protection should extend beyond the first sale of a product.<sup>58</sup>

#### *E. First Sale Doctrine*

The "first sale" doctrine if applied internationally would permit parallel imports because it limits patent protection to the first disposition of goods.<sup>59</sup> Under this doctrine, a patentee loses the ability to control, and the royalties from, subsequent dispositions of the patented goods.<sup>60</sup> The patent is said to have been "exhausted" upon the first sale of the good.<sup>61</sup> Thus, the purchaser of a patented good is free to resell the good without violating any patent laws and giving rise to a cause of action on behalf of the patentee.<sup>62</sup>

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50. *See id.* at 162.

51. *See Kremen, supra* note 46, at 162.

52. *See id.*

53. *See id.*

54. *See id.*

55. *See James Love, Comments of the Consumer Project on Technology to the Portfolio Committee on Health Parliament* (visited Oct. 14, 1998) <<http://www.cptech.or/pharm/sa/sa-10-97.html>>.

56. *See id.*

57. *See id.*

58. *See Kremen, supra* note 46, at 162, 163.

59. *See id.* at 162.

60. *See id.*

61. *See id.*

62. *See id.*



The first sale doctrine is normally applied only to subsequent sales of patented goods that occur domestically.<sup>63</sup> Countries have been hesitant to apply the first sale doctrine internationally due to the fear that importers would re-direct goods from poorer countries to the countries where the price is higher, and as a result, economically disadvantaged countries would be denied sufficient supplies of goods and technology that are extremely beneficial.<sup>64</sup> Ultimately, allowing parallel imports limits the monopoly power granted to patent holders, and therefore, the first sale doctrine reduces the level of intellectual property protection provided to multinational companies.<sup>65</sup>

### III. The Medicines and Related Substances Control Amendment Act's Effect on the Laws of South Africa.

#### A. *The Minister of Health's Powers Under Section 15(C)(a).*

South Africa has increased intellectual property rights protection in recent years. After the Uruguay Round trade negotiations of the General Agreement on Tariffs and Trade ("GATT") over Trade Related Aspects of Intellectual Property Rights agreement ("TRIPS"), South Africa, along with the other GATT members, signed the TRIPS agreement on April 15, 1994.<sup>66</sup> And in 1997, South Africa made buying and selling of counterfeit goods a crime.<sup>67</sup> Indeed, the Patents Act of 1978 provided patent protection for medicines, and Subsection 1(2) outlawed parallel imports.<sup>68</sup>

Despite the trend toward increasing intellectual property protection, many people believe the new law empowers the Minister of Health to selectively end patent rights for pharmaceuticals.<sup>69</sup> Under Section 15(C)(a),

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63. See Kremen, *supra* note 46, at 162.

64. See *id.* at 162, 163.

65. See *id.* at 163.

66. See Tony Hooper, Peter Davies, *The Medicines and Related Substances Control Amendment Bill (B30-97) and Its Effect on Intellectual Property Rights* (visited on Oct. 14, 1998) <<http://www.spoor.co.za/lib/genericdrugs.html>>.

67. See USTR, *supra* note 12, at 21, 22.

68. See Hooper, *supra* note 66.

69. See McNeil, *supra* note 8. See also, Simon Barber, *Plan Blunts Long-Term Threat to US Aid for SA*, BUS. DAY (S. Afr.), July 20, 1998, at 3. (Stating that the new law "appears to give the SA health minister the power to abrogate drug patents for the sake of controlling medicine costs." *Id.*)

[the Minister of Health] so as to protect the health of the public may . . . notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), 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.<sup>70</sup>

The United States Congress and some European countries have stated that they interpret this section to allow the Minister of Health to approve the use of more affordable medicines in violation of any patent right under the 1978 Patents Act of South Africa.<sup>71</sup> Minister of Health Zuma steadfastly denies that the provision ends patent rights.<sup>72</sup> Instead, she claims that the provision is only aimed at permitting parallel imports of medicines.<sup>73</sup> While the Act does permit parallel imports under section 15(C)(b), as will be discussed subsequently, it remains unclear whether or not section 15(C), as a

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70. Medicines and Related Substances Control Amendment Act, No. 101 (1997) (S. Afr.). The entirety of section 15C reads as follows:

Measures to ensure supply of more affordable medicines 15C.  
The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may

(a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), 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;

(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;

(c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

71. See McNeil, *supra* note 8.

72. See *id.*

73. See *id.* For an explanation of parallel imports and their potential effect on patent rights in South Africa see *discussion supra* Parts II.D. and *infra* Parts III.B.

whole, seeks to infringe on patent rights more so than the approbation of parallel imports.<sup>74</sup>

In defending the new law, South African Trade and Industry Minister Alec Erwin stated that “the government had taken a policy decision to stop drug companies from using their patents to prevent affordable health care.”<sup>75</sup> While this is surely the case, the extent to which the law infringes on patent rights is unclear. Upon closer examination, the law does not appear to give the Minister of Health the absolute power to abrogate patent rights, but instead the law seems to simply give her the power to authorize parallel imports.<sup>76</sup>

The part of section 15(C)(a) that has caused confusion is the language stating that pharmaceutical patent rights “shall not extend to acts in respect of such medicine which has been put onto the market.”<sup>77</sup> While it is unclear what “acts” are excluded from patent protection, it is clear that the law only addresses medicine which has been “put onto the market” by the owner. If the phrase “put onto the market” means broadly those patented medicines that have been exploited commercially, the law could deny patent holders any benefits of patent protection once they begin to sell their drugs. This would mean that once a pharmaceutical company proceeds to sell their patented medicine they have put their patented drugs “onto the market,” and the Minister of Health then may authorize the production of a drug that is an exact copy of the patented product.

If this interpretation is correct, the new law would allow the Minister of Health to effectively choose to abrogate patent rights whenever she deems it to be in the best interest of the public's health.<sup>78</sup> However, this does not appear to be the best interpretation of this section. The major importance of a patent is the right to exploit it commercially, and under this interpretation, a pharmaceutical patent would be essentially useless without the approval of the Minister of Health. It seems very unlikely that the legislature of South Africa would choose to entrust a single government official with the power to upend an entire area of established law without a much clearer declaration than 15(C)(a). Dr. Zuma, who has been the lead advocate of the new law and would be vested with this broad new power as Minister of Health,

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74. See USTR, *supra* note 12, at 21.

75. See Jacob Dlamini, *Erwin Defends Drugs Law, Suggests WTO Intervention*, BUS. DAY (S. Afr.), Oct. 22, 1997, at 2.

76. See *supra* note 15 for the entire text of Section 15C of the new law.

77. Medicines and Related Substances Control Amendment Act, No. 101 (1997) (S. Afr.) § 15C(a).

78. See McNeil, *supra* note 8.

has stated clearly that she does not believe the new law gives her the power to end all pharmaceutical patent rights.<sup>79</sup> It appears she is correct.

The phrase "put onto the market" most likely refers to each individual parcel of medicine that has been sold. Thus, a person loses patent protection against the resale of his or her goods. This is commonly known as the first sale doctrine and would effectively empower the health minister to allow people to parallel import a manufacturer's patented pharmaceuticals sold in other countries into South Africa. This would mean that a patent holder would still receive all of the benefits of the patent before and including the original sale of the medicine, but would lose protection against subsequent reselling by a buyer. While allowing parallel imports is a reduction in the patent protection afforded to pharmaceuticals, this interpretation seems much more reasonable than a near complete termination of pharmaceutical patent rights, especially in light of section 15(C)(b)'s express acceptance of parallel imports.<sup>80</sup>

At the very least, the language in 15(C)(a) needs to be clarified during the promulgation of regulations. If the complete, albeit selective, dissolution of patent protection for pharmaceuticals is in fact not the intent of this the new law, then it should be made clear that pharmaceutical patents will be honored in order to eliminate any confusion. As it stands, the new law appears to simply empower the Minister of Health to allow parallel imports. But the possibility that the Minister of Health may exploit the language of 15(C)(a) to further reduce patent protection can only increase the risk of investment from pharmaceutical companies. For the purposes of this comment, the new law will be analyzed under the assumption that section 15(C)(a) gives the Minister of Health broad powers to abrogate pharmaceutical patents, and subsequently, as if the new law only provides for parallel imports, as is evident in section 15(C)(b) discussed below.

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79. *See id.*

80. Section 15(C)(a) also states that the Minister of Health may act to protect the public health "notwithstanding anything to the contrary contained in" the Patents Act of 1978. § 15(C)(a). While this language clearly limits the application of the Patents Act, if all section 15(C), as a whole, does is permit parallel imports, then the only part of the Patents Act which is repealed is its prior prohibition of parallel imports under section 1(2) of the 1978 Patents Act.

*B. The New Law's Approval of Parallel Imports Under Section 15(C)(b).*

Unlike 15(C)(a) of the Act, the language of section 15(C)(b) has a much clearer intent. Section 15(C)(b) of the new law explicitly reverses the 1978 Patents Act's prohibition on parallel imports.<sup>81</sup> More specifically, the new law states that a drug that "meets the same quality standards and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate . . . may be imported."<sup>82</sup> Under this section, "a medicine which is available abroad and which is identical to one registered by the same manufacturer in South Africa need not be the subject of a separate registration and may therefore be imported and sold in competition with the product which is the subject of the local registration."<sup>83</sup> This provision is aimed at increasing local price competition and lowering prices by allowing the importation of drugs from other countries where they are cheaper.<sup>84</sup> It has also been suggested that this section gives South Africa, and in particular Minister of Health Zuma, leverage to force the industry to lower their prices.<sup>85</sup> Dr. Zuma can threaten to begin parallel importation of a manufacturer's drugs from other countries if the local prices do not conform with rates abroad.<sup>86</sup>

*IV. Compliance of the Act with South Africa's International Obligations Under TRIPS.*

Negotiations during the Uruguay Round of the GATT resulted in South Africa signing TRIPS in 1994.<sup>87</sup> Article 7 of the TRIPS accord states that the objective of the TRIPS agreement is:

[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the

81. *See id.* at § 15(C)(b).

82. *See id.* at § 15(C)(b). *See supra* note 14 for entire section.

83. *See Hooper, supra* note 66.

84. *See Love, supra* note 55. For a discussion of parallel imports and their potential effect on patent rights in South Africa and South Africa's compliance with the TRIPS agreement *see supra* p. 11, 12 and *see infra* p. 12-14.

85. *See Dlamini, supra* note 75.

86. *See id.*

87. *See Suresh Koshy, The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective*, 1 B.U. J. SCI. & TECH. L. 4 (1995).

mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.<sup>88</sup>

While the TRIPS agreement sought to harmonize intellectual property law between countries, members may implement local laws that provide more patent protection than the minimum protections mandated in TRIPS.<sup>89</sup> However, the Medicines and Related Substances Amendment Act may provide less protection than South Africa is permitted under TRIPS.

*A. TRIPS Does Not Authorize South Africa or Any Other Member Country to Exclude Pharmaceuticals From Product Patent Protection.*

Article 28(1) requires member countries to provide patent protection for the exclusive rights of “making, using, offering for sale, selling, or importing” a product or process.<sup>90</sup> A patentable product or process can be any invention “in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.”<sup>91</sup> However, “[m]embers may exclude from patentability inventions . . . within their territory of the commercial exploitation which is necessary to protect . . . public [morals] . . . human, animal or plant life or health or to avoid serious prejudice to the environment.”<sup>92</sup> Furthermore, Article 27(3) allows member countries to “exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals.”<sup>93</sup> But there is no exception for pharmaceuticals. As a result, it would appear that Section 15(C)(a) of the Medicines and Related Substances Control Amendment Act would violate the TRIPS agreement if, as some critics claim, it gives the Health Minister broad powers to eliminate such patents.<sup>94</sup>

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88. *Agreement On Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Final act Embodying The Results of The Uruguay Round of Multilateral Trade Negotiations*, 33 I.L.M. 83, 86-87 (1994). [hereinafter TRIPS].

89. See Koshy, *supra* note 87.

90. TRIPS, *supra* note 88, at 94. However, “[t]his right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.A *Id.*

91. See *id.* at 93.

92. See *id.* at 94.

93. See *id.*

94. See McNeil, *supra* note 8.

*B. Article 6 of TRIPS Does Not Prohibit South Africa From Permitting Parallel Imports.*

It does not appear that parallel imports are a violation of the GATT's TRIPS accords. Some pharmaceutical manufacturers have argued that TRIPS prohibits parallel imports.<sup>95</sup> They point to the fact that TRIPS Article 28 "gives the patent owner the exclusive rights to import [their] good."<sup>96</sup> However, the right to import is limited by Article 6 of TRIPS.<sup>97</sup> Article 6 makes it clear that "nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights."<sup>98</sup>

The theory behind the doctrine of exhaustion, or first sale doctrine, is that the owner of the property right has benefitted from the protection upon the products first sale.<sup>99</sup> Subsequently, a buyer may resell the product in competition with the patent holder without infringing on his or her patent rights.<sup>100</sup> This presents an opportunity for importers to acquire patented products, including medicines, from other countries where the price is lower and then import the product into a market where the price is higher.<sup>101</sup> Thus, under the doctrine of exhaustion, parallel imports do not violate patent rights.

TRIPS was the first intellectual property treaty to directly address parallel imports.<sup>102</sup> But all it decided was that such disputes are to be settled between individual countries.<sup>103</sup> Thus, there is no impediment in international law to parallel imports, and it does not appear that the Medicines and Related Substances Amendment Act has violated South Africa's obligations under TRIPS.

*V. The Potential Benefits and Problems of the New Law.*

*A. The Minister of Health's Potential Power Under Section 15(C)(a) to Abrogate Patent Protections for Pharmaceuticals.*

The traditional rationale for the existence of a patent system is that society benefits from more innovations and that the best way to

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95. See Love, *supra* note 55.

96. See *id.*

97. See *id.*

98. See *id.*

99. See *id.*

100. See Love, *supra* note 55.

101. See Kremen, *supra* note 46, at 162.

102. See *id.* at 173, 174.

103. See *id.* at 174.

cultivate them is through patent exclusivity.<sup>104</sup> Some potential benefits of a South African pharmaceutical patent system include: (1) greater foreign and domestic investment for research and development; (2) greater “transfer of pharmaceutical technology” to South Africa; and (3) greater availability of drugs.<sup>105</sup> For a developing country, however, these benefits may prove somewhat illusory, and ultimately, the costs of the patent system may outweigh the benefits.

It has been argued “that the policies justifying the protection of patents in developed countries are not necessarily applicable to developing countries.”<sup>106</sup> In some cases, piracy can benefit a country by simply providing patented technology without the additional cost of having to pay a royalty to acquire it.<sup>107</sup> The country’s economy not only receives a windfall from this cost savings, but also from exporting the counterfeit goods to other countries that also lack patent protections.<sup>108</sup> Similarly, the availability or supply of new drugs, which are often extremely expensive, might be limited by the low income of most South Africans.<sup>109</sup> Furthermore, as a developing country, the potential benefit of increased investment in local research and development and manufacturing facilities may be unlikely because of a lack of “trained technicians and other infrastructure” in South Africa.<sup>110</sup>

While these arguments undoubtedly have merit, they do not seem to ring true for South Africa. First, there appears to be adequate infrastructure to support domestic research and development and manufacturing facilities.<sup>111</sup> The 12 American pharmaceutical companies with facilities in South Africa together take in nearly 100 billion pounds in revenue a year.<sup>112</sup> Indeed, they account for less than half of the \$2 billion-a-year drug market in South Africa.<sup>113</sup> Thus, it appears that South Africa does have the

104. See *id.* A. Samuel Oddi, *The International Patent System and Third World Development, Reality or Myth?*, 1987 DUKE L.J. 831, 837 (1987). For a discussion of the rationale behind intellectual property rights or patents see *discussion supra* Parts II.B.

105. See Kirchanski, *supra* note 12, at 577.

106. See *id.* at 570.

107. See *id.* at 577.

108. See *id.*

109. See *id.* at 579.

110. See Kirchanski, *supra* note 12, at 578.

111. See Braid, *supra* note 13.

112. See *id.*

113. See McNeil, *supra* note 8.



necessary infrastructure and skilled workers as evidenced by this multi-billion dollar domestic industry.

Second, South Africa's problems with providing adequate medical care may have little to do with the royalties from patent protection. Mirryena Deeb, of the Pharmaceutical Manufacturing Association of South Africa, explained that the government of South Africa was already receiving the lowest prices on drugs, but public hospitals were sacrificing up to fifty percent of the drugs to theft.<sup>114</sup> Not only are drugs being stolen and resold in the private sector, but so are "bed[s], catering equipment, medical equipment, and computers," all of which drive up the cost of medical services.<sup>115</sup> Moreover, the long-standing cartel of middlemen in South Africa mark up the price of drugs up to 82 percent,<sup>116</sup> compared to the United States where distributors normally mark up prices only 25 percent.<sup>117</sup>

Lastly, while patent piracy may provide South Africa with cheaper copies of some drugs, it is difficult to copy new drugs because to do so often requires new technology.<sup>118</sup> Perhaps the greatest threat facing South Africa is that manufacturers, who incur approximately \$359 million in research and development per drug, may refuse to sell their drugs in a country where there is no patent protection.<sup>119</sup> Similarly, some drug makers have refused to sell drugs in India because of the lack of patent rights for pharmaceuticals.<sup>120</sup> One drug that becomes toxic soon after opening has been sold on the streets of India in jars.<sup>121</sup> Mirryena Deeb stated that "[i]f [drug manufacturers] can't control how it's made and sold, they won't sell . . . [because] [t]hey can't afford the liability [from] lawsuits."<sup>122</sup>

Ultimately, it appears that South Africa can benefit from a

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114. See Dlamini, *supra* note 75.

115. See Benetton, *supra* note 2.

116. See Braid, *supra* note 13.

117. See McNeil, *supra* note 8.

118. See Kirchanski, *supra* note 12, at 580.

119. See James Love, *HAI Seminar: World Trade Organization/GATT, Pharmaceutical Policies and Essential Drugs* (visited Oct. 4, 1998), <<http://www.cptech.org/pharm/bielefeld.html>>. It must be noted that issue has been taken with the U.S. Office of Technology Assessment (OTA) estimate of \$359 million for the cost of developing a new drug. *Id.* Mr. Love points out that most of the \$359 estimate is based on "heroic estimates of the costs of pre-clinical research, much of which is paid for by the government [of the United States], and conducted in [U.S.] government and university laboratories." *Id.*

120. See McNeil, *supra* note 8.

121. See *id.*

122. See *id.*

pharmaceutical patent system and could stand to suffer greatly without one. The policies against the implementation of a patent system do not appear applicable to South Africa. There is adequate infrastructure to support the multi-billion dollar domestic industry, and the high cost of medicines may have more to do with the inefficient distribution system than patent royalties. Indeed, whether or not the citizens or government of South Africa can afford the expensive new drugs is irrelevant if drug manufacturers refuse to introduce new drugs due to a lack of patent protection.

*B. The Health Minister's Power to Authorize Parallel Imports.*

While nearly all countries have some system of patent protection, many have taken different positions on the exhaustion of patents.<sup>123</sup> Many countries have not allowed patent rights to restrict parallel imports of patented goods.<sup>124</sup> In fact, some nations use their antitrust laws to encourage parallel imports.<sup>125</sup> Richard Sako noted, in regard to an order issued by Japan's antitrust enforcement agency to encourage parallel imports, that parallel imports are "generally considered to promote price competition in a market, and therefore restrictions on parallel importing are viewed with scrutiny under the antitrust rules and regulations of most countries."<sup>126</sup> Accordingly, the European Court of Justice has repeatedly stated that "patent rights do not, in general, provide a basis for stopping parallel imports."<sup>127</sup>

Other countries have decided differently. In *Boesch v. Graff*, the United States Supreme Court held that "one residing in the United States could not import or sell articles patented in the United States without the license or consent of the United States patentee, even though the articles were patented in a foreign country and purchased from a person authorized to sell them in that country."<sup>128</sup> Also, Kenya, which had experimented with allowing parallel imports, recently banned them citing an abundance of unsafe and

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123. See Love, *supra* note 55.

124. See *id.*

125. See *id.*

126. See *id.*

127. See *id.*

128. See Kremen, *supra* note 46. It must be noted, however, that the United States Supreme Court held that the "first sale doctrine, under which [the] owner of particular copy[righted material] is entitled, with authority of copyright owner, to sell or otherwise dispose of possession of that copy, is applicable to imported copies." *Quality King Distrib. Inc., v. L'Anza Research Int'l, Inc.*, 118 S. Ct. 1125 (1998). Thus, parallel imports are permitted under current U.S. copyright law.

counterfeit drugs.<sup>129</sup>

1. *Potential harmful consequences for South Africa from sanctioning parallel imports.*—The biggest problems in Kenya “were ascertaining whether parallel imports had been produced in accordance with good manufacturing practice, and [the manufacturer’s] inability to recall unsafe products.”<sup>130</sup> Kenya also discovered substantial evidence of “substandard and counterfeit products.”<sup>131</sup> While the Medicines and Related Substances Amendment Act stipulates that parallel imports of drugs must “meet the same quality standards” as the domestically registered drug,<sup>132</sup> it remains to be seen whether South Africa can ensure the safety of the drugs.

One of the major reasons why the United States does not permit parallel imports is the extra burden placed on the FDA to protect the public from unsafe counterfeit drugs.<sup>133</sup> Critics point out that “South Africa’s border guards are unable to stanch the flow of illegal immigrants, cocaine, endangered species and even rustled cattle,” and that they would be even less effective against “counterfeit drugs that have expired and were supposed to be destroyed but were just repackaged.”<sup>134</sup>

Other than these practical concerns, there are also the underlying fundamental principles of intellectual property protection to take into consideration. As the United States Supreme Court explained in *Boesch v. Graff*, “[t]he franchise which the patent grants consists altogether in the right to exclude everyone from making, using, or vending the thing patented without the permission of the patentee.”<sup>135</sup> The court reasoned that “when [the patent owner] sells the exclusive privilege of making or vending [his goods] for use in a particular place, the purchaser buys a portion of the franchise which the patent confers.”<sup>136</sup> In short, the purchaser of a patented product shares in the monopoly which “is derived from, and exercised under, the protection of the United States . . . [that] necessarily terminates at the time limited for its continuance by the

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129. See Claire Bisseker, *Beware of Counterfeit Medicine, Kenya Warns SA*, FIN. MAIL, Oct. 24, 1997.

130. See *id.*

131. See *id.*

132. See Medicines and Related Substances Control Amendment Act, No. 101 (1997) (S. Afr.) § 15(C)(b).

133. See Bisseker, *supra* note 129.

134. See McNeil, *supra* note 8.

135. See *Boesch v. Graff*, 133 U.S. 697, 703 (1890).

136. See *id.*

law which created it.”<sup>137</sup> Thus, the right of a purchaser to sell his or her goods in another country is dependent upon the amount of monopolistic protection given to the patent holder. As a result, the question for courts becomes whether the monopoly protection granted includes being shielded from competition from imports of the patent owner’s products that were originally sold in another country.

Indeed, parallel imports compel competition between products where the workings of the free market have been expressly removed by the grant of patent protection. And while the issue for courts is whether the law includes protection against parallel imports, the issue for law-makers should be whether the public is best served by limiting the monopoly power granted under patent protection by allowing parallel imports. There are benefits that could be realized by permitting parallel imports and reducing the amount of monopoly power granted. The potential harms discussed above must be weighed against these potential benefits.<sup>138</sup>

2. *Potential benefits for South Africa from allowing parallel imports.*—Some European countries and Japan have decided that it was in their best interest to allow parallel imports.<sup>139</sup> On July 1, 1997, the Supreme Court of Japan declared that allowing parallel imports did not violate domestic or international law.<sup>140</sup> In the BBS Aluminum Wheel Case, the petitioner, BBS, sought to prohibit parallel imports of its products based on a patent entitled “Wheel for Automobile.”<sup>141</sup> The products were manufactured, patented, and sold by BBS in Germany.<sup>142</sup> Jap-Auto, the respondent, then bought the BBS aluminum wheels in Germany and imported them into Japan and sold them.<sup>143</sup>

In addressing whether or not the importation of BBS goods into Japan violated international law, the court looked to Article 4b of the Paris Convention for the Protection of Industrial Property.<sup>144</sup> Article 4b provides that “[p]atents applied for in the various

137. *See id.*

138. *See Love, supra* note 55.

139. *See id.*

140. *See* Jinzo Fujino, *Parallel Imports of Patented Goods: The Supreme Court Talks About Its Legality* (visited Oct. 14, 1998) <<http://okuyama.com/c3v01ok.htm>>.

141. *See id.*

142. *See id.*

143. *See id.*

144. *See id.* The Supreme Court of Japan did not discuss the GATT TRIPS agreement in determining whether parallel imports violate international law. For a discussion of the TRIPS agreement and parallel imports *see discussion supra* Parts III.B.

countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries whether members of the Union or not.”<sup>145</sup> The court then reasoned that because patent rights in different countries are independent of one another, the legality of parallel imports is simply governed by domestic patent law.<sup>146</sup>

The court began its interpretation of Japan’s patent law by stating that “[t]he protection of an invention under patent law has to be achieved in harmony with public interest.”<sup>147</sup> The court sought to balance the rights of the patent holder with the interests of the public.<sup>148</sup> In doing so, the court first noted that a buyer of a product expects to receive all of the rights that the seller has in that product, including the right to resell the product.<sup>149</sup> The court then concluded that requiring the purchaser of goods to receive permission before reselling them would impede “the free flow of products on the market,” and on account of the enormous amount and importance of international trade, the freedom to import should not be so circumscribed.<sup>150</sup> Otherwise, the court stated it “would be contrary to the purpose of the patent law which aims at encouraging inventions so as to contribute to the development of industry.”<sup>151</sup>

Second, the Supreme Court of Japan recognized that a patent owner receives remuneration when he or she sells the patented products.<sup>152</sup> And even if parallel imports are allowed, this reward is still provided for the first disposition of the goods.<sup>153</sup> As a result, the court concluded that after the first disposition of the patented goods it is unnecessary to secure the patent holder “double profits through the process of distribution.”<sup>154</sup> Consequently, the court concluded that patent rights “should no longer extend to the acts of use, assignment or lease of the product,” and that parallel imports were legal.<sup>155</sup>

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145. See Fujino, *supra* note 140.

146. See *id.*

147. See *id.*

148. See *id.*

149. See *id.*

150. See Fujino, *supra* note 140.

151. See *id.*

152. See *id.*

153. See *id.*

154. See *id.*

155. See Fujino, *supra* note 140. The court also recognized an exception to patent rights exhaustion. *Id.* The court noted that if the parties contract so as to limit the places the product may be sold to outside of Japan and provide notice to subsequent purchasers which is “clearly indicated on the product,” then the first sale doctrine

The decision of the Supreme Court of Japan seems to suggest that the best way “to maintain a balance between the interests of the patentee and that of the public” is to limit the monopoly granted to patent holders and allow parallel imports.<sup>156</sup> According to the court, this would permit the free flow of goods while still retaining the patent holder’s benefits from their monopoly over the first sale of their goods.<sup>157</sup>

3. *Weighing the benefits and costs of parallel imports.*—Just as in Japan, the proper balance between the interests of the patent holders and the public in South Africa would seem to be to restrict the monopoly granted by patents. Doing so would promote more imports and make available desperately needed lower prices through the resulting competition. Indeed, the importance of such competition is magnified in poorer countries, such as South Africa, where consumers do not enjoy the strong competition found in more developed economies such as the United States or Japan.<sup>158</sup> Some medicines, such as the medicine for malaria, are indeed priced higher in South Africa than in Europe and the United States.<sup>159</sup>

Furthermore, if Mirryena Deeb, of the Pharmaceutical Manufacturing Association of South Africa is correct that South Africa already has access to some of the lowest prices on drugs,<sup>160</sup> then the pharmaceutical manufacturers have nothing to fear. If prices are not lower in other countries, then there would be no reason for the Minister of Health to import them into South Africa. And even if the Minister of Health was to import drugs from other countries, the manufacturer still obtains the royalty upon the first sale of the medicine in the foreign country. Hence, just as the highest court of Japan reasoned, there is no reason to provide companies “double-profits” through the chains of distribution.<sup>161</sup> In

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does not apply. *Id.* The court reasoned that subsequent purchasers will then be able to “decide whether or not to buy the patented product, taking into account the presence of such restrictions.” *Id.* However, it would seem to be quite easy for a patent holder to have its sales contracts include language exempting parallel imports. *Id.* The patent holder has a monopoly over his or her patented goods and therefore has a great deal of leverage over the buyer in negotiations. Fujino, *supra* note 140. As a result, the court’s decision may serve to prohibit parallel imports, which is obviously counter to the policies explained by the court and those espoused in this comment.

156. *See id.*

157. *See id.*

158. *See Love, supra* note 55.

159. *See id.*

160. *See Dlamini, supra* note 75.

161. *See Fujino, supra* note 140.

short, companies still receive the benefit of patent protection, but are less capable to charge higher prices in countries that lack strong domestic competition.

Also, parallel imports may drastically lower the prices of drugs. Comments from the Consumer Project on Technology pointed out that in the United Kingdom HIV drug prices were on average 30 percent cheaper from parallel importers.<sup>162</sup> Parallel imports therefore could result in a tremendous amount of savings for South Africa, where AIDS medicines can cost a single patient up to \$1,000 per month.<sup>163</sup> Dr. Zuma stated that the new Act is projected to save up to ten percent on the total amount spent on pharmaceuticals.<sup>164</sup> This could provide a dramatic increase in the availability of medical care for people in South Africa, which is second only to Portugal in the percentage of gross domestic product spent on pharmaceuticals.<sup>165</sup>

Lastly, the risk of unsafe products does not seem sufficient enough to warrant prohibiting parallel imports. Patients in South Africa are probably more fearful of not having any medical attention than receiving imposter drugs. One-fourth of the rural clinics in South Africa do not have running water or electricity, and long lines of patients are often unable to receive any medical attention at all because of a lack of supplies and medical staff.<sup>166</sup> In addition, under the new law, not all medicines will be allowed to be imported. The Minister of Health determines which drugs are allowed to be imported, who may do the importing, and under what conditions the drugs may be imported.<sup>167</sup> This being so, there should not be any more illegal drugs in South African markets than there currently are because patent knock-offs or unauthorized parallel imports are both still illegal. In fact, there is more of an incentive to import unsafe imposter drugs when parallel imports are not allowed because it is more profitable if the prices of patented drugs are kept higher. In the end, and despite the fear of unsafe products, it does appear wise for South Africa to promote competition by increasing the free market incentives to benefit many of its poor citizens by limiting the monopoly granted by patents.

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162. See Love, *supra* note 55.

163. See McNeil, *supra* note 8.

164. See Bisseker, *supra* note 129.

165. See McNeil, *supra* note 8.

166. See Benetton, *supra* note 2.

167. See Medicines and Related Substances Control Amendment Act, No. 101 (1997) (S. Afr.) § 15(C)(b).

## VI. Conclusion

In light of the infirmity suffered by so many South Africans and their inability to obtain even the most basic health care,<sup>168</sup> South Africa diverged from traditional notions of intellectual property rights. There is little doubt that the Medicines and Related Substances Control Amendment Act lessened the level of intellectual property protection formerly provided for pharmaceuticals in South Africa. It is less clear to what extent protection has been diminished.

Section 15(C) has been surrounded by international controversy for over a year, and despite the repeated urging by pharmaceutical companies and the United States to amend the language and clarify the law's intention, the law was nonetheless passed by the legislature and signed into law by President Nelson Mandela.<sup>169</sup> While it seems very unlikely that the hazy language of the act was intended to end patent rights for pharmaceuticals, the fear on behalf of the pharmaceutical companies and United States is justified. As discussed, the new law has potentially serious ramifications for South African citizens and pharmaceutical companies.

If the new law is intended to effectively dissolve patent rights for pharmaceuticals, then South Africa has violated its obligations under the TRIPS agreement. Even so, the greatest danger South Africa would face is being denied access to new advances in medicine. Pharmaceutical manufacturers have threatened that if the law does end patent rights for pharmaceuticals, then they will refuse to introduce any new drugs, including Aids vaccines.<sup>170</sup> A number of companies have already put investment plans on hold, pending clarification of the new law.<sup>171</sup> Indeed, companies have suggested they are willing to let people die unless patent protection is provided for pharmaceuticals.<sup>172</sup>

Fortunately, the law does not appear to end patent protection, but merely permits the Minister of Health to authorize parallel imports. In this case, the new law would not violate international law because it meets the minimum level of protection consistent with South Africa's TRIPS obligations. The new law does not allow patented drugs to be copied, but only allows patented drugs to be

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168. See Benetton, *supra* note 2.

169. See McNeil, *supra* note 8.

170. See Braid, *supra* note 13.

171. See *id.*

172. See McNeil, *supra* note 8.



imported, on terms and conditions specified by the Minister of Health, from other countries where the pharmaceutical companies sell them cheaper. Multinational companies will still receive their royalties from the first sale of the medicine, but will be less able to charge higher prices in countries that lack developed and competitive markets. As a result, there should be more conformity in international drug prices and lower prices in South Africa.

Parallel imports provide a limitation on the monopoly granted through patent protection. There is no such thing as absolute patent protection. Even in countries that provide high levels of patent protection, such as the United States, there are limits placed on patents, such as types and durations. For South Africa, allowing parallel imports seems to strike the correct balance between providing pharmaceutical companies exclusivity for their inventions and providing the public desperately needed medical care.

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