

Reportable
Case No 494/2000

In the matter between:

BIOTECH LABORATORIES (PTY) LTD

Appellant

and

**BEECHAM GROUP PLC
SMITH-KLINE BEECHAM PHARMA-
CEUTICALS (PTY) LTD**

First Respondent

Second Respondent

Coram: NIENABER, HARMS, ZULMAN, NAVSA and NUGENT JJA

Heard: 4 MARCH 2002

Delivered: 25 MARCH 2002

Subject: Copyright; State copyright; s 5(2) of the Copyright Act 98 of 1978.

JUDGMENT

HARMS JA/

HARMS JA:

[1] The battle about generic drugs is fought on many grounds – usually ethical, political, commercial or patent law considerations. In this particular case the ground happens to be copyright law. All turns on the copying of an approved package insert for a medicine. The copyist, the appellant (‘Biotech’), seeks to justify its admitted plagiarism on two grounds namely (a) that the respondents have failed to prove that the package insert was ‘original’ and (b) that, if original, the copyright therein vests in the State by virtue of the provisions of s 5(2) of the Copyright Act 98 of 1978. In the court below, Swart J, holding that the insert was an original work and that second respondent (‘Smith-Kline Beecham’) is the author and owner of the copyright therein, interdicted Biotech from infringing the copyright. The appeal is with his leave.

[2] Smith-Kline Beecham markets Augmentin, a medicine consisting of two substances: amoxycillin (a semi-synthetic penicillin) and potassium clavulanate. Amoxycillin is an antibiotic and potassium clavulanate protects it against

penicillin resistant organisms. Augmentin is registered in the name of Smith-Kline Beecham under the Medicines and Related Substances Control Act 101 of 1965. This Act prohibits the sale of medicines that are subject to registration unless registered (s 14 (1)). Applications for registration have to be submitted to the registrar appointed under the Act in the prescribed form and have to be accompanied by the prescribed particulars and samples (s 15(1)). If the application complies with the Act and regulations and the Medicines Control Council (the 'MCC') is satisfied that the medicine in question is suitable for its intended purpose, it 'shall approve of the registration thereof'. If it is not so satisfied, the applicant is notified and given the opportunity of responding to the reasons of the MCC. If the MCC is ultimately not satisfied, it rejects the application. (S 15(3).) Regulations may, amongst other things, prescribe the particulars in regard to the use of medicines, which have to be furnished when they are sold, and the manner in which the particulars have to be furnished (s 35(1)(viii)).

[3] The general regulations¹ under the Act require that a package insert must accompany each package of medicine sold. They also provide that package inserts must be in the prescribed format and must contain certain particulars such as the scheduling status of the medicine, its proprietary name and dosage form, composition, pharmacological classification and action, indications and contra-indications, warnings and so forth (reg. 10). A proviso permits the MCC (a) to allow an applicant to omit a prescribed heading, (b) to authorise the applicant upon application to deviate from the prescribed format or content or (c) to authorise upon application the inclusion of additional material.

[4] An applicant for registration has to submit with its application a package insert in the format stipulated (reg. 15). The MCC considers the insert in the course of the registration process and more often than not proposes to the applicant amendments or changes, some material and others insignificant. A lengthy debate may ensue and the applicant, unless it convinces the MCC, is in

¹ These were originally published under Government Notice R532 in the Government Gazette 4594 (Regulation Gazette 2117) of 21 February 1975 and have since often been amended.

practice obliged to accept the suggestions in order to obtain registration although on ordinary principles the MCC may not reject a package insert that complies with the regulations. The facts of this case are illustrative of the process. During July 1980, Smith-Kline Beecham lodged a concept submission with an insert leaflet. The concept was approved and the application was submitted with the original leaflet in September 1980. Someone discovered that with the drafting of the leaflet a prescribed section had been omitted and the leaflet was resubmitted during January 1981. Since the MCC was not satisfied with part of the clinical evidence, another leaflet was submitted during November omitting any reference to the objectionable material. During January 1982, a discussion took place between Smith-Kline Beecham and the MCC and as a result a further leaflet was prepared to 'include recommendations requested by the Council and an introduction discussed with Prof. Botha [a member of the MCC] regarding the activity of Augmentin against sensitive organisms'. So the process continued until the product and the insert were finally approved.

Thereafter, as data became available, the insert was further amended upon Smith-Kline Beecham's request.

[5] The patents that covered Augmentin have lapsed. The product is consequently freely marketable by others, provided they also obtain the necessary registration under the Act. Biotech applied for the registration of the same chemical composition but under the name Bio-Amoksoklav. As a latecomer it was not subjected to the same stringent registration requirements as was Smith-Kline Beecham and was entitled to rely on the fact that the scientific and technical data generated and supplied by the latter to the MCC had established the acceptability of the drug. However, Biotech had to submit a package insert for approval. Probably at the behest of the MCC, it copied Smith-Kline Beecham's package insert and obtained registration. Bio-Amoksoklav is sold with this package insert.

[6] ORIGINALITY: The issue is whether the insert, which is a literary work as defined in the Copyright Act, was 'original'. Works are only eligible for

copyright if they are ‘original’ (s 2(1)).² The genesis of the work was as follows. The first respondent (‘Beecham’) is Smith-Kline Beecham’s parent company and, presumably, the inventor of Augmentin. It prepared a master data sheet relating to Augmentin and also a uniform data base sheet for use by its subsidiaries in different countries. This was done in order to ensure standardisation in relation to the content of package inserts. At a later date Beecham prepared a further data base sheet comprising additional data that had been generated. Dr Kritzinger, Smith-Kline Beecham’s erstwhile medical director and the person responsible for the registration of medicines, made copious use of these documents in preparing the different inserts, first by compiling summaries and then by preparing synopses that ultimately comprised the insert, sometimes taking extracts verbatim from them. Drafts were also sent to other entities for comments and those received were incorporated. What cannot be gainsaid is that, in spite of this, he and his staff used their own

² The meaning of the term is discussed in *Klep Valves (Pty) Ltd v Saunders Valve Co Ltd* 1987 (2) SA 1 (A) 22H-23B.

language and skill to prepare the insert as a whole. He was able to identify particular paragraphs he had drafted personally but, in the light of the lapse of time, was no longer able to identify the lineage of each sentence. The work is essentially a compilation, something included within the definition of a literary work in the Act.

[7] The argument of Biotech on this issue amounts to this: a party claiming copyright has the evidentiary duty to identify those parts of the work for which originality is claimed; Smith-Kline Beecham had failed therein. Biotech relied upon a passage from *Jacana Education (Pty) Ltd v Fransden Publishers (Pty) Ltd* 1998 (2) SA 965 (SCA) 969E where it was pointed out that the existence of prior material tends to limit the scope of originality and requires more proof of its existence than would be the case with truly original works.

[8] Under the Act the inquiry is whether the ‘work’, in this case the compilation as embodied in the insert, was original. The inquiry is not whether its parts are original. A work may even be original if its making involves the

infringement of copyright in some other work (s 2(3)). A second version of any work is entitled to its own copyright provided it differs in substance from the first (i. e. is not a copy).³ Where, as in *Jacana*, a defendant does not copy the plaintiff's 'work' but takes from it parts that are primarily commonplace, the plaintiff's burden of proving originality in and infringement of his work may be more difficult than otherwise. In this case the position is different. It is common cause that Biotech substantially copied the 'work'. Had it copied only part of the document the position may have been different.

[9] The argument can be disposed of by means of an extract from *Ladbroke (Football) Ltd v William Hill (Football) Ltd* [1964] 1 All ER 465 (HL). Lord Reid said (at 469B-E):

'Broadly, reproduction means copying, and does not include cases where an author or compiler produces a substantially similar result by independent work without copying. If he does copy, the question whether he has copied a substantial part depends much more on the quality than on the quantity of what he has taken. One test may be whether the part which he

³ *Warwick Film Productions Ltd v Eisinger and Others* [1969] 1 Ch 508 presents an illuminating example.

has taken is novel or striking, or is merely a commonplace arrangement of ordinary words or well-known data. So it may sometimes be a convenient short cut to ask whether the part taken could by itself be the subject of copyright. But, in my view, that is only a short cut, and the more correct approach is first to determine whether the plaintiff's work as a whole is 'original' and protected by copyright, and then to inquire whether the part taken by the defendant is substantial. A wrong result can easily be reached if one begins by dissecting the plaintiff's work and asking, could section A be the subject of copyright if it stood by itself, could section B be protected if it stood by itself, and so on. To my mind, it does not follow that, because the fragments taken separately would not be copyright, therefore the whole cannot be. Indeed, it has often been recognised that if sufficient skill and judgment have been exercised in devising the arrangements of the whole work, that can be an important or even decisive element in deciding whether the work as a whole is protected by copyright.'

[10] STATE COPYRIGHT: The second issue, namely whether the copyright in the insert vests in the State, depends upon an interpretation of s 5(2) of the Act. The whole of s 5 may be quoted for contextual reasons –

'Copyright in relation to the state and certain international organizations

(1) This Act shall bind the state.

(2) Copyright shall be conferred by this section on every work which is eligible for copyright and which is made by or under the direction or control of the state or such international organizations as may be prescribed.

(3) Copyright conferred by this section on a literary or musical work or an artistic work, other than a photograph, shall subsist for fifty years from the end of the year in which the work is first published.

(4) Copyright conferred by this section on a cinematograph film, photograph, sound recording, broadcast, programme-carrying signal, published edition or computer program shall be subject to the same term of copyright provided for in section 3 for a similar work.

(5) Section 3 and 4 shall not confer copyright on works with reference to which this section applies.

(6) Copyright which vests in the state shall for administrative purposes be deemed to vest in such officer in the public service as may be designated by the State President by proclamation in the Gazette.

[11] The crisp issue is whether the insert was ‘made by or under the direction or control of the state’, it being accepted that the MCC is an organ of State.

Smith-Kline Beecham in an argument that found favour with Swart J relied for

purposes of interpretation upon a philosophy allegedly underlying the Act, namely that it seeks to create a system whereby the creator of an original work is afforded a qualified exclusive right to compensate him for the effort, creativity and talent expended and to act as an incentive for the creation of further and better works. It is convenient to give some background in order to assess the validity of the argument. In this regard Frank Muir's irreverent social history⁴ provides a useful introduction.

‘The biggest difficulty facing a would-be professional author at the opening of the eighteenth century was his lack of legal right to royalties on the sale of his books. Under the Romans, and well into the medieval period, the copyright in a manuscript belonged to whoever owned the piece of material it was written upon; it was a simple matter of owning a lump of tangible property. When printing came to England the government made haste to censor it by giving the Stationers' Company a monopoly on publishing, thus making the Stationers' Company the holder of all copyrights.

⁴ *The Frank Muir Book* 141-142.

Pressure built up during the latter part of the seventeenth century against the Stationers' Company monopoly, and strong pleas were made to successive governments to end it. The campaign eventually succeeded and in 1709 an Act, Statute 8 Anne, *c.* 19, was passed, the first in the world to give an author a right to his own property.

The booksellers who were behind the Act had no thought of bringing prosperity to the trade of author; it was a monopoly-breaking move for the benefit of the bookselling trade and authors were merely the excuse for it. By the wording of the act an author owned the copyright of his work, but the action of having it published gave the bookseller fourteen years exclusive rights in the work, after which the rights were supposed to revert to the author. In effect this meant that once the booksellers had paid the author a few guineas for the copyright, they could exploit the property, or barter it among themselves, for a period of fourteen years without necessarily paying anything more to the author:

What Authors lose, their Booksellers have won,

So Pimps grow rich, while Gallants are undone.

Alexander Pope (1688-1744)'

[12] The present Act, in its original form, attempted to be kinder to authors.

The concept of 'copyright' was replaced with an author's right, the 'ownership'

of which vested principally in the author. In this and other regards the object was to move in the direction of Continental law where the emphasis is on the rights (moral and other) of the author and not on the economic rights of employers and entrepreneurs. The good intentions did not last and hardly a year had passed when the Legislature (by amending s 21) reverted, as far as ownership was concerned, to the Anglo-American model where commercial rights tend to reign supreme. The definition of ‘author’ in s 1 also covers a large number of persons who, in the ordinary sense of the word, are not authors but persons with financial interests in the end result. For instance, the author of a computer program is the person who exercised control over its making. One consequently does not have to be a cynic in order to be sceptical about the philosophical premise.

[13] It is likewise difficult to establish historically any philosophy behind the recognition of State copyright. As Frank Muir made clear, copyright was initially nothing more than the right to copy and that right related to the right to

print, something the Crown by divine intervention had or approbated. For instance, the Crown had the prerogative of printing and publishing statutes.⁵

The Crown also laid special claim to the perpetual copyright in the Authorised English Translation of the Bible and the Common Book of Prayer. The Copyright Act of 1842⁶ made no reference to Crown copyright and it was then open to doubt whether the Crown could have enforced a perpetual copyright in works compiled by its servants, or whether it could only have claimed the term of copyright granted by that Act.⁷ It is probably against that backdrop that s 18 of the British Copyright Act of 1911, which became law in South Africa by virtue of the 1916 Act,⁸ was enacted. It provided that where any work was – ‘prepared or published by or under the direction and control of His Majesty or any Government department, the copyright shall, subject to any agreement with the author, belong to His Majesty, and in such case shall continue for a period of fifty years from the date of first publication of the work.’

⁵ *The Attorney-General for New South Wales v Butterworth & Co (Australia) Ltd* [1937-1938] 38 NSW State Reports 195.

⁶ 5 & 6 Vict. c. 45.

⁷ MacGillivray *A Treatise upon the Law of Copyright* (1902) 59-61.

⁸ Patents, Designs, Trade Marks and Copyright Act 9 of 1916, Third Schedule.

[14] Pursuant to the wording used in the 1956 UK Copyright Act, the Copyright Act 63 of 1965 provided for vesting of copyright in the State if the relevant work was ‘made by or under the direction or control’ of the government or State (s 39). This is the antecedent for the wording used in the present Act. The change from ‘prepared’ to ‘made’ does not appear to be of any significance.

[15] The general structure of the 1978 Act, excluding detail, is the following. Conferral of copyright and ownership of copyright do not necessarily coincide. Copyright can be conferred under three alternative circumstances: first, on a work made by a ‘qualified’ author (s 3); second, if the work is not made by a qualified author, by first publication (s 4); and third, on a work made by or under the direction or control of the State (s 5(2)). The initial ownership of copyright conferred by s 3 or 4 vests in the author unless the work was made in the course and scope of an employment contract or was commissioned (s 21(1)). If conferred by s 5, it vests in the State and not in the author (s 21(2)).

[16] Smith-Kline Beecham argued that it can be deduced from this structure that State copyright under s 5(2) is only conferred upon works that are ineligible for copyright under s 3 or s 4 because the State is not a ‘qualified person’ (qualified persons must either be individuals or incorporated juristic persons). I disagree. A work falling under s 3 or 4 and authored by an employee of the State in the course and scope of an employment would, irrespective of s 5, vest in the State under s 21(1)(d). In addition, as far as ranking is concerned, it should be noted that a work qualifying for State copyright is not entitled to copyright under either s 3 or 4 (s 5(5)). This implies that one has first to consider whether the work was made under the circumstances of s 5(2) and only if not, under s 3 or 4 but that does not mean that s 5(2) should not be interpreted restrictively. Allowing the State without more to reap what it did not sow does not appear to be in the spirit of our constitutional values.

[17] The UK provisions were the subject of two judgments;⁹ neither of which is of material assistance in the present case. Textbook writers generally only touch on the topic. Copyright no doubt vests in the Crown irrespective of whether the actual author was under a contract of service with the Crown.¹⁰ The provision is broad and may in certain circumstances apply to works made by a person under contract with the State.¹¹ Some argue that works made by State employees in the course of their duties are made under the ‘control’ of the State and that works made by independent contractors are made under the ‘direction’ of the State.¹² Whether a commissioned work falls under either appears to be open to debate.¹³

[18] It is not that clear whether the phrase ‘by the state’ was intended to cover works of organs of State only or also the works of employees. All the statutes since 1911, when dealing with employees generally, used the hackneyed phrase

⁹ *British Broadcasting Company v Wireless League Gazette Publishing Company* [1926] 1 Ch 433; *Ironside v HM Attorney-General* [1988] RPC 197 (Ch D).

¹⁰ Skone James *Copinger on the Law of Copyright* 6th ed (1927) at 248-249

¹¹ Alan Smith *Copyright Companion* 11.

¹² Laddie, Prescott and Vitoria *The Modern Law of Copyright and Designs* 2 ed I par 22.10.

¹³ *Ibid.* Also *Lester and Mitchell Johnson-Hicks on UK Copyright Law* (1989) 69.

‘in the course of the author’s employment’ (or something similar). Why a different wording should have been used in relation to State employees is unclear. It is fortunately not necessary to consider the scope of that expression because Biotech, rightly, did not submit that the work was made ‘by’ the MCC. Smith-Kline Beecham, however, argued that the use of the preposition indicated that State copyright could only arise where a work is made ‘for or on behalf of’ the State. The argument loses sight of the fact that the ‘by’ does not govern either ‘direction’ or ‘control’. They are governed by the preposition ‘under’. Clearly, an important pointer in assessing whether State copyright vests or not may be whether the work was made for or on behalf of the State but that is not the conclusive indicator.

[19] There was some argument on whether the work was made ‘under the direction’ of the State. In my judgment the State did not direct the making of the insert because it did not initiate its making and it did not prescribe the manner and means to be employed therein. The provision is consequently

inapplicable. That leaves the question of ‘control’. In this regard Biotech relied heavily on a number of decisions that deal with the meaning of the word in other statutory contexts, especially those that held that the power to control an activity may include the power to restrain and even veto it;¹⁴ consequently, since the MCC had the power to approve or disapprove the insert, it was made under its control.

[20] Apart from the fact that the ultimate decision whether or not to accept the MCC’s recommendations or to use the insert is that of the applicant, the major problem with the approach is that it focuses on the meaning of a word in isolation.¹⁵ The issue is not whether the MCC had the power to approve or disapprove the insert but whether the insert was *made* under its control. This appears to be a factual rather than a legal issue. An insert is of the utmost commercial importance to a pharmaceutical company. Not only is it required for purposes of registration of a medicine but it is also the ‘passport’ of the

¹⁴ E. g. *Van Rooy v Law Society (OFS) and Another* 1953 (3) SA 580 (O).

¹⁵ *Commissioner, South African Revenue Service v Dunblane (Transkei) (Pty) Ltd* 2002 (1) SA 38 (SCA) par 13.

medicine because it is the document that prescribing medical practitioners will have regard to in deciding whether or not to prescribe any particular medicine.

In this case Dr Kritzinger prepared the draft insert in his capacity as employee of Smith-Kline Beecham. As soon as it was completed, s 3 conferred copyright thereon as a literary work of which Smith-Kline Beecham was the owner by virtue of s 21(1)(d). Thereafter the draft was submitted to the MCC for its approval. During the approval process Smith-Kline Beecham amended the document, sometimes upon the suggestion or request of the MCC but, as conceded by Biotech, the MCC did not change the substance of the insert nor did it co-author the end result. Copyright once conferred in any particular work cannot again be conferred on the same work and copyright once vested in a party remains so vested unless transmitted under s 22.

[21] In order to meet this consequence Biotech submitted that once Dr Kritzinger conceived of the idea to prepare an insert he thenceforth acted under the control of the State. The proposition merely has to be stated to be rejected.

The anomalies abound. It would for instance mean that if Smith-Kline Beecham had decided not to submit the insert to the MCC, the copyright therein would still have vested in the State, it being blithely unaware that it had controlled the making of the work. If Beecham had prepared the leaflet in the UK for use in its UK application and had submitted it to the UK authorities, copyright would have vested in either Beecham or the UK government. Beecham would then have required the UK government's licence to submit the insert to the MCC and upon submission to the latter, copyright would have been transferred to the South African government.

[22] I prefer to adopt and adapt Ricketson's¹⁶ approach: the production of the work needs to be the principal object of State direction and control and not merely an incidental or peripheral consequence of some generalised governmental licensing or monitoring power; the direction and control should be directly and specifically expressed with respect to the work in question, and

¹⁶ Ricketson *The Law of Intellectual Property: Copyright, Designs & Confidential Information* par 14.180.

should not be inferred from the fact of some residual or ultimate government veto. On the facts of this case, the MCC did not ‘control’ the making of the work or the intellectual effort involved in its genesis; it controlled its fate to the extent that it had to determine administratively whether the insert complied with the regulations. Its statutory function is to control the sale of medicines and not to be the controlling mind behind the creation of the insert. An editor is not an author and even if ‘the meaning of a word is always another word’,¹⁷ control does not mean cooperation or consultation, at least not in the present context.

[23] I therefore agree with Swart J that the copyright in the insert vests in Smith-Kline Beecham and the appeal must consequently be dismissed. It would not be out of order to say something about the concerns of the MCC. It joined the Biotech team by claiming through its deponents that the ‘whims’ of copyright law should not interfere with its policies. It insists that the same medicines should have identical inserts. That may be a commendable ideal but

¹⁷ Harold Bloom *The Western Canon* 63-64.

it does not entitle it to disregard other parties' proprietary rights, in this case based upon statute. The evidence also establishes that identical inserts are not necessary and that at least one other competitor was able to produce an insert acceptable to the MCC that was not a copy of Smith-Kline Beecham's insert. This is not a case where the information can be presented in only one format, for instance, a mathematical formula, the batting list of a cricket team or an alphabetical list of the members of a society and it was thus unnecessary to consider whether or not this factor may affect the conferral of copyright.

[24] The appeal is dismissed with costs, including the costs consequent upon the employment of two counsel.

L T C HARMS
JUDGE OF APPEAL

AGREE:

NIENABER JA
ZULMAN JA
NAVSA JA
NUGENT JA