Questionnaire on Exceptions and Limitations to Patent Rights

The answers to this questionnaire have been provided on behalf of:

Country: REPUBLIC OF SOUTH AFRICA
Office: COMPANIES AND INTELLECTUAL PROPERTY COMMISSION

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Section I: General

This section is intended to obtain general information on exceptions and limitations to patent rights that are provided under the applicable laws. For the purpose of this questionnaire, the term "applicable law" refers to relevant national and regional statutory law and, where applicable, case law.

The terms used in the questionnaire are drafted in a general way aiming at providing a broad understanding of each concept used, assuming that the exact wording of these exceptions and limitations might differ under the applicable laws. More detailed explanations of the various exceptions and limitations may be found in the following documents: SCP/13/3, SCP/15/3 and CDIP/5/4.

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

   The standard for patentability is set out in Section 25 of the Patent Act 57 of 1978: **Novelty, Inventive Step and capable of being used or applied in trade or industry or agriculture (Section 25 of Patent Act 57 of 1978)**

   Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.[1]

The exclusions from patentability are set out in Section 25(2) of Patent Act 57 of 1978

- **Discovery;**
- **Scientific theory;**

[1] This question does not imply that the topic of exclusions from patentability is dealt with in this question exhaustively.

- **Mathematical method;**
- **Literary, dramatic, musical or artistic creation;**
- **Scheme, rule or method for performing a mental act, playing a game or doing business;**
- **Program for a computer and**
- **Presentation of information**

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Section 45(1) provides that the patentee is given the right to exclude other person from making; using; exercising, disposing or offering to dispose of/ importing the invention

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

- ☐ **X** Private and/or non-commercial use;
- ☐ Experimental use and/or scientific research;
- ☐ Preparation of medicines;[2]
- ☐ **X** Prior use;
- ☐ **X** Use of articles on foreign vessels, aircrafts and land vehicles;
- ☐ **X** Acts for obtaining regulatory approval from authorities;
- ☐ **X** Exhaustion of patent rights;
- ☐ **X** Compulsory licensing and/or government use;
- ☐ **X** Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.[3]

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

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2 For example, extemporaneous preparation of prescribed medicines in pharmacies.

3 For example, in some countries where patent rights extend to propagated or multiplicated material derived from patented biological material, certain uses by farmers of harvested plant material or of breeding livestock or other animal reproductive material under patent protection on his own farm do not constitute patent infringement. Similarly, in some countries, patent rights do not cover uses by breeders of patented biological material for the purpose of developing a new plant variety (see paragraphs 133 to 137 of document SCP/13/3).

Acts of non-infringement

69A.(1) **It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.**
(2) **It shall not be permitted to possess the patented invention made, used, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information as contemplated in that subsection.**

5.If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

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6. (a) What are the public policy objectives for providing the exception?

To permit the use by third parties of the subject matter of a patent in order to obtain marketing approval (Early working provision also called a Bolar-type provision)

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):
“Commercial scale” is not defined in the current patent Act 57 of 1978 and the phrase should, accordingly be given its ordinary grammatical meaning. As per Luxmoore J in McKenchnie Bros Ltd’s Application (1934) 51 RPC 461 AND 468 and Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another 1996 BP 455 (CP) AT 459G, in “ Ordinary parliance the phrase is used in contradistinction to research work, or work done in the laboratory”

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8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

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9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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Section III: Experimental use and/or scientific research [4]

11. If the exception is contained in statutory law, please provide the relevant provision(s):

Not provided for

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12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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13. (a) What are the public policy objectives for providing the exception?
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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

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15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

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[4] Exceptions and limitations on acts for obtaining regulatory approval are dealt with in Section VII of the questionnaire.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

- ☐ determine how the patented invention works
- ☐ determine the scope of the patented invention
- ☐ determine the validity of the claims
- ☐ seek an improvement to the patented invention
- ☐ invent around the patented invention
- ☐ other, please specify: ……

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

- ☐ Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)
- ☐ Research and/or experimentation must be conducted with or using the patented invention (“research with”)
- ☐ Both of the above

Please explain by citing legal provision(s) and/or decision(s):

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18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

- ☐ A non-commercial purpose
- ☐ A commercial purpose
- ☐ Both of the above
- ☐ The commercial intention of the experimentation and/or research is not relevant

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

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20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

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21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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Section IV*: *Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

Not provided for
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24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

No.....
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25. (a) What are the public policy objectives for providing the exception? Please explain:

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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

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27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

☐ Yes

☐ No

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

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28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

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29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 26(b):

26. A patent shall not be invalid by reason only of the fact that the invention in respect of which the patent was granted or any part thereof was disclosed, used or known prior to the priority date of the invention-

(a) if the patentee or his or her predecessor in title proves that such knowledge was acquired or such disclosure or use was made without his or her knowledge or consent, and that the knowledge acquired or the matter disclosed or used was derived or obtained from him or her, and, if he or she learnt of the disclosure, use or knowledge before the priority date of the invention, that he or she applied for and obtained protection for his or her invention with all reasonable diligence after learning of the disclosure, use or knowledge; or

***(b)* as a result of the invention being worked in the Republic by way of reasonable technicaltrial or experiment by the applicant or patentee or the predecessor in title of the applicantor patentee.**

NB:The above exception is only applicable to the inventor/ applicant/ predecessor in title. There is no exception for prior use by third parties. Any use thereof before lodgment of an application in the Patent office would destroy the novelty of the invention.

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

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33. (a) What are the public policy objectives for providing the exception? Please explain:

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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

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35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

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36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

- Yes
- No

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

- Yes
- No

If yes, please explain what those conditions are:

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38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

- **X** Yes
- No

If yes, please explain the conditions under which such use can continue to apply:

48.(1) A patentee of a patent restored in terms of section 47 shall not by virtue of the provisions of this Act institute any proceedings against or recover damages from any person who –

(*a*) infringed the patent after the lapse of a period of six months from the date on which the renewal fee was due and before the date on which the application for the restoration of the patent was advertised;

(*b*) used, offered to dispose of or disposed of any article made or imported in the period referred to in paragraph (*a*); or

[Para.(*b*) substituted by s.8(*a*) of Act no. 58 of 2002.]

(*c*) (i) during the period set out in paragraph (*a*) commenced using or exercising the invention to which the patent relates and who thereafter continues to use or exercise the invention; or

(ii) uses or offers to dispose of or disposes of any articles or products produced by the continued use or exercise referred to in subparagraph (i):

[Sub-para.(ii) substituted by s.8(*b*) of Act no. 58 of 2002.]

Provided that the exemption conferred by this subsection shall be limited to the particular person mentioned in paragraph (*c*) (i) or (ii), his executor, administrator, successor or assignee or acquirer, as the case may be.

(2) Where a patent has been restored under section 47, any person who, during the period referred to in subsection (1)(*a*) has expended any money, time or labour with a view to making, using, exercising, offering to dispose of, disposing of or importing the invention, may apply in the prescribed manner to the Commissioner for compensation in respect of the money, time and labour so expended.

[Sub-s.(2) substituted by s.8(*c*) of Act no. 58 of 2002.]

(3) The Commissioner may, after hearing the parties concerned, assess the amount of such compensation if in his opinion the application ought to be granted and determine the time within which such compensation shall be paid.

(4) Any amount assessed under subsection (3) shall not be recoverable as a debt or damages but, if it is not paid within the time determined by the Commissioner, the patent shall lapse.

Minnesota Mining and Manufacturing Co V Bondina Ltd 1973RPC 491

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39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

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40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 71 of the Patent Act 57 of 1978:

71. (1) Subject to the provisions of this section, the rights of a patentee shall not be deemed to be infringed-

***(a)* by the use on board a convention vessel of the patented invention in the body of the vessel or in the machinery, tackle, apparatus or other accessories thereof, if the vessel comes into the territorial waters of the Republic, temporarily or accidentally only, and the invention is used exclusively for the actual needs of the vessel; or**

***(b)* by the use of the patented invention in the construction or working of a convention aircraft or land vehicle or accessories thereof if the aircraft or vehicle comes into the Republic temporarily or accidentally only.**

(2) For the purposes of this section, vessels and aircraft shall be deemed to be vessels and aircraft of the country in which they are registered, and land vehicles shall be deemed to be vehicles of the country within which the owners are ordinarily resident.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

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44. (a) What are the public policy objectives for providing the exception? Please explain:

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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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45. The exception applies in relation to:

- ☐ Vessels **X**
- ☐ Aircrafts **X**
- ☐ Land Vehicles **X**

- Spacecraft

46. In determining the scope of the exception, does the applicable law apply such terms as ”temporarily” and/or “accidentally” or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes, the applicable law applies the terms temporarily or accidentally. There are no definitions of these terms provided in the Act.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

…..“**If the invention is used exclusively for the actual needs of the vessel”….. (see Section 71 of the Patent Act cited above)**

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48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

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49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

69A.(1) It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.

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52. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

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53. (a) What are the public policy objectives for providing the exception? Please explain:

Not to delay access to market of goods where regulatory approval is required.
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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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54. Who is entitled to use the exception? Please explain:

Any party wishing to enter the market on expiry of a patent that requires regulatory approval.
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55. The exception covers the regulatory approval of:

- **X** any products**: Not limited to any market sector**
- certain products. Please describe which products: ……

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

- X Making
- X Using
- X Selling
- X Offering for sale
- X Import
- Export
- Other. Please specify:……

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

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58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

None in so far as legislation related to patent law. Challenges are encountered with the regulatory authorities such as Medicines Control Council where the delay in processing applications to register medicines delays access to the market.

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Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

- **X** National
- Regional
- International
- Uncertain, please explain..……

If the exception is contained in statutory law, please provide the relevant provision(s):

45**(2) The disposal of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the right to use, offer to dispose of and dispose of that article.**

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If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Stauffer Chemical co V Agricura Limited 1979 BP 168 (C) **Judge Van Reenen sitting as the Commissioner of Patents, held that the South African courts would adopt the following principles distilled from decided cases in the United Kingdom and the United States of America, namely that:**
(i) Where the patentee himself sells or disposes of the patented article, that article is freed from all restraint which the patentee's monopoly had imposed upon it;
(ii) Where the patented article is disposed of by the patentee's assignee or his agent within the scope of his authority, it is similarly freed from such restraints; and
(iii) Where the sale of the patented article is by a license of the patentee, the matter must depend on the extent of the authority conferred on the licensee by the licensor under the license agreement.
The learned judge further held that Section 45 (2) of the current Patent Act 57 of 1978, to the effect that the "sale of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the right to use and dispose of that article", does not completely negate the third principle set out above, inasmuch as that section refers only to licensees of the patentee in, for example other countries of the world and not under the South African legislature had extended its legislative powers beyond the borders of its domain. Such a proposition is rightly abhorred by the South African courts. The decision in *Stauffer* case is clearly a blow against what may be termed "pirate importers" of the patented article into the South Africa. Provided the patentee of a South African patent is able and prepared to place limitations in a country of origin upon the sale in South Africa of his patented good imported into South Africa from that country of origin, purchasers in South Africa, from the likes of unauthorized jobbers, for resale in South Africa can be interdicted from so reselling on the basis of the protection afforded by South African patent.

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SPECIAL REGIME FOR MEDICINES (Material prepared by Adams & Adams)

PARALLEL IMPORTATION OF MEDICINES

TABLE OF CONTENTS

1. INTRODUCTION

Medicines form a critical part of an effective healthcare system. The challenge facing most health departments today is to provide the public access to medicines that are of good quality, safety andefficacy and that are economically affordable. This is in fact one of the key objectives of the South African National Drug Policy which has also assumed special importance in the face of the HIV/AIDS pandemic and other related emerging and opportunistic infections.

2. BACKGROUND

An important component of the transformation process of the healthcare services in South Africa is its expansion to reach even the most remote part of the country to ensure that all people, particularly those previously disadvantaged, have access to good quality healthcare. This key objective is, however, being constrained by the escalating costs of services, facilities and medicines. In an attempt to address the issue, the South African government introduced the Medicines and Related Substance Control Amendment Act
in 1997 (Act No. 90 of 1997) as a means to facilitate, among other things, access to affordable medicines by all. This Act allows for the importation and registration of medicines which are under patent, are already registered in South Africa, and which originate from any site of manufacture approved by Council, regardless of any existing patent rights.

3. LEGISLATIVE PROVISIONS

The Minister of Health is empowered by section 15C of the Medicines and Related Substances Control Act of 1965, as amended (Act No. 101 of 1965), to prescribe the conditions on which any patented medicine may be parallel imported into South Africa regardless of the provisions of the Patents Act, 1978 (Act 57 of 1978). A parallel imported medicine must have the same formulation, meet the same quality standards and is intended to have the same proprietary name as the medicine already available and registered in South Africa. In addition, any person or company, other than the person or company that is the holder of
the registration certificate of that medicine, may import such a medicine. It may also be obtained from any manufacturing site used by the original manufacturer and which is approved by Council in accordance with the current technical requirements. Thus, to procure a cost-effective or less expensive medicine than the one already registered and available in the Republic, the Minister may authorise, through a permit, the importation of the same medicine manufactured by, or on behalf of, the approved manufacturer from any other country and the restrictions imposed by the Patent Act shall not apply.
Parallel importation is defines in the Regulations as **"the importation into the Republic of a medicine protected under patent and/or registered in the Republic**
that has been put onto the market outside the Republic by or with the consent of the patentee in respect of such medicine"
The expressions "parallel importer", "parallel imported medicine(s)", "parallel imported", "to parallel import", "to be parallel imported" and "parallel importation permit" shall have the corresponding meanings to 'parallel importation'.

4. CONDITIONS FOR PARALLEL IMPORTATION OF A MEDICINE

4.1 Any patented medicine may be imported in terms of Section 15C and Regulation 7 of the Act if it is already registered in South Africa.
4.2 A person or company that wishes to import a patented medicine must apply to the Minister of Health for a permit to parallel import a medicine.
4.3 The holder of a certificate of registration for a medicine in South Africa shall not be entitled to prevent its importation into South Africa, nor its sale, on account of such registration or on account of the existence of a patent on such a medicine.
4.4 The parallel importer shall be responsible and liable for the parallel imported medicines, for example, in the event of a recall or adverse event, and must notify the Council of these situations.
4.5 The parallel importer shall be liable for destruction of any expired, parallel imported medicines still remaining on stock after the expiry date, whether during the duration of the permit or after the parallel importation permit has expired.

5. PROCEDURE FOR OBTAINING A PERMIT TO PARALLEL IMPORT MEDICINES

5.1 The application for a permit to parallel import a medicine must be submitted to the office of the Minister of Health. The application must be accompanied by the following:
i) Written confirmation of the lowest price at which the medicine is currently sold by the holder of the certificate of registration in South Africa dated not more than one month before the date of submission of the application for a parallel import permit;
ii) The price at which the parallel imported medicine will be sold in South Africa by the

importer;
iii) A declaration by the importer that the medicine to be imported is a medicine under patent in South Africa;
iv) The prescribed application fee;
v) A certified copy of his or her identity document, or in the case of a juristic person, a certificate of registration as such in the Republic;
vi) A certified copy of his, her or its registration in terms of the Pharmacy Act, 1974, where applicable;
vii) A certified copy of the licence in respect of the premises in terms of: -
(a) Section 19 of the Customs and Excise Act, 1964 (Act No. 91 of 1964); and
(b) Section 22 of the Pharmacy Act, 1974;
viii) An undertaking that he, she or it will ensure the continued safety, efficacy and quality of the medicine; and
ix) Any other information the Minister may require.
5.2 The Minister may, upon consideration, approve with or without conditions, or reject, such an application.
5.3 If a permit is issued, it shall be valid for a period of 24 months.
5.4 The permit holder must, at least three months before the expiry date, apply to the Minister for its renewal in accordance with the procedure prescribed by the Minister.
5.5 The Minister may, at any time and on good cause shown, cancel the permit to import any medicine.

6. PROCEDURE FOR OBTAINING REGISTRATION OF A MEDICINE THAT IS TO BE PARALLEL IMPORTED

6.1 After being issued with a permit to import a medicine, the importer must apply to Council for: -
i) Authorisation to import a sample of the medicine to be submitted together with the application for registration of the medicine; and
ii) Registration of the medicine, using Form MRF 1 (provided by the Registrar of Medicines).
6.2 An application for the registration of a parallel-imported medicine must be accompanied by the following:
i) Copies of the package insert and patient information leaflet, where available, which must be translated into English and verified;
ii) An appropriately labelled sample of the medicine in accordance with the requirements of Regulation 8 or Regulation 48;
iii) Information on the exporter, stating whether it is a manufacturer, packer, repacker, wholesaler or broker;
iv) A cGMP Certificate from a recognised authority, which must be specific for the manufacturer, packer, re-packer, laboratory, distributor, wholesaler or broker of the imported medicine;
v) Real-time stability data for the duration of shelf-life using a stability-indicating method for the active pharmaceutical ingredient, according to the requirements of the Guideline for Stability Studies - Addendum 4;
vi) Comparative dissolution data against the MCC-approved product (same formulation, same name, same dosage form, etc.) that has been procured in South Africa, in terms of the requirements for proof of efficacy (Also Refer to the Guidelines on Dissolution Testing) and using F2 values.
6.3 The following is the minimum information required for the registration of a parallel imported medicine:
i) Administrative Data (section A and B).
ii) Parts 1A, 1B and 1C.
iii) Part 26.
iv) Part 2D for repackaged medicines and if the packaging material is different from that used by the patent holder.
v) Part 2E (b) (i) and (c); for repackaged medicines only.
vi) Part 2F (a), (b), (d) and (e).
vii) Part 2G for repackaged medicines only.
6.4 Council will only consider approval of registration of the medicine if the importer has: -
i) been issued with a permit to parallel import the medicine;
ii) a registered office in South Africa;
iii) a storage facility approved by Council for such medicine;
iv) a responsible pharmacist as required in terms of the Pharmacy Act, 1974 (Act No. 54 of 1974);
v) undertaken to be responsible for ensuring that such medicine meets the safety, quality and efficacy standards as determined by Council and accepts liability for any consequences arising from the distribution and use of the medicine;
vi) in place recall procedures as determined by Council,
vii) complied with any other conditions as Council may determine; and
viii) an MCC-approved manufacturing site in the case where the imported medicine is to be repackaged.
6.5 The parallel importer may proceed with the sale of the medicine only after the medicine has been registered.

7. REGISTRATION OF MEDICINES TO BE PARALLEL IMPORTED

7.1 The evaluation and registration of medicines intended for importation will follow the same procedure as provided for in Section 15 of the Act and as prescribed in the regulations, except as specified under item 6.3 above.
7.2 Council may impose any conditions necessary for the registration of the medicine.
7.3 The Registrar shall keep a separate register for parallel imported medicines.

8. CANCELLATION OF REGISTRATION OF PARALLEL IMPORTED MEDICINES

Council may, on good cause shown and in consultation with the Minister, cancel the registration of any parallel imported medicine.

9. INFORMATION TO BE PROVIDED TO THE PATENT HOLDER OR HOLDER OR THE CERTIFICATE OF REGISTRATION

The importer must, within 30 days after registration of the medicine, inform the patent holder or the holder of the certificate of registration in South Africa, of this fact and submit a copy of the letter to the Registrar.

10. IMPORTATION OF MEDICINES

10.1 The parallel importer must inform the holder of the certificate of registration at least four weeks prior to importation, on a form determined by Council, of his or her intention to parallel-import the medicine. The requirements for post-importation identification and testing of medicines, as described in Addendum 2 of the Guidelines for the Registration of Medicines in South Africa, will apply.

10.2 The parallel importer may not manufacture or re-export any medicine registered in South Africa as a parallel imported medicine.

11. REPACKAGING AND RELABELING OF PARALLEL-IMPORTED MEDICINES

11.1 Where the medicine is to be repackaged in South Africa after importation, this must be done at a site approved and licensed by the Council for this purpose.

11.2 The medicine must be labelled, packaged and have a package insert and patient information leaflet as prescribed in terms of regulations 8, 9 and 10.

11.3 The parallel importer may use the proprietary name approved in South Africa as well as any trade marks applicable to the medicine in order to ensure the public health interests.

11.4 The words "Parallel imported medicine" or the abbreviation "PIM" must be included on the label of each distribution pack.

11.5 The batch numbers of repackaged medicines must be identical to those of the original medicines and all original packaging material must be destroyed.

12. INFORMATION TO BE PROVIDED TO THE MEDICINES CONTROL COUNCIL

The following information must be supplied to Council by the parallel importer:

12.1 Any change in the conditions under which the medicine was registered;

12.2 Any adverse drug reactions or events arising from the use of the medicine;

12.3 Any report of risks associated with the medicine that may affect its quality, safety or efficacy.

13. TRANSFER OF CERTIFICATE OF REGISTRATION

A certificate of registration for an imported medicine may only be transferred to another person or company with the approval of the Minister.

14. AMENDMENTS TO THE DETAILS OF A PARALLEL IMPORTED MEDICINE

The importer must apply to Council on form PIF 1, available from the office of the Registrar, for approval of any change in the conditions of registration of an imported medicine or change in the storage conditions or change in any of the particulars of the medicine.

15. FEES PAYABLE

An applicant for the registration of a medicine to be parallel imported shall pay an application fee and a registration fee as determined by Council.

16. FORMS TO BE COMPLETED

The following forms, obtainable from the office of the Registrar, must be completed in respect of an application for amendment to the details of a parallel imported medicine and for informing the patent holder of the intention of the parallel importer to import a medicine, respectively: PIF 1 and PIF 2.

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

Public interest.

.....

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

.....
.....
.....

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

- ☐ Yes
- ☐ No

☐ **X** Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

.....
.....
.....

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

.....
.....
.....

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

.....
.....
.....

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 56 of the Patent Act:

Compulsory license in case of abuse of patent rights

56. (1) any interested person who can show that the rights in a patent are being abused may apply to the Commissioner in the prescribed manner for a compulsory license under the patent.

[Sub-s.(1) substituted by s.45(*a*) of Act no. 38 of 1997.]

(1A) ..... (deleted)

[Sub-s.(1A) inserted by s.2(*a*) of Act no. 76 of 1988 and deleted by s.45(*b*) of Act no. 38 of 1997.]

(2) The rights in a patent shall be deemed to be abused if –

(*a*) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the Commissioner no satisfactory reason for such non-working;

(*b*) (deleted)

[Para (*b*) deleted by s.45(*b*) of Act no. 38 of 1997.]

(*c*) the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;

(*d*) by reason of the refusal of the patentee to grant a license or licenses upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a license or licenses should be granted; or

(*e*) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged therefore in countries where the patented article is manufactured by or under license from the patentee or his predecessor or successor in title.

(3) The patentee or any other person appearing from the register to be interested in the patent may in the prescribed manner oppose the application.

(4) (*a*) The Commissioner shall consider the application on its merits and may order the grant to the applicant of a license on such conditions as he or she may deem fit, including a condition precluding the licensee from importing into the Republic any patented articles.

[Para (*a*) substituted by s.45(*c*) of Act no. 38 of 1997.]

(*b*) If the Commissioner is of the opinion that an order directing the grant of a license is not justified, he may refuse the application.

(*c*) A license granted under this section shall include a provision that, subject to adequate protection of the legitimate interests of the licensee, the license shall, on application by the patentee, be terminated if the circumstances which led to its grant cease to exist and, in the opinion of the Commissioner, are unlikely to recur.

[Para (*c*) added by s.45(*d*) of Act no. 38 of 1997.]

(5) Any license granted under this section shall be non-exclusive and shall not be transferable except to a person to whom the business or the part of the business in connection with which the rights under the license were exercised has been transferred.

[Sub-s.(5) substituted by s.45(*e*) of Act no. 38 of 1997.]

(6) (deleted)

[Sub-s.(6) substituted by s.45(*f*) of Act no. 38 of 1997.]

(7) In determining the conditions on which any license is granted the Commissioner shall have regard to any relevant facts, including the risks to be undertaken by the licensee, the research and development undertaken by the patentee and the terms and conditions usually stipulated in license agreements in respect of the subject-matter of the invention, between persons who voluntarily enter into such agreements.

(7A) The Commissioner may order that a license granted in terms of this section shall be deemed to have been granted on the date on which the application has been received by the Registrar.

[Sub-s.(7A) inserted by s.2(*b*) of Act no. 76 of 1988.]

(8) Any order of the Commissioner under this section shall be made with a view to avoiding the abuse found by the Commissioner to have been established.

(9) The Commissioner may amend or revoke any license granted under this section.

(10) Subject to the conditions that may be attached to the license, a licensee under this section shall have the same rights and obligations as any other licensee under a patent.

[Sub-s.(10) substituted by s.45(*g*) of Act no. 38 of 1997.]

(11) (deleted)

(12) (deleted)

[Sub-ss.(11) and (12) deleted by s.45(*h*) of Act no. 38 of 1997.]

(13) (*a*) The Commissioner may, when ordering the grant of a license under subsection (4)(*a*), award costs against the applicant or patentee concerned or any person opposing the relevant application.

(*b*) In so awarding costs, the Commissioner shall *inter alia* have regard to –

(i) the nature and extent of the abuse found by him to have been established; and

(ii) Whether the application for a license under this section might have been avoided by the grant, by the patentee concerned to the applicant, of a voluntary license on reasonable terms.

(14) For the purposes of this section the expression 'patented article' includes any composition of matter or any product of a patented process or method or any product produced by a patented machine.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

Aftira Ltd V Carlton Paper of SA 1992 BP 331

AFITRA (PTY) LTD AND ANOTHER v CARLTON PAPER OF SA (PTY) LTD 1992 BP 331 (CP) 1992 BP p331

Citation	1992 BP 331 (CP)
Court	Court of the Commissioner of Patents
Judge	Eloff JP
Heard	November 23, 1992 ; November 25, 1992
Judgment	December 1, 1992
Counsel	LG Bowman SC (assisted by ABS Franklin) appeared for the applicants CE Puckrin SC (assisted by MM Jansen) appeared for the respondent

A
[zFNz] **Flynote**
An application for a compulsory, licence - Counter-application for a temporary interdict - B Application refused and counter-application granted, both with costs - Application for leave to appeal refused. Patents Act 57 of 1978, sections 56(1A), 56(2)(c), 56(2)(d), 65 and 76.
[zHNz] **Headnote**

In an application for a compulsory licence, brought in terms C of section 56(2)(c) and 56(2)(d) of the Patents Act 1978 in respect of South African patent no. 77/1894, the respondent counter-claimed for the grant of a temporary interdict, contending that no "special circumstances" of the kind contemplated in section D 56(1A) existed,

Held , that the validity of the patent was not in issue and that the diapers which were the subject of the applicants' compulsory licence application fell within the scope of the claims of the patent

Held , further, that, for the purposes of the interpretation of section 56, as far as English decisions are E concerned, those which are based on the current British statute, ie the 1977 Patents Act, are of limited value since sections 48 to 57 of that Act differ substantially from section 56 of the South African Patents Act 57 of 1978. Of greater value are decisions given on the earlier 1907 English Act as amended by the statutes of 1990, 1928 and 1932 F

Held , further and as to the meaning of "reasonable terms", that the decision in *Kamborian's Patent* (1961) 78 RPC 403 at 405(39)-406(9); *Cathro's Applications* (1934) 51 RPC 75 at 82; and *Brownie Wireless Co Ltd's Applications* (1929) 46 RPC 457 at 476-478 were of value

Held , further and in regard to the requirement of public interest and prejudice, that the *dicta* of Luxmoore J G in *Brownie Wireless* case *supra* at 473 and 474 should be adopted

Held , further, that, since section 56 permits of the loss of valuable intellectual property rights, the applicant must present clear and satisfactory evidence of his averments

Held , further, that a charge of unreasonable terms is not established merely on proof that the applicant can
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ELOFF JP

A sell the same sort of article at a lower price. (MacArthur J's judgment in *Sanachem (Pty) Ltd v British Technology Group plc* 1992 BP 276 (CP) at 290A-C followed)

Held , further, that other relevant considerations in deciding whether the patentee's prices are reasonable are the cost to him of producing and marketing the patented article, the terms and conditions on which B it negotiates with customers, and whether the facts show that the trade as a whole can carry the price charged

Held , further, that, on the charge of not granting a licence, the Court should be provided with evidence indicating, with reasonable precision, what reasonable terms are. The close reasoning adopted C by the Court of Appeal in *Smith Kline & French Laboratories Ltd's (Cimetidine) Patents* [1990] RPC 203 shows the sort of evidence that is expected in that type of case. The reasonable terms are not necessarily those offered by the applicant or those offered by the patentee. If possible, the Court should be afforded the guidance of what terms are normally applied to that D type of licence

Held , further, that the applicants had failed miserably in attempting to prove the abuses relied upon by them and had not come near to establishing a proper case on any of the two grounds

Held , further and in general, that where there is a difference between the versions put forward by the E deponents of the applicants' affidavits and the affidavits of the respondent, that is no reason for preferring the former. *In casu* the applicants did not ask that any of the conflicts should be resolved by *viva voce* evidence and the version of the respondent's witnesses should prevail

Held , further and as to the reasonableness of prices F charged by the respondent, that the applicants had not shown that, having regard to all the circumstances set out in the papers, the respondent had charged unreasonable prices. The applicants did little more than show that they could in certain sectors sell at lesser prices. That fell far short of showing that in all the circumstances the G respondent's prices and method of fixing prices were not reasonable

Held , further, that the matter in issue was not the first case where companies such as the applicants, who make use of patents acquired by others after considerable expense, are able to undercut. They had had no expense in the field of research and development.
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ELOFF JP
They did not have the respondent's expense in A advertising and in creating the market

Held , further, that the respondent's answer to the applicants' claim to serve a minuscule sector of the market was understandable and could not be said to be unreasonable. The grant of a licence to serve that sector of the community and to enable the B applicants to sell at its suggested prices would have been prejudicial to the respondent and to the larger dealers in the trade. Apart from that there was not admissible evidence of what the reasonable terms of royalty arrangement should be

Held , accordingly, that the application for a compulsory licence should fail C

Held , further, and in regard to the meaning of "special circumstances" in section 56(1A), by wording the section as it did, the Legislature contemplated that an applicant under section 56, who in good faith presents an application with reasonable prospects of success, should not be inhibited by injunction whilst the case is pending. Differently put, the D Legislature did not intend to afford a moratorium to an infringer who acts in bad faith or who should realise that he is not likely to succeed in his quest. It would be manifestly unjust for an applicant to enjoy the protection of section 56(1A) whilst his application is pending and that would constitute special circumstances. If the patentee E stands to be prejudiced if an interdict is not granted that could also constitute special circumstances

Held , further, that *in casu* the following constituted special circumstances: The application was ill-founded and was certainly shown to be such when the answering F affidavits were filed; the application lacked merit; at the latest, after the filing of the answering affidavits, the applicants should have realised that they were not likely to succeed; and their decision to continue to attempt to do so was no less than vexatious and an abuse of the statutory provision

Held , further, that the applicants had in fact given an undertaking, which was not purely unilateral, not to continue to import and endeavour to sell infringing G diapers and for them to do so in violation of that agreement was completely unacceptable conduct. It not only constituted breach of contract but demonstrated *mala fides*

Held , further, that section 56(1A) did not present a bar to the counter-claim and that, should application be made for leave to appeal, an interdict could continue
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ELOFF JP

A to operate

Held , further and as to the counter-claim, that the temporary interdict should be granted.
[zCIz] **Case Information**

The application for a compulsory licence was dismissed and the counter-claim allowed. The applicants were ordered to pay the respondent's B costs, excluding the costs incurred in respect of the inclusion of certain documents in the record. An application for leave to appeal was refused with costs.

L G Bowman SC (assisted by *A B S Franklin*) appeared for the C applicants.

C E Puckrin SC (assisted by *M M Jansen*) appeared for the respondent.

Cur adv vult.

D *Postea* (1 December 1992).
[zJDz] **Judgment**

Eloff JP: There are two applications before me, namely an application for a compulsory licence under the Patents Act by two companies to which reference might be made E by use of their abbreviated names, Afitra and Medtex, and a counter-application by the respondent, Carlton Paper. The application and counter-application relate to South African patent 77/1894, which was granted on 8 July 1987. The licence of the patent was firstly held by Kimberly-Clark of F South Africa (Pty) Limited and was on 15 November 1990 assigned to the respondent who has held it since. It relates to a dispensable unitary and elongated diaper. The trade name "Huggies" is applied to a large part of the respondent's G patented product. The ordinary term of the respondent's patent will expire on 29 March 1993, but an application for an extension is pending. That application is opposed by Afitra.

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The main application for the grant of a compulsorylicence is brought under section 56 of the Patents Act 57 of A 1978. The counter-application by the respondent is for an interdict for infringement pending action.

It can at once be said that it appears not to be B disputed that applicants infringed respondent's patent and intend, probably in anticipation of success in the main application, to import and deal in diapers which will be infringing products unless a compulsory licence is ordered. It was at one stage conceded in argument by applicants' C counsel that if the main application fails, the respondents have established at least their clear right and a reasonable apprehension of infringement for the purposes of the counter-application. As to that, more later. The validity of the patent is not in issue.

The respondent's patent appears to be a highly profitable one, and much success was attained in its exploitation not only locally but abroad. The product is E manufactured in South Africa. The success of the patent is in part demonstrated by the fact that the respondent has had in the past to ward off attempts at infringement and attacks on the validity of the patent.

Afitra, the first applicant, is a company in the F import/export business. It is a subsidiary of an Israeli company "Koor Trade Ltd". The infringing diapers which applicants have sold and wish to sell, if possible, are manufactured by an Israeli company known as American Israeli G Paper Mills. Medtex is in the business of supplying medical requirements including diapers to, *inter alia* , hospitals. Neither of the applicants are in a manufacturing business. The diapers they wish to import and have imported from Israel are at times sold under the brand name "Hogla".
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ELOFF JP

A Although the applicants' founding papers do not make it clear, one infers that the Hogla diapers were not manufactured in pursuance of an invention made by Afitra's parent Israeli company or the American Israeli Paper Mills. B Some other patent was used. Whether is was the respondent's patent or some other overseas patent that has expired, is not dealt with. However, there is no suggestion that the manufacturers incurred any research and development costs, which may in part account for the fact that the applicants C can claim that they can sell Hogla diapers at amounts which may in certain instances be less than is in certain quarters charged for the Carlton diapers.

D I mentioned earlier that counsel for the applicants seemed on the first day of argument to concede that the sale of the Hogla diapers would constitute an infringement of the Carlton patent. On the second day of argument Mr *Bowman* raised an argument inconsistent with this concession. He E contended that the respondents have to show by reference to the patent specification that the Hogla diapers fall in its terms. I am of the view that the general tenor of the evidence before me clearly demonstrated that it was accepted all round that the Hogla diapers do infringe. By way of F explanation I may refer to the founding affidavit of Margeot, a director of the applicants, who says in paragraph 17 that if the application for a compulsory licence is not successful the applicants will be liable "for the payment of damages G for infringement of the patent".

I return to the background circumstances. I am told that when in May 1991 the applicants commenced the importation of Hogla diapers a representative of the respondent informed one Givon, an Israeli who features as a
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ELOFF JP

consultant of the applicants, that they were infringing A respondent's patent rights. There is also evidence that a retailer, Pick 'n Pay, to which applicants supplied Hogla diapers, was also warned of infringement. Givon says that he made contact with respondent's representatives and B endeavoured to come to a business arrangement. *Inter alia* , Givon requested the grant of a licence on payment of a royalty. On 7 May 1991 Afitra wrote Carlton a letter in which it summarises various discussions between the parties. In that letter the express terms of the undertaking given by Afitra C are summarized as follows:

"Having identified the possibility that the diapers we are importing from the abovementioned manufacturer may infringe on a patent granted to Messrs Kimberly-Clark D Corporation of the United States for which your goodselves are the licensee, and the said patent currently being in force in the Republic of South Africa, we undertake to cease importing any product which infringes on the said patent. With your consent and understanding the only diapers we shall still be importing and marketing are the contents of fourteen containers en route to South Africa. Twelve E of these containers are destined to Messrs Pick 'n Pay, whereas two others are destined to Messrs Medtex of Johannesburg."

Later, on 8 July 1991, Afitra wrote respondent a further letter in which it is, *inter alia* , also said: F

"Although the scientists of Messrs Hogla are assuring us that the process of manufacture of the two products are different and therefore an infringement of the patent is debatable, we, on our part, in G conjunction with the marketing division of Messrs Hogla, have decided to adhere to our undertaking to you in the abovementioned referenced letter until such time that the Kimberly-Clark/Carlton Paper's patent no. 77/1894 lapses."

I shall later return to an argument addressed by the
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A applicants' junior counsel that these letters contain no more than unilateral undertakings which could be withdrawn at will.

B On 16 July 1991 respondent faxed a letter to Givon agreeing to a limited importation of Hogla diapers on certain conditions, and stipulating a royalty of 20 cents per diaper. This was not accepted. Further discussions came to naught, and then, so we are told, Givon was told of the possibility of acquiring a

compulsory licence. He decided, C notwithstanding his written undertakings to honour the patent, to follow that course. He attempts to justify this new direction as follows:

D "I point out that that undertaking was given when we were still unaware of the possibility of an application for compulsory licence under the patent and I had in mind the expiry of the patent in March 1993. In short, the applicants have discovered a new route, the application for a compulsory licence, and the applicants have remained within the law. To the E extent that the importation of the diapers is authorised by the provisions of section 56(1)(A) of the Act, these importations do not constitute a reneging of the undertaking."

The present application was launched in September of F this year, and the main prayer is simply for an order

"... granting the applicants a compulsory licence in respect of patent 77/1894 in terms of section 56 of the Patents Act no. 57 of 1978."

G That section entitles an interested person "who can show that the rights of a patent are being abused" to apply for a compulsory licence. Sub-section (2) lists a number of ways in which it can be said that the licence is being abused. I was told that the applicants rest their case on two such
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instances, namely that the demand for the patent is not being A met to an adequate extent and on reasonable terms, and that the respondent allegedly refused to grant applicant, a licence upon reasonable terms.

I proceed to summarize the evidence adduced by the B applicants in support of the two alleged instances of abuse. In regard to the first of these a number of affidavits were filed containing largely hearsay matter, which was correctly summarized I think by the deponent to the main answering C affidavit, Mr Partridge. He said:

"Each of the affidavits set out ... contain the following averments:

(i) that the demand for the respondent's D patented diaper in the Republic is not being met to an adequate extent;

(ii) that the demand for the respondent's patented diaper in the Republic is not being met on reasonable terms;

(iii) that the respondent does not have an extra large diaper available on the South African market; and E

(iv) that the quality of the respondent's patented diaper is inferior."

The deponents concerned are the head of the marketing of Medtex, who deals with complaints allegedly made by F hospitals concerning the prices charged for and quality of Huggies diapers; the proprietor of a small retail outlet who speaks of the prices charged by the respondent as opposed to those for which Afitra is willing to supply them and the extent to which the demand is not being met by the G respondent; the proprietor of a relatively small retail outlet who complains of demands for diapers not being met by the respondent; another similar affidavit by another small retailer; and lastly an affidavit by a sales representative of Afitra who speaks of complaints allegedly made to her from
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ELOFF JP

A certain small retailers.

Then there is the affidavit of Margeot, applicants' director, who deposes to prices charged by the respondent as compared to the prices at which applicants can sell Hogla B diapers.

As to quality there is the affidavit of Mrs Machanik who complains of rash and irritation experienced by a baby after the use of Huggies. Then there is some evidence of a C testing of the Huggies diapers by a French institute which appears to have been used on previous occasions by Hogla's manufacturers.

D The substance of these allegations, even some of the hearsay, is fully dealt with by the respondent. Mr Partridge, *inter alia* , makes the following points.

The price structuring of the health care segment of E the disposable diaper market differs markedly from the price structuring of diapers in the consumer segment.

Discounts are given by the respondent to purchasing organisations in the private health care sector of the F market, resulting in discounted prices.

The value of the alleged testing of the French organisation is in question. In any event, said Mr G Partridge, from 20 August 1992 the respondent commenced manufacture of the new Huggies disposable diaper which is much improved. Such complaints as may have been made previously no longer apply. The diaper tested by the French institute was pre-20 August 1992.
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ELOFF JP

The South African demand is met adequately by the A respondent on reasonable terms. The comparisons put forward by the applicants' deponents are largely incorrect. As to the instances put forward by relatively small retailers, the deponent said that these are "business on the fringe of the B market place" who are not representative of the "mainstream distributors" in the various sectors of the disposable diaper market. The instances mentioned on behalf of the applicants "relate only to a minuscule fraction of the South African market". The mainstream suppliers would appear to be C generally the major supermarkets chains, and in the private health care sector the customers are also identified. As far as this is concerned I have the impression that it is a large part of the applicants' case that they wish to acquire that small section of the market. They calculate that the market D represents about 5% of the whole and accounts for approximately eight million diapers per annum. In argument it was suggested that if I was minded to order a compulsory licence I could limit it so as to prohibit dealing by the E applicants with the large retailers listed by Partridge in his affidavit.

In accordance with normal business practice, purchasers of Huggies who place large orders, get substantial F discounts, leading to low prices. Other factors also play a role in the prices charged by the respondent, eg the advertising done by the purchaser, the display space allocated to the Huggies diapers, long term support and so on. G

Proof of the quality of Huggies and the reasonableness of its prices is afforded, says Mr Partridge, by the very substantial proportion which it holds in the market in the face of opposition. Respondent's share of the
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A health care segment is close to 100% and of the consumer segment 55%.

In fixing prices respondent has moreover to bring into reckoning its high development costs. Thus advertising B over ten years cost it over R28 776 673. Its high investment in plan and equipment are also taken into account.

Specifically in regard to Mrs Machanik's complaint C a full answer is given. Over and above that, respondent says, that as against a complaint from this lady, respondent sold 174 193 000 diapers from June 1990 to date and received but 13 complaints in relation to the problems of so-called "super absorbent material migration". Mrs Machanik was the D only customer who raised the specific complaint that she did.
I should add that Mr Partridge's affidavit is supported by other affidavits. Replying affidavits were E filed, followed by a fourth set of affidavits.

I should incidentally, observe that there were applications from both sides to strike out. These related to the question of hearsay to the efforts to make out a further case over and above that which should have been made in the F first instance and so on. I did not deal with these specifically or separately. I will base my decision only on admissible evidence, and by adhering to well established G principles as to how a case should be made out.

As regards the second alleged instance of abuse, namely refusal to grant a licence on reasonable

terms, the evidence adduced is that respondent was at one stage willing to grant a limited licence on the basis of a 43% royalty. That, said Mr Givon, is unreasonable. The applicant's profit
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ELOFF JP
margin will be 10%. In an answer Partridge disputes these A averments.

I should at once observe that there is a complete want of admissible evidence of what a reasonable royalty in B the trade is, or what the usual other licensing terms are. All the applicant could produce was in an effort in a replying affidavit to make use of an article in a magazine, apparently one subscribed to by applicants' senior counsel, dealing with certain percentages, and the sort of percentage C that obtained in licensing transactions. The admissibility of this was objected to.

It is now opportune to consider certain aspects of section 56. I reproduce so much of it as appears to be D relevant.
"56(1) Any interested person who can show that the rights in a patent are being abused may apply to the Registrar in the prescribed E manner for a compulsory licence under the patent.
(1A) Pending the final determination of an application for a compulsory licence the applicant shall not, except under special circumstances, be prohibited by interdict from infringing the patent. F
(2) The rights in a patent shall be deemed to be abused if -
(a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after G the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the Commissioner no satisfactory reason for such non-
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A working;
(b) the working of the invention in the Republic on a commercial scale or to an adequate extent is being prevented or hindered by the importation of the patented article;
(c) the demand for the patented article B in the Republic is not being met to an adequate extent and on reasonable terms;
(d) by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of C the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that the licence or licences should be granted; D or
(e) ...
(3) ...
(4) (a) The Commissioner may order the grant to the applicant of a licence on such E conditions as he may deem fit, including a condition precluding the licensee from importing into the Republic any patented articles.
(b) If the Commissioner is of the opinion that an order directing the grant of F a licence is not justified, he may refuse the application.
(5) ...
(6) ...
G (7) In determining the conditions on which any licence is granted the Commissioner shall have regard to any relevant facts, including the risks to be undertaken by the licensee, the research and development undertaken by the patentee and the terms and conditions usually stipulated in licence agreements in respect of the subject-matter of the invention, between
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ELOFF JP
persons who voluntarily enter into such agreements. A
(7A) The Commissioner may order that a licence granted in terms of this section shall be deemed to have been granted on the date on which the application has been received by the Registrar. B
(8) Any order of the Commissioner under this section shall be made with a view to avoiding the abuse found by the Commissioner to have been established."

I was referred to only one South African decision C dealing with this section. It is in the matter of *Sanachem (Pty) Ltd v British Technology Group plc* , delivered in the Transvaal on 5 October 1992. * As far as English decisions are concerned D it would appear that those which are based on the current British statute, ie the 1977 Patents Act, are of limited value since sections 48 to 57 of that Act

differ substantially from our section. (See Terrell on *The Law of Patents* , 12th ed p 515-520) . Of greater value are decisions E given on the earlier 1907 English Act, as amended by statutes of 1919, 1928 and 1932. It permits of the grant of a compulsory licence

"... if the demand for the patented article in the F United Kingdom is not being met to an adequate extent and on reasonable terms."

Also

"... by reason of the refusal of the patentee to G grant a licence or licences upon reasonable terms, and it is in the public interest that a licence or licences be granted"

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A As to "reasonable terms" the decision in *Kamborian's Patent* (1961) 78 RPC 403 at 405 (39) - 406 (9) is of value. The Court said:

B "The applicants contend that they are unable to meet this demand because of the price, and the price is too high because of the unreasonable royalty.

The question of whether the terms are reasonable or not falls, I think, to be judged in the light of C what the customer is prepared to pay. There is not evidence before me of public dissatisfaction with the price of the machine at the date of the application."

Cathro's Application (1934) 51 RPC 75 at 82 holds that the demand for an article is not met on reasonable terms if the D patented article is sold at an excessive price. (See *Burrell: South African Patent Law and Practice,* 2nd ed p 341) . This was adopted in the South African case where MacArthur J said (at E page 12):

"If the user of the patented article is paying an excessive price then clearly the needs are not being met on reasonable terms.

The question of what terms are reasonable will depend on the circumstances of each case, but in F *Brownie Wireless Co Ltd's Applications* (1929) 46 RPC 457 at 476 - 478, it was said that it was not unreasonable to charge a royalty which the trade would carry."

In regard to the requirement of public interest and prejudice to the industry certain dicta of Luxmoore J in the G *Brownie Wireless* case *supra* should be quoted. At 473 it was said:

"Again the phrase used in this connection is

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that the trade or industry 'Is prejudiced,' an A expression which must necessarily depend for its precise interpretation on the facts of the particular case under consideration."

At 474: B

"Is this to be construed in its widest meaning, namely, the interest of the community including every class which goes to constitute that body, namely, the purchasing public, the traders and the manufacturers, the patentee and the licensees, and inventors C generally, or is it to be construed simply with regard to the purchasing public? In my view the former is the correct view."

This passage was quoted with approval in the judgment of MacArthur J at p 15-16.
The dates on which the questions in issue fall to be considered are the dates of the application or the date of hearing. To these guidelines, which I respectfully adopt, I E would add a few further observations which may possibly be trite. Since section 56 permits of a loss of valuable F intellectual property rights, the applicant must present clear and satisfactory evidence of his averments. A charge of unreasonable terms is not established G merely on proof that the applicant can sell the same sort of article at a lower price.

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A As MacArthur J said in the judgment previously referred to (at page 9):

"As a bald statement of fact this is quite unpersuasive. What is known from the papers is that the applicant is not a licensee but is selling the B product at a lower price. If the argument was correct it would mean that an infringer could come into the market by cutting its prices and, because is was

selling infringing goods at a lower price, then demand a licence by saying the needs of the C Republic are not being met to an adequate extent."

Other relevant considerations in deciding whether the patentee's prices are reasonable are the cost to him of producing and marketing the patented article, the terms and conditions on which it negotiates with customers, whether the D facts show that the trade as a whole can carry the price charged.

On the charge of not granting a licence the Court should be provided with evidence indicating, with reasonable E precision, what reasonable terms are. The close reasoning adopted by the Court of Appeal in *Smith Kline & French Laboratories Ltd's (Cimetidine) Patents* [1990] RPC 203, shows the sort of evidence that is expected in that type of case. The reasonable terms F are not necessarily those offered by the applicant or those offered by the patentee. If possible the Court should be afforded the guidance of what terms are normally applied to that type of licence.

G I turn then to the question of whether the applicants have proved the abuses relied upon by them. In my view they have failed miserably and have not come near establishing a proper case on any of the two grounds.
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In general, where there is a difference between A versions put forward by the deponents of applicants' affidavits and the affidavits of the respondent, I find no reason for preferring the former. The applicants do not ask B that any of the conflicts should be resolved by *viva voce* evidence. The version of the respondent's witnesses should prevail.

As to the reasonableness of prices charged by the C respondent, I do not think that the applicant has shown that, having regard to all the circumstances set out in the papers, the respondent charged unreasonable prices. The applicants did little more than to show that they could in certain sectors sell at lesser prices. That falls far short of D showing that in all the circumstances the respondent's prices and method of fixing prices are not reasonable.

This will not be the first case where companies such E as the applicants, who make use of patents acquired by others after considerable expense, are able to undercut. They have no considerable expense in the field of research and development. They did not have respondent's expense in advertising and in creating the market. F

None of Partridge's averments in this regard are questioned. The applicants do not counter the respondent's evidence of its putting up an infrastructure for its business. The respondent's statement of why it grants large G discounts to large suppliers is not suggested to reflect a harmful business practice, or to be prejudicial to the business community as a whole. And Partridge established acceptable criticisms of Margeot's incorrect statements regarding the costs of Carlton diapers.
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ELOFF JP

A The argument that regard should be had to the need of the small business who cannot afford to take large quantities of diapers cannot be sustained. Partridge's evidence in this regard cannot be said not to make business B sense. The demands of the public as a whole have to be considered. I cannot fault the submission that if the respondent's were to allow a discount also to small purchasers it would present problems in connection with the C business relationship with the large purchasers.

As to the question of the quality of the respondent's product there is nothing to counter the statement of its deponents that even though there may have been some D shortcomings in its products, this altogether altered for the better by the time the application was launched and certainly at the date of the hearing.

I turn to the refusal to grant a licence. E Partridge's answer to the applicant's claim to serve the 5% of the market previously alluded to is understandable and cannot be said to be unreasonable. The grant of a licence to serve that sector of the community and to enable the applicants to sell to it at its suggested prices will be F prejudicial to the respondent and of the larger dealers in the trade. Apart from that there is no admissible evidence of what the reasonable terms of royalty arrangements should G be.

As far as the vital concern of public interest is concerned, there is nothing to support the applicants. The authorities listed earlier require proof that the interests of the community as a whole should be considered. Evidence of this from the applicants is sorely lacking. At best small
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traders and the applicants will possibly benefit. It was A never established that the applicants, if given the licence to serve the 5% previously alluded to, will be able to maintain the existing price structure. And simply nothing was placed before me to counter the point made that lots of B local interests stand to be harmed if the respondent's business is adversely affected by the forced intrusion into its patented rights. This ground of abuse was also not established. C

For these reasons the application must fail.

This renders it unnecessary to consider the argument that by reason of its undertakings Afitra is precluded from invoking section 56. I shall however revert to that and D discuss it in another context. I end off my discussion on this part of the case by recording that the application stands to be dismissed with costs.

As far as the counter-claim is concerned, I mentioned E earlier that counsel conceded that should the application be dismissed the respondent's clear right and apprehension of harm was probably established. Reference was, however, made to section 56(1A) which, it will be recalled, states that F pending final determination of an application for a compulsory licence the applicants should not, except under special circumstances, be prohibited by interdict from infringing the patent.

I would have thought that once the application for G a compulsory licence is out of the way, as it now is, nothing in this section stands in the way of an interdict. It is however possible to argue that while the section 56 application is pending an interdict might not be sought. It
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A is furthermore reasonably clear that dismissal of the main application will be followed by an application, or applications, for leave to appeal. If those are brought it may well be said that final determination of the application has not eventuated. It is accordingly necessary for me to B consider whether special circumstances exist.

What are special circumstances? It seems to me that by wording the section as it did the Legislature contemplated C that an applicant under section 56, who in good faith presents an application with reasonable prospects of success, should not be inhibited by injunctions while the case is pending. Differently put, I cannot imagine that the Legislature intended to afford a moratorium to an infringer D who acts in bad faith, or who should realise that he is not likely to succeed in his quest. If it would be manifestly unjust for an applicant to enjoy the protection of section 56(1A) whilst his application is pending, that, in my view, would also constitute special circumstances. And if the E patentee stands to be prejudiced if an interdict is not granted, that could also constitute adequate special circumstances in the present case.

The application was ill-founded and was certainly F shown to be such when the answering affidavits were filed. I repeat my findings in regarding the lack of merit of the application. At latest after the filing of the answering affidavits the applicants should have realised that they were not likely to succeed, and their decision to do so is no less G than vexatious and an abuse of the statutory provision.

The undertaking previously alluded to by Afitra is in point. I have now to consider the contention that Afitra's undertaking was purely unilateral. I cannot accept
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ELOFF JP
this contention at all. It will be recalled that the A undertaking was given in response to warnings by the respondent to stop infringing. When Afitra gave the undertaking which it did, a reciprocal agreement came into place, and that is how Partridge saw it, as appears from his B affidavit. The undertaking was of course only given by Afitra. But without Afitra, Medtex would not supply Hogla diapers, and the undertaking accordingly also constitutes special circumstances as far as it is concerned. For the

applicants to have continued to import and endeavour to sell C Hogla diapers in violation of the agreement is in my judgment completely unacceptable conduct. It not only constitutes breach of contract but demonstrates *mala fides.*

The patent has only a few more months to go. True, D there is an application for an extension but that might fail. It would be unjust to compel the respondent to stand unprotected in the face of infringement whilst its monopoly has only three or more months to go. E

The prospect of the respondent recovering damage eventually, when all is over, is as I held when discussing the counterclaim, questionable.

The respondent has spent enormous amounts of money F to build up a market in South Africa, while the applicants have spent nothing.

I conclude that section 56(1A) does not present a bar G to the counter-claim, and should the application be made for leave to appeal an interdict can still operate.

I turn then to the question of the counter-claim. The question of reasonable apprehension of harm presents no
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A difficulty. No sooner had the applicants launched their application, if not before that, they arranged for the shipment of large quantities of Hogla diapers for the purpose of sale in South Africa in violation of the respondent's patent. There is still little doubt that if they are not B restrained they will infringe on a substantial scale.

I turn then to the question whether, if unsuccessful at the end, the applicants can meet claims for damages. It C is interesting that they anticipate possibly being held liable for damages, for Margeot said that they are building up a contingency fund to pay either royalties or damages. He said that these companies are able to pay such damages. Partridge questions this averment, and his attitude is D understandable.

There is furthermore the problem of the amount for which damages is likely to be ordered. For applicants it is contended that that will at most be of the order of R90 000, E that is on the assumption that under section 56(6) damages can be assessed on the basis of a reasonable royalty. Partridge points out that if the patent is extended and the action for damages heard only after a year or two, respondent's claim will be substantially in excess of this F amount. I consider the respondent's concern to be a real one. Added to this is the fact that, in my view, applicants have no real answer to the charge of infringing and it would G be unjust to allow them to proceed.

As far as the balance of convenience is concerned, the applicants have no apprehension of a loss should they ultimately, in spite of everything, get a compulsory licence. The respondent is willing to provide ample security to meet any such claims as the applicants might have should it be
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held that they should have had a compulsory licence and were A incorrectly interdicted. There can be no question of the respondent's ability to make good its undertaking.

As against the applicants' possible loss and B inconvenience on being interdicted, the respondent's disadvantage if the restraint is not issued, is greater.

The counter-application should be granted.

I lastly touch on the question of costs. The C respondent has included masses of unnecessary papers in the Court file. Those are documents listed in the Court record from pages 153 to 228 and 240 to 282.

I make the following order: D

1. The application for a compulsory licence is dismissed.
2. The applicants, their servants or agents are E interdicted from infringing the rights of the respondent in and to South African patent no. 77/1894 by selling, disposing of or offering for sale or F offering for disposal the Hogla diapers, or any diapers which fall within the claims of the said patent, such interdict to operate pending the determination of an action instituted by the respondent against the applicants or until the expiry G date of the patent, whichever date is the earlier.
3. The applicants are to pay the costs of the respondent in respect of the application for a compulsory licence, such costs to include the costs of two

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A counsel. The costs will, however, not include the costs relative to the inclusion in the papers of the documents from pages 153 to 228 and 240 to 282.

4. The costs of the counter-application, brought by the B respondent for relief set out in paragraph 1 of this order, will be costs in the cause of the action instituted by the respondent.

C *Postea* (1 December 1992).

Eloff, J.P.: Application is now made for leave to appeal against the judgment just delivered. It is in particular urged that the application involves consideration and interpretation of section 56 which has, save possibly for D the *Sanachem* judgment, not been interpreted by our Courts. The problems are, accordingly, so it is urged, *res nova* . It is certainly true that I had virtually nothing to go on by way of precedent. But in view of the facts of the case and the E conclusion which I could reach on the facts, any possible questions as to the interpretation of this section did not present any difficulty.

Having regard to the facts of the case and the clear F findings which I made, this is not a case in which leave to appeal should be granted. The prospect of success of the projected appeal are not adequate.

G The application for leave to appeal is dismissed with costs including the costs of two counsel.
Applicants' patent agents: *Hahn & Hahn* , Pretoria.
Respondent's patent attorneys: *Spoor and Fisher* , Johannesburg.

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

- ☐ X **Non-working or insufficient working of the patented invention**
- ☐ X **Refusal to grant licenses on reasonable terms**
- ☐ X **Anti-competitive practices and/or unfair competition**
- ☐ X Public health
- ☐ X National security
- ☐ National emergency and/or extreme urgency
- ☐ X Dependent patents
- ☐ Other, please specify:

- o **The rights in a patent shall be deemed to be abused if the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;**

- o **The rights in a patent shall be deemed to be abused if the demand for the patented article in the Republic is met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged**

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

To protect the public interest.

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.....

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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69. If the applicable law provides for the grant of compulsory licenses on the ground of "non-working" or "insufficient working", please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Section 56 (2) (a), the Act does not define "non-working". However, in terms of this provision, the rights in a patent shall be deemed to be abused if the patented invention is not being worked in the Republic on a commercial scale after an expiry of a period of four (4) years subsequent to the date of application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the Commissioner no satisfactory reason for such non-working;

The meaning of "Commercial scale" is to be defined on merits depending on the nature of the invention and the circumstance of the case (See Strachan and Henshaw Ltd V Pakcel Ltd 1949 66 RPC 49)

70. Does the importation of a patented product or a product manufactured by a patented process constitute "working" of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

Yes, the importation of the product constitutes "working" of a patent as far as it is not involving excessive pricing (see Section 56 (2) (e) above

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?

- **X Yes**
- No

If yes, what is the time period? **Four (4) subsequent to date of application or three years subsequent to the date on which that patent was sealed, whichever period last expires.**

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

- **X Yes**
- No

If yes, what are "legitimate reasons"?

If the granting of license is not justified

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on "reasonable terms and conditions" and within a "reasonable period of time", please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

Defining the "Reasonable terms" requires consideration of the patentee's cost of production and marketing the article, the terms and conditions on which it negotiates with customers, and whether the trade can carry that price. Evidence of "reasonable terms" should be provided, as should the evidence that the patentee's prices were not reasonable. [see above Afitra (Pty) Ltd v Carlton Paper of SA(Pty) 1992 BP 331 (CP)

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74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

- **Denying a competitor access to essential facility;**
- **Engaging in excessive pricing**
- **Engaging in an exclusionary act**

.....

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

Compulsory licenses in respect of dependent patents: Section 55 of the Patent Act:

55. Where the working of a patent (hereinafter referred to as a dependent patent) without infringement of a prior patent is dependent upon the obtaining of a license under that prior patent, the proprietor of the dependent patent may, if agreement cannot be reached as to such license with the proprietor of the prior patent, apply to the Commissioner for a license under the prior patent, and the Commissioner may grant such a license on such conditions as he may impose, but including a condition that such license shall be used only for the purpose of permitting the dependent patent to be worked and for no other purpose:
Provided that the Commissioner shall not grant such a license unless –
(*a*) the invention claimed in the dependent patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the prior patent;
(*b*) the proprietor of the dependent patent granted the proprietor of the prior patent on reasonable terms a cross-license to use the invention claimed in the dependent patent; and
(*c*) the use authorised in respect of the prior patent is not assignable except with the assignment of the dependent patent.

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76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

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77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Section 4 of the Patent Act: patent shall in all respects have the like effect against the State as it has against a person: Provided that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the Commissioner on application by or on behalf of such Minister and after hearing the patentee.

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78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

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79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

Considerable burden of proof on the applicant for compulsory licensing
.....

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 4 of the patent Act 57 of 1978: State bound by patent

4. A patent shall in all respects have the like effect against the State as it has against a person: Provided that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the Commissioner on application by or on behalf of such Minister and after hearing the patentee.

CHAPTER XIV of the Patent Act 57 of 1978
Acquisition of rights to inventions and patents by the state
Acquisition of invention or patent by State
78. The Minister may, on behalf of the State, acquire, on such terms and conditions as may be agreed upon, any invention or patent.
Assignment of certain patents to the State
79.(1) The proprietor of an invention relating to any armaments as defined in section 1 of the Armaments Development and Production Act, 1968 (Act no. 57 of 1968), shall, if called upon to do so by the Minister of Defence, assign the invention or the patent obtained or to be obtainedfor the invention to that Minister on behalf of the State.
(2) The assignment and any agreements therein contained shall be valid and effectual and may be enforced by appropriate proceedings in the name of the Minister of Defence.
(3) Where an invention has been so assigned, the Minister of Defence may, by notice in writing to the Registrar, direct that the invention and the manner in which it is to be performed shall be kept secret.

(4) Every application, specification, amendment of specification or drawing received at the patent office relating to any invention in respect of which notice in terms of subsection (3) has been given, shall be sealed up by the Registrar and the contents of such application, specification, drawing or other document shall not be divulged without the written permission of the Minister of Defence.
(5) The patent for any such invention may be made out in the name of the proprietor and sealed, but such patent shall be delivered to the Minister of Defence and not to such proprietor and shall be the property of the State, and no proceedings shall lie for the revocation of the patent.
(6) The communication of any such invention to the Minister of Defence or to any personauthorised by him to inquire into the invention shall not, nor shall anything done for the purpose of the inquiry by such person, be deemed to be publication or use of the invention so as to prejudice the grant or validity of any patent for the invention.
(7) The Minister of Defence may by notice in writing to the Registrar direct that any invention directed to be kept secret need no longer be kept secret, and thereupon the specification and drawings may be published.
(8) The said Minister shall pay to the proprietor of the invention or patent such reasonable compensation as may be agreed upon or as may, in default of agreement, be determined by arbitration or, if the parties so agree, by the Commissioner.
Minister may require inventions to be kept secret in certain circumstances
80.(1) If the Minister is of opinion that in the national interest an application, specification, drawing or other document relating to any invention should be kept secret, he may order the Registrar to keep the invention secret and to notify the applicant accordingly, and if any Minister of State desires to acquire such invention on behalf of the State, the provisions of section 79 shall as far as applicable apply, and for that purpose the reference in section 79 to the Minister of Defence shall be deemed to be a reference to the said Minister of State.
(2) Whenever any order issued by the Minister under this section is withdrawn, any steps which were prior to the date of that order taken under this Act in connection with the application which was the subject of that order, and which were interrupted in consequence of that order, may be proceeded with as if the interruption had not occurred, and any period which may have elapsed between the date on which that order was lodged with the Registrar and the date of withdrawal thereof shall not be taken into account in the computation of any period of time prescribed by or under this Act.
(3) If the proprietor of an invention has suffered loss or damage by reason of that invention having been kept secret in pursuance of an order under subsection (1), the Minister shall pay to him such reasonable compensation as may be agreed upon or as may, in default of agreement, be determined by arbitration or, if the parties so agree, by the Commissioner.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its (their) brief summary:

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83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

- ☐ Non-working or insufficient working of the patented invention
- ☐ Refusal to grant licenses on reasonable terms
- ☐ Anti-competitive practices and/or unfair competition
- ☐ **X** Public health
- ☐ **X National security**
- ☐ National emergency and/or extreme urgency
- ☐ Dependent patents
- ☐ Other, please specify: ……

84. (a) What are the public policy objectives for providing government use in your country?

Public/State interest

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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85. If the applicable law provides for the grant of government use on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

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86. Please indicate how many times and in which technological areas government use has been issued in your country:

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87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

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88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

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Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions
[Information for this section is submitted by Mr. Tom Suchanandan, DST,South Africa]

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

See question 95

The draft Bill Notice 688 of 2011 (Plant Breeder's Rights Act No. 15 of 1976 was revised in 1996) provides for certain exceptions to acts which would otherwise destroy the novelty of a variety for purposes of obtaining plant breeder's rights protection. For example, plant material may in terms of the draft Bill be sold for the sole purpose of evaluating the variety in field tests, laboratory trials, small scale

processing trials or other prescribed tests or trials, without the sale of the propagating material being viewed as exploitation of the variety and thus potentially novelty destroying.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):
See

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

See question 97

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

See question 98

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:
The proposed provisions contained in sections 9(1)(d) and 9(2) are of crucial importance. A farmer is now restricted to only use harvested material on land occupied by him from a **protected variety (as opposed to propagating material** which is the current position). Propagating material has a wide definition and includes any reproductive or vegetative material of a plant that can be used for the propagation of such plant whilst maintaining the essential characteristics of the original plant. Small farmers must carefully consider that the implications are of these restrictions for them. Furthermore, the exchange of such harvested material derived from protected varieties between farmers is prohibited. The proposed section 9(1)(2) expressly prohibits farmers from saving, exchanging, propagating or using protected varieties of **vegetatively propagated crops**

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):

Exceptions to the breeder's right were the use of the variety privately and for non-commercial purposes, experimental purposes, and for breeding other plant varieties. A protected variety could be used for these acts without the authorization from a plant breeder's right holder. Farmers were also allowed to use for propagating purposes, on their own holdings, the product of the harvest that they had obtained by planting on their own holdings the protected variety.

The first approach involved situating the traditional practices of farmers as exceptions to the exclusive rights of plant breeders under existing IPR laws. The second approach involved acknowledging farmers through benefit sharing mechanisms such as financial payments and technology transfers. The third approach was to develop plant variety protection regimes which recognized their heterogeneous plant varieties.

1) Notwithstanding section 33*(a)*, a plant breeder's right in respect of a variety obtained in a legitimate manner does not extend to—
(a) any act done in respect of that variety for private or non-commercial purposes;
(b) any act done in respect of that variety for experimental purposes;
(c) any act done in respect of that variety for the purposes of breeding other varieties and, except where section 6(3) applies, any act contemplated in section 6(1) and (2) in respect of such other varieties; or
(d) a farmer who on land occupied by him or her uses harvested material obtained on such land from that variety for the purposes of propagation, as long as that harvested material is not used for the purposes of propagation by any person other than that farmer.
(2) The provision of subparagraph (1)*(d)* shall not apply to vegetatively propagated crops and shall only apply as prescribed.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

1) Notwithstanding section 33*(a)*, a plant breeder's right in respect of a variety obtained in a legitimate manner does not extend to—
(a) any act done in respect of that variety for private or non-commercial purposes;
(b) any act done in respect of that variety for experimental purposes;
(c) any act done in respect of that variety for the purposes of breeding other varieties and, except where section 6(3) applies, any act contemplated in section 6(1) and (2) in respect of such other varieties; or
(d) a farmer who on land occupied by him or her uses harvested material obtained on such land from that variety for the purposes of propagation, as long as that harvested material is not used for the purposes of propagation by any person other than that farmer.
(2) The provision of subparagraph (1)*(d)* shall not apply to vegetatively propagated crops and shall only apply as prescribed.

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

The objective of the plant breeders' rights policy is to stimulate economic growth by:
1 Providing an internationally recognised system for plant variety protection
2 Ensuring the availability of plant varieties for South African agriculture.
3 Encouraging the participation of those previously excluded from economic activity by recognising their informal systems of innovation and creativity.
4 Encouraging the sustainable use and conservation of plant genetic resources for food and agriculture.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

A draft policy on plant breeders' rights was published in the Government Gazette during October 2010 with an invitation for written submissions, the deadline for which was 12 November 2010.
According to the draft policy, Plant Breeders' Rights Act 15 of 1976 allows a farmer to re-sow protected material on his/her farm or holding. This is referred to as a farmer's privilege.
The draft policy stated that this had been abused to the extent that investment in the breeding of certain crops had decreased significantly.
The draft policy also posited that plant genetic diversity had been eroded – rather than enhanced – by the granting of plant breeders' rights. This had implications for intellectual property rights and the sustainable use of biodiversity.
On the issue of traditional rights related to plant genetic resources for food and agriculture (PGRFA), the draft policy proposed these should not be commercialised for personal gain.

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

The rights do not apply if the breeder has had reasonable opportunity to exercise his or her right in respect of the propagating material of the protected variety.

A person who procured any propagating material of a variety in a legitimate manner shall not infringe the plant breeders' right if he or she re-sells the propagating material, sells any plant, reproductive material or product derived from the propagating material for the purposes other than the further propagation or multiplication thereof, uses or multiplies the propagating material in the development of a different variety, uses the propagating material for purposes of bona fide research, uses the propagating material for private or non-commercial purposes or is a farmer who on land occupied by him or her uses harvested material obtained on such land from that propagating material for the purposes of propagation provided that harvested material obtained from the replanted propagating material shall not be used for the purposes of propagation by any other person other than that farmer.

99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Cabinet has approved the publication of the Plant Breeders Rights Amendment Bill, 2011 for public comment. T he Bill aims to strengthen the protection of intellectual property rights related to new varieties of plants,

"Such protection contributes to economic growth, as it has a positive impact on the competitiveness of South Africa's agriculture sector."

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

Challenges that breeders have are rights of save, use, exchange seed and propagation material. Section 23 of the Act provides for certain exceptions, which allows a farmer to use farm saved seeds and propagating material on land occupied by him or her without paying royalties. The law does not, however, allow the exchange of protected seeds between farmers.

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

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102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

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(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

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In addition, in relation to each exception and limitation, please explain:

(i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

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(ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

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103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

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[End of Questionnaire]