

**Submissions on Behalf of**

**INTERPAT**

**Concerning Proposals Affecting the**

**PATENT SYSTEM**

**in the Interim Report of the**

**INTELLECTUAL PROPERTY & COMPETITION REVIEW COMMITTEE**

**8 May 2000**

## **INTERPAT**

INTERPAT is an association of research-based pharmaceutical companies which is committed to the improvement of intellectual property laws around the world. Sound intellectual property protection is essential in order to provide the incentive for these pharmaceutical companies to invest in research and development in the search for new medicines for the treatment and prevention of diseases.

Member companies are multinational, research-oriented pharmaceutical companies with substantial world-wide turnover in innovative pharmaceutical products. Representatives are the key intellectual property experts from the member companies. The organization has regular meetings to discuss initiatives focused on fostering the improvement of laws by advocating governmental actions to improve, strengthen and harmonize intellectual property regimes throughout the world. Work groups targeting specific areas of the world develop initiatives for their specific regions.

A current key issue for INTERPAT is the world-wide implementation of the TRIPS Agreement which entered into force on January 1, 1995 as a result of the GATT negotiations. An example of work product stemming from INTERPAT is the attached publication which is aimed at providing a valuable resource for those involved in issues related to TRIPS. The footnote on page 1 provides a listing of the current member companies of INTERPAT.

Attach: "An analysis of the Pharmaceutical-Related Provisions of the WTO TRIPS (Intellectual Property) Agreement" by Jacques, J. Gordlin, Ph.D.

INTERPAT welcomes the extensive analysis by the Committee in its Interim Report and supports many of the proposed changes. It makes the following comments.

#### Manner of new manufacture

INTERPAT supports the Committee's recommendation in relation to the test for patentability as applied in Australia. This does provide for the development of the patent system to cover new areas of technology and is superior to the fixed definitions applied in some other countries.

#### Exclusions from manner of manufacture

We support the recommendation of the Committee that mere discoveries should not be included as patentable subject matter. However, care needs to be exercised in defining this exclusion to ensure that it does not exclude, from patentable subject matter, matter that goes beyond mere discovery. An example is a pharmaceutical substance isolated from natural material or which may be isolated from natural material but is in fact synthesized. While the mere identification of a gene sequence might be excluded, strips of DNA and RNA which are not found in isolated form in nature are more than a mere discovery. A substance which has been so isolated satisfies the requirements for novelty since it has not existed in that form before and provided it is industrially useful, constitutes an invention. The current law, as applied by the Courts is, we submit, satisfactory. Any attempt to proscribe mere discovery in the Act is likely to lead to ambiguity and possibly result in the exclusion of things which are both discovery and invention.

In relation to utility, we agree with the recommended approach based on the USPTO revised interim utility guidelines and that this should form part of the examination criteria provided that the assessment is based on the description of the invention. The applicant should only be required to indicate a credible utility. It should not be a requirement to provide evidence to supplement or support what is said in the description. The examiner is not in a position to test any such evidence and this would only serve to complicate the examination process. Of course, in revocation proceedings, where the opponent produces evidence to challenge the presumption that the invention is useful, the patentee may be required to support the utility.

### Inventiveness or obviousness test

We agree that the European standard for obviousness is appropriate. Combinations of prior art documents should only be permitted where it would be obvious to the persons skilled in the art to combine the information to provide the solution. The application of a universal standard of inventive step is of advantage to industry. It creates a level of certainty and conformity. Where the same art exists, it is not unreasonable to expect that a patent valid in one country will be valid in another or if invalid in one country will be invalid in another.

### Admission of Prior Art

In the United States of America, Europe and other countries, it is necessary to describe an invention in the light of the prior art. It is necessary to show not only that the invention is novel but what in it is novel. As a consequence, it is practice for patent specifications to begin with a full description of what was known before, including matters that were generally known and matters which were published but not generally known. Usually this traces the steps taken by the inventor pointing to the positive and negative aspects of what was published or proposed by others.

In Australia, the law is that, all that is necessary is that the invention is novel, "does not have to go further and say what in it is novel" - see *BUSM v Fussell*.

However, patent specifications drafted for use in other countries are usually lodged in Australia in the same form. Indeed under the Patent Cooperation Treaty, the specification in an application entering the National Phase in Australia is the specification of the international application.

In recent times, the Australian courts have used admissions of prior art to invalidate the patent contrary to the manner in which those statements are used in other countries. Attached are pages of the decision of the Full Bench of the Federal Court in *Bristol Myers Squibb v Faulding*. Thus, what is required in many countries may lead to invalidity in Australia. As a consequence, a wise applicant is required to review and possibly amend the Australian specification after entry to the national phase to remove admissions to prior art. An Australian applicant filing an international application in Australia is wise to use the international format and also amend subsequently for Australia. This is so because amendment of the

specification in the United States or Europe can be difficult. To some extent this defeats the purpose of the Patent Cooperation Treaty. We therefore urge you to a recommendation that for purposes of new manner of manufacture and inventive step admissions of prior art be treated in the same way as they are treated in Europe and the United States.

#### Innovation Patent

We note that under the proposals for an innovation patent, no examination will occur before grant. This has the potential to create significant uncertainty and it is inconsistent with other aspects of the recommendations that the examination of patent applications should be thorough and that the granted patent should be presumed valid. We agree with proposal that there be a lower threshold of novelty provided that the same test is applied at the Patent Office level as it is applied by the courts (on the balance of probabilities test).

#### Administration of the patent system

We note the Committee's statement that it attaches "the greatest importance to ensuring that patents are granted when, and only when, they meet the statutory pre-conditions. The Committee notes that this will also ensure that patents that are granted are, and are known to be, strong, certain and enforceable. This will reduce the uncertainty involved in patent enforcement and increase the value of those inventions that legitimately attract the benefit of patent protection, thus further enhancing the incentive for innovation associated with the patent system". We agree with that sentiment but point out that the proposal regarding examination for the innovation patent is inconsistent with it.

Also, we agree with the proposal to apply a "balance of probabilities" approach in the examination process provided that there is a corresponding presumption of validity in the patent once granted.

#### Disclosure of prior art requirements

The proposition that the examiner should be aware of the pertinent prior art which is known has some attractions. But there are real difficulties with the practical implementation of a recommendation which would oblige an applicant to put this material before the examiner.

To whom is the material known? If this is to include anyone within to Corporate structure then it is an impossible requirement for a multi-national company with many thousands of employees in many countries to comply with. If it is merely the persons responsible for the filing and prosecution of the application then others in the company might avoid providing them with materials of which they should be aware.

What prior art should be disclosed? Only that art which is directly relevant to patentability or should it include matters which have a general relevance? Clearly the latter would create a mischief and a volume of prior art placing a heavy burden on both applicants and the Patent Office.

When should it be disclosed? Clearly the material should be available to the examiner when the case is before him. If acceptance is recommended then the materials might arrive too late and it is not a date of which the applicant is aware. We suggest that material known at the time that a request for examination is made should be provided.

Would it be necessary constantly to update the prior art as further material becomes known to the applicant? This requirement would place a considerable burden on applicants and on examining staff who would be required to re-assess the application.

Would it be necessary to submit copies of the references? Again, this provides a substantial volume of material for Patent Office files much of which would be of little relevance and it would place a cost burden on applicants. If it is not provided, there is a burden on the Patent Office to obtain details of the materials.

Would it be necessary to provide a translation of materials not in English? Again, this would place a significant cost burden on applicants.

What penalties would apply for non-compliance? In our view, the penalty should not go to the validity of the patent as occurs in the United States. This is a draconian measure. In our submission, the penalty should be that insofar

as that piece of prior art is concerned, the presumption of validity would no longer apply. In other words, the presumption of validity would apply except insofar as a cited reference was demonstrably known to the applicant but not provided to the examiner within the appropriate time requirements.

The system as it applies in the United States is unwieldy and works to the disadvantage of the patent system. The European and Japanese Patent Offices work very well without requiring a U.S. style prior art disclosure. Adopting the U.S. approach will only complicate the Australian granting process without any obvious benefit.

### Enforcement

We agree with the ACIP report referred to insofar as an appeals board should be established to hear the following matters:

Hearings related to review of internal decisions of examiners. This would be most important under the proposed system of balance of probabilities where a significant number of cases may go to the board.

Disputes related to requests for extension of time.

Opposition hearings including related ex-parte matters.

Re-examination and revocation proceedings.

We submit that this board should be independent of the examining function of the Patent Office and be seen to be so. This does not mean that it is independent of IP Australia. It could and should operate as a division of IP Australia as does the Patent Office, Trade Marks Office and Designs Office. IP Australia's submission appears to be an overly pessimistic view of the adverse consequence for the examining officers and appears to ignore the fact that the Board would provide a body of precedent to guide examiners.

### Presumption of validity of granted patents

For the reasons given before, we would support the recommendation in relation to novelty and inventive step. But this should not apply to procedural matters or to the question of what constitutes patentable subject matter. Otherwise this would confine the development of the concept of manner of manufacture which is a desirable feature of the system as explained by the High Court in the NRDC case and as embraced in your interim report.

### Appeals and enforcement

We support the position of ACIP as quoted in the report. There is a need for a relatively inexpensive process for appeals from Patent Office decisions and to hear invalidity and infringement issues. While there are many cases of significant importance that would continue to be appealed to and litigated before the Federal Court, there are also a significant number of cases where a less expensive option would be taken if available and where, at the moment, the costs of litigation are not warranted. A Federal Magistracy could be comprised by experienced practitioners and this would not interfere with the current work of the Magistracy.

We believe that appeal to the Federal Magistracy should be on the materials presented to the Patent Office.

We are not in favour of pre-grant opposition because we believe it can be used as a mechanism to delay the grant of a patent and to allow infringing activity to occur before grant. However, it is important that there be a relatively inexpensive mechanism for third parties to object to a patent. Hence, we would support the removal of pre-grant opposition only if there was a post-grant opposition or revocation procedure available either before the Patent Office, a new tribunal or the Federal Magistracy.

The length of trials in the Federal Court in Australia generally go far beyond the length of trials in other countries. This might arise because the presiding judiciary are not experienced in intellectual property matters and therefore significant time is taken to explain points that would not need to be explained to a specialist intellectual property jurist. In addition, because practitioners cannot be confident that the judge will be aware of the relevant issues, the preparation is significantly more extensive

than would otherwise be the case. Arguments are run that would not be run before an experienced IP jurist. Not only has this resulted in much more expense but some decisions are at odds with international patent practice. The establishment of a specialist intellectual property court within the Federal Court as exists within the High Court in England would go a long way towards obviating this major deficiency in Australia, particularly, when coupled with a Federal Magistracy. The Committee might wish to consider some of the arrangements being considered in Europe to establish a common speciality Court to deal with European Patent litigation (Optional Protocol on the Settlement of Litigation concerning European Patents - a copy follows.).