

Federal Court of Australia

[\[Index\]](#) [\[Search\]](#) [\[Download\]](#) [\[Help\]](#)

F.Hoffman-La Roche AG v New England Biolabs Inc [2000] FCA 283 (28 April 2000)

Last Updated: 10 May 2000

FEDERAL COURT OF AUSTRALIA

F.Hoffman-La Roche AG v New England Biolabs Inc [2000] FCA 283

PATENTS - patent application - claims in relation to a purified thermostable DNA polymerase - appeals from decision of a delegate of the Commissioner of Patents pursuant to [s 60\(5\)](#) of the [Patents Act 1952](#) (Cth) - nature of an appeal from an opposition hearing before a delegate - whether appeal a full hearing of factual issues on the merits - nature of onus - whether it must be "*practically certain*" that patent would be invalid - whether Court should permit grant unless "*quite clear*" that patent would not stand - whether opponent's case must be "*clearly*" made out - whether legislative scheme limits scope of appeal - whether nature of appeal limits evidence that may be adduced - whether evidence of a particular expert relevant

[Patents Act 1952](#) (Cth) [ss 59\(1\)](#), [60\(1\)](#), [60\(5\)](#), [146\(1\)](#), [148\(2\)](#), [150](#); Pt V

[Patents Act 1990](#) (Cth) [ss 3](#), [19](#), [19\(1\)](#), [138](#), [138\(3\)](#), [154\(1\)](#), [158\(2\)](#), [160](#); Sch 1

[Federal Court of Australia Act 1976](#) (Cth) [ss 24](#), [24\(1A\)](#)

Genetics Institute Inc v Kirin-Amgen Inc (1999) 163 ALR 761 referred to

McGlashan v Rabett (1909) [9 CLR 223](#) referred to

Stamp v Powell Pty Ltd (1918) [24 CLR 339](#) cited

Henry Berry & Co Pty Ltd v Potter (1924) [35 CLR 132](#) referred to

Commissioner of Patents v Microcell Ltd (1959) [102 CLR 232](#) considered

Kaiser Aluminium & Chemical Corp v Reynolds Metal Co (1969) [120 CLR 136](#) cited

Farmwerke Hoechst Aktiengesellschaft Vormals Meister Lucius v Commissioner of Patents (1971) 45 ALJR 235 referred to

Montecatini Edison S.p.A v Eastman Kodak Co (1971) 45 ALJR 593 considered

General Electric Co.'s Applications [1964] RPC 413 referred to

Dennison Manufacturing Co v Monarch Marking Systems Inc (1981) 51 AOJPTMD 1716 referred to

Dennison Manufacturing Co v Monarch Marking Systems Inc (1983) 66 ALR 265 referred to

R D Werner Co Inc v Bailey Aluminium Products Pty Ltd (1987) 8 IPR 339 referred to
R D Werner Co Inc v Bailey Aluminium Products Pty Ltd (1989) 25 FCR 565 referred to
to

ON APPEAL FROM THE COMMISSIONER OF PATENTS

F.HOFFMAN-LA ROCHE AG v NEW ENGLAND BIOLABS INC

NG 947 OF 1997

NEW ENGLAND BIOLABS INC v F.HOFFMAN-LA ROCHE AG

NG 1035 OF 1997

EMMETT J

28 APRIL 2000

SYDNEY

IN THE FEDERAL COURT OF AUSTRALIA

NEW SOUTH WALES DISTRICT REGISTRY

NG 947 OF 1997

**ON APPEAL FROM THE COMMISSIONER OF
PATENTS**

BETWEEN:

**F.HOFFMAN-LA ROCHE
AG**

APPLICANT

AND:

**NEW ENGLAND BIOLABS
INC**

RESPONDENT

NG 1035 OF 1997

**ON APPEAL FROM THE COMMISSIONER OF
PATENTS**

BETWEEN:

**NEW ENGLAND BIOLABS
INC**

APPLICANT

AND:

**F.HOFFMAN-LA ROCHE
AG**

RESPONDENT

JUDGE:

EMMETT J

DATE:

28 APRIL 2000

PLACE:

SYDNEY

EX TEMPORE REASONS FOR DECISION

1 I have before me two appeals arising out of opposition proceedings under the provisions of the [Patents Act 1952](#) (Cth) ("the 1952 Act") as continued in force under the [Patents Act 1990](#) (Cth) ("the 1990 Act"). F. Hoffman-La Roche AG ("the Applicant") claims a patent relating to a purified thermostable enzyme. The first claim in the Specification ("Claim 1") is in the following terms:

"1. A purified thermostable DNA polymerase isolated from a Thermus species which catalyses combination of nucleoside triphosphates to form a nucleic acid strand complementary to a nucleic acid template strand, said polymerase having a molecular weight of about 86,000 to 95,000 daltons as compared to phosphorylase B by SDS-PAGE."

Claims 2 to 7 are ancillary to Claim 1 and all relate to a purified thermostable DNA polymerase. There are 101 claims in all, but for present purposes, I do not think it is necessary to indicate the nature of Claims 8 to 101.

2 In proceedings before a delegate of the Commissioner of Patents, opposition to the grant of a patent to the Applicant was mounted by New England Biolabs Inc ("New England Biolabs"). The Delegate upheld the opposition in relation to Claims 1 to 7 but concluded that the application should proceed to grant in respect of the balance of the claims. The Applicant has appealed against the rejection of Claims 1 to 7 and New England Biolabs has appealed against the decision to permit the balance of the claims to proceed to grant.

3 One of the grounds of opposition relied on by New England Biolabs is that the alleged invention was published in Australia before the priority date of each of the claims. The principal publication relied on by New England Biolabs is a paper ("the Kaledin Paper") published in 1980 by A. S. Kaledin and others entitled "*Isolation and Properties of DNA Polymerase from the Extremely Thermophilic Bacterium Thermus aquaticus YTI*" Biokhimiya (1980) vol. 45, pp. 644-651. The paper begins with the following abstract:

"A DNA polymerase was isolated from the thermophilic bacterium T. aquaticus YTI. As a result of six stages of purification an electrophoretically homogeneous preparation of the enzyme with a molecular weight of about 62,000 was obtained."

4 In a section of the Kaledin Paper entitled "*Determination of Molecular Weight of Enzyme*" the following appears:

"The molecular weight of the enzyme was determined by two methods: by electrophoresis under denaturing conditions and by ultracentrifugation in a 5-20% sucrose density gradient. The data of electrophoresis in polyacrylamide gel containing sodium dodecyl sulfate...indicate that the enzyme behaves like a homogeneous protein. The molecular weight of the DNA polymerase was computed by

comparing the mobility of the enzyme with the mobilities of marker proteins with known molecular weights and it was found to be 62,000 per monomeric unit. During analytical ultracentrifugation DNA polymerase sediments as one discrete symmetrical peak somewhat faster than bovine serum albumin. The approximate molecular weight of the enzyme, calculated using the equation of Martin and Ames...is 60,000.

New England Biolabs contends that that anticipates Claims 1 to 7 of the Specification lodged on behalf of the Applicant. The Applicant, on the other hand, contends that the Kaledin Paper, while it may describe a DNA polymerase, does not anticipate all of the integers comprised in Claims 1 to 7 of the Specification.

5 A question arises as to precisely what it is that was disclosed by the Kaledin Paper. The Applicant contends that an essential integer of Claim 1 is the isolation of a DNA polymerase having a particular molecular weight, being a molecular weight of 86,000 to 95,000 daltons. New England Biolabs contends, on the other hand, that the reference to molecular weight in the Kaledin Paper is consistent with the enzyme described in Claim 1, notwithstanding that the figures are clearly different. New England Biolabs seeks to explain the difference in the figures in two ways.

6 Two different measurements are referred to in the Kaledin Paper. The first concerns a process known as sucrose density gradient measurement ("SDG"). The other is the process referred to in Claim 1, namely, a measurement involving the process known as electrophoresis, involving a polyacrylamide gel ("SDS-PAGE"). The measurement of the enzyme by SDG in the Kaledin Paper was stated to be 60,000 daltons. The measurement by SDS-PAGE was stated to be 62,000 daltons. New England Biolabs contends that there is an inconsistency on the face of the Kaledin Paper indicating an error from which it should be concluded that the molecular weight calculated by SDG is in fact in excess of 66,000 daltons. It is common ground that there is an inconsistency. The Applicant, however, contends that the figure of 60,000 is correct and that the error contained in the Kaledin Paper in that respect relates to what was observed in the SDG process.

7 New England Biolabs also contends that the 62,000 dalton figure measured by SDS-PAGE is not a measurement of the enzyme itself but can most likely be explained as being a measurement of a contaminant in the solution, being a different enzyme that had some properties similar to that of the enzyme of interest.

8 The Applicant contends that, having regard to the factual matters involved in such assertions on the part of New England, it could never be concluded that the Kaledin Paper anticipated Claims 1 to 7 in the Specification. On the other hand, New England Biolabs seeks to adduce evidence designed to demonstrate that, on the balance of probabilities, there was in the solution produced as described in the Kaledin Paper an enzyme such as is described in at least Claim 1, albeit that the Kaledin Paper does not actually specify the molecular weight referred to in Claim 1.

9 In support of its contentions, New England Biolabs seeks to rely on evidence of Dr Dale William Mosbaugh, which it wishes to adduce in the form of an affidavit sworn on 3 September 1999. Dr Mosbaugh is a Professor in the Department of Environmental and Molecular Toxicology and Research Core Director and Centre

Investigator in the Environmental Health Sciences Centre at Oregon State University in Corvallis, Oregon, United States of America. There does not appear to be, for present purposes, any issue as to the qualifications of Dr Mosbaugh to give evidence in relation to the matters to which he directs his attention.

10 Objection is taken to [section 3](#) of Dr Mosbaugh's affidavit. [Section 3](#) is headed "*Isolation of Full-length Taq DNA Polymerase by Kaledin and by Chien*". Alice Chien and others are the authors of another paper relied on by New England Biolabs as anticipating Claims 1 to 7, being "*Deoxyribonucleic Acid Polymerase from the Extreme Thermophile Thermus Aquaticus*", published in Journal of Bacteriology, Vol. 7 No. 3, September 1976 pages 1550-1557 ("The Chien Paper"). The Chien Paper is referred to in the Kaledin Paper.

11 I have heard extensive argument on the admissibility of [section 3](#) of the affidavit, although I have not yet heard argument as to the form of the relevant paragraphs and their admissibility from that point of view. The objection at this stage has been taken at a level of principle.

12 First of all, it was said that the material is irrelevant, having regard to the principles to be applied in determining the question of novelty. Second, however, objection was taken on the basis that the nature of the proceeding is such that I should not entertain evidence of this nature at this stage. In the course of argument on that latter question, further questions of principle have been raised, which it is desirable to determine for the purposes of ruling on the admissibility of this evidence and the extent to which oral evidence on the question should ultimately be permitted.

RELEVANCE

13 As I apprehend, there are three ultimate factual questions sought to be established by [section 3](#) of the affidavit. They are as follows:

1. Certain techniques for measuring apparent molecular weight will result in an apparent molecular weight value lower than other techniques. In particular, an enzyme that will measure approximately 92,000 daltons by SDS-PAGE will measure approximately 72,000 daltons by SDG.
2. When, during the process of gel filtration chromatography, a protein tends to stick to a gel filtration resin, the interaction will cause it to exhibit a lower apparent molecular weight value than its actual molecular weight or than it would have using other techniques.
3. Full length Taq DNA polymerase binds to phosphocellulose and elutes at relatively high salt gradients. A fragment of the enzyme claimed by the Applicant, as referred to in the Specification and known as "the Stoffel Fragment", either does not bind to phosphocellulose or binds weakly and elutes at the beginning of the salt gradient identified in the Chien Paper. The enzyme described in the Chien Paper elutes well after the Stoffel Fragment does on the salt gradient.

14 I shall explain each of those matters and their significance.

Different Techniques For Measuring Apparent Molecular Weight

15 New England Biolabs seeks to explain the apparent discrepancy in the measurements in the Kaledin Paper by demonstrating that an enzyme measured by SDG will exhibit a lower molecular weight than when measured by SDS-PAGE. Thus, New England Biolabs seeks to establish that, assuming Kaledin measured his enzyme as having a molecular weight in excess of 66,000 daltons by SDG, that is consistent with a measurement of the same enzyme by SDS-PAGE of approximately 92,000. The evidence of Dr Mosbaugh is designed to demonstrate, if otherwise admissible, that an enzyme measured by SDG at in excess of 66,000 could be the same enzyme measured by SDS-PAGE at 92,000. The Applicant contends that even if that is correct, that would not be sufficient for the Kaledin Paper anticipate Claims 1 to 7.

16 I consider that New England Biolabs is entitled at least to adduce the evidence that it relies upon in order to support its contention. It may well be, irrespective of the nature of this appeal, that it could be established, on the balance of probabilities, that Kaledin did in fact produce in his solution the enzyme described by Claim 1. That however of itself may not be sufficient to constitute anticipation of Claim 1. But until that evidence is before me, there will be no basis upon which New England Biolabs can mount its case. I consider, therefore, that the material is relevant and that evidence of that nature is admissible, if the only ground of objection is relevance.

17 Dr Annabelle Bennett, senior counsel for the Applicant, contends that it would be erroneous to permit such evidence to be adduced, since it relates to knowledge acquired after the priority date. However, the fact which New England Biolabs wishes to establish is not that such knowledge was relevant to the question of novelty as at the priority date but that such knowledge enables one to determine today whether, as a matter of fact, there was in Kaledin's solution the enzyme in question. As I have said, whether that is sufficient to constitute novelty is a different question all together.

Gel Filtration

18 The second factual matter to which Dr Mosbaugh's affidavit relates concerns the process of gel filtration. Gel filtration is a third method for determining the molecular weight of a protein. Gel filtration is a process which can be used as part of a purification procedure as well as a means to estimate the molecular weight of an unknown sample, as it separates proteins on the basis of size. This is another aspect, so far as New England Biolabs' case is concerned, of the attempt to distinguish or explain the discrepancy in the Kaledin Paper.

19 New England Biolabs proposes to adduce evidence that will establish that the inventors described in the Applicant's Specification observed that the enzyme of Claim 1 tends to stick to a gel filtration resin. Accordingly, if the proposition advanced by Dr Mosbaugh is correct, during gel filtration the enzyme in question will exhibit a lower apparent molecular weight value than its actual molecular weight or a lower molecular weight than would be derived using other techniques. That again is relied on as a basis for explaining why those responsible for the Kaledin Paper may have determined a molecular weight below that described in Claim 1, but nevertheless isolated the same enzyme.

20 For the reasons I have briefly given, I consider that that evidence is relevant to the case sought to be mounted on behalf of New England Biolabs. Again, as I have said, whether that is sufficient to establish lack of novelty is a different question altogether.

Phosphocellulose Chromotography

21 The third matter relied on concerns a different question, but it is related to the relationship that the Kaledin Paper bears to Claim 1 and the ancillary claims. One possibility that has been foreshadowed to explain why Kaledin Paper shows a molecular weight of 62,000 by SDS-PAGE is that the authors in fact isolated a fragment of the enzyme described in Claim 1, rather than a full length enzyme and that they did not at any time isolate the full length enzyme itself. The third area of disputed factual material is designed to establish that the Stoffel Fragment behaved in a different way from the enzyme identified in the Chien Paper, which New England Biolabs says is the same enzyme identified in the Kaledin Paper.

22 Once again, I consider that this material is relevant to the case which New England Biolabs has foreshadowed that it wishes to pursue. Again, I comment that it may not necessarily be decisive one way or the other. However, in order to enable the question to be raised, I consider that it is relevant for New England Biolabs to establish that a fragment of the enzyme described in Claim 1 behaves in a way that is likely to be different from the enzyme described in the Kaledin Paper.

23 For those reasons, I have indicated to the parties that I consider that evidence relating to the above three matters is relevant to the case that New England Biolabs seeks to make out. However, other grounds are relied on by the Applicant by way of objection to evidence of that nature, which require a consideration of the nature of the proceeding before me.

NATURE OF OPPOSITION PROCEEDINGS

24 The Applicant applied for a patent prior to the commencement of the 1990 Act. While the 1952 Act was repealed by [section 230](#) of the 1990 Act, [section 234\(3\)](#) of the 1990 Act provides that Part V of the 1952 Act, as in force immediately before the commencement of the 1990 Act, continues to apply in relation to an application lodged under the 1952 Act and that had not been finally dealt with. The Applicant's application is such a one.

25 Part V of the 1952 Act is headed "*OPPOSITION*". [Section 59](#) relevantly provides:

"(1) The Minister or a person interested may, at any time within 3 months after the date of the advertisement of the acceptance of an application for a standard patent and complete specification, or within such further period, not exceeding 3 months, as the Commissioner, on an application made to him within the first-mentioned period, allows, by notice in writing lodge at the Patent Office, oppose the grant of the patent on one or more of the following grounds, but on no other ground:

(a) that the invention, so far as claimed in any claim, was obtained from the opponent, or from a person of whom the opponent is the legal representative, assignee, agent or attorney;

(b) in the case of an invention communicated from abroad, that the invention was not communicated to the applicant by the actual inventor or his legal representative or assignee;

(c) that the invention, so far as claimed in any claim, is the subject of-

(i) a claim of the complete specification of another application for a standard patent lodged in Australia; or

(ii) the claim of a petty patent specification of an application for a petty patent lodged in Australia,

being in either case a claim the priority date of which is earlier than the priority date of the first-mentioned claim;

(d) that the invention, so far as claimed in any claim, is the subject of a claim of earlier priority date contained in the complete specification or petty patent specification of a patent;

(e) that the invention, so far as claimed in any claim, was published in Australia before the priority date of that claim;

(f) that the invention, so far as claimed in any claim, is not a manner of manufacture within the meaning of [section 6](#) of the Statute of Monopolies;

(g) that the invention, so far as claimed in any claim, was obvious and did not involve an inventive step, having regard to what was known or used in Australia on or before the priority date of that claim;

(h) that the invention, so far as claimed in any claim, was, before the priority date of that claim, otherwise not novel in Australia; and

(i) that the complete specification does not comply with the requirements of [section 40](#)."

For present purposes, it is clear that the grounds relied on by New England Biolabs are grounds specified in [section 59](#)(1).

26 Under [section 60](#)(1) of the 1952 Act:

"Where a notice of opposition is given under section 59, the opponent shall serve a copy of the notice on the applicant, and the Commissioner shall, after hearing the applicant and the opponent, if desirous of being heard, decide the case ."

[Section 60](#)(5) then provides:

"The applicant, and an opponent who, in the opinion of the Federal Court is entitled to be heard in opposition to the grant, may appeal to the Federal Court from a decision of the Commissioner under this section.

27 [Section 154](#)(1) of the 1990 Act provides that the Federal Court has jurisdiction with respect to matters arising under that Act. Similar provision was contained in [section 146](#)(1) of the 1952 Act the language of which is relevantly the same as [section 154](#)(1). There is no doubt as to the jurisdiction of the Court to entertain the present appeals pursuant to [section 60](#)(5).

28 [Section 160](#) of the 1990 Act, which is relevantly in the same terms as [section 150](#) of the 1952 Act, provides:

"On hearing an appeal against a decision or directions of the Commissioner, the Federal Court may do any one or more of the following:

- (a) admit further evidence orally, or on or affidavit or otherwise;
- (b) permit the examination and cross-examination of witnesses, including witnesses who gave evidence before the Commissioner;
- (c) order an issue of fact to be tried as it directs;
- (d) affirm, reverse or vary the Commissioner's decision or direction;
- (e) give any judgment, or make any order, that, in all the circumstances, it thinks fit;
- (f) order a party to pay costs to another party."

29 While [section 60](#)(5) uses the word "*appeal*", it is clear that a proceeding in this Court under [section 60](#)(5) is in the original jurisdiction of the Court. The appeal is not an appeal *stricto sensu* but is a hearing *de novo*. It is common ground that in such a hearing an opponent has the onus of satisfying the Court that the grant of a patent should not be made. The nature of that onus is the subject of contention before me.

30 It is clear, however, that since the proceeding is a hearing *de novo*, it is for the Court to determine what evidence should be permitted on the hearing. That question must depend upon the nature of the proceeding. It would of course be open to an opponent simply to tender the material that was before the Commissioner or his delegate. The Court could, subject to all proper objections, admit that evidence.

31 That is not the course that has been adopted in the present case. Rather, New England Biolabs has foreshadowed a desire to read extensive affidavits raising at least the matters that were raised before the Commissioner's delegate. The Applicant, however, says that, having regard to the nature of the appeal and a proceeding under Part V generally, there ought to be significant constraints imposed on the evidence that New England Biolabs is permitted to adduce.

32 It is clear enough that [section 160](#) and its predecessor, [section 150](#), purport to be enabling provisions. A question may arise as to whether or not, even in the absence of

those provisions, the Court would in any event have been empowered to admit further evidence and determine the nature of the evidence and the extent to which examination and cross-examination of witnesses should be permitted. The exercise of the control that [section 160](#) clearly contemplates must be governed, it seems to me, by the nature of a proceeding under Part V of the 1952 Act.

33 New England Biolabs contends that the proceeding is in the nature of a trial of factual issues, in the same way as any other proceeding before the Court is a trial of factual issues. Specifically, New England Biolabs contends that there is no real difference between the determination of issues relating to novelty and obviousness that would arise in an opposition proceeding as compared with the issues as to novelty and obviousness that would arise in a revocation suit.

34 The Applicant on the other hand contends that the overriding issue in an opposition proceeding is whether it is "*practically certain*" that the patent to be granted on the specification would have been invalid on the grounds of opposition relied on. Alternatively, it is put that the Court should not refuse to allow the grant unless it is "*quite clear*" that the patent could not stand upon one of the grounds of objection relied on. The Applicant also puts it in a third way, namely, that the Court should not find for an opponent in opposition proceedings unless satisfied that the opponent's case has been "*clearly*" made out.

35 The Applicant relies both on the scheme of the legislation and on authorities of some standing in support of those propositions. It is, I think, fair to say that the authorities relied on, while persuasive, are for various reasons not directly in point.

SCHEME OF THE LEGISLATION

36 There are several aspects of the scheme of the legislation that appear to me to support the position maintained by the Applicant. First, there is [section 160](#), and [section 150](#), its predecessor. It may be that the reference to the powers of the Court is simply to indicate that the appeal is to be by way of hearing *de novo* and not an appeal limited to the evidence before the Commissioner. On that view, the empowering of the Court to admit further evidence and to permit examination and cross-examination is by way of confirming that the hearing is a hearing *de novo*. However, the presence of [section 160](#) is a factor that, coupled with the other matters to which I shall refer, is of significance.

37 The presence of [section 160](#) suggests that it is within the power of the Court to constrain further evidence and the extent of examination and cross-examination. No suggestion has been made in the course of argument before me that there is any constitutional invalidity involved in [section 160](#). The Federal Court, being a Court established under Chapter III of the Constitution, should exercise its powers and its jurisdiction in respect of the judicial power of the Commonwealth in accordance with judicial process.

38 Thus, in so far as the section purported to authorise the Court, for example, to deprive a party of a fair opportunity to present its case, there could be some basis for challenging its validity. As I have said, however, no challenge is taken to the validity of the provision. [Section 160](#) does, however, indicate that the Court may exercise a discretion as to the extent to which further evidence will be admitted, beyond that

which was before the Commissioner and the extent to which examination and cross-examination of witnesses might be permitted. Such a constraint is indicative of a proceeding different from one intended to resolve all disputed questions.

39 The second matter that is significant as to the nature of the proceeding is [section 158\(2\)](#) of the 1990 Act, which provides:

"Except with the leave of the Federal Court, an appeal does not lie to the Full Court of the Federal Court against a judgment or order of a single judge of the Federal Court in the exercise of its jurisdiction to hear and determine appeals from decisions or directions of the Commissioner."

[Section 158\(2\)](#) was preceded by [section 148\(2\)](#) of the 1952 Act which was in the same terms. Thus, the scheme, as contemplated in the 1952 Act as well as in the 1990 Act, is that there is no appeal as of right from any determination that a single Judge may make in relation to an appeal. Ordinarily, of course, where a final order is made by a judge of this Court, there is an appeal as of right to the Full Court under [section 24](#) of the *Federal Court of Australia Act 1976* (Cth). However, under [section 24\(1A\)](#), an appeal in respect of an interlocutory judgment may only be brought with leave. Thus, the legislature has expressly likened a determination made on an appeal under [section 60\(5\)](#) to a determination in an interlocutory proceeding.

40 The third matter in the scheme of [the Act](#) is [section 19](#) of the 1990 Act, coupled with the provisions of section 138 of the 1990 Act, each of which has its predecessor in the 1952 Act. Section 138 of the 1990 Act provides that any person may apply to a prescribed Court, which includes the Federal Court, for an order revoking a patent. At the hearing of the application, the respondent is entitled to begin and give evidence in support of the patent and, if the applicant gives evidence disputing the validity of the patent, the respondent is entitled to reply. Under section 138(3), after hearing the application, the Court may revoke the patent either wholly or so far as it relates to a claim but only on the grounds that are there specified.

41 [Section 19](#) provides:

"(1) In any proceedings in a court in which the validity of a patent, or of a claim, is disputed, the court may certify that the validity of a specified claim was questioned.

(2) If a court issues a certificate, then, in any subsequent proceedings for infringement of the claim concerned, or for the revocation of the patent so far as it relates to that claim, the patentee, or any other person supporting the validity of the claim is, on obtaining a final order or judgment in his or her favour, entitled to full costs, charges and expenses as between solicitor and client, so far as that claim is concerned."

There is a public interest in establishing the validity or otherwise of a patent. However, [section 19](#) recognises that the nature of litigation in the common law system is such that any determination will be binding only *inter partes*. Accordingly, it would be possible, theoretically at least, for revocation proceedings to be commenced by a

third party even after unsuccessful revocation proceedings had been determined by the Court.

42 A determination that a patent be revoked is of course in a sense a real action because the revocation is good for all the world. However, a refusal to revoke is binding only on the party seeking to revoke. Accordingly, [section 19](#) imposes a sanction on any person who seeks to re-agitate such a question. The nature of proceedings *inter partes* might be contrasted with proceedings under some systems of law whereby a proceeding that is properly characterised as a real action determines status as against the whole world (see, for example, *Justinian's Institutes*, 4.6.1).

43 The proceeding before me is not a proceeding in which the validity of a patent is disputed. For the purposes of the 1990 Act, "patent" is relevantly defined in Schedule 1, pursuant to [section 3](#), as a "standard patent". "Standard patent" is defined as "letters patent for an invention granted under [this Act](#)". "Claim" relevantly means "a claim... of the specification relating to the complete application on which the patent was granted". No patent has, by definition, been granted at the present stage because the proceedings have only reached the stage of opposing the grant. Accordingly, [section 19](#) has no application.

44 If a proceeding under [section 60\(5\)](#) involves a full hearing on the merits, at least on the grounds that can be relied on under [section 59](#), the sanction created by [section 19](#) would not be available if, following unsuccessful opposition, a grant were made and revocation proceedings were commenced. In other words, even if I were to conclude that the opposition to the grant of a patent should fail, that would be no bar to commencement of fresh proceedings, at least by a third party, without the sanction of [section 19](#). In such proceedings the validity of any patent granted could be called in issue on precisely the same grounds as had been rejected in the opposition proceedings. It may be that, if the opposition proceedings are tantamount to a full hearing on the merits, an issue estoppel might arise in relation to an opponent. Clearly, if the proceeding is of the nature contended for by the Applicant, no such estoppel would arise.

45 The final matter which seems to me to be significant in relation to the nature of the proceeding is the other side of the matter to which I have just referred. An opponent may have a second chance, assuming there is no issue estoppel, to challenge the validity of a patent granted following unsuccessful opposition proceedings. Certainly a third party can challenge the validity of any patent by revocation proceedings without penalty under [section 19](#) if the opposition proceedings fail. However, successful opposition results in the refusal of a patent. That refusal would be by a single judicial officer without any right of appeal. Certainly, appeal might be permitted with leave, but it is, it seems to me, a curious circumstance that a single judicial determination could resolve a matter against an applicant that might be of great commercial significance, without there being any right of appeal.

46 There is of course a very significant public interest in ensuring that patents which could not be valid should not be permitted to go on to the register. There is a public interest in ensuring that monopoly is afforded only to patents that are valid. Further, there is a public interest in ensuring that no applicant for a patent should be put in a position to make threats of infringement in respect of a patent that would clearly be

revoked in revocation proceedings. Nevertheless, the above considerations lead me to conclude, from an examination of the scheme and structure of the legislation, that opposition proceedings should not be considered as being on the same footing as a revocation suit.

47 The fact that the legislation contemplates two stages at which the question of validity of a patent might be challenged indicates that there must be a distinction between the two proceedings. Such an approach is consistent with the proposition that pre-grant opposition is intended to provide a relatively inexpensive mechanism for resolving third party disputes as to validity. The purpose of pre-grant opposition proceedings is to provide a swift and economical means of settling disputes that would otherwise need to be dealt with by the courts in more expensive and time consuming post-grant litigation; that is, to decrease the occasion for costly revocation proceedings by ensuring that bad patents do not proceed to grant (see *Genetics Institute Inc v Kirin-Amgen Inc* (1999) 163 ALR 761 at paragraph [19]). It is a good thing to have some process by which patents that are obviously invalid will not be allowed to clutter the register (see *McGlashan v Rabett* (1909) [9 CLR 223](#) at 229).

Leading Authorities

48 The approach that I favour has support from a long line of cases. I do not consider, however, that any of those cases is necessarily directly in point, as I indicated earlier. Criticism of reliance on the authorities is based on the propositions that they are not concerned directly with the nature of opposition proceedings, or alternatively where they are so concerned this question was not in issue, either because only one party appeared before the Court or because it appears to have been common ground and not disputed by either party. However, I shall refer to some of those authorities since they do give me considerable comfort in the conclusion that I have reached.

49 In *McGlashan v Rabett* (above) there was opposition to a patent application under the *Patents Act 1903* (Cth) ("the 1903 Act") on the ground of want of novelty. Griffith CJ said (at 228):

"For these reasons I think that this Court, acting upon the principle that it should not refuse to allow the grant of a patent unless it is quite clear that it cannot stand upon the ground of want of novelty, should allow it. It by no means follows that the patent will be valid when granted. Upon all the materials before us it is impossible to say that it has been proved affirmatively that substantially the same combination has ever been in use in the Commonwealth before, and upon that ground I think that the patent should be granted, without expressing any opinion as to the validity of the patent when granted."

50 In *Stamp v Powell Pty Ltd* (1918) [24 CLR 339](#) there was again an appeal from an opposition determination based on want of novelty. Barton J (at 434) referred to the passage from *McGlashan v Rabett* (above), to which I have just referred.

51 In *Henry Berry & Co Pty Ltd v Potter* (1924) [35 CLR 132](#) there was an appeal, following a decision on an opposition on the ground of want of novelty. Starke J (at 141) referred to *McGlashan v Rabett* (above) and *Stamp v Powell* (above) saying:

"the Court should not refuse to allow the grant of a patent unless it is quite clear that it cannot stand upon the ground of want of novelty, for the grant of a patent is no decision that the patent will be valid when granted."

That comment is significant. In other words, the fact that opposition is unsuccessful is no guarantee that the patent will be valid.

52 *Commissioner of Patents v Microcell Ltd* (1959) [102 CLR 232](#) involved proceedings at an earlier stage in the registration process than opposition. That case also arose under the 1903 Act. Section 41 of that Act required that an examiner was to report to the Commissioner whether an invention was or was not novel. Section 46 then provided that, if the Commissioner was satisfied that no objection existed to the specification on the ground that the invention was already patented in the Commonwealth or was already the subject of any prior application, the Commissioner, in the absence of any other lawful ground of objection, was to accept the application and specification without any condition. If he was not so satisfied, he could refuse to accept the application and specification.

53 A strong Full High Court considered that it was well-settled that the Commissioner ought not to refuse acceptance of an application and specification unless it appears **practically certain** that letters patent granted on a specification would be held invalid (at 244-5). Of significance, however, is that the Court observed that, whereas refusal of acceptance is final, acceptance is not. The Court referred to the fact that an application may thereafter be opposed after acceptance on any of the grounds mentioned in section 56 of the 1903 Act. Further, if the patent were granted, its validity was then open to attack in proceedings for infringement or revocation. Thus, while the case is not in point in so far as it was concerned only with the standard to be applied in relation to rejection at the application stage, the rationale for the Court's approach is equally applicable at the opposition stage.

54 In *Kaiser Aluminium & Chemical Corp v Reynolds Metal Co* (1969) [120 CLR 136](#), a Deputy Commissioner of Patents had dismissed an objection on the ground that the opponent showed no *locus standi* and directed that the application proceed to grant. The opponent appealed to the High Court and produced further evidence of *locus standi*. The Court was satisfied that the opponent had standing and therefore remitted the case to be decided on the merits (at 143). I do not consider that the observations made by Kitto J advance the matter.

55 In *Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius v Commissioner of Patents* (1971) 45 ALJR 235 Gibbs J was concerned with a question of amendment. In passing, his Honour observed that, in certain appeals, the Patent Appeal Tribunal, which is now replaced by this Court, "will allow the appeal unless **it clearly appears** that a patent granted on the specification will be invalid, because a refusal is final whereas an acceptance is not" (at 239, E). Gibbs J referred to *Commissioner of Patents v Microcell Ltd* (above) and to *McDonald v Commissioner of Patents* (1913) [15 CLR 713](#). His Honour regarded it as clear that the proposed amendments would make the patent bad and ought to be refused. The case is not of great weight because it does not involve the same question as is before me.

56 In *Montecatini Edison S.p.A. v Eastman Kodak Co* (1971) 45 ALJR 593, Gibbs J also had before him an appeal brought from a decision of a Deputy Commissioner granting an application, following opposition proceedings. The application related to a product to be prepared by a polymerization procedure using a novel type of catalyst. His Honour observed (at 595) that he found *"it impossible to hold... that the effective components of the respondent's catalyst were the same as those already known and used."* His Honour said that before he could so hold, it would be necessary for him to resolve in favour of the appellant the conflict of evidence between the witnesses for the parties. Both parties before him agreed that he ought not find in favour of the appellant on the issue of want of novelty or that of obviousness unless he was satisfied that the appellant's case had been **clearly made out**.

57 Gibbs J referred to *Commissioner of Patents v Microcell Ltd* (above) at 595. His Honour considered that in the case before him it was *"impossible to decide the questions that have arisen except by applying the principle that the grant should not be refused unless it has been **clearly shown** that the grounds of opposition have been made out"* (at 596, B). His Honour observed, in referring to *Commissioner of Patents v Microcell Ltd* (above), that whereas that case involved rejection at the application stage, there had been no Australian authority that established a similar rule in opposition proceedings. His Honour referred, however, to decisions under English legislation, in particular, to *General Electric Co.'s Applications* [1964] RPC 413, at 452-3.

58 One important distinction so far as the English legislation is concerned is that one of the grounds upon which the grant of a patent could be opposed under the *Patents Act 1949* (UK) was that the invention is *"obvious and clearly does not involve an inventive step having regard to matter published"*. Thus, the UK Act itself imports a standard by reference to which opposition was to be considered. That standard was not imported into revocation proceedings. In *General Electric Co.'s Applications* (above) Diplock LJ observed that the difference in phraseology between the opposition grounds and the revocation grounds reflected the difference in the character of the proceedings upon opposition to the grant of a patent and in an action for the revocation of a patent. His Lordship said:

"The effect of the former is to dismiss the applicant's claim in limine in pursuance of the public policy, inherent in the adoption of a system of granting only 'examined patents,' that the register shall not be cluttered up with patents which would be certain to be revoked by the Court in a revocation action." (at 452, line 19).

59 However, His Lordship said that it was apparent, both from the wording of the provisions, and from the comparison of the procedure in relation to opposition with the procedure in an action for revocation, that the jurisdiction to refuse the grant of a patent on the grounds specified in the opposition paragraph should be exercised only in **clear cases** (at 453). His Lordship went on to say:

"The right principle is that if on the face of the written evidence filed there appears to be a bona fide conflict of fact or credible expert opinion upon a question on the answer to which the existence or non-existence of the ground for refusal specified in s. 14(1)(e) [an

opposition ground] *depends, the Comptroller should not exercise his jurisdiction to refuse the grant unless, after cross-examination of the witnesses if he thinks fit to order it, the conflict is clearly resolved in favour of the party opposing the grant.*" (at 453).

There is explicit in that comment a recognition that cross-examination should not necessarily be permitted and that, even if it is, it is only when any conflict is **clearly** resolved that the grant should be refused. While, as I have said, the difference in the legislation detracts somewhat from the weight that should be given to that decision, the arguments of principle, it seems to me, apply equally in the context of the current Australian legislation.

60 In *Dennison Manufacturing Co v Monarch Marking Systems Inc* (1981) 51 AOJPTMD 1716 Fullagar J considered the nature of a proceeding under section 60(5) of the 1952 Act. His Honour considered (at 1717) that it was clear that the proceedings before the Court, although called an appeal, were by way of re-hearing dependent upon such admissible evidence as was tendered in the Court. The Court on appeal had all the powers conferred on the Commissioner by section 60, including those conferred by section 60(2). His Honour also considered that it was quite clear, although it was common ground and therefore apparently not argued, that the Court is by law bound to allow the appeal unless it appears to the Court **clear** that a patent grant on a specification could not be upheld (at 1717).

61 Fullagar J referred to *Henry Berry & Co Pty Ltd v Potter* (above) and to *Montecatini Edison S.p.A. v Eastman Kodak Co* (above) as well as *Commissioner of Patents v Microcell Ltd* (above). His Honour was clearly of opinion that one of six claims was anticipated. The claims that were dependent upon that claim were also therefore anticipated. However, his Honour was not satisfied that a patent confined to what is within the scope of claim 6 would be "*clearly bad*" (at 1722). His Honour drew a distinction between a claim that would be clearly bad and a claim that his Honour "*was not satisfied*" was other than a patentable invention.

62 Fullagar J's decision was upheld by a Full Court of this Court (*Dennison Manufacturing Co v Monarch Marking Systems Inc* (1983) 66 ALR 265). Smithers J observed, without demurring in any way, that:

"It was common ground before this court that a grant should not be refused in respect of any claim upon the grounds of novelty or obviousness unless it be clearly shown to the court that the ground has been made out." (at 266).

Franki J also noted, without demur, that:

"It was common ground before us that a grant should not be refused in respect of any claim upon the grounds of want of novelty or obviousness unless it appeared to the court clear that the ground had been made out: Montecatini Edison SpA v Eastman Kodak Co (1971) 45 ALJR 593 at 595-6." (at 270).

63 In *R D Werner Co Inc v Bailey Aluminium Products Pty Ltd* (1987) 8 IPR 339 King J of the Supreme Court of Victoria considered an appeal against a dismissal of

opposition proceedings. His Honour (at 334) referred to the same proposition of Gibbs J in *Montecatini Edison S.p.A v Eastman Kodak Co* (above), which had been cited without demur by the Full Court in *Dennison Manufacturing Co v Monarch Marking Systems Inc* (above). An appeal to the Full Court of this Court was dismissed: *R D Werner & Co Inc v Bailey Aluminium Products Pty Ltd* (1989) 25 FCR 565

64 In the course of his reasons in the Full Court, Lockhart J examined *McGlashan v Rabett* (above), *Stamp v Powell Pty Ltd* (above) and *Henry Berry & Co Pty Ltd v Potter* (above), without suggesting that the observations made in those cases were of no relevance to then current legislation, namely the 1952 Act. Lockhart J observed (at 582-3) that:

"When objection to the grant of a patent on the ground of want of novelty is taken, the courts will uphold the objection if it is a very clear case of absence of invention, or of something which obviously possesses no inventive merit whatsoever. There are sound reasons why a patent should not be granted if it is manifestly without any inventive merit."

It is implicit in that observation that, unless there is a clear case of absence of invention or a clear case of obviousness, there is no basis for refusing the grant of a patent, subject of course, as was made clear in the earlier High Court cases, to the validity being capable of challenge in revocation proceedings.

65 Finally, in *Genetics Institute Inc v Kirin-Amgen Inc* (above), the question of the grant of leave to appeal from a decision of Heerey J came before the Full Court. While the question presently before me was not directly in issue in the appeal, the observations made by the Court in a joint judgment are consistent only with recognition of a proposition that pre-grant opposition proceedings raise an issue which is different from the issue that would arise for determination in any revocation proceeding (see, for example, paragraph [17])

66 I have been taken to a number of other authorities in which questions have arisen as to the nature of the evidence that should be permitted in proceedings such as these. I do not regard any of those authorities as decisive one way or the other. As I have said, however, I do draw some comfort from the cases to which I have just referred for my conclusion, based on the scheme of the legislation, that there is a significant distinction to be drawn between the nature of an opposition proceeding under section 60 (or under the 1990 Act for that matter), on the one hand, and proceedings for revocation on other. The former is, in a sense, in the nature of an interlocutory proceeding, although any analogy tends to be misleading. There are some suggestions in early High Court authorities, that an opposition proceeding is in the nature of a summary proceeding (see *McGlashan v Rabett* (above) at 229-230 and *Henry Berry & Co Pty Ltd v Potter* (above) at 138). Either analogy might suggest that the question to be determined in an opposition proceeding is whether there is a serious question as to whether or not a patent, if granted, might be valid. If there is, then the application should proceed to grant.

67 The language employed in the cases to which I have referred suggests that it should appear clear to the Court that no patent granted in respect of the specification would be valid. I consider that, before the Court would uphold an opposition to the grant of a

patent, the Court should be clearly satisfied that the patent, if granted, would not be valid. That, however, is not to say that an opponent should not be permitted appropriate opportunity to lead evidence-in-chief as to the facts that are designed to demonstrate, with the requisite degree of clarity, that a patent, if granted, would not be valid. Where the subject matter of the patent is one of complexity, of necessity, the evidence that an opponent would be entitled to adduce would itself be of considerable complexity.

68 I am not persuaded at this stage that evidence of the nature sought to be adduced from Dr Mosbaugh is such as should be excluded, subject of course to the evidence being otherwise in admissible form. On the other hand, it may be that when I have seen all of the evidence sought to be relied upon by New England Biolabs, I could form the view that, whatever evidence is adduced by the Applicant, I would not be satisfied with the requisite degree of clarity that a patent, if granted, would not be valid. Alternatively, it may be that I would be satisfied on the basis of that material, and nothing else, that a patent could well be invalid if granted. In that case, of course, it would be necessary to consider the evidence sought to be adduced on behalf of the Applicant.

69 I would expect that there would be no occasion for extensive cross-examination of witnesses for either party, assuming both parties adduce evidence. That is not to say, of course, that one would ordinarily exclude all cross-examination. For example, it may be that counsel would seek to elicit evidence from a witness that is otherwise not available. However, extensive cross-examination to demonstrate that a witness's views ought not to be accepted or are unreliable, would, in my view, be permitted only in very exceptional circumstances.

70 I consider that the material in question to which objection has been taken should be permitted subject to all proper objections as to form.

I certify that the preceding seventy (70) numbered paragraphs are a true copy of the Reasons for Judgment herein of the Honourable Justice Emmett.

Associate:

Dated: 9 May 2000

Counsel for the Applicant: Dr A.C. Bennett SC & Mr S. Burley

Solicitor for the Applicant: Sprusons:Solicitors

Counsel for the Respondent: Mr B. Caine & Ms K. Howard

Solicitor for the Respondent: Blake Dawson Waldron

Date of Hearing: 10, 11, 12, 17, 18, 19, 20, 26, 27 & 28 April 2000

Date of Decision: 28 April 2000