NEW ZEALAND INTELLECTUAL PROPERTY OFFICE

# 2009 Business Updates

## Request for postponement of acceptance under section 20(1) of the Patents Act 1953

Applicants may at any time prior to acceptance request that a patent application not be accepted for a period of up to 18 months from the date of filing of the complete specification or from the 31 month examinable date for applications entering the New Zealand national phase (see Information for clients No.9 published 20 December 1999).

Applicants may request postponement of acceptance of up to 18 months in a letter to IPONZ (e.g. in a letter accompanying a new patent application or subsequent letter). IPONZ will not subsequently require or request the filing of a Patents Form 14.

For new applications filed online, applicants can request a postponement of acceptance of either 15 or 18 months by selecting the appropriate option provided on the online application form. There is no need for the applicant to provide a follow-up letter or to file subsequent Patents Form 14.

Applicants may also choose to make a request for postponement of acceptance through the online correspondence system.

Please note, that the time period provided under s.20(1) for any postponement of acceptance is rigidly bound to the filing date of the application or 31 month examinable date, as appropriate. The postponement period provided under s.20(1) is not extendible under the extensions of time provided under s.93 to place an application in order for acceptance.

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## English Language Translation – Entry into New Zealand PCT National Phase

In accordance with Regulation 3 of the Patents (Patents Cooperation Treaty) Regulations 1992, an English translation and accompanying certificate of verification, i.e. a verified translation, of any document which forms part of a PCT application for entry into the national phase in New Zealand and which is not in the English language, shall be filed at IPONZ within three (3) months of the commencement of national phase (31 months from earliest priority). Typically, those documents which will require a verified translation are the description, claims and figures.

Where a request to enter national phase is filed on or after 1 November 2008, and the verified translation is not filed at the time of entry into national phase, IPONZ will inform the applicant in writing and set a date three (3) months beyond the commencement of national phase (31 months from earliest priority date) for the verified translation to be filed.

If a request for entry into national phase was made prior to 1 November 2008 and a verified translation was not filed at the time of the request or since, IPONZ will inform the applicant in writing of the requirement to file the verified translation and provide a period of three months from the date of the letter for the verified translation to be filed.

In accordance with Regulation 3(2) & (4) of the Patents (Patents Cooperation Treaty) Regulations 1992 as amended, applicants may request, in writing, a further extension of time of, at most two (2) months of the date set, for providing a verified translation. Any request for an extension of time to provide a verified translation should be made prior to the expiry of the extension period.

Failure to provide a verified translation within the three month period, or within the two month extension period (i.e. a total of five (5) months) will result in the application being made void under section 26F(d) or Section 26F(e) of the Patents Act 1953. An application made void under this practice cannot be restored under section 37 of the Patents Act 1953.

Please note that applicants may file an application for entry into the national phase including verified translations of documents and subsequent verified translations or requests for extensions of time to provide a verified translation online using respectively the online filing and online correspondence modules.

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## Online filing facility for patent applications

An online facility for filing patent applications was introduced by IPONZ in early November 2008. The facility has a number of differences from the existing methods of filing a patent application on paper.

The online filing facility allows registered users to file patent applications in the English language accompanied by either a provisional specification or a complete specification, and allow requests for entry into national phase in New Zealand from Patent Cooperation Treaty (PCT) applications.

Applicants are able to file online applications for: “divisional" applications and request antedating of the application; patents of addition; and to designate whether the application is a “convention application” or a “non-convention” application.

The online filing facility does not provide an option for filing of a “complete after provisional” specification i.e. a complete application which claims priority from one or more earlier filed applications accompanied by a provisional specification. However, a complete after provisional specification can be filed either using the online correspondence facility provided by IPONZ or on paper.

## Patent forms 1, 2 and 3 and entry into national phase requests.

The use of the online application form by a registered user satisfies certain filing requirements of a new patent application. When using the online application form there is no need to file separate patent forms 1, 2, or 3 or an “entry into national phase request form” with the online application or to send these patent forms separately at a different time. Under Regulation 9, IPONZ accepts the online form as a suitable alternative to the identified forms.

## Requirements for online filing of patent specifications:

As with filing a patent application on paper, only one copy of a provisional or complete specification is required to be provided with an application made using either the online filing or the online correspondence facilities. Only a single specification document can be attached to the online application, preferably in the .pdf document format.

All specifications, other than those accompanying entry into national phase applications that are filed online, should be in the English language and include a first page that is either a patent form 4 (provisional specification) or a patent form 5 (complete specification) as appropriate.

Alternatively, a first page that clearly indicates that the specification is a “Provisional Specification” and includes the title of the invention will be an acceptable alternative to a form 4, and a first page that clearly indicates that the specification is a “Complete Specification” and includes the title of the invention will be an acceptable alternative to a form 5.

If the complete specification is filed (using the online correspondence facility) to complete an earlier filed provisional specification or specifications, the alternative front page should include an indication of the earlier application numbers and dates of filing from which priority is being claimed.

For national phase entry applications, applicants may attach an English language translation (including as part of a single document the certification of the translation) or a copy of the English pamphlet of the international specification to the online filing form. Amended pages may also be attached as a separate document. IPONZ will generally recover the other pertinent documents for the application from WIPO and applicants are requested not to attach other documents to the online filing form for national phase entry.

Users should be aware that the online application “forms” are not permanent forms, but rather online data entry forms for creating a patent application record in the IPONZ patent database. Consequently, except for a brief period of up to 90 days for which they are stored and can be presented and printed for the applicant, thereafter the “forms” no longer exist and IPONZ does not store or keep a record of the completed form. Of course, the data extracted from the form immediately the application is submitted is part of the patent application record. IPONZ considers that the process complies section 26 of the Electronic Transactions Act 2002 which sets out the legal requirement to retain information that is in electronic form.

## Authorisation of agent

An authorisation of agent form is not required when filing a patent application using the online filing facility, as the agent will be recognised as the appointed agent. Regulation 14 requires the applicant to provide a written and signed authorisation of agent to the satisfaction of the Commissioner. The signatory requirements of applicants and/or their representative are considered by the Commissioner to have been met when filing online using the online filing form. (see also the practice note on General Signatory Requirements for Online Filing of Patents and Designs)

## Convention applications: verified convention documents and verified translation certificates

An electronic copy of the convention document (including the verification certificate) as a single electronic file, may be attached and uploaded with the online filing form to satisfy the requirements under regulation 25(1). The document may be in the electronic form as provided by the originating office or may be derived from a scanned paper document and verification certificate.

Original verification certificates of English translations do not need to be supplied to IPONZ, a scanned electronic copy of the verification certificate uploaded with the translated specification will be deemed to satisfy regulation 25(2).

Alternatively these documents which support the claim to convention priority may be filed at a later date, either on paper or preferably as electronic documents via the online correspondence facility.

## Declaration of inventorship:

The online filing form provides the option of providing various inventorship details equivalent to a patent form 6 (a declaration of inventorship). If these parts of the online forms are completed at the time of filing then a declaration of inventorship signed by the applicant will not be required at a later date.

## General signatory requirements for online filing of patents and designs

With the introduction of patents and design applications online filing facilities, IPONZ considers that the user logon requirements which must be completed before an application can be filed online satisfy the conditions under Section 22 of the Electronic Transactions Act 2002 for a legal requirement for a signature to be met by means of an electronic signature.

Therefore, regulation 13 of the Patents Regulations 1954, and regulation 19 of the Designs Regulations 1954, (which provide (in part) that an application to the Commissioner for the granting of a patent or registration of a design shall be signed by the applicant or his agent) are met by a user completing the logon requirements of the online filing facilities and becoming a registered user.
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## Swiss-type claims (superseded)

This is a guide to the examination of applications relating to the Swiss-type claims under the Patents Act 1953 ("the Act"). This Guide does not constrain the judgment and discretion of the Commissioner of Patents, and each application will be considered on its own merits.

### Introduction

The method of medical treatment exclusion to patentability has historically caused problems where a known substance, already used to treat a particular medical condition, is found to be useful in treating some other medical condition, this second use having been previously unrecognised. The substance itself cannot be patented because is not new. As most recently confirmed by the Court of Appeal in *Pfizer Inc v The Commissioner of Patents* [2005] 1 NZLR 362, the method of treating the particular medical condition cannot be patented either. Without patent protection, there may be little incentive to investigate the properties of existing pharmaceuticals to determine if they have other, previously unknown, medical uses.

In the European community, where methods of medical treatment are also unpatentable, the Swiss-type claim was devised to enable second medical uses to gain some patent protection. These claims were termed "Swiss-type" claims since they were first allowed in a 1984 decision of the Swiss Federal Intellectual Property Office. If the use of the compound for the specified therapeutic purpose is new, then such a claim is considered to be novel even if the same substance had previously been used in medicine for a different purpose. The protection of second therapeutic use by Swiss-type claims was allowed by the Commissioner of Patents in a Practice note which appeared in Patent Office Journal 1412 on 7 July 1997, and was approved by the Court of Appeal in *Pharmaceutical Management Agency Ltd v Commissioner of Patents.*

### First therapeutic use - forms of claim

Suitable forms of claim which have been allowed for the first indication of a therapeutic use of a compound are:

i. (Substance X) for use in the treatment of (medical condition Y).

ii. (Substance X) for use as a (Y-treating agent).

iii. As a (Y treating agent), the (substance X).

iv. (Substance X) for use in therapy (or for use as a medicament).

## Second therapeutic use - form of "Swiss-type" claims

The following is the general form of a Swiss-type claim:

> The use of [known compound X] for the manufacture of a medicament for the treatment of [new therapeutic indication Y]

The particular wording of a Swiss-type claim does not need to be exactly as above, as long as it contains the essential integers.

In addition, the following types of claim are **not** acceptable Swiss-type claims:

> i) Known substance X for use in the treatment of medical condition Y. *This is a claim merely indicating the suitability for use of substance X,*
> ii) The use of known substance X in the treatment of disease Y. *This is an unpatentable method of treatment claim.*
> iii) Commercial package containing as an active pharmaceutical agent compound X together with instructions ... for treating condition Y. *If the pharmaceutical use of X is already known, the claim is only distinguished from the prior art by the content of the instructions, and this represents a mere presentation of information and thus not a patentable invention under section 2.*
> iv) A process for the manufacture of a medicament for use in the treatment of medical condition Y, characterised by the use of substance X. *This claim does not adequately define the use of substance X, thus is unclear under section 10(4).*
> v) The use of known compound X for the manufacture of a medicament for the treatment of new therapeutic indication Y, wherein the medicament is administered orally. *The mode of administration should only indicate the form of the medicament, such as "the medicament is formulated for oral administration", rather than impart a monopoly on the administration of the medicament.*

## Swiss-type claims and section 2

Swiss-type claims to substances or compositions can only derive novelty from their intended use if the use is a therapeutic method excluded under section 2 of the Patents Act 1953. In *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [2000] 2 NZLR 529 (Pharmac) the Court of Appeal stated:

> In this particular field where [the new use] cannot be captured with a method claim, we would accept the designation of purpose as sufficient

Swiss-type claims are not allowable for the new use of a known substance in, for example, non-surgical cosmetic methods. However, an application may include both claims to the second medical use of a compound for therapeutic purposes, and claims to cosmetic or other patentable methods using the compound, providing the therapeutic and non-therapeutic methods are distinguishable.

Likewise, genuine Swiss-type claims (wherein the novelty derives from the new use) are only acceptable when directed to the treatment of humans. Methods of treating non-human animals are allowable under section 2, thus the *"designation of purpose"* cannot provide novelty to claims in Swiss-type format for the treatment of non-human animals. If it is clear that the Swiss-type claims, when read in light of the specification, are directed to the treatment of humans only, there would not usually be any need for an explicit restriction. Conversely if the claims or specification do indicate the use of the medicament in the treatment of non-human animals, amendment may be necessary.

If an application includes unpatentable method of treatment claims, such as "The use of X to treat Y", amendment of these claims to convert them into Swiss-type claims does not constitute added matter.

Claims may be expressed in the general Swiss-type format whether or not the substance is known or has been used in therapy previously. There is no requirement for evidence concerning prior medical use to be included in the specification.

## Second medical use claims - the new use

### i) Treatment of a new disease or condition

The decisions of the Commissioner in the 7 July 1997 Practice note, and the Court of Appeal in *Pharmac,* established that the use of a substance for a new and inventive therapeutic application can be protected by a Swiss-type claim. Typically, Swiss-type claims are used to protect the use of a substance or composition in the treatment of a specified disease, where it had previously been used for the treatment of a different disease. Providing the use of the substance in the treatment of the disease or therapy is not known, such claims are considered to be novel. Guidance on evaluating novelty may be taken from the decision in *Schering A.G.'s Application* [1985] RPC 553, wherein it is stated:

> … a "second pharmaceutical use" invention, which is also referred to as the "second medical indication", that is to say an invention based on the discovery that a drug already known for a particular medical activity (or activities) has another useful medical activity unconnected with the first and which had not previously been expected.

### ii) New method, time, frequency or dosage of administration

Swiss-type claims which attempt to distinguish the new use from the prior art by the way in which the medicament is used are not acceptable, as they only define a new method of treatment. Such claims are therefore excluded from patentability under section 2 of the Act. A claim which defines the use in terms of the mode of administration, or the quantity, frequency or timing of dosage is therefore considered to be an attempt to monopolise a new method of treatment, disguised by drafting it in the Swiss-type format. This follows from the decision of the UK Court of Appeal in the *Taxol case (Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [2001] RPC 1) approved by the Assistant Commissioner in*Abbott Laboratories,* (P16/2003).

The claim in question in the *Taxol* case had the wording:

> Use of taxol and sufficient medications to prevent severe anaphylactic reactions, for manufacturing a medicamentation for simultaneous, separate, or sequential application for the administration of from 135 mg/m2 up to 175 mg/m2 taxol over a period of about 3 hours or less as a means for treating cancer and simultaneously reducing neutropenia.

The UK Court of Appeal held that this claim defined an improvement in the method of administering an existing treatment; it did not define a new and inventive therapeutic purpose (taxol was known to treat cancer). In particular, it was noted that all the claimed steps were in fact directed at actions taken by the doctor, tailored to the individual patient, rather than being directed at the manufacturer. *Aldous LJ, Bristol-Myers Squibb v Baker Norton Pharmaceuticals:*

> The claim is an unsuccessful attempt to monopolise a new method of treatment by drafting it along the lines of a Swiss-type claim. When analysed it is directed step-by-step to the treatment. The premedication is chosen by the doctor, and administered prior to the taxol according to the directions of the doctor. The amount of taxol is selected by the doctor as is the time of administration. The actual medicament that is said to be suitable for treatment is produced in the patient under supervision of the medical team. It is not part of a manufacture.

Therefore, if the "new medical use" in a claim relates to the manner in which the doctor performs the treatment then an objection should be made under section 2 that the claim defines a method of treatment. For example, a claim which includes a dosage specific to the weight or size of the patient (as in the *Taxol* case) is not allowable. Any claim in which the "medicament" is only synthesised inside the patient's body also defines a method of treatment.

Moreover, the UK Court of Appeal in Taxol concluded that the second medical use must be aimed at a different end-result from the prior art, rather than merely a different method of obtaining the end-result. Buxton LJ, *Bristol-Myers Squibb v Baker Norton Pharmaceuticals:*

> The novelty cannot lie in the method of use, but in the new therapeutic purpose for which the substance is based.

The United Kingdom Court of Appeal in *Taxol* made the following comments on the interpretation of the *Court in Pharmac*, on the novelty providing feature of a Swiss-type claim:

110. Mr Waugh QC placed reliance upon the recent decision of the Court of Appeal of New Zealand in *Pharmaceutical Management Agency Limited v Glaxo Group and others*, in which judgment was given on the 17 December 1999. But it does not seem to me to assist him. In their analysis of *Eisai*, the Court of Appeal of New Zealand said, at paragraph [38] of their judgment, that:

"The step necessary to render Swiss-type claims acceptable would be to recognise what is in fact the situation, that the novelty as well as the inventiveness resides in the newly discovered purpose for which the medicament is to be used."
At paragraph [65] they said:

"Once it is accepted that there can be new invention in the discovery of previously unrecognised advantageous properties in a chemical compound, the obligation to make patent protection available must apply."

111. In the present case, however, the drug, taxol, is exactly the same; the method of administration, by injection and infusion, is exactly the same; and the therapeutic application or purpose, namely the attempt to treat cancer, is exactly the same. The only difference is the discovery that if the drug is infused over a shorter period an undesirable side-effect, neutropenia, is less that it otherwise would be, while the therapeutic effect remains. No "previously unrecognised advantageous properties in [the] chemical compound" have been discovered. All that has been discovered (important though that discovery is) is that if the compound is administered over a shorter period, one of its disadvantageous side-effects will be less than it otherwise would be.

112. In my view this is not a second medical use claim of the kind validated by *Eisai*or any of the cases that were drawn to our attention in which the principle of *Eisai*has been applied.
The *"previously unrecognised advantageous properties"* referred to in *Pharmac* must be found in the chemical compound, and not the dosage regime or the dosage amount. The novelty must reside in the *newly discovered purpose*, and not the mode of administration or the amount, timing or frequency of dosage.

This conclusion is supported by the UK Patent's Court and Court of Appeal in *Merck and Co Inc's patents [Alendronate]* [2003] FSR 29 (upheld by the UK Court of Appeal [2003] EWCA Civ 1545). In this case, a Swiss-type claim based on a new dosage regime (a single weekly administration of 70 mg of alendronate as opposed to daily administration of 10mg) was refused.

### iii) New mechanism or technical effect

Swiss-type claims that relate to the same therapeutic use as the prior art, but claim a different technical effect or mechanism of action, will be rejected as lacking novelty; how a treatment works is irrelevant. An objection under section 2 that the claim defines a discovery rather than a manner of new manufacture may also be made.

The UK Patents Court in the *Taxol* case held that a new piece of information about how a treatment worked did not constitute an invention if it did not lead to a new use. This was upheld by the UK Court of Appeal. Swiss-type claims based solely on a new technical effect when treating the same condition will not be allowed.

### iv) New advantage to known use

The discovery of an unexpected advantage in a known treatment does not constitute a new therapeutic use, although it may form the basis of such a use. In the *Taxol* case, the claim was based partly on the unexpected discovery that a shorter infusion time for a chemotherapeutic agent led to a lessening of the harmful reduction in white blood cells (neutropenia). However, the shorter infusion time had already been disclosed - this was merely an additional piece of information about a known treatment. Jacob J, *Bristol-Myers Squibb v Baker Norton Pharmaceuticals:*

> …there is a big difference between new information that a prior proposal previously thought unworkable in fact works and new information to the effect that a prior proposal has an additional advantage.

### v) Co-administration

In the pre-acceptance hearing concerning an application by *Abbott Laboratories*(P16/2003) the Assistant Commissioner considered claims directed to the use of a known compound, ritonavir, in the manufacture of medicaments when formulated for sequential or co-administration with a novel compound, for ritonavir's known use. The novelty of the Swiss-type claims, for the known compound, did not reside in the therapeutic application, but in the suitability for co-administration of the medicament. The Assistant Commissioner decided that the claims were analogous to those of the *Taxol* case and did not comply with the definition of Swiss-type claims. The same consideration applies when there has been a synergistic effect identified with the co-administration of the two compounds. A claim to the use of known compound X in the manufacture of a medicament for synergistically enhancing the effect of compound Y, in a treatment for which X and Y are already known for, is not a proper Swiss-type claim because the novelty does not reside in a new therapeutic use.

Likewise, if a claim is directed to the use of compound X in the manufacture of a medicament for enhancing the effect of compound Y, in a treatment that X was not previously known for, the claim is not a valid Swiss-type claim. The novelty does not reside in the new therapeutic application of compound X, because compound X does not provide the indicated therapeutic effect. The novelty resides in the administration of compound X with compound Y to enhance the effectiveness of compound Y. As decided in*Taxol* and approved in *Abbott Laboratories*, such claims are not valid Swiss-type claims and should be regarded as method of treatment claims.

### vi) The new therapeutic use

Swiss-type claims can only be used to protect the use of a substance for a specified new and inventive therapeutic application. It must be clear from the claims, read in light of the specification, that the indicated treatment is in fact therapeutic. For example, a Swiss-type claim for the use of a compound in the treatment of a condition that can be improved or prevented by "selective occupation" of a receptor, or a condition "associated with a receptor", does not define a therapeutic treatment. If a claim is defined in mechanistic terms, it must be clear that the mechanistic activity itself is therapeutic.

The therapeutic use must be defined in clear and unambiguous terms. Such as, for a therapeutic indication defined mechanistically as a condition ameliorated by antagonism or agonism of a receptor, it must be disclosed or known from the prior art that both agonism and antagonism of that receptor result in therapy. The specification should disclose the medical conditions that are treated by the particular mechanistic activity. If there are no specific medical conditions disclosed or known to be treated by that activity, then the claim is not directed to a new therapeutic use, but to the mere discovery of a physical property of a chemical compound.

## Second therapeutic use claims - the substance or composition

### i) Assessing novelty

The scope of the substance defined in a second therapeutic use claim was considered by the UK Court of Appeal in *American Home Products v Novartis*, [2001] RPC 8, concerning Swiss-type claims for the use of a known antibiotic (rapamycin) for inhibiting organ or tissue transplant rejection. The UK Court of Appeal held that the claim did not cover derivatives of rapamycin - thus finding the claim not infringed by the use of a rapamycin derivative as an immunosuppressant.

### ii) Fair basis when the substance is defined by chemical structure or class

Swiss-type claims are often worded to cover derivatives of a compound, or compounds comprising a particular structure, which by definition include derivatives. Claims of this type must be considered carefully to determine whether there is support for a claim extending beyond the exemplified embodiment(s), particularly where there is only one such embodiment.

If the specification discloses a general principle capable of general application, a claim in correspondingly general terms may be acceptable. There is no need to show proof of its application in every individual possible instance which could fall within the scope of the claim. *Aldous LJ, American Home Products v Novartis:*

> Thus if the patentee has hit upon a new product which has a beneficial effect but cannot demonstrate that there is a common principle by which that effect will be shared by other products in that class, he will be entitled to a patent for that product but not for the class, even though some may subsequently turn out to have the same beneficial effect... On the other hand, if he has disclosed a beneficial property which is common to the class, he will be entitled to a patent for all products of that class (assuming them to be new) even though he has not himself made more than one or two of them.

### iii) Defining the active ingredient by functional activity

Claims are often made for the second medical use of a group of compounds defined functionally; for example, as antagonists of a particular receptor. This type of claim was at issue in *Pfizer's Patent,* [2001] FSR 201, which included claims to the second medical use of phosphodiesterase inhibitors. Such claims are not inherently objectionable, and in this case there was no suggestion that this form of claim was unduly broad and speculative. Although, the mere fact that a member of a functional class of compounds can be used to treat a disease does not mean that all such compounds will, particularly if there is no evidence that the treatment is related to that specific activity. It was established in *Pfizer's Patent,* that a claim to, for example, "the use of an inhibitor of A in the manufacture of a medicament for the treatment of disease X" is anticipated by any disclosure of the use in treating disease X of a compound which inhibits A, regardless of whether the treatment is explicitly stated as being caused by the inhibition of A.

## Unity

Where the substance is known to have a therapeutic use, second therapeutic use claims directed to a variety of different diseases may give rise to a unity objection. A unity objection may be avoided if the conditions are related (and unrelated to the known conditions), or if there is a common mechanism linking the treatments.

## Second therapeutic use and apparatus

The Commissioner in the 7 July 1997 Practice note, and the Court of Appeal in *Pharmac*approved Swiss-type claims only for pharmaceutical compositions or medicaments indicating a new therapeutic use. The indication of a new therapeutic use to distinguish from the prior art any other product or apparatus will not provide patentable subject matter unless the new use inherently necessitates a novel material difference.

## Fair basis for the therapeutic use in Swiss-type claims

Swiss-type claims, which are to the further medical use of a substance or composition, must be supported by evidence that it is (or at least is likely to be) effective for the specified use. The specification should therefore provide, in the description as filed, an indication that *in vivo* or *in vitro* tests have been conducted and that positive results ensued (not necessarily quantified). Lack of any data, even rudimentary, in the description of an application which includes claims to a second therapeutic use should be objected to under section 10(4) as lacking fair basis.

A Swiss-type claim must meet the equivalent provisions of a selection patent in that the actual discovery of the new properties must be disclosed. As stated in *Pharmac*:

> Just as there can be invention and novelty in the discovery of unrecognised properties in known substances qualifying for patent protection under the doctrine of selection patents and under the decision in NRDC, so there can be invention and novelty in the discovery of unrecognised properties of known pharmaceutical compound

Additionally the general principles established in *Olin Mathieson Chemical Corp. v Biorex Laboratories Ltd* [1970] RPC 157 should be applied to determine the fair basis of Swiss-type claims. In *Olin Mathieson* it was established that if a person skilled in the art could make a prediction based on the common general knowledge of the art, and what was further disclosed in the specification, and that if the prediction could be made with a reasonable degree of certainty, the prediction is sound, Graham, J. at 193:

> If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so.

For a prediction on a further therapeutic use of a known compound to be considered a sound prediction, it must be based on actual experimental data otherwise the prediction is based only what is already known in the art. A Swiss-type claim is novel only if the further therapeutic indication is not known from the prior art. Thus the prior art cannot be relied upon to support the “discovery” of the further therapeutic properties. Such a prediction made in the absence of any experimental data is unsupported and cannot be made with any degree of certainty, and is therefore not a sound prediction. As established in *Olin Mathieson*, a claim based on a prediction that is not sound is not fairly based on the disclosure.

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