

Vawda, Yousuf A.

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Compulsory licensing jurisprudence in South Africa: Do we have our priorities right?

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**COMPULSORY LICENSING
JURISPRUDENCE IN SOUTH AFRICA:
DO WE HAVE OUR PRIORITIES RIGHT?**

Yousuf A Vawda



RESEARCH PAPERS

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COMPULSORY LICENSING JURISPRUDENCE IN SOUTH AFRICA: DO WE HAVE OUR PRIORITIES RIGHT?

Yousuf A Vawda BA BProc LLM LLD¹

SOUTH CENTRE

DECEMBER 2018

¹ Honorary Research Fellow, University of KwaZulu-Natal, yawday@ukzn.ac.za. I gratefully acknowledge the efforts of my research assistant Mr Bonginkosi Shozi LLB LLM candidate.

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Any comments on this paper or the content of this paper will be highly appreciated. Please contact:

South Centre
Ch. du Champ d'Anier 17
POB 228, 1211 Geneva 19
Switzerland
Tel. (41) 022 791 80 50
Fax (41) 022 798 85 31
south@southcentre.int
www.southcentre.int

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ABSTRACT

Compulsory licences are generally available on a variety of grounds, most notably on patents where the patentee is found to have abused its rights in one manner or another. This research paper attempts to review South African case law on applications for compulsory licences since the inception of the current legislation, analyse the interpretations placed on the relevant sections, and draw conclusions about judicial reasoning, impediments to the grant of such licences, and generally the courts' approach to disputes relating to patents.

Les licences obligatoires autorisant l'utilisation d'un brevet peuvent être délivrées pour diverses raisons, notamment quand le titulaire de brevet a abusé de ses droits d'une manière ou d'une autre. Le présent document examine la jurisprudence sud-africaine relative aux demandes de licences obligatoires depuis l'introduction de la législation en vigueur, analyse les interprétations qui sont faites des dispositions en la matière et dresse des conclusions sur le raisonnement juridique, sur les obstacles à l'octroi des licences et, de manière générale, sur la manière dont les tribunaux traitent les différends relatifs aux brevets.

Las licencias obligatorias de patentes suelen otorgarse por diferentes motivos, especialmente cuando se demuestra que el titular de una patente ha abusado de sus derechos de una manera u otra. Este documento de investigación tiene por objeto examinar la jurisprudencia de Sudáfrica sobre las solicitudes de licencias obligatorias desde la institución de la legislación vigente, analizar las interpretaciones de los artículos pertinentes y extraer conclusiones sobre el razonamiento jurídico, los impedimentos para la concesión de dichas licencias y en general, sobre el enfoque adoptado por los tribunales en las controversias sobre patentes.

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I. INTRODUCTION

Compulsory licences are generally available on a variety of grounds, most notably on patents where the patentee is found to have abused its rights in one manner or another. Despite the existence of relevant provisions in over a century of patent legislation, not a single compulsory licence has been granted on a pharmaceutical-related patent in South Africa.² This raises obvious questions, particularly in the context of the impact of pharmaceutical patents on the affordability of and access to medicines.³ Why has the resort to this pathway to access been so under-utilised, or so unsuccessful when it eventually receives a hearing?

This research paper attempts to review the case law on applications for compulsory licences since the inception of the current legislation, analyse the interpretations placed on the relevant sections⁴, and draw conclusions about judicial reasoning, impediments to the grant of such licences, and generally the courts' approach to disputes relating to patents. It concludes, among others, that the very architecture of the patent landscape, combined with an overly formalistic approach to judicial interpretation and adjudication, may be responsible for the lack of efficacy of this provision in the law.

² CM Correa, 'Pharmaceutical innovation, incremental patenting and compulsory licensing,' South Centre Research Paper 41 (September 2011), p. 17. Available from <http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=7F43CAC7AF4FFD19FE2197CA78343A43?doi=10.1.1.357.5792&rep=rep1&type=pdf> (accessed 5 September 2018) and YA Vawda, 'Patent law in emerging economies: South Africa,' in *Emerging Markets and the World Patent Order*, FM Abbott, CM Correa and P Drahos, eds. (2013), p. 300.

³ See, for example, ER Gold *et al*, 'Are patents impeding medical care and innovation?' *PLoS Med* 7(1) (2009). Available from <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1000208&type=printable> (accessed 5 September 2018).

⁴ Sections 55 and 56 of the Patents Act 57 of 1978. The Competition Act 89 of 1998 envisages the issuing of a compulsory licence as a remedy for anti-competitive practices, through its provision for divestiture in section 58(1)(a)(iv), but this provision has not been used to date.

II. BRIEF HISTORY OF PATENT LEGISLATION

As a former British colony, early patent law in South Africa was based on the corresponding legislation in force in Britain at the time, with the four provinces pre-dating the Union of South Africa in 1910 all passing patent legislation in one form or another.⁵ There were two further iterations of the Patents Act before the current legislation. It is noteworthy that South Africa acceded on 1 December 1947 to the Paris Convention⁶, became a member of the World Trade Organization (WTO) on 1 January 1995⁷, and became bound to the Patent Cooperation Treaty on 16 March 1999.⁸ South Africa's membership of the WTO and hence a signatory to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement⁹ necessitated the adoption of national legislation and regulations to give effect to the TRIPS Agreement. This was accomplished through the passage of the Intellectual Property Laws Amendment Act.¹⁰

⁵ The earliest of such laws in the provinces was Act 17 of 1860 passed by the parliament of the Cape of Good Hope, with the earliest Union legislation being the Patents, Designs, Trade Marks and Copyright Act 9 of 1916. See T Burrell, *Burrell's South African Patent and Design Law* (1999), p. 5.

⁶ Paris Convention for the Protection of Industrial Property, 20 March 1883.

⁷ See https://www.wto.org/english/thewto_e/countries_e/south_africa_e.htm (accessed 27 August 2018).

⁸ See <http://www.cipc.co.za/index.php/trade-marks-patents-designs-copyright/patents/> (accessed on 27 August 2018).

⁹ Annex 1C to the Marrakesh Agreement Establishing the WTO, signed on 15 April 1994 at Marrakesh, Morocco.

¹⁰ Intellectual Property Laws Amendment Act 38 of 1997.

III. ANALYSIS OF THE COMPULSORY LICENSING PROVISIONS

South Africa utilises the depository system for patent applications, under which applications are examined as to formalities with no substantive search and examination required. One of the drawbacks of this system is that the statutory requirements for patentability¹¹ are not tested in the application process unless the validity of the patent is challenged during revocation or infringement proceedings.¹² This usually entails a substantive application before the Commissioner of Patents, in effect a judge of the High Court of South Africa having jurisdiction,¹³ a process involving considerable time and expense.

Applications for compulsory licences on the other hand, though similarly time-consuming and expensive, ordinarily attract the necessary ventilation of the legal requirements by virtue of the prescribed procedure, namely judicial interpretation.¹⁴ This paper attempts to examine the judicial interpretation of those requirements, namely, the grounds upon which an application may be brought and the ensuing outcomes, through an analysis of relevant case law.

As a general proposition on the issue of patent protection, the courts have adopted the position that the basic rationale underlying patent protection is that it is desirable in the public interest that inventions are developed and improved, requiring disclosure in exchange for a monopoly for its use – the essential *quid pro quo* of intellectual property theory.¹⁵ This approach has been reiterated, notably, in the decisions of the Supreme Court of Appeal (SCA).¹⁶ Applications for compulsory licences are brought, under legislative provisions, primarily when an applicant claims that the patentee or its licensee has abused its rights.

The relevant provisions in the Patents Act dealing with compulsory licences, reproduced here in their entirety, are as follows:¹⁷

‘55. Compulsory licences in respect of dependent patents.

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 licence under that prior patent, the proprietor of the dependent patent may, if agreement cannot be reached as to such licence with the proprietor of the prior patent, apply to the commissioner for a licence under the prior patent, and the commissioner may grant such a licence on such conditions as he may impose, but including a condition that such licence shall be used only for the purpose of

¹¹ Section 25 of the Patents Act.

¹² Sections 61 to 64, and sections 65 to 71 of the Patents Act, respectively.

¹³ See sections 17 and 18 of the Patents Act for the general powers of, and proceedings before, a commissioner.

¹⁴ Section 56 (1), (3) and (4) of the Patents Act.

¹⁵ Vawda, *op. cit.*, p. 287.

¹⁶ *Letraset Ltd v Helios Ltd* 1972 BP 243 (A) at 246D-E. See also *Syntheta (Pty) Ltd v Janssen Pharmaceutica NV & Another* 1999 (1) SA 85 SCA.

¹⁷ A government use order is catered for in the Patents Act in terms of section 4 (‘State bound by patent’) and section 78 (‘Acquisition of invention or patent by State’), but unnecessarily requires prior negotiation with the patent holder. These provisions appear not to have been utilised, and there appears to be no reported case law.

permitting the dependent patent to be worked and for no other purpose: Provided that the commissioner shall not grant such a licence 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-licence 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.

[S. 55 amended by s. 44 of Act No. 38 of 1997.]

56. Compulsory licence in case of abuse of patent rights.

(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 licence under the patent.

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

(1A)

[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)

[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 licence or licences 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 licence or licences 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 therefor in countries where the patented article is manufactured by or under licence 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 licence 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 licence is not justified, he may refuse the application.

(c) A licence granted under this section shall include a provision that, subject to adequate protection of the legitimate interests of the licensee, the licence 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 licence granted under this section shall be non-exclusive and shall not be transferable except to a person to whom the business or part of the business in connection with which the rights under the licence were exercised has been transferred.

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

(6)

[Sub-s. (6) deleted by s. 45 (f) of Act No. 38 of 1997.]

(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 persons who voluntarily enter into such agreements.

(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.

[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 licence granted under this section.

(10) Subject to the conditions that may be attached to the licence, 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)

[Sub-s. (11) deleted by s. 45 (h) of Act No. 38 of 1997.]

(12)

[Sub-s. (12) deleted by s. 45 (h) of Act No. 38 of 1997.]

(13) (a) The commissioner may, when ordering the grant of a licence 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 licence under this section might have been avoided by the grant, by the patentee concerned to the applicant, of a voluntary licence 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.’

The interpretation applied to the relevant grounds upon which an application for a compulsory licence may be sustained are now discussed under their respective headings.

3.1 *Dependent patent (section 55)*

Only one discernible application appears to have been reported in terms of section 55. In the matter of *Atomic Energy Corporation of South Africa v The Du Pont Merck*¹⁸, the application for a dependent patent was met with a counterclaim, among others, that the alleged dependent patent was invalid, and hence ought to be revoked. Du Plessis J accepted that while the court would not hold a patent to be a dependent patent if it was in any event

¹⁸ *Atomic Energy Corporation of South Africa v The Du Pont Merck* 1997 BIP 90 (CP). The patents in this case related to radio-pharmaceuticals.

susceptible to revocation, the applicant's assertions constituted *prima facie* proof that the invention was both novel and involved an inventive step. It was further held that much like its counterpart in a compulsory licence application in terms of section 56, an applicant for a licence in terms of section 55 bore an onus to prove that the royalty it had offered was reasonable.¹⁹ The court held that the applicant's allegations constituted *prima facie* proof of what a reasonable royalty would be in the circumstances.²⁰ In the event, the court concluded that as there were a number of factual disputes in the respective versions of the parties, the matter be referred to trial.²¹ For that very reason, the court also held that it was not able to accede to another counterclaim, for a temporary interdict, because the prospects and convenience of the parties were evenly balanced.²²

3.2 *The patented invention is not being worked in the Republic on a commercial scale or to an adequate extent (s 56(2)(a))*

The exact meaning of this ground was the subject of enquiry in several decisions. In *Sanachem (Pty) Ltd v British Technology Group PLC*²³, the court rejected the applicant's contention that the respondent (patentee) had not worked the invention to an adequate extent. It held that the term 'worked' meant 'exploitation', and included working by importation,²⁴ as was the situation in this instance. Further it held that the term 'adequate extent' means 'sufficient or commensurate with the needs of the Republic'.²⁵ This latter interpretation was followed in the decision of *Delta G Scientific (Pty) Ltd v Janssen Pharmaceutics NV and Another*²⁶. The court also held that the fact that the market in South Africa was fully supplied did not mean the invention could not be worked to a greater extent or to an adequate extent, and that in each case regard must be had to extent to which the invention can reasonably be expected to be worked in the circumstances to determine if the working of the invention has been adequate. However, the applicant had failed to show that the invention could be worked in South Africa to a greater extent within the remaining term of the patent.²⁷

3.3 *The demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms (s 56(2)(c))*

In evaluating this ground, McArthur J in *Sanachem* reiterated that what is understood by 'reasonable terms' will depend on the circumstances of each case, and that '(i)f the user of the patented article is paying an excessive price then clearly the needs are not being met on reasonable terms.'²⁸ The court further held, citing the English decision of *Brownie Wireless Co Ltd's Applications*²⁹ that 'it was not unreasonable to charge a royalty which the trade would carry'.³⁰ However, the court held that, as the applicant had not provided any evidence

¹⁹ *Atomic Energy Corporation of South Africa v The Du Pont Merck* 93-95.

²⁰ *Atomic Energy Corporation of South Africa v The Du Pont Merck* 94.

²¹ *Atomic Energy Corporation of South Africa v The Du Pont Merck* 92-95.

²² *Atomic Energy Corporation of South Africa v The Du Pont Merck* 95.

²³ *Sanachem (Pty) Ltd v British Technology Group PLC* 1992 BP 276 (CP). The patent in this case related to agrochemical substances.

²⁴ *Sanachem (Pty) Ltd v British Technology Group PLC* 285.

²⁵ *Sanachem (Pty) Ltd v British Technology Group PLC* 286.

²⁶ *Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* 1996 BP 455 (CP) at 459. The patent related to agricultural fungicides.

²⁷ *Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* 460.

²⁸ *Sanachem (Pty) Ltd v British Technology Group PLC* paras 289-290.

²⁹ *Brownie Wireless Co Ltd's Applications* (1929) 46 RPC 457 476-478.

³⁰ *Sanachem (Pty) Ltd v British Technology Group PLC* 290.

of public dissatisfaction with the prices at which the products were sold, it could not succeed on this ground either.³¹

3.4 *The refusal to license on reasonable terms prejudices trade or industry or agriculture in the country, and it is in the public interest that a licence be granted (s 56(2)(d))*

This ground was visited in some detail in the matter of *Sanachem* which outlined the three components which must be satisfied namely, refusal to license on reasonable terms; prejudice to trade, industry or agriculture; and the public interest.³²

The concept of 'reasonable terms' has already been elaborated under the discussion of subsection 56(2)(c) *supra*. The court accepted that, although the evidence pointed to the respondent having refused to give a licence, 'technically speaking without proof of an outright and definite refusal to grant a licence to the applicant, the *onus* cannot be discharged under subsection 56(2)(c)'.³³ As regards prejudice the court held that while its meaning depended on the circumstances, the intention of the legislature was 'to see that the patentee does not cause harm to the trade or to those who use the patented article'.³⁴ In considering the meaning of 'public interest', MacArthur J quoted the dicta of Luxmoore J in *Brownie Wireless* that the term must

'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 generally, (and not) be construed simply with regard to the purchasing public.'³⁵

In *Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd*³⁶ the applicant alleged that it was able to sell the patented product at a lesser price than the patentee. Following *Sanachem*, Eloff JP held that a charge of unreasonable terms is not established merely on proof that the applicant can sell the same sort of article at a lower price. Other relevant considerations need to be considered when deciding whether the patentee's prices are reasonable, such as the cost of producing and marketing the patented article, the terms and conditions on which it negotiates with customers, and whether the facts show that the trade as a whole can carry the price charged.³⁷

On the aspect of not granting a licence on reasonable terms, it was held that the court should be provided with evidence indicating, with reasonable precision, what reasonable terms are. The reasonable terms are not necessarily those offered by the applicant or the patentee.³⁸ Finally, the court held that the term 'prejudice' must be interpreted widely, depending on the circumstances of each case, and again quoted with approval the dicta of Luxmoore J in *Brownie Wireless supra*.³⁹ For these reasons, the application failed. *Afitra* was

³¹ *Sanachem (Pty) Ltd v British Technology Group PLC* 291.

³² *Ibid.*

³³ *Sanachem (Pty) Ltd v British Technology Group PLC* 292.

³⁴ *Ibid.*

³⁵ *Sanachem (Pty) Ltd v British Technology Group PLC* 293.

³⁶ *Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd* 1992 BP 331 (CP). The patent related to a device for a baby diaper.

³⁷ *Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd* 347.

³⁸ *Ibid.*

³⁹ *Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd* 346.

followed in *Delta*, in which the applicant had alleged that the refusal to grant a licence based on its offer of a royalty of 6% of the applicant's selling price, was a refusal to grant a licence on reasonable terms. Streicher J held that the application must fail because the applicant had not provided evidence indicating, with reasonable precision, what reasonable terms are.⁴⁰

3.5 *The demand is being met by importation and the price charged is excessive in relation to the price charged in countries of manufacture (s 56(2)(e))*

In *Sanachem*, MacArthur J held that this subsection called for a comparison between the local price for the imported article and the prices charged in countries where it was manufactured. The court compared the prices for the imported product in the respective local and overseas markets and was not convinced that the prices charged by the licensees were excessive compared to the overseas price. It accordingly held that the application must fail on this ground as well.⁴¹

A brief consideration of the law regarding interdicts to restrain continued infringements is necessary, as it sheds some light on the courts' attitude to compulsory licensing.

⁴⁰ *Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* 468.

⁴¹ *Sanachem (Pty) Ltd v British Technology Group PLC* 296.

IV. APPLICATION FOR INTERDICT TO RESTRAIN CONTINUED INFRINGEMENT (SS 56(1A), 45 AND 65(5))

The repealed section 56(1A) read as follows:

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.⁴²

In a sequel to the refusal of an application for a compulsory licence in *Sanachem supra*, and the grant of leave to appeal to the Appellate Division, the patentee in *British Technology Group Ltd v Sanachem (Pty) Ltd*⁴³ applied for an interdict to restrain the continued infringement of its patent pending the appeal. It argued that the appeal had little prospects of success because the patent was due to expire in approximately one year, and that there was little likelihood that the Appellate Division would hear the appeal before the expiry; that the continued infringement would have nullified the provisions of section 45(1) of the Patents Act relating to the effect of a patent, and that it would not be adequately remunerated. The application was refused as the patentee had failed to demonstrate ‘special circumstances’ entitling it to the relief of an interdict. The patentee had raised as one of the special circumstances, the contention that its chosen licensees would not be adequately remunerated, and that allowing the continued infringement would frustrate the whole basis of the patent being granted. MacArthur J distinguished between general and special circumstances, the latter being defined as ‘something of an exceptional nature which in the exercise of a judicial discretion would be sufficient to justify the relief sought’⁴⁴ and held that the contention raised did not constitute special circumstances. In addition, the court held that the licensees had no *locus standi* in the matter as they had not been recorded in the register of Patents in terms of section 65(5) and could not claim damages. Finally, the court rejected the patentee’s contention that the balance of convenience was irrelevant because a final interdict was being sought, and held that ‘no matter what the interdict is called, the effect of this particular interdict, if granted, must be temporary in nature if the Appellate Division were to uphold the appeal and grant a compulsory licence ... It is on that basis therefore that I consider the balance of convenience must be determined’.⁴⁵

However, as a result of changes in the legislative landscape since *British Technology* a court today might well adopt a different approach, leading to potentially different outcomes.

⁴² Repealed in terms of the Intellectual Property Laws Amendment Act 38 of 1997.

⁴³ *British Technology Group Ltd v Sanachem (Pty) Ltd* 1993 BP 415 (CP).

⁴⁴ *British Technology Group Ltd v Sanachem (Pty) Ltd* 418.

⁴⁵ *British Technology Group Ltd v Sanachem (Pty) Ltd* 419.

V. IMPLICATIONS FOR INTERPRETATION UNDER THE CONSTITUTION

As *British Technology* was decided under the regime as it existed prior to the promulgation of the Intellectual Property (IP) Laws Amendment Act, 1997, the effect of the repeal of section 56 (1A) is that the requirement to prove ‘special circumstances’ is no longer a consideration. However, it is submitted that the repeal was unfortunate as it constituted sound law – requiring evidence of exceptional circumstances to justify an exceptional remedy, namely an interdict.

As regards the disqualification of licensees from having *locus standi* as they were not registered as such in the Patents Register, section 38 of the Constitution of the Republic of South Africa, 1996, may well come into play should an applicant be, for example, a patient group arguing that it does have standing in terms of one or all of sub-sections 38 (c), (d) and (e), and that the fundamental right to access to health care was adversely affected by a pharmaceutical patent. Even during the pre-Constitutional era, the interests of non-litigant parties were considered in patent litigation, for example, in interpreting the meaning of ‘public interest’ as in *Sanachem supra*.

A somewhat different approach to the question of an interdict to restrain a continued infringement was evident in the matter of *Cipla Medpro v Aventis Pharma*.⁴⁶ For one, the court was freed from the prohibition in section 56(1A) on an interdict against infringing the patent, except under special circumstances. Apart from this issue, it was a significant test case for the extent to which courts are required to apply broad constitutional principles (in this instance, the right of access to health care services and medicines) in intellectual property disputes. The principle that the public interest is a consideration in intellectual property disputes had already been established in a previous unsuccessful application for a compulsory licence.⁴⁷ In *Aventis*, the holder of the patent (Aventis Pharma SA) maintained that the generic manufacturer (Cipla Life Sciences) had infringed its patent by registering and commencing the manufacture and marketing of a cheaper version of the former’s cancer medicine. Cipla countered that the patent was invalid on account of ambiguity and lack of novelty and inventive step, essential requirements for patentability. The Treatment Action Campaign (TAC), as *amicus*, argued that the provisions of the Patents Act must be interpreted in a manner consistent with the Constitution, and that the rights of the patent holder need to be balanced with those of persons requiring the life-saving medication. Secondly, when considering the requirement of ‘balance of convenience’ in interdict proceedings which potentially threaten the right to access medicines, the party requesting the interdict must prove that its grant will not harm the public interest. It also argued that, on the available information on the record, the interdict-seeker failed to discharge its onus of proof; and that, in line with courts in the USA and India, the court must assess whether a satisfactory alternative remedy (such as damages) is available to the party seeking an interdict.

In its judgment, the Court accepted TAC’s argument that the broader public interest, and not merely those of the litigating parties, ought to be considered when determining the balance of convenience in interdict proceedings, citing both South African and US Supreme

⁴⁶ *Cipla Medpro v Aventis Pharma* (139/12) *Aventis Pharma SA v Cipla Life Sciences* (138/12) [2012] ZASCA 108 (26 July 2012).

⁴⁷ *Syntheta (Pty) Ltd v Janssen Pharmaceutica NV & Another* 266.

Court case law.⁴⁸ However, it concluded that the public interest would not be served by denying an interdict on the facts of this case.⁴⁹ It noted that Cipla's opposition was based on commercial considerations, namely, its need to establish a presence in the generics market.⁵⁰ Furthermore, it noted that there was no evidence before it that Aventis could not continue to meet the demand for the medicine,⁵¹ nor was Cipla able to demonstrate that its product offered either superior medicinal benefits,⁵² or more than a marginal saving on the cost of its generic version in relation to Aventis' generic version.⁵³ And finally, it held that there would be no material disruption of medicine supply to patients should the interdict be granted.⁵⁴

While making a concession to the consideration of the public interest when determining the balance of convenience, and admitting public health advocates as amicus, the judgment was not unexpected given the constraints imposed by the legislation and the approach of the judiciary. The court appeared to be reluctant to apply a human rights-based approach to the interpretation of intellectual property disputes, in the manner that it characterised TAC's opposition to the grant of the interdict as 'no more than opposition to the monopoly that the law confers upon a patentee', concluding that '(t)o refuse an interdict only so as to frustrate the patentee's lawful monopoly seems to me to be as abuse of the discretionary powers of a court'.⁵⁵ It also highlights the perversity of patent holders being able to frustrate generic competition, and hence access to cheaper medicines, by introducing their own generic versions when such a threat is imminent. No interrogation was undertaken as to the motives of Aventis (in the same manner that Cipla's commercial motives were foregrounded) in registering and marketing its own generic product only at the stage that Cipla was on the verge of launching its product, and the long-term impact of such practices on accessibility and affordability of medicines.⁵⁶

The court took a rather narrow view on the question of awarding damages (royalties) as an alternative to the interdict, holding that this would be tantamount to granting a compulsory licence. As the court acknowledged that the issue of patent validity still stood to be determined in the revocation proceedings, the awarding of damages would certainly have been a less restrictive means of resolving an interim dispute. This approach is out of step with other jurisdictions such as India and the USA, where there is now strong precedent for the granting of judicial, royalty-bearing licences rather than injunctions.⁵⁷ Articles 50.1 and 44.1 of the TRIPS Agreement require member countries to provide provisional measures and permanent injunctions to prevent infringement, including the entry of infringing, imported products into the market. Although these provisions require that provisional measures and injunctions should be *available* in at least some circumstances, these circumstances can be *strictly limited* by equitable principles, including the interest of the public in access to

⁴⁸ *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences* para [46].

⁴⁹ *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences* para [52].

⁵⁰ *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences* para [42].

⁵¹ *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences* para [55].

⁵² *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences* para [55].

⁵³ *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences* para [58].

⁵⁴ *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences* para [55].

⁵⁵ *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences* para [56]. See also discussion in J Berger and A Rens, *Innovation and Intellectual Property in South Africa: The Case for Reform* (accessibsa, 2018), p. 37-38. Available from <http://ip-unit.org/wp-content/uploads/2018/05/Innovation-IP-in-SA.pdf> (accessed 5 September 2018).

⁵⁶ A Gray, Y Vawda and C Jack, 'Health Policy and Legislation,' in *South African Health Review 2012/2013*, A Padarath, R English, eds. (2013), p. 13.

⁵⁷ See the US Supreme Court decision in *eBay Inc. v. MercExchange, L.L.C.* 547 U.S. 388 (2006), and the Indian High Court decision in *Hoffman La Roche v. Cipla & Anr*, IA No. 642/2008 in CS (OS) No.89/2008.

medicines. Thus, in the absence of exceptional grounds for provisional or injunctive relief, remuneration in the form of on-going royalties can be awarded instead of an injunction or interdict.⁵⁸

⁵⁸ B Baker and Y Vawda, 'Submission by UKZN-Affiliated Academics on the Draft Intellectual Property Policy of the Republic of South Africa Phase 1 2017.' Available from [http://law.ukzn.ac.za/Libraries/2017-doc/Submission by UKZN Academics on SA Draft IP Policy 2017 - 23 October 2017.sflb.ashx](http://law.ukzn.ac.za/Libraries/2017-doc/Submission%20by%20UKZN%20Academics%20on%20SA%20Draft%20IP%20Policy%202017%20-%2023%20October%202017.sflb.ashx) (accessed 5 September 2018).

VI. HAS OUR PATENT LAW EVOLVED WITH THE CHANGING ENVIRONMENT?

It is evident from a reading of sections 55 and 56 that the grounds for a compulsory licence are very narrowly defined, limited to the five instances mentioned therein. This is no doubt due to the fact that our legislation has, in this regard, hardly evolved since the adoption of its British antecedents. It has not kept sufficiently abreast of developments in international law and in modern commerce, in particular, the impact of granting what amounts to long-term monopolies to multinational corporations with global reach. As a result, the issue of ‘access’ of the public to inventions in exchange for protection (the essential *quid pre quo*) has not featured in the equation. Even though with the advent of the TRIPS Agreement, the permissible grounds upon which a compulsory licence or government use order may be granted were not limited, this development has not been taken on board.⁵⁹ In the wake of global health crises, such as the HIV/AIDS pandemic, the WTO further clarified important concessions to enable the use of flexibilities such as compulsory licences.⁶⁰ In the context of this over-arching declaration:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all,⁶¹

the Doha Declaration made the following authoritative statement:

Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.⁶²

As a consequence many countries, both developing and developed, have utilised these provisions (including the invocation of a public health emergency) to issue compulsory licences to facilitate the provision of quality, affordable generic equivalents of patented medicines to their populations.⁶³ In almost all of these instances, the grounds for granting compulsory licences have been considerably expanded to include public health considerations, and to address the issue of the unaffordability of essential medicines.⁶⁴

Despite courts having conceded the necessity of considering the interests of the public in the adjudication of patent disputes, there is little evidence of cases actually being decided in line with this consideration prior to the advent of the Constitution. Further, it is submitted, in the case of *Aventis*, the courts have missed the opportunity to so decide in the era of the

⁵⁹ Article 31 of the TRIPS Agreement does not limit the grounds, but merely elaborates conditions on which ‘use without authorisation’ may be granted, *inter alia*, prior negotiations, non-exclusivity of licences, the right to adequate remuneration, judicial review.

⁶⁰ World Trade Organization, ‘Declaration on the TRIPS agreement and public health’ adopted at the Doha WTO Ministerial on 14 November 2001 (WT/MIN(01)/DEC/2). Available from https://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed 5 October 2018).

⁶¹ Doha Declaration, para 4.

⁶² Doha Declaration, para 5b.

⁶³ Such countries include Malaysia, Mozambique, Zambia, Indonesia, Zimbabwe, Thailand, Ghana, Brazil, United States of America, Italy, Ecuador and India. See M Khor, *Compulsory License and “Government Use” to Promote Access to Medicines: Some Examples* (Third World Network, 2014), p. 24.

⁶⁴ Khor, *op. cit.*, pp. 8-18.

Constitution. In that instance, it is submitted, the court deferred to an overly formalistic and traditional approach of prioritising the patentee's rights above considerations of public interest, notwithstanding the social value of the alleged infringing product.

In *Aventis*, the court took the view that 'Cipla contends that damages will be an adequate remedy if it is found in due course that the patent is valid but I do not think that can seriously be considered. The very nature of the market is such that it will be almost impossible to determine what sales would have been made but for the presence of Cipla's product.' With respect, this is an inadequate reason for not considering damages. Cipla did not help its case by failing to provide evidence to the court to enable it to arrive at reasonable estimates of the potential loss. However, in contemporary commerce, it is eminently possible to make such calculations based on actuarial and other data which companies use, in any event, to devise their sales and other strategies.⁶⁵

Further, it was stated that 'nor is it an answer to its claim for an interdict that Aventis might be awarded a reasonable royalty as an alternative to damages. That is a remedy available at the option of a patentee and it cannot be compelled in effect to license the use of its patent'.⁶⁶ While it is correct that a compulsory licence is not there for the taking, and that an applicant must establish the necessary grounds in order to succeed, these *dicta* appear to suggest a reluctance on the part of the courts to interfere with the patent holder's rights. Licences are granted voluntarily (through agreement between parties) or involuntarily (through judicial or governmental intervention in granting compulsory licences) when the circumstances exist under which the patentee *can* be compelled. The approach adopted here appears to suggest that the court is antithetical to the grant of such licences.

⁶⁵ See for example, M Sipkoff, 'Big Pharma uses effective strategies to battle generic competitors,' available from <http://www.drugtopics.com/clinical-news/big-pharma-uses-effective-strategies-battle-generic-competitors> (accessed 4 September 2018), which explores how industry anticipates and estimates expected losses due to generic competition.

⁶⁶ *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences* para [41].

VII. IS THE APPROACH OF THE COURTS DEFERENTIAL TO PATENT HOLDERS?

There are several other instances of what appears to be deference towards the interests of patent holders. One relates to the anomalous practice in infringement proceedings that, even if it was found that the invention was not patentable, it would remain valid absent a counterclaim for revocation.⁶⁷ The *Strix* judgment cites with approval the dicta in *Thomas Grant v Winkelhaak Mines Limited*⁶⁸ that '(e)ven if a defence of invalidity is successful, thereby defeating an infringement action, the patent remains on the register and the proprietor can sue others on the patent.'⁶⁹

Another instance is the manner in which the courts have dealt with applications for amendments to patent specifications. In the appeal of *Bateman Equipment Ltd and Another v The Wren Group (Pty) Ltd*⁷⁰, one of the grounds upon which the amendment was challenged was that the respondent had not furnished 'full reasons' as required in section 51(1).⁷¹ The SCA took the view that there was no basis for concluding that the requirement to furnish full reasons in section 51(1) applied to applications governed by section 51(9),⁷² holding that

'to require in those circumstances a setting out of full reasons (in support of an application to amend the specification) could be unnecessary and formalistic ... in this instance, the onus is on the objector to make out a case that the paucity of reasons is such that the Court should exercise its discretion against the patentee'.⁷³

This resort to a differentiation between the requirements for the two types of application is, it is submitted, flawed for a number of reasons. Firstly, no reasonable explanation is provided for the departure from the standard requirement that an applicant in interlocutory proceedings must properly motivate its case, by furnishing reasons for the proposed amendment. It is surely inadequate to state that 'the Court is usually aware of the reasons'.⁷⁴ Secondly, the court fails to follow its own advice that 'the nature and object of amendment proceedings must be seen in the context of our patent system as a whole' (see *infra*) in isolating subsection (9) and not reading section 51 holistically. Clearly, it applies to all applications for amendment of a specification under the section, including those under subsection (9). The main distinction is that the latter relates to an interlocutory application during pending court proceedings, to be made in the court where the proceedings are pending, for obvious reasons of convenience. *Kimberly-Clark of South Africa (Pty) Ltd. formerly*

⁶⁷ *Strix Ltd v Nu-World Industries (Pty) Ltd* 2016 (1) SA 387 (SCA).

⁶⁸ *Thomas Grant v Winkelhaak Mines Limited* 1985 BP 143 (CP).

⁶⁹ *Strix Ltd v Nu-World Industries (Pty) Ltd* para [152].

⁷⁰ *Bateman Equipment Ltd and Another v The Wren Group (Pty) Ltd* 2000 (1) SA 649 (SCA).

⁷¹ Section 51(1) of the Patents Act reads: 'An applicant for a patent or a patentee may at any time apply in the prescribed manner to the registrar for the amendment of either the relevant provisional specification or the relevant complete specification, and shall in making such application, set out the nature of the proposed amendment and furnish his full reasons therefor.'

⁷² Section 51(9) provides: 'Where any proceedings relating to an application for a patent or a patent are pending in any court, an application for the amendment of the relevant specification shall be made to that court, which may deal with such application for amendment as it thinks fit but subject to the provisions of subsections (5), (6) and (7), or may stay such pending proceedings and remit such application for amendment to the registrar to be dealt with in accordance with subsections (2), (3) and (4).'

⁷³ *Bateman Equipment Ltd and Another v The Wren Group (Pty) Ltd* para [3].

⁷⁴ *Ibid.*

*Carlton Paper of South Africa (Pty) Ltd v Proctor & Gamble SA (Pty) Ltd*⁷⁵ is cited as authority for the proposition that an applicant for an amendment in terms of section 51(9) does not have to give full reasons.⁷⁶ However, in that case Plewman JA appears to suggest otherwise, as is evident from these *dicta*: ‘While I do not suggest that the reasons can be other than the true reasons or that they need not be given in full the above statement is not a realistic reflection of what the basis for opposition to an amendment will be in practice’⁷⁷ (italics added). These *dicta* indicate that the approach to the critical issue of the necessity to furnish reasons in such interlocutory applications is far from settled. Finally, placing the onus on the objector rather than the party seeking the relief, appears to unfairly shift the burden of proof requirement.

Of particular concern is the following paragraph:

‘The nature and object of amendment proceedings must be seen in the context of our patent system as a whole. (Issue 1) Ours is a non-examining country and an alleged inventor is entitled to a patent for his supposed invention without having to satisfy anyone of its merit or validity. He does not have to give any reasons for his choice of wording. Should he sue for infringement, he has no duty to assist the alleged infringer in establishing whether his monopoly is valid or not. (Issue 2) Why should he be saddled with a burden if he wishes to reduce the scope of his protection in an attempt to render the patent valid, while in obtaining or enforcing a monopoly he bears no similar burden? (Issue 3) As much as it is in the public interest that persons with inventive minds should be encouraged to give the results of their efforts to the public in exchange for the grant of a patent (cf *Miller v Boxes & Shooks (Pty) Ltd* 1945 AD 561 at 568 and 578), it is in the public interest that patents should be rectified or validated by way of amendment.’ (numbering added)

A discussion of the numbered propositions follows. As regards issue 1 above, it is doubtful that an alleged inventor is entitled to a patent for his supposed invention without having to satisfy anyone of its merit or validity. While section 34 of the Patents Act requires that the registrar ‘examine in the prescribed manner’, the accompanying Regulations⁷⁸ effectively result in confining the examination of a patent application to formalities. Nonetheless one of the formalities to be complied with namely, Form P3, requires the applicant to make a declaration to the effect that ‘to the best of my/our knowledge and belief, if a patent is granted on the application, there will be no lawful ground for the revocation of the patent.’⁷⁹ If the form is not satisfactorily completed, presumably the patent will not be granted. If this declaration is to have any meaning, it is therefore incorrect, as the judgment intimates, that an alleged inventor is entitled to a patent for his supposed invention without having to vouch for its merit or validity.

The next proposition, issue 2, is equally unfounded. The assumption here is essentially that if the patentee is not obliged to identify the prior art and show that its invention differs from prior art in the patent application process, it cannot be required to establish same during

⁷⁵ *Kimberly-Clark of South Africa (Pty) Ltd. formerly Carlton Paper of South Africa (Pty) Ltd v Proctor & Gamble SA (Pty) Ltd* (A488/96) [1998] ZASCA 39.

⁷⁶ *Bateman Equipment Ltd and Another v The Wren Group (Pty) Ltd* para [4].

⁷⁷ *Kimberly-Clark of South Africa (Pty) Ltd. formerly Carlton Paper of South Africa (Pty) Ltd v Proctor & Gamble SA (Pty) Ltd* para [24]-[25].

⁷⁸ Regulations 40 and 41 of the Patent Regulations, 1978.

⁷⁹ Form P3 of the Patent Regulations, 1978.

the process of an application for its amendment. The rationale for the depository system for considering patent applications has always been premised on the understanding that a patent would be granted if it complied with the formalities, but that its validity could be tested in a substantive application for revocation. The proposition in issue 2 renders the role of the superior courts as the final arbiter of the validity of a patent granted without substantive examination meaningless. The reference to “render[ing] the patent valid” misconstrues the purpose of amendments to patent specifications and suggests a doubt in the court’s mind about the validity of the patent. The recourse to an application for amendment could never have been intended to give a patentee who was granted a patent based on a deficient patent specification the opportunity to make an otherwise invalid patent valid. It is inconceivable that the intention of the legislature, through section 51, was to allow patent holders whose specifications did not comply with the requirements of the Act to validate a patent that should never have been granted.

Finally, as regards issue 3, it is incomprehensible how the public interest is served by reinforcing a monopoly protection, in particular a highly contested one, by the approach adopted in *Bateman*. In this context, the only interest that appears to be advanced is that of the patent holder. Any appreciation of the notion of ‘access’ as a public interest in relation to an essential product, facility or service is absent.

Regrettably, the much-vaunted *quid pro quo* of patent theory has failed to materialise when considering the supposed benefits intended to accrue to the public.

VIII. CONCLUSION

On occasion, applications for compulsory licences were defeated because the applicant had failed to discharge the necessary evidential burden, as in *Syntheta*, where the court found that ‘no serious attempt has been made to prove the essential jurisdictional facts.’⁸⁰

Another reason for the paucity of such applications may be the judicial procedure required, involving not inconsiderable cost, especially for relatively small entrepreneurs who may be precluded from challenging patent holders, particularly multinational corporations, by the risks entailed in entering the market and the high costs of litigation.

It is contended, however, that the very architecture of the patent landscape, the rather limited grounds on which an application for a compulsory licence may be brought, combined with the overly formal approach to judicial interpretation and adjudication, including an apparent deference to patent holders over the broader public, may be responsible for the dearth of such applications, and hence the lack of their grant.

It is precisely because of consequences such as those mentioned above, and others, that the South African government has seen fit to address the problems associated with the current patent regime, resulting in the adoption by Cabinet of a new policy with particular focus on public health.⁸¹ The IP Policy of South Africa Phase 1 draws its inspiration from the Constitution, and recognises that ‘there is a need for a comprehensive IP Policy that will promote a holistic, balanced and coordinated approach to IP that is mindful of the many obligations mandated under the South African Constitution.’⁸² The policy expressly recognises the need to reform the regime as it relates to compulsory licences, as the following statement indicates:

South Africa’s unique challenges, including especially vulnerable populations and urgent development concerns, *will require the scope of compulsory licences to be strengthened and clarified* in a manner that is fair and compliant in relation to both international obligations and national law. Following due process, guidelines will be introduced, including legal process for government use, and a renewed effort to facilitate the process of exporting IP goods, such as medicines, to the African continent.⁸³ (italics added)

Given, it is submitted, the problematic interpretations of many provisions of the Act, and the deferential attitude towards patent holders vis-à-vis the broader ‘public’, new legislation will have to directly address many of these issues in order to clarify the purpose of such provisions and achieve the intended balance between the interests of patent holders, and consumers and the broader public. Significantly, it will have to factor in the impact of a rights-based Constitution in both the prioritisation and protection of fundamental rights, as well as in the manner of interpretation of patent legislation. How this policy formulation will translate into legislation remains a major challenge.

⁸⁰ *Syntheta (Pty) Ltd v Janssen Pharmaceutica NV & Another* 14.

⁸¹ Department of Trade and Industry, Republic of South Africa, Intellectual Property Policy of the Republic of South Africa Phase I (2018). Available from https://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf (accessed 13 September 2018).

⁸² *Ibid*, p. 3.

⁸³ *Ibid*, p. 27.

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SOUTH CENTRE

**Chemin du Champ d'Anier 17
PO Box 228, 1211 Geneva 19
Switzerland**

**Telephone: (41 22) 791 8050
Fax: (41 22) 798 8531
Email: south@southcentre.int**

**Website:
<http://www.southcentre.int>**

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