

LAWS 489 : LEGAL WRITING.

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LX HU HUSTWICK, C.M. Amoxicillin: useful selection or unjustified monopoly?

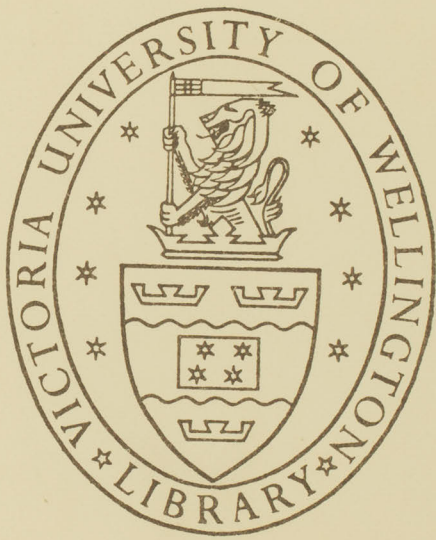


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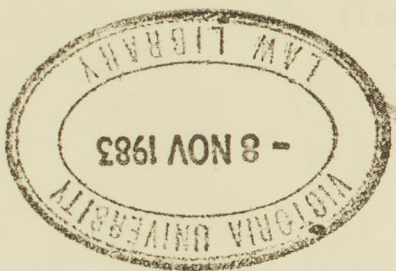
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A publication may disclose a class of chemical substances, in general terms. Subsequently, an inventor may single out selected compound(s) as having some special property not possessed by the class as a whole. This creates a problem with regard to the competing rights of the original publisher, the later inventor and the general public: specifically, what patent monopoly (if any) is the later inventor entitled to? This paper examines a recent New Zealand judgment, which was concerned with this problem (admittedly in a limited sense, as the original publisher and the later inventor were the same company, or employees thereof).

I. INTRODUCTION

A. Background

1. History of the case

A patent application in New Zealand undergoes the following procedure on its passage to eventual grant:

- (a) Filing of the application, accompanied by a specification - sections 8 and 9.
- (b) Examination - section 12.
- (c) Acceptance (after any objections arising from step (b) have been overcome) - section 20(1).
- (d) Publication - section 20(2).
- (e) Possible opposition, by any interested party - section 21.
- (f) Grant of the patent (after any opposition, in step (e), has been overcome) - section 27.

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The case under review relates to one of Beecham's patent applications. Beecham filed Application No. 157516 in New Zealand on 18 August 1969. The application related to Amoxycillin, a synthetic penicillin. Being a convention application, it claimed priority from the corresponding application filed in the United Kingdom on 23 August 1968.¹ The New Zealand application was accepted on 24 February 1972. The monopoly sought is defined by the claims of the complete specification. The claims of the accepted specification were as follows:

Claims 1-3: Amoxycillin and its salts and hydrates.

Claims 4-5: A synergistic combination of one of these compounds with a penicillin.

Beecham's application was opposed by Bristol, initially on three grounds. The ground of insufficiency had been dropped by the time the case reached the Court of Appeal; the opposition at this stage of the proceedings was on the grounds of prior publication and obviousness, only. For both grounds, the document relied on was Beecham's British Patent No. 978,178 (hereafter referred to as the "Beecham OMP patent"). That patent was published on 5 May 1965 (i.e. before the priority date of the application in suit). The Beecham OMP patent has a general formula which includes Amoxycillin (and various other compounds) within its scope. The preparation of Amoxycillin is not specifically disclosed.

The outcome of the opposition proceedings was that Beecham's patent was sealed on 21 October 1982. However, the patent monopoly granted was considerably more restricted than that which had been applied for.

2. General

The synthetic penicillin compound, Amoxycillin, has been a resounding commercial success. According to a Bristol affidavit, Amoxycillin trihydrate² topped the list of major drug prescriptions (other than hospital medicines) in New Zealand for the year ended 31 March 1979.³ A valid patent gives the owner the right to stop others from using his invention,⁴ unless a licensing agreement has been entered into. Amoxycillin is a widely-used and effective medicinal compound, so the patent rights had a commercial value which was worthy of a full-scale legal battle. As stated in the Court of Appeal judgment in the case under review, delivered by Cooke J.:⁵

"Amoxycillin has proved such a successful drug that it has led to litigation on almost a global scale between the parties. Litigation has taken place in at least 14 countries. The results have varied and in most countries appeals are still pending."

Some of the more significant overseas proceedings are summarised below, in Parts 3-5.

3. British contract case : Beecham Group Ltd. v. Bristol Laboratories International S.A.⁶

This case related to a licence agreement between the same parties (i.e. Beecham and Bristol) in 1959. The question in issue was whether Beecham were obliged to add the Beecham OMP patent and U.K. Patent No. 1,241,844 (the British Amoxycillin patent) to a list of scheduled patents, as inventions existing in

1959. The relationship between the Beecham OMP patent and the British Amoxycillin patent was not analysed to any great extent. The conclusion was that the subject matter of the Beecham OMP patent had not been invented in 1959. Hence, any subsequent developments described in the British Amoxycillin patent could not have been invented then.

4. British opposition case : Beecham Group Ltd.'s (Amoxycillin) Application⁷

As in New Zealand, an initial claim was made to the compound itself, unrestricted to method of use. During the examination stage, however, the claim was amended to relate to a pharmaceutical composition adapted for oral administration to human beings, containing Amoxycillin as an active ingredient. Bristol's opposition on the grounds of prior publication and obviousness was rejected by a majority of the Court of Appeal.

5. Australian Amoxycillin application : Beecham Laboratories Pty. Ltd.'s Application⁸

Beecham's Australian application, as accepted, contained similar claims to its New Zealand counterpart. Bristol opposed the application. As a result of Bristol's submissions, the Assistant Commissioner required the claims to be restricted. The claims were accordingly amended along the same lines as in the British opposition case. The patent which was granted contained claims to pharmaceutical compositions adapted for oral administration, but no claims to the active compound per se.

B. Nature of the Proceedings

Accepted patent applications are advertised in the Patent Office Journal, in the form of abridgements. Abridgements give brief descriptions of the subject matter. The actual complete specifications ~~are~~ made available⁹ for members of the public to inspect at the same time as the Journal is issued.

The provisions for opposition to the grant of a patent are set out in section 21 of the Patents Act 1953. Within three months of the date of publication of the complete specification, any person interested may give notice, to the Commissioner, of opposition to the grant of the patent on any of the ten specified grounds.¹⁰ Such proceedings provide a means for anyone with "a real, definite, and substantial interest"¹¹ to oppose the grant of the patent.

Opposition would appear to be an important adjunct to the pre-acceptance examination carried out in the Patent Office¹² - the ground relied on can be something which was either missed or not fully argued during examination, or some matter (e.g. obviousness) which could not be raised at that stage.

However, although oppositions are by no means uncommon, some authorities are dubious about the value of such proceedings.¹³ The benefit of any doubt must be given to the applicant. If the patent is granted, the unsuccessful opponent can still bring a revocation action;¹⁴ an unsuccessful applicant has no comparable "second chance." Thus, a contested opposition will usually result in an amendment to the specification, rather than an outright refusal to grant the patent. The amendment is more likely to strengthen, rather than weaken, the resulting patent.

The statutory grounds relied on in the case under review are as set out in paragraphs (b) and (e) of subsection (1) of section 21:

"(b) That the invention, so far as claimed in any claim of the complete specification, has been published in New Zealand before the priority date of the claim -

(i) In any specification filed in pursuance of an application for a patent made in New Zealand:

(ii) In any other document ...

(e) That the invention, so far as claimed in any claim of the complete specification, is obvious and clearly does not involve any inventive step having regard to matter published as mentioned in paragraph (b) of this subsection, or having regard to what was used in New Zealand before the priority date of the applicant's claim "

(emphasis added).

Only novelty within New Zealand, and not worldwide novelty, is required.

The Beecham OMP patent was a document within subparagraph (ii) of paragraph (b).

C. Role of the Scientific Adviser

Where matters of some technical difficulty are being considered, there is a provision for an independent scientific adviser to be appointed by the court or judge, at its or his discretion or after request by all parties to the proceedings.¹⁵ The job of the scientific adviser is to "inquire and report upon any questions

of fact or opinion not involving questions of law or construction". The scientific adviser must remain strictly neutral; it is not his place to judge the case.

This was the first New Zealand case in which such an adviser had been appointed. Professor R.J. Ferrier, Professor of Organic Chemistry at Victoria University of Wellington, was appointed for the Supreme Court hearing, and his services were retained for the subsequent appeal. He provided technical advice when required, rather than furnishing a formal report.¹⁶

Bristol were opposed to the appointment of a scientific adviser. Their counsel submitted that "the adviser could readily transgress the limits of his proper role and express views to the Judge which the parties may wish to challenge but would have no opportunity of doing".¹⁷

Certainly, the use made of the scientific adviser during the Supreme Court proceedings would have done nothing to allay Bristol's fears. The scientific adviser was consulted between the time of the hearing and the issuance of the judgment. Neither party would be aware of the content of these discussions. Doubtless, the consultation related only to technical matters, and did not influence the decision. However, it is submitted that justice should not only be done, but be seen to be done.¹⁸

D. Prior Proceedings

1. Decision of the Commissioner¹⁹

It was held that Claim 1 (the claim to the compound per se) had been anticipated by the Beecham OMP patent. All the claims were deemed to be obvious, having regard to the disclosure in that

document. The Assistant Commissioner (who was the hearing officer in this case) could not "envisage any amendment of the claims which would save the application".²⁰

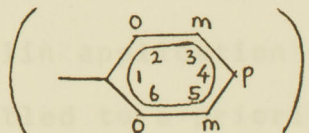
2. Supreme Court judgment²¹

Barker J. completely overturned the Assistant Commissioner's decision. He held that there had been no prior publication and that Bristol had "not discharged its onus under s 21(1)(e) of the Act [of showing] that the invention was obvious and clearly [did] not involve any inventive step".²² The Commissioner was directed to seal Beecham's patent.

II. RELEVANT SPECIFICATIONS : CHEMICAL BACKGROUND

The penicillin compound, Ampicillin (disclosed in U.K. Patent Specification No. 902,703 and its New Zealand counterpart, No. 129316) had been both widely-used and effective. Any contender to take its place would need to be at least as effective.

The Beecham OMP patent related to compounds derived from Ampicillin by the addition of a hydroxy group (-OH) to the benzene ring



present in the parent molecule.

There are three possible positions at which the hydroxy group can be added, i.e. o (ortho), m (meta) and p (para), as shown in the preceding diagram. (Position 2 is equivalent to position 6, and position 3 is equivalent to position 5.) There are thus three completely separate compounds (structural isomers), each having different physical and chemical properties.

A further complication arises because each of these three compounds contains (in a different part of the molecule) what is termed an "asymmetric centre". Hence, each compound is capable of resolution into two mirror images, which are termed optical isomers or epimers and may be labelled as dextro (+) and laevo (-). Epimers have identical physical and chemical properties, except for different reactions with other asymmetric compounds etc. That exception is an important one. It is well-known, in the pharmaceutical industry, that one optical isomer may form a more effective medicament than the other.

The Beecham OMP patent disclosed all three structural isomers, each as a mixture of its two epimers. No specific method was given for isolating the individual epimers. The Beecham OMP patent was published in New Zealand on 5 May 1965. A corresponding New Zealand patent had not been applied for.

The specification in suit (No. 157516) relates to the (-) epimer of the p-hydroxy compound, i.e. Amoxycillin. Amoxycillin had not been specifically disclosed in the Beecham OMP patent, but was within the ambit of the general formula depicted therein.

The Amoxycillin application was a convention application, thereby entitled to a priority date of 23 August 1968. This priority date was later than the date on which the Beecham OMP patent was published in New Zealand. It was not, therefore, possible to overcome the prior publication and obviousness objections merely by showing that the Amoxycillin application's priority date was earlier than the publication date of the cited document.

III. ISSUES

A. Prior Publication

1. Meaning of the term

A prior publication must anticipate the invention as claimed, i.e. it must disclose all the features of the claimed invention.

2. Statutory provisions

According to section 21(1)(b)(ii), prior publication is the publication in New Zealand, before the priority date of the claim in question, of the invention, as claimed in any claim of the complete specification. The publication can be in "any ... document" (with some exceptions, which are not relevant in this case).²³

3. Case law

(a) Hill v. Evans²⁴

This case contains a useful discussion of what constitutes prior publication. In order to anticipate an alleged invention, the antecedent statement must contain sufficient information to allow "a person of ordinary knowledge of the subject"²⁵ to put the discovery into practice. Additional experimentation should not be necessary. If further practical details need to be worked out before applying the discovery, this "affords sufficient room for another valid patent".²⁶

Even if a document suggests to the person skilled in the art that the preparation of a particular compound would be advantageous, it may be possible to obtain a valid patent if the method of preparation was not immediately apparent from that document.

(b) General Tire & Rubber Co. v. Firestone Tyre and Rubber Co. Ltd.²⁷

If the anticipation is by prior publication, both documents (i.e. the specification in suit and the alleged prior publication) must be construed as at their relevant publication dates.²⁸

"To anticipate the patentee's claim the prior publication must contain clear and unmistakeable directions to do what the patentee claims to have invented ... A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee."

This extract emphasises the difference between prior publication and obviousness. If the earlier publication gives a clear indication that it would be desirable to follow a certain line of research, the later specification may be obvious, but will not have been prior published.

(c) British contract case : Beecham Group Ltd. v. Bristol Laboratories International S.A.²⁹

The House of Lords was not obliged to determine the validity or otherwise of any of the patents involved. The issue was whether, under a licence agreement between the two parties, Beecham were bound to add the Beecham OMP patent of 1962 and the Amoxycillin patent of 1968 to a list of scheduled patents, as inventions existing at the date of the agreement (i.e. in 1959). It was considered that there was no invention in a particular penicillin compound until it had been produced and its therapeutic characteristics had been ascertained.

(d) E.I. Du Pont de Nemours & Co. (Witsiepe's) Application³⁰

The difference between the language used in the revocation provisions³¹ and the opposition provisions³² is alluded to.

According to the revocation provisions, "what is alleged to have been anticipated must lack novelty 'having regard to what was known or used' before the priority date of the patent in question".³³

The opposition provisions could not have a wider scope than those for revocation. The applicant must be given the benefit of any doubt at the opposition stage, because (unlike the opponent) he would have no further opportunity to present his argument.

(An unsuccessful opponent can still apply for revocation.)

"[C]onsequently, 'has been published' in [the opposition provisions] must be construed as restricted to publication in circumstances in which what is alleged to have been published can be said to have been 'known or used'."³⁴

A compound which has been predicted, but not actually manufactured, is not a "known substance". Merely listing compounds within a general formula, without having manufactured them, would not amount to anticipation of those compounds.

4. Test for prior publication

In the case of a chemical compound, it would appear that the compound has not been anticipated until it has actually been produced, and at least some of its properties have been specified. The subject matter of the specification in question must have been entirely disclosed in the earlier document. "A signpost ... upon the road to the patentee's invention"³⁵ is insufficient.

5. Decision

The objection of prior publication failed. Counsel for Bristol had argued that Amoxycillin was disclosed in the Beecham OMP patent as one of the two epimers in the p-hydroxy mixture. This argument was rejected. Amoxycillin had not been separately made or isolated. It would have been difficult, if not impossible, to isolate it from the mixture. Amoxycillin is normally manufactured directly from the appropriate epimeric forms of the starting materials (6 - aminopenicillanic acid and α - amino - p - hydroxyphenylacetic acid).

The writer submits that the decision in regard to this matter is correct. The case law makes it clear that it is insufficient for an alleged anticipating document to merely refer to the compound in question. It must be apparent from the document that the compound has been produced.³⁶ Preferably, a method of preparation and/or some properties of the compound will have been specified.

Amoxycillin had not previously been produced (except as part of a mixture comprising equal amounts of another compound, from which it could not readily be isolated). Therefore, it had not been prior published.³⁷

B. Obviousness

1. Meaning of the term

An invention is obvious if it lacks an inventive step. As this is a difficult test to apply, many attempts have been made to paraphrase the requirement. However, British courts have warned "against treating the words of much-quoted decisions as if they

were the words of a statute "³⁸ Obviousness is to be "judged by the standard of a man skilled in the art concerned : competent, 'good at his job', but not imaginative or of an inventive turn of mind "³⁹

Various factors, e.g. fulfilment of a long-felt want, commercial success etc., can be advanced as arguments against the obviousness of the invention. How convincing such arguments will be depends upon the court's assessment of the whole situation. Commercial success, for instance, may arise more from advertising than from the intrinsic merits of the invention.

There is a danger that any invention may seem obvious in hindsight. Often, it is fairly simple to work back from the specification and see how the inventor gleaned his idea from various sources. This may not, however, mean that the idea was obvious when first proposed by the inventor.

2. Statutory provisions

The grounds for opposition and for revocation are not identical. Section 21(1)(e) (opposition): "That the invention ... is obvious and clearly does not involve any inventive step having regard to matter published ... or having regard to what was used in New Zealand before the priority date of the applicant's claim" (emphasis added).

Section 41(1)(f) (revocation): "That the invention ... is obvious and does not involve any inventive step having regard to what was known or used before the priority date of the claim in New Zealand ".

The ground for opposition cannot be wider in scope than the ground for revocation.⁴⁰ A specification should not be struck down for obviousness at the opposition stage, unless it is reasonably certain that it would not withstand a full-scale revocation action.

3. Selection patents

If a class of chemical substances has been disclosed in general terms, a later inventor may single out a selected group as having some special property not possessed by the class as a whole. A selection is only possible if no member of the selected group has been specifically disclosed before.

4. Case law

(a) Sharp & Dohme Inc. v. Boots Pure Drug Co. Ltd.⁴¹

Lord Hanworth M.R. quoted Mr. Cripps as counsel:⁴²

"[W]as it for all practical purposes obvious to any skilled chemist in the state of chemical knowledge existing at the date of the patent which consists of the chemical literature available ... and his general chemical knowledge, that he could manufacture valuable therapeutic agents by making the [compounds in question]?"

This has henceforth been known as the "Cripps question".

Applying this test to the application in suit, it would appear obvious, following publication of the Beecham OMP patent, that the manufacture of Amoxycillin could result in a "valuable therapeutic agent". However, this may not be sufficient. It was strongly argued that it was not obvious to concentrate resources on this line of research, rather than on other equally "obvious" possibilities.

(b) I.G. Farbenindustrie A.G.'s Patents ⁴³

Maugham J. cautioned that a selection patent was not inherently different from any other type of patent. It was still "open to attack on the usual grounds of want of subject-matter, want of utility, want of novelty and so forth".⁴⁴

However, he laid down three requirements for selection patents, which have been generally approved in subsequent decisions, and have acquired an authoritative nature:⁴⁵

"First, a selection patent to be valid must be based on some substantial advantage to be secured by the use of the selected members Secondly, the whole of the selected members must possess the advantage in question. Thirdly, the selection must be in respect of a quality of a special character which can fairly be said to be peculiar to the selected group."

(c) Johns-Manville Corporation's Patent ⁴⁶

Diplock L.J. warned against paraphrasing the words of the Act. No single verbal formula was likely to be appropriate in all cases. However, he felt that "it is enough that the person versed in the art would assess the likelihood of success as sufficient to warrant actual trial".⁴⁷ If so, the invention is obvious.

Obviousness will, therefore, depend very much on the facts of the case. This test does not help in the case under review - the "likelihood of success" was a contentious point.

(d) Imperial Chemical Industries Ltd. (Howe's) Application ⁴⁸

This was a very similar case to the present one. The issue was whether a claim to an optically active isomer was obvious in the light of prior disclosure of racemic mixtures. It was held that, as there was nothing in the cited documents or elsewhere to suggest that resolution of the racemic mixture into its individual isomers might result in any benefit, the objection as to obviousness failed.

The first two grounds for distinguishing this case given by the Assistant Commissioner in his decision on the Amoxycillin case are of minor importance. However, as he rightly pointed out in his third ground, the benefits of isolating the individual compounds from a mixture of epimers are well-known in penicillin chemistry. Often, one epimer is found to be more effective than the other.

(e) British contract case : Beecham Group Ltd. v. Bristol Laboratories International S.A. ⁴⁹

The chain of appeal proceedings reached the House of Lords. In that judgment, Lord Wilberforce commented on chemical selection patents. He expressed the view that a general claim for therapeutic and antibiotic properties would not invalidate a "subsequent more specific claim for specific properties".⁵⁰ The latter claim would constitute a different invention to that of the originating patent.

(f) British opposition case : Beecham Group Ltd's (Amoxycillin) Application⁵¹

Browne L.J. considered that the particular factual situation was important.⁵²

"Beecham's behaviour [in following several lines of research, and not merely concentrating on the preparation of Amoxycillin] seems to me completely inconsistent with that of anyone who thought it was obvious that further research into the [Beecham OMP patent] penicillins and in particular the para-minus epimer, might well produce the winner in the race to find a new and better successor to Ampicillin."

He felt that neither the applicants nor the opponents had shown any particular interest in the subject matter of the Beecham OMP patent, when it was published. Browne L.J. concluded that the opinions as to obviousness given by Bristol's experts had "a strong element of hindsight, the dangers of which in this context are well known."⁵³

Templeman L.J. presented a dissenting judgment. Beecham had argued that the inventive step lay in the preparation of Amoxycillin and the discovery of its high blood level absorption characteristics. According to Templeman L.J., this was not an inventive step in the light of the disclosure of the Beecham OMP patent. The subject matter of the Amoxycillin application was merely the result of routine testing. "[I]t was obvious that the best epimer [from the Beecham OMP patent] should be identified and tested in the form of a composition suitable for oral administration to human beings."⁵⁴

The majority and minority judgments disagree on whether the preparation of Amoxycillin was the result of following a non-obvious line of research, or was merely the result of routine testing. Templeman L.J. addressed his judgment to the further problem of the scope of the claims. Were the applicants entitled to claim compositions containing Amoxycillin, which were limited only to being suitable for oral administration (i.e. the form in which any compound from the Beecham OMP patent might be expected to be administered)?

5. Test for obviousness

Tests derived from earlier cases may offer guidance, but should not be relied on. In the end, it is perhaps better to just look to the dictionary meaning of "obvious", i.e. "very plain".⁵⁵ Obviousness is a question of fact. All relevant circumstances should be considered.

6. Decision

In an opposition, the onus is on the opponent to show that the invention is obvious and clearly does not involve any inventive step. Bristol had not discharged that onus.

Pharmaceutical research is long and expensive. Testing of a compound involves six separate stages, culminating in full toxicological study and clinical trials.⁵⁶ The Beecham OMP patent was applied for in Britain in 1962, but it was not until 1968 that Amoxycillin was tested in man and found to produce substantially higher blood levels than Ampicillin.

Although Amoxycillin was the culmination of an obvious line of research, the invention itself was deemed not to be obvious, and to involve an inventive step, as a sufficiently distinctive advantage had been discovered.

C. Scope of the Patent

1. Case law : The Mullard Radio Valve Co., Ltd. v. Philco Radio and Television Corporation of Great Britain, Ltd.⁵⁷

An inventor is "not entitled to claim a monopoly more extensive than is necessary to protect that which he has himself said is his invention".⁵⁸ The invention lay in the discovery that a particular juxtaposition of components gave new and useful results. Therefore, the article was to be claimed with reference to that juxtaposition, only.

2. Decision

In the case under review, the invention lay in the unique advantage of Amoxycillin, i.e. its high oral absorbability in man. It was this advantage which overcame the objection of obviousness and lack of inventive step. Accordingly, the scope of the patent should be limited to the use of the compound in a composition for oral administration to human beings.

Bristol's appeal was allowed, but only to a limited extent. The patent should not be sealed in the form initially applied for. The claims should be appropriately restricted.

3. Subsequent events

By order of the Court of Appeal, the claims of the Amoxycillin specification have now been amended. The present claims take the

same form as those allowed in the United Kingdom, Australia, and also South Africa. The principal claim, as amended, reads:

"A pharmaceutical composition adapted for oral administration to human beings containing as an active ingredient [Amoxycillin] or a non-toxic ... salt thereof, the said [Amoxycillin or salt thereof] being substantially free of the corresponding (+) epimeric form."

IV. RATIO

There may be a valid selection patent derived from a relatively small originating class of compounds, provided that:

1. The particular compound(s) selected have not been actually produced previously.
2. The selected compound(s) share an unexpected and useful property, which is stated in the specification and is not possessed by other members of the originating class.
3. Sufficient time and labour has been involved in producing the compound(s) and determining the property selected for.
4. The scope of the claimed invention is appropriately limited. The compound(s) per se cannot be claimed. The claims must have some link with the property selected for.

The first two factors are the normal standards for any selection patent. The remaining factors are additional standards, necessary because the selection is made from a relatively small originating class.

V. CONCLUSIONS

A. Was the Decision Reasonable and Fair?

In attempting to answer this question, two hypothetical situations and the actual situation pertaining in New Zealand will be considered.

1. What if the earlier publication had been a current New Zealand patent, not belonging to Beecham? How would the earlier patentee feel? It is probably reasonable to reward the time and effort taken to produce the particular preferred isomer, especially as its favourable properties were not apparent until after it had been produced. However, the claims which were eventually allowed were only limited to compositions "adapted for oral administration" - this is probably the most common form of administration of penicillin compounds. If the actual compound could not be claimed on the grounds of obviousness, might not the patentee be somewhat disgruntled at the allowance of claims to the compound's principal (and obvious, for a penicillin compound) use? This situation would be ameliorated to some extent, as the Amoxycillin patent would be prior-claimed by the earlier patent.⁵⁹ As each patentee, in marketing Amoxycillin, would be infringing the other's patent, they would need to come to a cross-licensing arrangement.
2. What if the Beecham OMP patent had actually been a New Zealand patent, still in Beecham's name (cf. the situation in the United Kingdom)? Is it fair to allow an extension of

the monopoly period by means of such a selection patent? Should the later patent be limited to a patent of addition,⁶⁰ which would expire at the end of the main patent's term? However, such a limitation would seem to be unwarranted in view of the Court of Appeal's decision with regard to obviousness.⁶¹

3. The actual New Zealand situation. Beecham neglected to file a New Zealand equivalent to the Beecham OMP patent. Is it fair that they should be granted a monopoly by this indirect method (through the Amoxicillin patent)?

As with any selection patent, there is an element of "unfairness" in this decision. The unfairness is more evident in this case, because the use of the selected compound has not been limited to one which would be inappropriate for other members of the originating class.

B. Significance : Interpretation of Chemical Specifications

It is common for chemical specifications to include general formulae, covering many possible compounds. A patentee may not have a complete monopoly, except with respect to compounds which have been actually produced, and for which some properties have been specified. However, the decision in this case has probably not drastically changed the prevailing situation. This problem has existed since the introduction of the concept of a "selection patent".⁶²

C. Was the Decision Correct?

There may be some justification for allowing a selection from a fairly limited originating class, especially in the pharmaceutical field, where testing standards are rigorous. However, with regard to obviousness, the dissenting judgment of Templeman L.J. in the British opposition case⁶³ is convincing.

In the present case, it was held that the claims should have some link with the property selected for. The amended claims do not appear to satisfy this requirement. Any compound within the scope of the originating Beecham OMP patent might be expected to be administered in the form of "[a] pharmaceutical composition adapted for oral administration ...". The invention as claimed does not relate to an unexpected property of Amoxycillin.

It is difficult to see how this objection could be overcome. The actual unexpected property is high oral absorbability in man. This is an intrinsic property of the compound, rather than a pointer to any particular formulation more limited in scope than that of the presently-allowed claims. Claims to "[a] pharmaceutical composition adapted for oral administration to human beings and having high oral absorbability in human beings ..." would, in practical terms, be identical to the present composition claims.

In conclusion, it would appear that a valid selection can be made in a case similar to that of Amoxycillin, but only if the property involved is substantially different from the properties of the other compounds of the originating class. The property which validates the selection must be apparent from the invention as claimed.

FOOTNOTES

- 1 Patents Act 1953, s.11(4).
- 2 The trihydrate is the normal form in which Amoxycillin crystallises.
- 3 [1981] 1 N.Z.L.R. 600, 609.
- 4 By way of an action for infringement.
- 5 [1981] 1 N.Z.L.R. 600, 601.
- 6 [1978] R.P.C. 521.
- 7 [1980] R.P.C. 261.
- 8 Unreported. A copy of the decision was obtained from a reliable source.
- 9 In the Patent Office Library.
- 10 Patents Act 1953, s.21(1) and(2). The three-month period may be extended by a further month, provided that the application to do this is made within the original three-month period.
- 11 New Things Ltd.'s Application (1914) 31 R.P.C. 45, 46.
- 12 Patents Act 1953, s.12.

13 e.g. T.A. Blanco White, Patents for Inventions (4th ed.,
Stevens & Sons, 1974) 236-237.

14 Patents Act 1953, s.41.

15 Patents Rules 1956, R.5.

16 [1980] 1 N.Z.L.R. 192, 195; [1981] 1 N.Z.L.R. 600, 601.

17 Beecham v. Bristol-Myers [1980] 1 N.Z.L.R. 185, 190.

18 As Barker J. deemed that the advice he received did not
constitute a "report" within the meaning of R.5, the
requirements of subcls. (2), (3) and (5) of R.6A (as
inserted by R.3 of the Patents Rules 1956, Amendment No. 1
of 1976) were not complied with. This rule requires the
reports of an independent scientific adviser to be made
in writing to the court. Copies of the reports are then
forwarded to the parties to the proceedings, who are given
the opportunity (on application) to cross-examine the
adviser.

19 Patent Office Journal 1189, 421, published in June 1978
(henceforth P.O.J. 1189).

20 Ibid. 427.

21 [1980] 1 N.Z.L.R. 192.

22 Ibid.251.

- 23 See the Patents Act 1953, s.59 (1) .
- 24 (1862) 4 De G.F. & J. 288; 45 E.R. 1195 - referred to in the Supreme Court judgment ([1980] 1 N.Z.L.R. 192, 215).
- 25 (1904) 45 E.R. 1195, 1199.
- 26 Idem.
- 27 [1972] R.P.C. 457 - applied in the Commissioner's Decision (P.O.J. 1189, 424); referred to in the Supreme Court and Court of Appeal judgments ([1980] 1 N.Z.L.R. 192, 215-216; [1981] 1 N.Z.L.R. 600, 606).
- 28 Ibid. 485 - 486.
- 29 [1978] R.P.C. 521 - referred to in the Commissioner's Decision (P.O.J. 1189, 427) and the Supreme Court judgment ([1980] 1 N.Z.L.R. 192, 223-224); applied in the Court of Appeal judgment ([1981] 1 N.Z.L.R. 600, 607-608).
- 30 [1981] F.S.R.377 - applied in the Court of Appeal judgment ([1981] 1 N.Z.L.R. 600, 606-607).
- 31 Section 32(1)(e) of the U.K. Patents Act of 1949, which is equivalent to s.41(1)(e) of the New Zealand Act.
- 32 Section 14(1)(b) of the U.K. Patents Act of 1949, having its New Zealand counterpart in s.21(1)(b).

- 33 [1981] F.S.R.377, 396.
- 34 Idem.
- 35 General Tire & Rubber Co. v. Firestone Tyre and Rubber Co.Ltd.
[1972] R.P.C.457, 486.
- 36 A contrary decision would make it possible for an unscrupulous individual or company to publish lists of theoretically possible compounds, and thereby deny patent rights to a subsequent manufacturer of the compounds.
- 37 The claims of the patent, as granted, relate to pharmaceutical compositions comprising Amoxycillin "being substantially free of the corresponding (+) epimeric form ". This amendment overcomes any lingering doubts about anticipation by the previously-disclosed epimeric mixture.
- 38 T.A. Blanco White, op.cit. (4th ed.) 152-153.
- 39 Ibid. 150.
- 40 Ibid. 236-237.
- 41 (1928) 45 R.P.C. 153 - referred to in the Commissioner's Decision (P.O.J. 1189, 424).
- 42 Ibid. 173.

- 43 (1930) 47 R.P.C. 289 - referred to in all three judgments (P.O.J. 1189, 425-426; [1980] 1 N.Z.L.R. 192, 239-240; [1981] 1 N.Z.L.R. 600, 609).
- 44 Ibid. 322.
- 45 Ibid. 322-323.
- 46 [1967] R.P.C. 479 - referred to in the Commissioner's Decision (P.O.J. 1189, 424) and the Supreme Court judgment ([1980] 1 N.Z.L.R. 192, 236).
- 47 Ibid. 494.
- 48 [1977] R.P.C. 121 - distinguished in the Commissioner's Decision (P.O.J. 1189, 427) and referred to in the Supreme Court judgment ([1980] 1 N.Z.L.R. 192, 246).
- 49 [1978] R.P.C. 521 - referred to in all three judgments (P.O.J. 1189, 427; [1980] 1 N.Z.L.R. 192, 241-243; [1981] 1 N.Z.L.R. 600, 607).
- 50 Ibid. 567.
- 51 [1980] R.P.C. 261 - referred to in the Commissioner's Decision (P.O.J. 1189, 427); followed in the Supreme Court judgment ([1980] 1 N.Z.L.R. 192, 230, 238-239, 243-245); in the Court of Appeal judgment, the opinion of Browne L.J. was agreed with ([1981] 1 N.Z.L.R. 600, 610).

- 52 Ibid. 298.
- 53 Ibid. 298.
- 54 Ibid. 304.
- 55 General Tire & Rubber Co. v. Firestone Tyre and Rubber Co. Ltd. [1972] R.P.C. 457, 497.
- 56 Supreme Court judgment : [1980] 1 N.Z.L.R. 192, 204.
- 57 (1936) 53 R.P.C. 323 - applied in the Court of Appeal judgment ([1981] 1 N.Z.L.R. 600, 612-613).
- 58 Ibid. 346.
- 59 See Allen & Hanburys Ltd. (Hayes') Application [1977] R.P.C. 113. Amoxicillin would probably be deemed to have been "specifically mentioned" in the earlier specification. The Beecham OMP patent has examples covering all three compounds, i.e. o-, m- and p-, but each in the form of a mixture of epimers. The individual epimers are not separately isolated. The p- compound is claimed, but only in the form of a mixture of the two epimers. However, the general formula does include Amoxicillin within its scope, and the statement is made that "It is to be understood that the present invention includes both epimeric forms [e.g. Amoxicillin] as well as the dl- mixture ". Although Amoxicillin is not actually prepared in the Beecham OMP patent, it has been "specifically mentioned" to the extent required to uphold a prior claiming objection against the Amoxicillin specification.

60 Patents Act 1953, s.34.

61 See s.34(7). The principal purpose of a patent of addition is to protect an obvious improvement in, or modification of, the main invention.

62 T.A. Blanco White, op.cit. (4th ed.) 119-122.

63 Beecham Group Ltd's (Amoxycillin) Application [1980]
R.P.C. 261, 298.

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