Contents

Please note: Only a small selection of the papers presented at the 4th FICPI Open Forum, Florence 1999 are available in electronic form.

PAPER: FLO/1.1.1 by Heinz BARDEHLE

Grace Period

6. The Grace Period was the corner stone of the WIPO-Harmonization Treaty (PLT).

The draft of this Treaty covers in it's Art. 12 the so called international Grace Period of 12 months, set before the priority (in contrast to the Grace Period according to Art. 55 EPC Grace Period of 6 months before the European filing date in case of obvious abuse). The Treaty was not adopted by the Diplomatic Conference in The Hague because of problems with the U.S. patent system of first to invent.

Now the Commission of the EU has taken an initiative to revive the idea of an international Grace Period. The Commission invited the organizations of the interested circles and individuals to a hearing on October 5, 1998 in Brussels (see enclosed time table).

The subject matter was introduced by 3 speakers:

M. Alain Gallochat, Directeur juridique de l'Institut Pasteur, Paris

M. Farag Moussa, President de la Federation internationale des assocations dÍnventeurs (IFIA), Geneve;

M. Brian Yorke, Head of corporate intellectual property at Novartis International, Bale.

The first two speakers strongly supported the idea of the Grace Period whereas Mr. Yorke clearly expressed his rejection of the Grace Period. He therewith introduced the views of the later speakers from the chemical industry.

The majority of speakers supported the idea of an international Grace Period under the preference of only 6 months, some with the proposal of 12 months. The supporters did not propose any relationship between a publication and an effect of priority so that the previous argument of the opponents was not raised.

The remarkable experience of this hearing is the strong and unanimous opposition of the big chemical industry which was in the position of a minority in the hearing. One reason for this opposition is that in a patent system with a Grace Period it would be more difficult for the patent departments of chemical enterprises to require the inventors not to publish before the filing date. An early publication is often the strong desire of scientists working in industry, who want to establish a particular reputation in the respective science.

The main reason for the rejection of the Grace Period is an alleged legal uncertainty. In this context the following example was given:

Publication of interesting subject matter by a third party.

Desire of a chemical enterprise to copy the subject matter of this article.

Waiting for 18 months in order to discover a corresponding patent application which could have been filed just one day before the publication date.

Further waiting for the term of the duration of the Grace Period in case that after the 18-months-period no published patent application has been found.

This additional waiting time is unacceptable for the chemical industry.

Another example for an alleged legal uncertainty is the following case which played a certain role in my own experience in the time when we had in Germany a Grace Period:

A patent application or a patent is published, the subject matter of which is of interest for a competitor. He finds a publication anticipating the published protection right with a date within the Grace Period. However, the publication does not show any relationship to the applicant. The interested competitor is not sure whether the anticipating publication may be irrelevant because it stems from the applicant.

With regard to the first case, several proponents of the Grace Period have submitted their view, that the applicant who enriches the state of the art by the publication of his ideas deserves more care than the competitor who just wants to copy ideas from another party. An applicant, who submits his teaching to the public and uses the Grace Period in order to avoid the failure of his patent application does something which should be encouraged by our legal system. In contrast, the competitor who just wants to copy without submitting any new ideas to the public should not be supported; to do so would discourage early publishing applicants from informing the public about their new ideas.

With regard to the second case I had explained in my written submission the solution to request from the applicant a statement whether he is entitled to invoke the Grace Period with regard to the publication or not. If he would not honestly clarify the situation he would loose his rights to claim the benefits of the Grace Period. This was the way of this matter in Germany under our earlier Grace Period.

The arguments of the proponents of the Grace Period from the association of inventors was essentially to help the innocent inventor who publishes his invention without knowing that this would be destroy the novelty of a later patent application. Therefore, the Grace Period would particularly be an important help for the individual inventor.

In contrast thereto I had submitted the view that there are several branches of our industry in which new technical developments take place outside the factories of the inventors.

Examples:

a. Shoe machines, tested in shoe making plants;

b. Machines for the chemical industries, tested in chemical plants;

c. Agricultural machines, tested in the open air on the fields;

d. Sporting articles (windsurfers), tested in areas with public accessability;

e. Bandages, protheses, equipment for the treatment of joints, tested on patients in hospitals with the assistance of physicians.

In the conclusions of the hearing given by Mr. Waterschoot, he pointed out that obviously the chemical industry is unanimously against the Grace Period. Further, he acknowledged the majority of supporting voices and in particular the need of certain industries to bring new ideas to the level of a mature invention by testing which cannot be done behind closed doors but sometimes under conditions with public access, and their needs must be considered.

From the side of the chemical industry the proposal was submitted to introduce or use the system of provisional application. This, however, is a dangerous trap because an applicant relying on a provisional application may later find that his disclosure is not adequate for a good patent. This was clearly expressed by the representative of the EPO, Mr. E. Koch, who reported about the experience of the EPO where patent applications filed in a premature state would normally lead to an unsuccessful examination procedure because of lack of enabling disclosure.

My conclusion is that it will be difficult for the chemical industry to prevent the further discussion about the Grace Period. However, the chemical industry will continue to strongly fight against any initiative of the Commission. Therefore, it is necessary for the organisations of the interested circles being in favour of the Grace Period to urge the Commission to issue a paper, possibly a Directive, for the introduction of the Grace Period at least in the EU. It was determined in the discussion that only a worldwide Grace Period would make sense because a Grace Period limited to only some countries would be misleading and prevent applicants from obtaining patent protections in countries without the Grace Period. This is true but we live in Germany quite well with our international Grace Period in our Utility Model system because it gives applicants at least a protection in Germany. If the territory of the European Union or of the member states of the EPC would be prepared to introduce a Grace Period this would cover a big market (about which our politicians so favourably speak) and would be an example for other countries in the world to follow. It will of course be the best solution to go ahead with the WIPO Harmonization Treaty but excluding the religious war about first to file and first to invent in the United States. We live with the first to invent system in the United States and will have to continue to live with it. Nobody can say that our life under this system is only miserable. It is better to reach a satisfactory solution under the PLT for some important items of our patent system instead of hunting for the 100%-solution which is not possible for the time being. Therefore, it is my view to encourage WIPO to go ahead with the Draft Treaty including a possible reservation for the US to maintain their first to invent system in order to improve the situation of our applicants in a wide area of items of our patent system.

PAPER: FLO/1.1.2 by Robert MITCHELL

Grace Period and First-to-File

Harmonization of substantial patent law is dead. The present Patent Law Treaty being negotiated in Geneva relates to harmonization of formalities and not anything that matters, such as “first to file” or “grace period”. During the negotiations leading towards the first round of the Paris Convention some 110 years ago, the wish list of items to be included in the Convention was similar to the list of substantive provisions forming part of the Basic Proposal.1

Patent law seems to be among the most jealously guarded of national laws. This may be as result that Patent Law should be, more logically, an internationally enforceable unitary system. Regardless of the efforts of WIPO and predecessor organizations over the last century, individual countries have continued to improvise their patent laws without regard to their impact internationally. In many cases some national laws appear to be discriminatory to foreign applicants, while still arguably being within the letter of the Paris Convention.

On the face of it, the lack of a Grace Period is one of the unfriendly features, to an applicant, of most national or regional patent laws. The fact that the Grace Period exists in some countries such as the United States and Canada only raises the level of confusion to the applicant and to the public.2 Because of global markets and the need for an American or Canadian applicant to eventually file in foreign countries under the Grace Period, applicants from those countries cannot rely on the Grace Period.

The Grace Period, in Canada, allows an applicant to file a Canadian Patent even though the invention might have been published or used publicly anywhere in the world, by the applicant, before the filing date of the application in Canada.3

Aside from certain European industrial players, and the National Governments which they influence, most interested parties favor a Grace Period. Heinz Bardhele in his paper recites, that various associations, including AIPPI and FICPI4, have passed resolutions to the effect that a Grace Period should be introduced in domestic and regional patent laws.

The advantages to the potential applicant are numerous.

The special circumstances surrounding University research argues strongly for a Grace Period. Within the last twenty years, the importance of the University researcher as a substantive user of the patent system cannot be underestimated or ignored. University research has gradually moved from pure research to applied research, as government funding of such research has not kept up with expenses. The United States Government, since the early 1970s, has allowed universities full ownership of patents, where it had previously been the major beneficiary of such rights. At the same time it transferred most of the burden of funding such research to the universities. Canadian universities have been undergoing a similar transition over the last 15 years.

The result is that universities have had to concentrate their research more and more to the applied sciences at the expense of pure research. By making inventions that are more useful in the immediate future, universities have used the patent system to protect their useful (industrially applicable) inventions. Any patent practitioner, who has dealt with the universities, is aware of the

"Publish or Perish" policies of such institutions. The pressures that such policies place on the inventor-researcher results in premature publications of discoveries or inventions, even before the usefulness or industrial applicability can be fully appreciated.

However when the Grace Period is being considered for countries other than the United States, it must be considered in the context of a First-to-File system. The United States, as we know, has a First-to-Invent system. In such a system, as long as the inventor proceeds to file a patent application within the Grace Period of 12 months from publication or other novelty damaging act, the inventor will still have confidence that he will prevail, even if others have derived his invention or have filed before the first inventor on a similar invention.

A First-to-File system is an arbitrary system at best. Compared to a First-to-Invent system, it is brutal and a somewhat over-simplified method by which an inventor may be entitled to a patent. Opponents to a First-to-File system characterize the regime as a mere race to the Patent Office. In fact, in some national patent offices, the receipt of a patent application is determined by the hour and minute it is received.

However, in view of the adoption of a First-to-File regime by every industrialized country, with the notable exception of the

United States, it is futile to argue the merits of a First- to-Invent system in the present global context.

Canada has adopted a First-to-File system as a result of amendments to its Patent Law adopted in October 1989. However the Canadian Parliament, while maintaining the Grace Period in the amended Act, omitted to protect the inventor who wishes to rely on the Grace Period, by juxtaposing a First-to-File system without having a provision in the Law that would protect an applicant, taking advantage of the Grace Period.5

The Grace Period does not fit easily into a First-to-File system. At first glance, a First-to-File system operates better on the basis of absolute novelty. The Grace Period was a so-called pillar of the Patent Law Treaty discussions leading up to the Diplomatic Conference of 1991. The proposal for a Grace Period was presented in the Basic Proposal preceding the Diplomatic Conference, as Article 12.6 The Grace Period as set out in Article 12 of the Basic Proposal7 provides that the Grace Period is counted back from the Priority Date.8

Opponents to a Grace Period, argue further that counting the Grace Period from the priority date, potentially adds another 12 months to the period of uncertainty about whether a patent application exists. In a system, with Absolute Novelty, this period of uncertainty is 18 months; but with a Grace Period counted from the priority date, that period of uncertainty can extend to 30 months.

One of the main objections for a country to adopt a First- to-File system, if it has a First-to-Invent system, is the concern for the fate of the first inventor. Under a First-to-Invent system a first inventor, although a late filer, could prevail in any number of situations. However, even in a First- to-Invent system, the first inventor, who chooses not to file a patent application, is also at a disadvantage. The first inventor may choose not to file because either he does not believe his invention to be patentable; has received a negative patentability opinion; wants to rely on his trade secrets, or, is ignorant of the advantages of proceeding under the patent system. This same first inventor might not contemplate publishing his invention to allow his invention to become published

prior art, which would be patent-defeating on an international scale. This first inventor, under these conditions, if a resident of Canada or the United States, would be in a position without any rights, and might be obliged to stop the use of the invention, if a patent has been obtained by a later inventor who proceeds to obtain a patent.

In most European countries, a "Prior User Right" tradition has developed. That right may be expressed as a mere possession of the invention according to French Law, or to more restrictive pre-conditions, as in German Law, such as showing evidence of substantial investment either in preparation or in commercialization of the invention.

Thus, with a "Prior User Right" provision, an inventor who either chooses not to proceed with patent protection or has been preceded at the Patent Office and therefore loses all of his rights to a patent, can nevertheless, under certain conditions, gain immunity from a patent infringement suit on the basis of a patent that may have been obtained by another independent inventor who has filed a patent application after the first inventor at least began preparations to commercialize the "infringing" product, process or apparatus.

Prior User Rights were contemplated in the Basic Proposal. In Article 20, a first inventor, who was using or preparing to use the invention claimed in a subsequently obtained patent, acquired a Prior User Right under Section 20 of the Basic Proposal, and could continue to use the process, product or apparatus which otherwise would infringe the patent.

The prior user must meet certain conditions that are set out in Article 20, such as showing that the invention was being used or that effective or serious preparations were undertaken for such use. The right would be a personal right and not transferable without the sale of the enterprise or business in which the use or preparations for use were made.

There is therefore a strong and compelling reason to include prior user rights in a First-to-File system. However a Prior User Right, as presently proposed in Article 20 of the Basic Proposal, includes a feature which seriously limits the Grace Period as set out in Article 12.

According to Article 20, a prior user of an invention may be entitled to a Prior User Right even though the prior user may have derived its use from the Patentee's earlier publication (published during the Grace Period). Thus, if a country should introduce a Prior User Right based on Article 20 of the Basic Proposal, the Grace Period, as contemplated by Article 12, would be flawed. The Grace Period can thus be undermined by 3rd parties who would have immunity from liability to the Patentee even though the 3rd party might have copied the invention from the applicant's earlier publication and should normally be an infringer.

Asian and European observers have argued that derivation in the case of prior user rights must be allowed less the Grace Period, according to Article 12, creates a first-to-publish instead of a first-to-file system.

Such reasoning is difficult to support when the principles of a Grace Period and Prior User Rights are carefully analyzed. If an inventor should publish fully his invention in a publication prior to filing his application, a prior art bar is created, effective against any later-filed patent application by other inventors. This concept exists presently in every patent system whether it is a First-to-File system or a First-to-Invent system and whether or not the Grace Period is incorporated in the national patent regime.

Under Article 12, the only person who can still file a patent application is the inventor who published the invention. If an inventor publishes his invention, in a first-to-file system with absolute novelty, a bar is created against every inventor, from filing a patent application claiming an invention described in the publication. Thus, in a sense, there exists presently, a de facto first-to-publish system.

The only difference between this scenario and a First-to-File system with a Grace Period is that the inventor, who has published, is excepted and can still file a patent application as long as it is filed within 12 months after the publication. In the former case, that is, absolute novelty, the inventor would no longer have the right to file a patent application.

To allow for prior user rights based on derivation of the information from the inventor's publication only creates an unmerited advantage for the party who has decided to copy from the publication. This scenario is unfair to the inventor who is relying on the Grace Period.

If a third party has independently invented the same invention, that person may be established as a prior user by providing evidence that he or she was not aware of the earlier publication.

Possibly, an improved Prior User Right provision that can be used in a First-to-File system with a Grace Period, would be based on an AIPPI resolution passed at the Amsterdam congress in 1989. The AIPPI resolution is as follows:

"ARTICLE 308 privilege of prior use

(l)(a) Subject to subparagraph (b), the owner of a patent shall not enjoy, under that patent, rights against activities within the scope of the patent, not authorized by him, of a person (the prior user) who, at the date of the filing of the application, or where priority is claimed, at the priority date of the application on which the patent is granted, and with a view to industrial or commercial exploitation,

(i) was actually engaged in such activities, or

(ii) was engaged in serious preparations, involving, from the viewpoint of the prior user, significant investment, for such activities,

in the territory and any other place or space to which the sovereignty of the Contracting State extends and in or for which State the patent is granted. It is understood that the expression "industrial or commercial exploitation" comprises every form of exploitation for useful or economic purposes.

(b) Where the prior user engaged in activities or preparations therefore, obtained knowledge of the invention protected by the patent from or in consequence of acts performed by the owner of the patent or his predecessor in title, subparagraph (a) shall not apply in respect of the said activities.

(2) Paragraph (l) shall not apply to a successor in title of the prior user unless that successor in title is the owner of the enterprise or business, or that part of the enterprise or business, in which the prior user engaged in the activities or preparations referred to in paragraph (l)(a). (Under lining is mine)

AIPPI is of the opinion that the rule should be mandatory". According to the AIPPI resolution, any prior user who derives the use from a publication of the patentee, during the Grace Period, would not be entitled to Prior User Rights.

Another problem would be encountered unless Prior User Rights were included in a Patent Law Harmonization Treaty. For instance unless Prior User Rights are limited to the above AIPPI proposal, France would be able to maintain, in its national laws, Article 31 of the 1978 Law, which reads:

"ARTICLE 31

Toute personne qui, de bonne foi, à la date de dépôt ou de priorité d'un brevet, était, sur le territoire où la présente loi est applicable, en possession de l'invention, objet du brevet, a le droit, à titre personnel, d'exploiter l'invention malgré l'existence du brevet.

Le droit reconnu par le présent article ne peut être transmis qu'avec l'entreprise à laquelle il est attaché".

As can be seen, the scope of the Prior User Right in French Law is much broader than that contemplated by Article 20 of the Basic Proposal. A 3rd party acquires a Prior User Right, who might only have thought of the invention before the effective filing date of the patent. In France the 3rd party can expand his use of the invention within the French territory to include anything which falls within the scope of the claims. This allows the prior user to copy anything which is described in a patent and within the scope of the claims. One can easily see where some countries might extend Prior User Rights much more broadly than contemplated.

Thus it is important that Prior User Rights be harmonized when adopted in different countries so that the rights of Patentees are not eroded.

Canada is the only industrialized country to have introduced a First-to-File provision in its Patent Law, in recent years. However Canada maintained a 12 month Grace Period as a remnant of its previous law, which was based on a First-to-Invent system. As previously mentioned, Canada's Law is flawed because in some circumstances an inventor relying on the Grace Period may be barred from obtaining a Patent, even though an application may have been filed within the Grace Period. Someone who might have been first to make an invention but decided not to file a patent application in Canada yet proceed with its commercialization may be stopped by a later filed application. Canada did not introduce an effective Prior User Right when brought in First to File provision.

As we can see, it appears that Prior User Rights may be considered important in a First-to-File system. However such a system becomes complicated when a Grace Period is introduced in the mix. The Patent Law as amended in Canada is an example of some of the problems that might occur if the provisions establishing a first-to-File system are mixed with a Grace Period and Prior User Rights are contemplated.

However I believe that with careful drafting such a mix can be satisfactorily accomplished.

FOOTNOTES

(1) WIPO Draft of the Treaty as Presented to the Diplomatic Conference 1991.

(2) Although some countries such as the Russian Federation and Mexico have a form of conditional Grace Period, they are not considered true Grace Period countries that are friendly to foreign applicants in view of the complicated nature of their laws in respect of the Grace period.

(3) Section 28.2(1) Canadian Patent Act

(4) FICPI Resolution passed at Edinburgh 1981, Vienna 1983, Funchal 1986 and Hilton Head 1987.

(5) For instance under Section 28.2 (1)(d) of the amended Canadian Patent Act, an applicant, who might read details of a basic invention of the first inventor in a published document, and proceeds to file a patent application on the applicant's own improvement before the first inventor has filed a patent application, describing the invention in his patent application as prior art, creates a bar against the first inventor's application.

(6) ob.cit. 1

(7) Article 12 from the Draft of the Treaty Presented to the Diplomatic Conference, 1991

Disclosure Not Affecting Patentability (Grace Period)

1. [Circumstances of Disclosure Not Affecting Patentability]

Disclosure of information which otherwise would affect the patentability of an invention claimed in the application shall not affect the patentability of that invention where the information was disclosed, during the 12 months preceding the filing date or, where priority is claimed, the priority date of the application, I. II.

by the inventor,

by an Office and the information was contained (a) in another application filed by the inventor and should not have been disclosed by the Office,

III.

or

(b) in an application filed without the knowledge or consent of the inventor by a third party which obtained the information direct or indirectly from the inventor, or

by a third party which obtained the information direct or indirectly from the inventor.

2. ["Inventor"] For the purposes of paragraph (l), "inventor" also means any person who, at the filing date of the application, had the right to the patent.

3. [No Time Limit for Invoking Grace Period] The effects of paragraph (1) may be invoked at any time.

4. [Evidence] Where the applicability of paragraph (l) is contested, the party invoking the effects of that paragraph shall have the burden of proving, or of making the conclusion likely, that the conditions of that paragraph are fulfilled.

(8) The 12 month Grace Period, both in the United States and Canada, is counted back from the actual filing date, not the priority date.

PAPER: FLO/1.2. by Robert ARMITAGE

Biodiversity, Disunity, Utility and Scope: the Implications for Obtaining Commercially Meaningful Patent Claims for the Biotechnology Inventor

Introduction

Biotechnology inventors have it easy. Powerful tools are now present to permit the exploration of life at its most fundamental level. From PCR to PC's, molecular biologists have the tools to identify and analyze all the genetic information of a particular species. With this ocean of genetic opportunity, inventions can be made at a fast and furious pace.

Biotechnology patent professionals do not have it so easy. They work in an arena of limited judicial and administrative precedent. They must digest and make legal sense of the masses of scientific information that can be produced with breath-stealing speed. Moreover, they must justify to inventors and their corporate and university assignees the costs, uncertainties, and limitations the profession faces in seeking to broadly patent their pioneering research results.

Biodiversity itself appears to assure a steady stream of potentially patentable discoveries. Compounding the opportunities for patenting is the reality that genetic information differs markedly between species. Each time the DNA of a new strain of even a simple, single-cell organism is completed, hundreds to thousands of novel and nonobvious DNA sequences are discovered, foretelling the existence of an equal complement of novel and nonobvious proteins.

However novel and nonobvious it might be, new DNA and new proteins do not patent themselves. Crucial issues of patentability are manifest in attempting to effectively and exclusively claim the seemingly endless wealth of novel and non-obvious subject matter that flows from biodiversity. Among the many issues related to effective patenting of modern biotechnology inventions are the following three:

If you have discovered a thousand proteins, related by source but not by structure, do you need to file a thousand patent applications to obtain effective patent coverage?

If you have unraveled DNA coding all or part of a host of novel genes, what is the "practical utility" needed for a complete patent application?

If you are the pioneer in discovering some new genetic milestone, how can the invention be claimed to provide some commercially meaningful protection — not just be limited to the new DNA sequence that is the actual and sole source of the discovery?

This paper takes a brief frolic into these issues for the biotechnology inventor from the vantage point of U.S. patent law and practice.

Disunity: Genes as "Independent and Distinct" Inventions, One from the Other

The U.S. Patent and Trademark Office uses two distinct standards for addressing the issue of whether or not claims should be restricted as a formal matter such that the filing of a divisional patent application will normally be needed to secure protection of all the potentially novel and non-obvious subject matter disclosed in an application for patent. For applications filed under the Patent

Cooperation Treaty, the U.S. Patent and Trademark Office discharges its treaty obligations by applying the "unity of invention" standard under the PCT 1.Moreover, the practice of the U.S. Patent and Trademark Office is to respect during national stage prosecution of an international (PCT) application, the determination of unity:

Any international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (PCT Article 3(4)(iii) and 17(3)(a), PCT Rule 3.1, and 37 CFR 1.475). Observance of this requirement is checked by the International Searching Authority and may be relevant in the national (or regional) phase.

The decision in Caterpillar Tractor Company v. Commissioner of Patents and Trademarks , 231 U.S.P.Q. 590 (E.D. Va. 1986), held that the Patent and Trademark Office interpretation of 37 CFR 1.141(b)(2) as applied to unity of invention determinations in international applications was not in accordance with the Patent Cooperation Treaty and its implementing regulations. In the Caterpillar international application, the USPTO acting as an International Searching Authority, had held lack of unity of invention between a set of claims directed to a process for forming a sprocket and a set of claims drawn to an apparatus (die) for forging a sprocket. The court stated that it was an unreasonable interpretation to say that the expression "specifically designed" as found in former PCT Rule 13.2(ii) means that the process and apparatus have unity of invention if they can only be used with each other, as set forth in MPEP § 806.05(e).

Therefore, when the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. No change was made in restriction practice in United States national applications filed under 35 U.S.C. 111 outside the PCT.

M.P.E.P. §1850, Revisions 6.2.

The alternative to the PCT's "unity of invention" rule is the domestic U.S. practice of looking at the possible "independent and distinct" nature of subject matter present in patent applications. The Manual of Patent Examining Procedure defines both these terms for U.S. patent examiners in section 802.01:

"The term 'independent' (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed or (2) process and apparatus incapable of being used in practicing the process".

"The term 'distinct' means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use, or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER (though they may each be unpatentable because of the prior art). It will be noted that in this definition the term related is used as an alternative for dependent in referring to subjects other than independent subjects".

The grave difficulty for many biotechnology inventors is that under either of these two definitions, a single discovery can produce a hoard of disunified, independent and distinct inventions, potentially

requiring the filing of a hoard of divisional patent applications to reassemble claims to the discovery as a whole. Given that patent applications have been filed encompassing hundreds to thousands — to perhaps tens of thousands — of gene sequences, who can afford filing a thousand applications costing nearly a thousand dollars each?

The U.S. Patent and Trademark Office has not been unsympathetic to the impracticability of filing divisional patent applications by the thousands. In 1996, Commissioner Lehman set out a policy under which the Office would maintain inventions together in the parent patent application:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35

U.S.C. § 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35

U.S.C. § 121 and 37 C.F.R. §1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 C.F.R.

§1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application.

Accordingly, in most cases, up to ten (10) independent and distinct nucleotide sequences will be examined in a single application without restriction. It has been determined that normally ten sequences constitute a reasonable number for examination purposes. The PTO believes that allowing applicants to claim up to ten (10) independent and distinct nucleotide sequences in a single application will promote efficient, cost- effective examination of these types of applications. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten (10). In other cases, applicants may petition pursuant to 37 C.F.R. § 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions.

Commissioner's Notice, October 17, 1996.

The practice as announced for national patent applications is further applied to international patent applications:

International applications filed under the Patent Cooperation Treaty (PCT) and national stage applications filed under 35 U.S.C. § 371 will be treated in a similar manner. Under 37 C.F.R.

§1.475 and §1.499 et seq., when claims do not comply with the requirement of unity of invention, i.e., when the claimed subject matter does not involve "one or more of the same or corresponding

special technical features," 37 C.F.R. §1.475(a), an additional fee is required to maintain the claims in the same application. 37 C.F.R. §1.476(b).

Commissioner's Notice, October 17, 1996.

This practice, accordingly, avoids the need to pay excess search fees for applications in which the United States is the International Searching Authority 2 The mathematical implications of the U.S. Patent and Trademark. Office's practice for sequence-type claims is straightforward. U.S. applicants are ten times better off than they would have been had each sequence been a separate invention. However, they still face dozens to hundreds of potential divisional applications where the inventions include a broad array of new DNA sequences. Thus, the legal bill may fall from the millions of dollars to mere hundreds of thousands of dollars to file on all elements of an invention that is, for example, a fully sequenced bacterial genome.

Utility: All DNA Can Encode Polypeptides; All Polypeptides Can Serve As Useful Sources of Nutrients

Biotechnology holds great promise for mankind. Ergo, how could "practical utility" impede the ability of biotechnology inventors to obtain patents.

Biotechnology based research may lead to more powerful medicines, cures for the plagues that have followed mankind through the centuries, improved crops, more productive domesticated animal species, salvation for a natural environment ravaged by pollution, and even more conclusive molecular methods for tying murder suspects to their crimes. Despite this potential, a great many U.S. patent examiners have — over much of the past decade — imposed numerous rejections on biotech inventions for lack of utility!

Efforts to change the practice of patent examiners in imposing stringent utility requirements have focused on private sector efforts to have the Commissioner of Patents and Trademarks publish "Utility Guidelines". Ultimately, the Commissioner promulgated both "guidelines" and a sweeping legal analysis of the law on disclosures of utility for pharmaceutical- and biotechnology-related inventions. These Utility Guidelines effectively superseded the previous provisions of the Manual of Patent Examining Procedure, that, in § 608.01 (p), provided the only Patent and Trademark Office guidance for patent examiners with regard to utility rejections.

As indicated below, these new guidelines are largely positive for biotechnology inventors:

Proof of Safety.

The FDA has a clear Congressional mandate to prevent any drug from entering interstate commerce without first establishing that the drug is "safe" for its intended use. Safety goes to the heart of the FDA's existence. In light of this, to what extent should the Patent and Trademark Office regard "safety" as bearing on utility and, thus, the ultimate question of patentability? The M.P.E.P. formerly resolved the "safety"/patentability issue for assertions of drug utility with the terse statement that:

Although absolute safety is not necessary to meet the utility requirement under this section, a drug which is not sufficiently safe under the conditions of use for which it is said to be effective will not satisfy the utility requirement (In re Hartop et al., 311 F.2d 249, 135 USPQ 419 (C.C.P.A. 1962); In re Anthony, 162 USPQ 594 (C.C.P.A. 1969); In re Watson, 186 USPQ 11 (C.C.P.A. 1975)). Proof of safety shall be required only in those cases where adequate reasons can be advanced by the examiner for

believing that the drug is unsafe, and shall be accepted if it establishes a reasonable probability of safety.

Since "absolute safety" is either a non-existent or an unattainable goal for any drug, the M.P.E.P.'s requirement for "sufficient" safety provides some leeway for inventors. However, the issue of "sufficiency" creates a highly subjective standard of patentability: sufficient under what criteria? Moreover, the notion of being "sufficiently safe" inherently requires a cost-benefit assessment based on extensive clinical data. Finally, the issue of safety, if a serious consideration in the patent examination process, would implicate all the safety information available to the inventor as being possibly material to the patent examination process. Thus, the inventor would be obligated to disclose all of this information during examination.

The requirements for proof of safety pose even more complex problems for inventors. Safety is never decided in an abstract context for a pharmaceutical product, but rather in the context of conditions and indications for use. Safety is always relative; it is invariably true that drugs have side effects, even ultimately toxic side effects.

The new utility guidelines take a much more realistic view of what safety means in a patent context. The Patent and Trademark Office now takes the position:

The Examiner must confine his or her examination, for purposes of utility, to compliance with the statutory requirements of the patent law. Other agencies of the government have been assigned the responsibility of ensuring conformance to standards established by statute for the advertisement, use, sale or distribution of drugs.53 Thus, while an applicant may on occasion need to provide evidence to show that an invention will work as claimed, it is improper for an Examiner to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness.54 [Footnotes omitted.]

Most interesting are the cases cited in support of the "no safety data" rule established under the guidelines. In footnote 54, the guidelines cite the very same cases that formerly were cited to support the contrary position, i.e., Hartop, Watson, and Anthony, as well as In re Sichert, 566 F.2d 1154, 196 USPQ 209 (1977), In re Krimmel, 292 F.2d 948, 130 USPQ 215 (C.C.P.A. 1961), and Ex parte Jovanovics, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981).

From a former "safety" requirement that could have been so broadly read as to require complete FDA-style reporting, the Patent and Trademark Office appears to have now completely deferred the safety consideration to the FDA.

Human Testing Data

Nothing could be clearer than the Patent and Trademark Office's current statement on the absence of the need for human clinical data. The new guidelines are adamant:

There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders,51 even with respect to situations where no art-recognized animal models exist for the human disease encompassed by the claims.52 Examiners should not impose on applicants the unnecessary burden of providing evidence from human clinical trials. [Footnotes omitted.]

This recent revelation of the Office appears guided by a 30-year old decision of the Court of Customs and Patent Appeals, In re Isaacs, 347 F.2d 889, 146 USPQ 193 (1963). The guidelines extract the following quotation from Isaacs:

No authority has been cited and we have been able to find none which requires that in order to secure a patent, utility of a pharmacologically active substance must be proved by in vivo testing. The mere fact that the claimed invention may have possible utility in vivo does not warrant disregard of in vitro activity where the claims are not limited to in vivo use.

347 F.2d at 889, 146 USPQ at 195.

The former M.P.E.P. statements on human testing were, of course, constrained by the same body of law, but formulated the legal requirements somewhat less generously:

More particularly, if the utility relied on is directed solely to the treatment of humans, evidence of utility, if required, must generally be clinical evidence. (Ex parte Timmis, 123 USPQ 581 (Bd. App. 1959)) although animal tests may be adequate where the art would accept these as appropriately correlated with human utility (In re Hartop et al., 311 F.2d 249, 135 USPQ 419 (C.C.P.A. 1962); Ex parte Murphy, 134 USPQ 134 (Bd App. 1960)) or where animal tests are coupled with other evidence, including clinical evidence and a structural similarity to compounds marketed commercially for the same indicated uses, (In re Jolles, 628 F.2d 1322, 206 USPQ 885 (C.C.P.A. 1980)).

Inventors of human therapies — in biotechnology or any related pharmaceutical field of endeavor — have an obvious dilemma. Many of these inventors begin the arduous process of human clinical development with some basic pharmacological discovery. The discovery is typically made in an animal test system, sometimes only on isolated animal tissues. Given the practical need to publish promptly on basic discoveries, the timing of the patent application precedes any hope of human testing. Thus, the patent application will necessarily be devoid of direct proof of utility. Moreover, whether actual commercial utility — as opposed to “practical utility” — can ever be established depends on the rigorous FDA process. New drugs meeting the FDA standard are few and those few are estimated on average to require an investment of $500 million in research and development.

In light of these difficulties, it is fortunate that the Patent and Trademark Office appears to have adopted the position that credible science produces credible human therapy patents.

Credibility vs. Incredibility for an Asserted Utility.

The nub of the rejection for lack of utility has historically been grounded on the “incredibility” criterion. A patent examiner, on the basis of some evidence or reasoning, can assert that a disclosed utility is not to be believed. A person skilled in the art must regard the alleged utility as “incredible”. In this case, rejections for either a lack of utility under 35 U.S.C. § 101 or a failure to enable use under 35 U.S.C. § 112 can be made — and were being routinely made — in biotechnology-related patent applications.

The gist of the pre-guideline rationale stated in the M.P.E.P. was the following:

If the asserted utility of a compound is believable on its face to persons skilled in the art in view of the contemporary knowledge in the art, then the burden is upon the examiner to give adequate support for rejections for lack of utility under this section [citations omitted.]. On the other hand,

incredible statements [citations omitted] or statements deemed unlikely to be correct by one skilled in the art [citations omitted] in view of the contemporary knowledge in the art will require adequate proof on the part of applicants for patents.

The guidelines now make it reasonably clear that the "incredibility" standard does not apply to utilities within the mainstream of scientific endeavor. The standard appears in the guidelines as follows:

Cases decided by a Federal court in which a claimed invention was held to lack utility under §101 because it was "inoperative" have been rare. Uniformly, in these cases the utility asserted by the applicant was "incredible in the light of knowledge of the art, or factually misleading"10 when initially considered by the Examiner. Examples include: an invention asserted to change the taste of food using a magnetic field,11 a perpetual motion machine,12 a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field,13 uncharacterized compositions for curing cancer14 and a method of restoring hair growth.15 In view of the rare nature of such cases, Examiners should not label an asserted utility "incredible" unless it is clearly appropriate to do so.

If the restatement of the law in the guidelines is faithfully followed by patent examiners, the "rare" rejection for lack of § 101 practical utility should become almost nonexistent in the industrial biotechnology arena. Since inventions of the industrial and academic biotechnology type are devoid of perpetual motion, rarely rely on magnetic or other mystical force fields or wholly uncharacterized (and, thus, mysterious) compositions, this form of rejection should all but disappear.

The Federal Circuit's Utility Analysis in Brana

The Federal Circuit took the opportunity to review the Patent and Trademark Office's utility guidelines in In re Brana.3 The court stated its view that "utility" issues for biologically useful subject matter were not issues of first impression:

At issue in this case is an important question of the legal constraints on patent office examination

practice and policy. The question is, with regard to pharmaceutical inventions, what must the applicant prove regarding the practical utility or usefulness of the invention for which patent protection is being sought. It is not a new issue; it is one which we would have thought had been settled by case law years ago [footnote omitted.] We note the Commissioner has recently

addressed this question in his Examiner Guidelines for Biotech Applications, see 60 Fed. Reg. 97 (1995); 49 Pat. Trademark & Copyright J. (BNA) No. 1210, at 245 (Jan. 5, 1995). 34 U.S.P.Q.2d 1439.

In Brana, the court reaffirmed the basic principle, set forth originally in Nelson v. Bowler4, that useful pharmacology represents practical usefulness and, therefore, disclosure of pharmacology is sufficient to meet the requirement for utility under 35 U.S.C. § 101. In Brana, disclosure of anti-tumor activity ("a better action and a better action spectrum as anti-tumor substances") was considered sufficient, particularly since the patent specification cited comparable compounds in the prior art that had been tested in two lymphocytic tumor models.

The Patent and Trademark Office argued that the failure of the application to "disclose a specific disease" rendered its claims unpatentable. The Federal Circuit rejected this argument, finding that the model system was enough for persons skilled in the art to infer specific therapeutic application:

Since one of the tested [prior art] compounds... was found to be highly effective against these two lymphocytic leukemia tumor models, applicants' favorable comparison implicitly asserts that their claimed compounds are highly effective (i.e., useful) against lymphocytic leukemia.

Having lost on the question of specificity of the utility allegation, the Patent and Trademark Office's second argument, that the inventor's evidence of utility was "inadequate to convince one of ordinary skill in the art that the claimed compounds were useful as antitumor agents," was likewise rejected. The court responded to this assertion by reversing the playing field. It held that the examiner's evidence that the claimed subject matter was not useful was inadequate to shift the burden to the inventor to demonstrate utility. The court held that the evidence relied upon by the Patent and Trademark Office — references discussing the correlation between tests in laboratory animals and effects in humans — could shift the burden of proof "only if applicants must prove the ultimate value in humans of their asserted utility".

Further, the court rejected the notion of inherently "incredible utility" as applying here:

The purpose of treating cancer with chemical compounds does not suggest an inherently unbelievable undertaking or involve implausible scientific principles [citations omitted.] Modern science has previously identified numerous successful chemotherapeutic agents.

We do not rest our decision there, however. Even if one skilled in the art would have reasonably questioned the asserted utility, i.e., even if the PTO met its initial burden thereby shifting the burden to applicants to offer rebuttal evidence, applicants proffered sufficient evidence to convince one of skill in the art of the asserted utility. In particular…test results showing several compounds…exhibited significant activity against the L1210 standard tumor model in vivo.

34 U.S.P.Q.2d at 1441-2.

The Patent and Trademark Office suggested that the above standard animal model was not predictive of effects in humans, but the court totally rejected the notion that effects in humans were needed to establish that novel compounds were useful. The court again reiterated the appropriateness of useful pharmacology, and useful pharmacology alone, to establish practical utility:

Our court's predecessor has determined that proof of an alleged pharmacological property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utility. [Citations omitted.] In concluding that similar in vivo tests were adequate proof of utility the court in In re Krimmel stated:

We hold as we do because it is our firm conviction that one who has taught the public that a compound exhibits some desirable pharmacological property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment of humans.

34 U.S.P.Q.2d at 1442.

The court also noted the distinction between FDA and PTO functions: "The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans". In effect, the court was "endorsing" the broad outlines of the Commissioner's utility guidelines by simply reiterating its longstanding precedents.

Post-Brana Guidance from PTO Officials: Utility for Bits & Pieces of Genes

Recently, John Doll, Director, Biotechnology Examination, Technology Center 1600, U.S. Patent and Trademark Office, waded into the most controversial area of gene patenting: rules regarding "expressed sequence tags" — small pieces of DNA encoding a complete gene and "single nucleotide polymorphism" — the single DNA base differences characterizing each individual member of a species 5.

Although some SNPs and ESTs may not directly identify genes, they may still be extremely useful and thus satisfy the utility requirement. SNPs and ESTs may have specific utilities that are separate and distinct from the genes to which they correspond. For example, SNPs can be used to trace ancestry or parentage. ESTs can be used for chromosome identification and gene mapping. Both can be used to identify genes that contribute to predisposition to disease.

Claims to DNA elements useful for forensic identification, the identification of tissue type or origin, chromosome mapping, chromosome identification, or tagging of a gene of known and useful function must fulfill the enablement requirement. For any invention, enablement is satisfied when, by reading the patent application, an individual who has skill in the technology would have been able to make and use the invention as intended without undue experimentation.

In fact, it is common for the patentability of DNA elements to hinge on whether sufficient information has been given to enable at least one credible or specific utility. Examples of

potentially non-enabled utilities for a DNA sequence fragment include its use to locate disease-associated genes when the disease has no known genetic origin; as an antisense reagent when the corresponding protein to be suppressed is unknown; as a triplex probe to inhibit expression of a protein when the protein and its function are unknown; and to locate and identify genes of unknown utility.

The Doll optimism is far from a universal one, however. The last quoted paragraph above was the only view that the U.S. Patent and Trademark Office took when initially confronted with EST claims in the now-infamous "Venter EST applications". 6. The Venter EST application took great pains to identify "utilities" for the gene pieces obtained by randomly collecting and reporting DNA sequences found by "reverse transcribing" RNA found in human cells that was in the process of producing protein products encoded by the RNA. These utilities included:

Probes to isolate coding sequences and complete genes, which may then be mapped to chromosomal locations. Chromosome markers.

Isolation of complete genes through use of the EST probes.

Expression of complete genesin recombinant host cells to obtain their protein products.

Diagnostic probes, to detect the presence of a specific mRNA in a particular cell type, or in genetic linkage analysis, or to locate gene regions associated with genetic disease.

Regulators of gene expression through triple helix formation or antisense methods.

Individual identification for forensic and other purposes.

Reagents to identify tissue specimens by organ type or by species.

The U.S. Patent and Trademark Office had no difficulty rejecting Venter's '195 EST application for lack of utility (Office Action dated August 20, 1992):

The mere mention of general possible uses is not sufficient to establish a definite utility because the instant application does not disclose a patentable utility for the oligonucleotides or other nucleotides of the claimed inventions in their currently available form. Given what is disclosed in the instant application, it would be necessary for one to do further work in order to establish a utility for many of the nucleotides embraced by the claims. The instant application does not teach one of skill in the art the significance of any putative result of any of the tests or processes alluded to in the application. Although the oligonucleotides embraced by the claims may be hybridized to a variety of different preparations of other nucleic acids, one of skill in the art has no clue as to the significance of any results of such hybridization because the instant application fails to provide any basis for the interpretation of any putative results. Thus, given the invention in its currently available form, others would be compelled to experiment, interpret results, and invent a patentable utility for the claimed nucleotides.

The NIH sought a legal opinion 7 from leading patent law scholars on the utility issues presented by the examiner's rejection. These scholars focused on the lack of specificity that Director Doll mentioned in his last paragraph:

In sum, although the utility issues raised by these patent applications have no clear answers, in light of recent caselaw it is not surprising that the PTO rejected the claims of the '195 application for lack of utility, nor would we be surprised to see the Federal Circuit affirm the rejection on this ground. The primary reasons for this reaction are: (1) many of the asserted utilities involve use for vaguely identified diagnostic or therapeutic purposes, with no indication of the particular diagnostic or therapeutic purposes for which any particular sequence or group of sequences might be used; (2) most of the sequences may not be put to the asserted uses without further experimentation which appears to go beyond routine experimentation, and the outcome of which is uncertain; and (3) the utilities that appear least problematic on enablement and operability grounds--use of the sequences as probes for finding full-length cDNAs or as chromosome markers--are most vulnerable to challenge on the ground that they are merely of interest to researchers and don't yet amount to practical utility in currently available form.

23 AIPLA Q. J. 20.

With the liberalization apparent in the U.S. Patent and Trademark Office utility guidelines and the ambiguous attitude of Director Doll, it is now possible that the U.S. Patent and Trademark Office will be issuing patents that lack what the courts will eventually see as some "practical utility in currently available form".

Scope of Protection: Threading Patent Claims Through the Eye of the "Written Description"/Enablement" Needles of Patentability

The Underlying Problem Confronting Biotechnology Inventors: Function Dominates Form.

The U.S. Patent and Trademark Office has, however, granted a number of patents on biotechnology inventions, only to have these patents invalidated at the Court of Appeals for the Federal Circuit.

Knowing what broad claims are unpatentably broad does not necessarily, however, provide guidance as to what commercially meaningful claims might meet the requirements for patentability.

Biotechnology inventors have an arsenal of distinct, but highly suspect armaments in their battles with patent examiners to broaden patent claims. One is to simply mandate that any related compounds that are bioactive are encompassed by the claims. Limitations of this type often appear as, "having in vivo biological activity against disease X". Since the patent laws presumably prevent the patenting of inert materials, limiting a patent claim to any material with any biological activity at all is, in reality, a non-limitation limitation. While this absurdity can be avoided by limiting the claims to compounds with appreciable activity, e.g., "having in vivo biological activity against disease X sufficient for commercial use as a medicine," such a limitation doesn't avoid the central problem: a person skilled in the art is left to make and test endless compounds — in effect forcing the skilled person to make the very invention, the commercially useful drugs — that the inventor purported to have disclosed as justification for getting the claim in the first place.

Biotechnology, it seems, inherently lulls inventors into defining what they have invented in terms of what it does rather than what it is. If a potential protein drug is discovered through genetic engineering, a person skilled in the art can readily assume that numerous derivatives and analogues may share the same or a similar biological function. The original discoverer may synthesize a few of these analogues, demonstrate appreciable biological effects, and —understandably — attempt to lay claim to all the rest of the field that has been opened. As an example:

A protein, except as existing or occurring in nature, comprising:

(A) all or part of the amino acid sequence set forth in SEQ. ID. NOS. 1, 2 or 3;

(B) an amino acid sequence at least 50% homologous with an amino acid sequence defined in (A), said protein having the in vivo biological property of stimulating the production of enzyme Y.

The inherent difficulty with a claim of the above scope under U.S. patent law lies both in the arena of a "written description" and the enablement. First, the genus — except for the biology limitation — is not merely large, but decidedly infinite. Once all the carbon atoms now existing in the universe have been used in the synthesis of only a relatively few of the various amino acid sequences contemplated by (A), there will be no matter left in the universe to finish making the vast remainder of (A), much less any of (B), much less proceed with the in vivo biological testing needed for (C). Further, although the preamble of the claim purports to limit the claim to non-naturally occurring proteins (avoiding a claim that reads on products of nature), the novelty of the claim rests on the possibly tenuous assumption that no known protein has the biological property of stimulating the production of enzyme Y. If such exists, the claim likely lacks novelty since (A) and (B) together potentially read on every protein under the sun. 8

Effectively, therefore, the above claim can be recast in simple, non-patent terms, as follows:

All the novel proteins (except for the naturally- occurring forms) that stimulate enzyme Y in vivo that have at least some substantial structural relationship to one of the three proteins actually described in the patent specification.

The Federal Circuit and one of its predecessor courts, the Court of Customs and Patent Appeals, have spent decades developing the basis on which claims, such as the above, can run afoul of the

requirements for patentability. Judge Rich, in a 1963 dissent9, summarized a number of bases for invalidating such a claim:

The usual reasons for objection to functional language in claims are these:

1. The claim covers everything which would produce a stated result or effect. (Example: a "single-means" claim.)

2. The functional language gives the claim a scope such that it reads on the prior art.

3. The claim is vague--the public cannot tell what would infringe it; it does not clearly define.

4. The scope of the claim is unjustifiably broad--it covers too much more than was actually invented and disclosed by the applicant.

137 U.S.P.Q. at 163.

Two of the four "reasons" set forth above are based on 35 U.S.C. § 112, first paragraph: the last of the four "reasons" is now recognized under the "written description" rubric, the first is now properly countenanced as an "enablement" defect. The third "reason" relates to potential indefiniteness under 35 U.S.C. § 112, second paragraph10. As recast, the above claim to the set of proteins stimulating enzyme Y is clearly a "single means claim" 11 and clearly lacks enablement, if not definiteness.

However, Federal Circuit precedent has now clarified that the fourth reason set forth by Judge Rich — permitting the claim to cover much more than was actually invented — must be considered in terms of the "written description" requirement. Simply setting forth the objective of the inventive activity ("proteins that stimulate enzyme Y in vivo"), but not demonstrating possession of the corresponding things (i.e., chemical compounds or chemical structures demonstrating achievement of that objective), can only mean that the invention has neither been completely conceived nor otherwise possessed by the inventor. Possessing the objective for the invention is not possession of the invention itself.

The salient decision of the Federal Circuit in this regard is Fiers v. Revel12. The Federal Circuit was asked to decide which of three rival foreign inventor groups had made an invention first (which, under then existing U.S. law, left the foreign inventors relying strictly on the filing dates of their patent applications). The common invention in issue was defined in terms of a simple claim (the "count" in patent interference terminology). This count effectively set forth the objective of the research:

A DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide.

The Board of Patent Appeals and Interferences in the U.S. Patent and Trademark Office, concluded that evidence of a completed invention must be found in the patent application:

The Board... determined that Fiers' disclosure of a method for isolating the DNA of the count, along with expert testimony that his method would have enabled one of ordinary skill in the art to produce that DNA, did not establish conception, since Tsuccess was not assured or certain until the [β-IF] gene was in fact isolated and its sequence known.' The Board relied on our opinion in Amgen Inc. v.

Chugai Pharmaceutical Co., in which we addressed the requirements necessary to establish conception of a purified DNA sequence coding for a specific protein. Accordingly, the Board held that Fiers was entitled only to the benefit of his April 3, 1980 British application date because only that application disclosed the complete nucleotide sequence of the DNA coding for β-IF. That date was subsequent to Sugano''s March 1980 Japanese priority date. [Emphasis supplied.]

The Federal Circuit then went on to deny a second inventor the right to rely on a prior-filed patent application, even though again, it described the contested claim (count) and the manner by which it could be implemented in practice:

An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. [The second inventor's] specification does not do that. [That] application does not even demonstrate that the disclosed method actually leads to the DNA, and thus that he had possession of the invention, since it only discloses a clone that might be used to obtain mRNA coding for β-IF. A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that [the second inventor] was in possession of the DNA. [His] argument that correspondence between the language of the count and language in the specification is sufficient to satisfy the written description requirement is unpersuasive when none of that language particularly describes the DNA.

Thus, where the claim effectively reads on the inventor's research objective, but the underlying patent specification does not describe a commensurate accomplishment of that objective, i.e., through the structures of the products encompassed by the claims, the invention has neither been conceived nor described. (There is under U.S. patent law the ability to avoid completely both the enablement and written description issues with the "all the novel proteins that stimulate enzyme Y" claim, provided a Hyatt-type "single means" format is avoided. If this can be done, the claim — although functional in a "means-plus-function" sense — is not objectionable under 35 U.S.C. § 112 13 and, more importantly, provides a reasonable claim breadth 14 and the possibility to extend protection to corresponding products.15

Over the years, a number of techniques have been devised to claim the knowable, but as yet unaccomplished parameters of the invention. A few of the strategies that have been tried in the United States are set forth below.

Sufficient for Bioactivity.

The prototype of the "sufficient-for-bioactivity" claim was the Amgen claim in its erythropoietin patent (U.S. Patent 4,703,008, Lin):

7. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron uptake.

As attractive as such a claim is to an inventor, it was unappealing to the Federal Circuit, and this claim was invalidated based on an insufficient support in working examples (or other description) of sufficiently duplicative sequences.

Hybridization.

Many inventors have attempted to obtain broad claims by describing as part of the invention DNA's that hybridize to an isolated clone: Amgen's '008 erythropoietin patent contained such a claim:

1. A purified and isolated DNA sequence encoding erythropoietin, said DNA sequence selected from the group consisting of:

(a) the DNA sequences set out in FIGS. 5 and 6

or their complementary strands; and

(b) DNA sequences which hybridize under stringent conditions to the DNA sequences defined in (a).

Amgen patent attorneys were apparently building on the earlier claims draftsmanship in U.S. Patent 4,530,901, Lin (July 23, 1985), in which the hybridization claim read:

A recombinant DNA molecule consisting of segments of DNA. . . selected from the group consisting of:

(a) the DNA inserts of [named clones],

(b) DNA sequences which hybridize to any of the foregoing DNA inserts and which code on expression for a polypeptide of the IFN-α type, and

(c) DNA sequences which code on expression for a polypeptide of the IFN-α type coded for on expression of any of the foregoing DNA sequences and inserts... .

The IFN-α inventor creatively claimed (a) what he made, (b) whatever hybridizes to what he made and retains the characteristic biological activity, and (c) whatever is degenerate (in terms of the genetic code) with either of the above. The claims require stringent conditions while the IFN-α claims do not. This points to one of the difficulties with this approach: hybridization is not an unambiguous result. A second difficulty, of course, arises out of the very degeneracy of the genetic code. It is possible for a DNA encoding a totally unrelated polypeptide to "hybridize" under some conditions with one of the degeneracies here, yielding the prospect that these drafted claims could read on so many future unrelated inventions that accidentally share a pharmacological action as to fail to "particularly point out" the actual invention.

Significant Homology.

Some inventors have defined the knowable embodiments of a recombinant DNA invention by expanding claims to DNAs with "substantial" homology:

1. An isolated DNA molecular having a nucleotide sequence encoding a bovine adrenotropic hormone receptor wherein the DNA sequence is substantially homologous to the sequence in FIGS. 1A-1C (SEQ ID NO:3).

U.S. Patent 5,280,112, Jan. 18, 1994, Cone, et al.

Other inventors have injected breadth by devising a percentage of homology. As is apparent from the examples below, inventors expressing percentages have reached no consensus as to the proper

quota (and, possibly, no rationale based on the prior art, scope of exemplication, or other non-arbitrary basis for establishing a quota): (1) Forty Percent:

4. A vector comprising DNA encoding an insulin receptor or a fragment thereof encoding a biologically active insulin receptor polypeptide.

8. The vector of claim 4 wherein the DNA encodes a predetermined, site-specific mutant insulin receptor which is greater than about 40 percent homologous with the insulin receptor of FIG. 1b and which exhibits a biological activity in common with the insulin receptor of FIG. 1b.

U.S. Patent 4,761,371, Aug. 2, 1988, Bell, et al. (2) Fifty Percent:

2. The DNA segment of claim 1, wherein said DNA segment comprises a segment selected from the group consisting of (a) a segment encoding amino acids 137 to 193 of SEQ ID NO: 2 and

FIG. 13; (b) a segment encoding amino acids 159 to 215 of SEQ ID NO: 4 and FIG. 8; and (c) a segment encoding an amino acid sequence having at least 50% homology with the amino acid sequence of (a) or (b).

U.S. Patent 5,260,208, Nov. 9, 1993, Petre, et al. (3) Seventy-Five Percent:

1. Isolated DNA encoding a vitamin K dependent carboxylase selected from the group consisting of: (a) isolated DNA selected from the group consisting of DNA which encodes bovine 94,000 dalton vitamin K dependent carboxylase and comprises the sequence... [listed]; (b) isolated DNA which hybridizes to the complementary strand of isolated DNA of (a) above under stringent conditions represented by a wash stringency of 0.3M NaCl, 0.03M sodium citrate, and 0.1% SDS at 70o C. and which encodes a vitamin K dependent carboxylase at least 75% homologous to isolated DNA of (a) above; and

(c) isolated DNA differing from the isolated DNAs of (a) and (b) above in nucleotide sequence due to the degeneracy of the genetic code, and which encodes a vitamin K dependent carboxylase.

U.S. Patent 5,268,275, Dec. 7, 1993, Stafford, et al.

(4) Ninety Percent:

1. A recombinant DNA molecule comprising a T-DNA 780 gene transcription activating element which comprises a nucleotide sequence as in Table 1, from about nucleotide - 427 to about nucleotide - 348 or a functionally equivalent nucleotide sequence with at least about 90% homology thereto and which further comprises a nucleotide sequence from about nucleotide - 290 to about nucleotide - 271 or a functionally equivalent nucleotide sequence, with at least about 90% homology thereto, and a plant- expressible gene comprising a TATA region wherein said gene is not the 780 gene and wherein said gene is expressed at an enhanced level under the regulatory control of said transcription activating element.

U.S. Patent 5,196,329, Mar. 23, 1993, Gurley, et al.

While this mathematical approach is more definite than a mere requirement for “substantiality”, it suffers from the potential defect of being merely arbitrary. It could be viewed by a court as particularly pointing out or distinctly describing what the inventor believes that he or she can get

away with, rather than demonstrating possession of something that was actually invented. The Amgen court, and even the Fiers v. Sugano court, might look to the patent specification for the experimental justification for the recited percentage, declining to validate a patent to an arbitrary guess.

"Written Description" Guidelines to the Rescue?

The U.S. Patent and Trademark Office has set forth draft guidelines 16 to assist both patent examiners and patent practitioners to wind their way through the thicket of caselaw that now defines at least in part the parameters for describing an invention being claimed. These guidelines were most proximately the result of the Federal Circuits Lilly decision.17

The issues in these guidelines were the subject of a pre-announcement commentary by Director Doll, speaking on behalf of the U.S. Patent and Trademark Office:

An area of patent law that is still developing relates to the kind of information that must be included in the patent application of a biotechnology-related invention in order to sufficiently identify and distinguish its characteristics from other subject matter (in other words, satisfaction of the written description requirement). In the case of the Regents of the University of California v. Eli Lilly, the court held that in order to claim a specific DNA sequence, such as the human DNA encoding insulin, more is required than a mere statement that it is part of the invention, plus a fragment of the claimed nucleic acid, plus a reference to a potential method of isolating the entire sequence. As a result of the Lilly case and several earlier cases, the USPTO is preparing interim examination guidelines for determining compliance with the written description requirement that should be made available for public comment within the next 3 months

There has been considerable debate and discussion over how the issuance of a patent on DNA fragments of a gene will affect the patenting of full-length genes. The USPTO views this situation as analogous to having a patent on a picture tube. The picture tube patent does not preclude someone else from obtaining a patent on a television set. However, the holder of the picture tube patent could sue the television set makers for patent infringement if they use the patented picture tube without obtaining a license.

In a second example, a patent might be granted for compound X, which is disclosed to have a specific use (such as a headache remedy). If other investigators find that X has a new and unexpected use, perhaps in combination with compound Y, for treatment of heart arrhythmias, they may have to obtain a license from the individual who first patented compound X in order to sell XY.

In summary, once a product is patented, that patent extends to any use, even those that have not been disclosed in the patent. A future nonobvious method of using that product may be patentable, but the first patent would have been dominant.

The Doll comments are curious in several respects. First, the "picture tube" has only utility if it can display a picture. Aimlessly shooting electrons at a phosphor to make it glow in the dark is the prior art; the television was the invention that gave meaning to the picture tube and the invention of the television is presumably the predicate discovery that would have permitted the picture tube itself to be patented.

Second, the analogy between the patenting of a bona fide product, compound X, and the inferential discovery of the putative partial structure of a still unknown product, is akin to finding an auburn hair at the murder scene and then claiming the reward when the murderer turns out to be a red-bearded madman. When there are many detectives at the scene of the crime, there are many potential reward claimants. Is it possible that a host of EST inventors might lay a rightful claim to a therapeutic protein product? Consider where the first claimant finds 30 DNA base pairs and claims the proteins made from the DNA comprising the 30 base pairs. The next claimant makes the very same claim with the first 40 base pairs, followed by claimants with 50, 60, 70 and 80. When the later discovery is made of the isolated and purified protein and its useful physiological property, is the ultimate inventor to share the rewards with six clue finders? Director Doll not only seems to think so, but views the EST patentees as the "primary patent holder":

A patent is granted to a large fragment of DNA, within which exists a gene of great medical interest, even though the location of the open reading frame with the fragment has not been determined. The person who actually discovers and isolates the gene may also be able to receive a patent. Alternatively, many patented DNA fragments such as ESTs or SNPs may be isolated that turn out to be part of the same gene. In both cases, the second patent holder may have to obtain licenses from or pay fees to the primary patent holder but is not prevented from obtaining the second patent.

The fallacy with the Doll compound X analogy is that the discovery of compound X is the discovery of the complete structure — or other complete and distinctive characterizing information — for compound X. The discovery of an EST sequence may be the discovery of the EST compound itself, but it is not legally or logically the discovery of every compound that merely contains that sequence.

The Lilly decision reflects an analogous concern over breadth. The University of California inventors were allegedly the first to discover a mammalian proinsulin DNA sequence, namely the cloning of rat proinsulin cDNA. The patent issued attempted to claim every mammalian proinsulin cDNA. This represented a group of specific compounds of unknown structure that would have produced a patent broad enough to cover, in particular, the as yet undiscovered human proinsulin cDNA compound. Hence, it appears impossible to reconcile the analogy offered by Director Doll on behalf of the USPTO18and the clear guidance of the Federal Circuit.

The actual "written description" draft guidelines are no less problematic. Consider, for example, the opening salvo of argumentation:

A gene comprising SEQ ID NO: 1"; "A mRNA comprising SEQ ID NO: 1"; and "A cDNA comprising SEQ ID NO: 1" implicitly recite specific structures such as promoters, enhancers, coding regions, and other regulatory elements in the preamble which must be sufficiently described in the specification so as to show the applicant was in possession of the claimed inventions.

In contrast, use of less specific, generic preamble language, such as "composition," "nucleic acid," "DNA," and "RNA," does not typically present a written description problem. These terms are sufficiently general that one skilled in the art can readily envision a sufficient number of members of the claimed genus to provide written description support for the genus.

The guidelines — taken at face value — suggest that you can solve a written description defect by simply making the invention more generic, i.e., substantially broader in scope. While some circumstances may fit this general proposition, it would necessarily seem to be the exception and not a rule.

There are other strange anomalies in the guidelines. A further example is given for monoclonal antibodies:

[C]onsider the following claim to a genus:

A monoclonal antibody which specifically binds to the novel cancer associated TAG-31 antigen but which does not substantially bind normal adult human tissues, wherein said monoclonal antibody has a binding affinity of greater than 3 times 109 M-1 for TAG-31.

Considering the claim as a whole, it is drawn to a genus of monoclonal antibodies. Although the specification does not disclose the complete structure of a representative number of species to support the claimed genus of antibodies, it does disclose multiple monoclonal antibodies which have the isotype claimed as well as the binding specificity and binding affinity characteristics recited in the claims. In this well-developed art, additional identifying characteristics for a substantial portion of the genus are well-known (e.g., number of chains, disulfide bonds, constant and variable regions, etc.). Thus, applicant's disclosure combined with what was known in the art are sufficient to describe the claimed genus of monoclonal antibodies in such full, clear, concise and exact terms to show applicant was in possession of the claimed antibodies.

What the U.S. Patent and Trademark Office guidelines suggest is a "well-developed art," is in fact an empirical and unpredictable art in terms of having structure-activity relationships. Further the "additionally identifying characteristics for a substantial portion of the genus" that are well known, are merely the general structural features common to every antibody produced in every mammalian cell type. Moreover, the claim reads on every antibody with an

affinity "greater than 3 times" a benchmark reference. Such an open-ended scale clearly preempts future work in a manner that the courts have condemned in the past. See In re Fisher, 166 U.S.P.Q. 18, 427 F.2d 833 (C.C.P.A. 1970), where the Federal Circuit's predecessor court sustained a rejection to a claim containing a minimum potency limitation: 19

The issue thus presented is whether an inventor who is the first to achieve a potency of greater than 1.0 for certain types of compositions, which potency was long desired because of its beneficial effect on humans, should be allowed to dominate all such compositions having potencies greater than 1.0, including future compositions having potencies far in excess of those obtainable from his teachings plus ordinary skill.

It is apparent that such an inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on his teachings. Such improvements, while unobvious from his teachings, are still within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. That paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved. In the present case we must conclude, on the

record before us, that appellant has not enabled the preparation of ACTHs having potencies much greater than 2.3, and the claim recitations of potency of "at least 1" render the claims insufficiently supported under the first paragraph of 35 U.S.C. 112. [Emphasis supplied.]

166 U.S.P.Q. at p. 23-24.

It remains to be seen how the "written description" issue will ultimately be resolved and to what extent it will limit the scope of valid patent claims in the biotechnology arena.

However, given the public statements of Director Doll and the proposed guidelines of the U.S. Patent and Trademark Office, it appears that the Office will only serve as a limited impediment to getting broad biotechnology patent claims, leaving it to the courts — not the Office — to eventually trim the excess.

Conclusions

The biotechnology inventor appears to have overcome the Dark Ages of patent prosecution in the United States. The patent examiners who so forcefully restated meritless rejections for lack of utility have given way to a new breed of patent examiner who not only finds useful inventions useful, but appears prepared to step up to if not over the line on what is a practical utility in a presently available form. Similarly, U.S. biotechnology inventors have been cut a "ten for one" break on the issue of unity of invention. The immediate potential savings to the industry is in the millions of dollars in Office fees and associated expenses. Finally, the Office seems to signal that it has heard the Federal Circuit on the issue of "written description," but it may be prepared to grant claims that — again — appear to march close against, if not tread over, the sometimes zigging and zagging line drawn by the Federal Circuit.

APPENDIX A:

Examination of Patent Applications Containing Nucleotide Sequences

I. Introduction

Biotechnology is expected to be an important growth industry from now until well into the twenty-first century, particularly in the United States, one which will produce new therapeutics for the benefit of mankind. The Patent and Trademark Office (PTO) has taken a very active role in working together with its customers to simplify and standardize PTO policies and procedures and to encourage and promote the growth of this industry for the benefit of humanity.

For at least a decade, researchers in the biotechnology industry have been filing patent applications claiming isolated DNA or RNA sequences of nucleotides, referred to as nucleotide or nucleic acid sequences. Scientific and technological advances now permit researchers to identify large numbers of gene sequences rapidly. The ease of using automated techniques for sequencing large numbers of nucleotides in a nucleic acid has resulted in the filing of a growing number of patent applications, many of which recite thousands of individual nucleotide sequences with each sequence reciting at least several hundred nucleotides. The examination of these applications presents unprecedented search and examination challenges, even with the most modern, up-to-date equipment.

Faced with these challenges, the PTO held public hearings on issues relating to patent protection of nucleotide sequences on April 16, 1996, in San Diego, California and on April 23, 1996, in Arlington,

Virginia. At those hearings, the PTO received several recommendations that restriction practice pursuant to 35 U.S.C. § 121 should be applied to patent applications claiming nucleotide sequences.

This Notice responds to comments received during the hearings. This Notice clarifies PTO's policy for examination of patent applications that claim large numbers of nucleotide sequences.

II. The PTO Will Permit Applicants to Claim Up to Ten Independent and Distinct Nucleotide Sequences In One National Application

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions".

35 U.S.C. § 121. Pursuant to this statute, the Rules of Practice in Patent Cases provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted". 37 CFR §1.l42(a). See also 37 CFR §1.141(a).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. § 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR §1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR §1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application.

Accordingly, in most cases, up to ten (10) independent and distinct nucleotide sequences will be examined in a single application without restriction. It has been determined that normally ten sequences constitute a reasonable number for examination purposes. The PTO believes that allowing applicants to claim up to ten (10) independent and distinct nucleotide sequences in a single application will promote efficient, cost- effective examination of these types of applications. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined.

Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten (10). In other cases, applicants may petition pursuant to 37 C.F.R. § 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions.

III. Under the Unity of Invention Standard in an International

Application or National Stage Application Filed Under 35 U.S.C. § 371 Up to Ten Nucleotide Sequences Will Be Searched and/or Examined Without Payment of An Additional Fee International applications filed under the Patent Cooperation Treaty (PCT) and national stage applications filed under 35 U.S.C. § 371 will be treated in a similar manner. Under 37 CFR §1.475 and §1.499 et seq.,

when claims do not comply with the requirement of unity of invention, i.e., when the claimed subject matter does not involve “one or more of the same or corresponding special technical features,ö 37 CFR §1.475(a), an additional fee is required to maintain the claims in the same application. 37 CFR §1.476(b).

The Commissioner has decided sua sponte to partially waive 37 CFR §1.475 and §1.499 et seq. to permit applicants to claim up to ten (10) nucleotide sequences which do not have the same or corresponding special technical feature, without the payment of an additional fee. The PCT permits inventions which lack unity of invention to be maintained in the same international application for the payment of additional fees. Thus, in international applications, for each group for which applicant has paid additional international search and/or preliminary examination fees, the PTO has determined that up to four (4) such additional sequences per group is a reasonable number for examination. Further, claims directed to the selected sequences will be examined with claims drawn to any sequence combinations which have a common technical feature with the selected sequences. Nucleotide sequences encoding the same protein are considered to satisfy the unity of invention standard and will continue to be examined together.

IV. Examples of Nucleotide Sequence Claims That Are the Subject of this Notice

Examples of typical nucleotide sequence claims impacted by this Notice include:

(1) an isolated and purified DNA fragment comprising DNA having at least 95% identity to a DNA sequence selected from SEQ ID Nos. 1- 1,000; (2) a combination of DNA fragments comprising SEQ ID Nos. 1-1,000; and

(3) a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000. Applications claiming more than ten (10) individual independent and distinct nucleotide sequences in alternative form, such as set forth in example 1, will be subject to a restriction requirement. Only the ten (10) nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined.

Applications claiming only a combination of nucleotide sequences, such as set forth in example 2, will generally not be subject to a restriction requirement. The presence of one novel and nonobvious sequence within the combination will render the entire combination allowable. The combination will be searched until one nucleotide sequence is found to be allowable. The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence. If no individual nucleotide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable.

Applications containing only composition claims reciting different combinations of individual nucleotide sequences, such as set forth in example 3, will be subject to a restriction requirement. Applicants will be required to select one combination for examination. If the selected combination contains ten or fewer sequences, all of the sequences of the combination will be searched. If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth above for example 2. More specifically, the combination will be searched until one nucleotide sequence is found to be allowable with the examiner choosing the order of search to maximize the identification of an allowable sequence. The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed.

In applications containing all three claims set forth in examples 1-3, the PTO will require restriction of the application to ten sequences for initial examination purposes. Based upon the finding of allowable sequences, claims limited to the allowable sequences as in example 1, all combinations, such as in examples 2 and 3, containing the allowable sequences and any patentably indistinct sequences will be rejoined and allowed.

Rejoinder will be permitted for claims requiring any allowable sequence(s). Any claims which have been restricted and non- selected and which are limited to the allowable sequence(s) will be rejoined and examined.

V. Other Possible Solutions

The PTO is pursuing other possible ways to efficiently examine applications that claim large numbers of nucleotide sequences, including the following:

A. Software Development - Using private contractors, the PTO will attempt to identify, modify or develop software tools to aid in searching and the analysis of search results.

B. Feedback - The PTO will pursue and evaluate suggestions from applicants, members of the bar, industry, scientists, government, and inventors.

C. International Cooperation - The PTO will encourage greater cooperation between the other patent offices of the world in the area of biotechnology. The PTO will work with these offices to share resources thereby minimizing duplication of search and examination.

D. PTO Outside Search Center - The PTO will explore the possibility of establishing an outside search center which would perform standard searches for all patent applicants submitting applications containing nucleotide sequences.

E. Search Standards - The PTO will explore the possibility of establishing quality and proficiency standards for prior art searches so that applicants can perform their own pre-examination searches. Applicants could then submit their searches with their applications, and the PTO could examine applications based on applicants' searches.

F. Communication - The PTO will communicate its procedures for searching the prior art and how the current hardware and software have been optimized for examination needs.

Any questions, comments or suggestions regarding this Notice should be directed to Esther M. Kepplinger, Supervisory Primary Examiner, Group Art Unit 1302: by mail to Box Comments-Patents, Assistant Commissioner for Patents, Washington, DC 20231; by FAX to (703) 305-3601; or by electronic mail addressed to ekepplin@uspto.gov.

Date: October 17, 1996

Bruce A. Lehman

Assistant Secretary of Commerce and

Commissioner of Patents and Trademarks

APPENDIX B:

Request for Comments on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 1 "Written Description" Requirement

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice and request for public comments.

SUMMARY: The Patent and Trademark Office (PTO) requests comments from any interested member of the public on the following interim guidelines. These guidelines will be used by PTO personnel in their review of biotechnological patent applications for compliance with the "written description" requirement of 35 U.S.C. §112 ¶1. Although the guidelines are directed primarily to written descriptions of biotechnological inventions, they reflect the current understanding of the PTO and apply across the board to all relevant technologies.

DATES: Written comments on the interim guidelines will be accepted by the PTO until September 14, 1998.

ADDRESSES: Written comments should be addressed to Box 8, Commissioner of Patents and Trademarks, Washington, D.C. 20231, marked to the attention of Scott A. Chambers, Associate Solicitor or to Box Comments, Assistant Commissioner for Patents, Washington, D.C. 20231 marked to the attention of Linda S. Therkorn. Alternatively, comments may be submitted to Scott Chambers via facsimile at (703) 305-9373 or by electronic mail addressed to "scott.chambers@uspto.gov" or to Linda Therkorn via facsimile at (703) 305-8825 or by electronic mail addressed at "linda.therkorn@uspto.gov".

FOR FURTHER INFORMATION CONTACT: Scott Chambers by telephone at (703) 305-9035, by facsimile at (703) 305-9373, by mail to his attention addressed to Box 8, Commissioner of Patents and Trademarks, Washington, D.C. 20231, or by electronic mail at "scott.chambers@uspto.gov"; or Linda Therkorn by telephone at (703) 305-8800, by facsimile at (703) 305-8825, by mail addressed to Box Comments, Assistant Commissioner for Patents, Washington, D.C. 20231, or by electronic mail at "linda.therkorn@uspto.gov".

SUPPLEMENTARY INFORMATION: The PTO requests comments from any interested member of the public on the following interim guidelines. These guidelines will be used by PTO personnel in their review of biotechnological patent applications for compliance with the "written description" requirement of 35 U.S.C. §112 ¶1. Although the guidelines are directed primarily to written descriptions of biotechnological inventions, they reflect the current understanding of the PTO and apply across the board to all relevant technologies. Because these guidelines govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

Written comments should include the following information:

1) name and affiliation of the individual responding; and 2) an indication of whether the comments offered represent views of the respondent's organization or are they respondent's personal views. The PTO is particularly interested in comments relating to: 1) the accuracy of the methodology; 2) relevant factors to consider in determining whether the written description requirement of 35 U.S.C. 112 1 is satisfied; 3) whether the scope of these guidelines should be limited to certain technologies, such as biotechnology, or even a particular area of biotechnology such as nucleic acids, or encompass all technologies generally; 4) whether the scope of these guidelines should be expanded

to include processes and/or product-by-process claims; and 5) the impact these guidelines may have on currently pending applications as well as future applications.

Parties presenting written comments are requested, where possible, to provide their comments in machine-readable format in addition to a paper copy. Such submissions may be provided by electronic mail messages sent over the Internet, or on a 3.5" floppy disk formatted for use in either a Macintosh, Windows, Windows for Workgroups, Windows 95, Windows NT, or MS-DOS based computer.

Written comments will be available for public inspection on or about September 14, 1998, in Suite 918, Crystal Park 2, 2121 Crystal Drive, Arlington, Virginia. In addition, comments provided in machine-readable format will be available through anonymous file transfer protocol (ftp) via the Internet (address: comments.uspto.gov) and through the World Wide Web (address: www.uspto.gov).

Interim Guidelines for the Examination of Patent Applications Under The 35 U.S.C. §112 ¶1 "Written Description" Requirement

These "Written Description Guidelines" are intended to assist Office personnel in the examination of patent applications for compliance with the written description requirement of 35 U.S.C. 112, 1, in view of University of California v. Eli Lilly1 and the earlier cases Fiers v. Revel and Amgen, Inc. v. Chugai Pharmaceutical Co.3 These Interim Guidelines are directed primarily to determining whether there is written description support for product claims and are not intended to specifically address the description necessary to support process or product-by-process claims. Similarly, these Guidelines are not intended to directly address the question of new matter, which is currently addressed in the Manual of Patent Examining Procedure

2163.06-.07. The Final Guidelines may address these additional issues if public comment suggests they should be addressed. These guidelines are based on the Office's current understanding of the law and are believed to be fully consistent with binding precedent of the Supreme Court, the Federal Circuit, and the Federal Circuit's predecessor courts.

These guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. They are designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law.

Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any failure by Office personnel to follow the guidelines is neither appealable nor petitionable.

These guidelines are intended to form part of the normal examination process. Thus, where Office personnel establish a prima facie case of lack of written description for a claim, a thorough review of the prior art and examination on the merits for compliance with the other statutory requirements, including those of 35 U.S.C. 101, 102, 103, and 112, is to be conducted prior to completing an Office action which includes a rejection for lack of written description.

Office personnel are to rely on these guidelines in the event of any inconsistent treatment of issues involving the written description requirement between these guidelines and any earlier guidance

provided from the Office. Although these guidelines address examples principally drawn from the biotechnological arts, they are intended to be equally applicable to all fields of invention.

I. General Principles Governing Compliance with the "Written Description" Requirement For Applications

The first paragraph of 35 U.S.C. 112 requires that the "specification shall contain a written description of the invention..". This requirement is separate and distinct from the enablement requirement.4 This written description requirement has several policy objectives. "[T]he `essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed".5 Another objective is to put the public in possession of what the applicant claims as the invention. The written description requirement prevents an applicant from claiming subject matter that was not described in the specification as filed, and the proscription against the introduction of new matter in a patent application6 serves to prevent an applicant from adding information that goes beyond the subject matter originally filed.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.7 This requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications for the benefit of the public in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.8

II. Evaluate Whether The Application Complies With the "Written Description" Requirement

The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact.9 The examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.10 Office personnel should adhere to the following procedures when reviewing patent applications for compliance with the written description requirement of 35 U.S.C. 112, 1.

A. Review the entire application to determine what applicant has invented, the field of the invention and the level of predictability in the art

Prior to determining whether the claims satisfy the written description requirement, Office personnel should review the entire specification, including the specific embodiments, figures, sequence listings, and the claims, to understand what applicant has invented and the correspondence between what applicant has described, i.e., has possession of, and what applicant is claiming. Such a review should be conducted from the standpoint of one of skill in the art at the time the application was filed and should include a determination of the field of the invention and, thus, the level of predictability in the art. Predictability of the structure of a species can be premised upon:

(1) Whether the level of skill in the art leads to a predictability of structure; and/or

(2) Whether teachings in the application or prior art lead to a predictability of structure.

There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between structure and function in the art, one skilled in the art will be able

to reasonably predict the complete structure of the claimed invention from its function. Thus, in some factual situations, the written description requirement may be satisfied through disclosure of function alone when there is a well-established correlation between structure and function. In contrast, without such a correlation, prediction of structure from function is highly unlikely. In this latter case, disclosure of function alone will not satisfy the written description requirement.11

B. For each claim, determine what the claim as a whole covers

Each claim must be separately analyzed and given its broadest reasonable interpretation.12 The entire claim, including its preamble language and transitional phrase, must be considered. "Preamble language" is that language in a claim appearing before a transitional phase, e.g., before "comprising," "consisting essentially of," or "consisting of". The transitional term "comprising" (and other comparable terms, e.g., "containing" and "including") is "open-ended"-it covers the expressly recited subject matter alone or in combination with other uns tated subject matter.13 There must be adequate written description to support the claimed invention including the preamble.14 The claim as a whole, including all limitations found in the preamble, the transitional phrase, and the body of the claim, must be described sufficiently to satisfy the written description requirement.15 For claims of the form "A [structure] comprising SEQ ID NO: 1" there may be a written description problem if the claim as a whole, including its preamble and transitional phrase, is directed to an invention of unpredictable structure that is not fully described.

For example, when the term "gene," "mRNA," or "cDNA" is recited in the preamble, it implies a specific structure (or a small genus of specific structures) when used in the traditional sense, i.e., to mean the structure having the naturally occurring sequence. Thus, "A gene comprising SEQ ID NO: 1"; "A mRNA comprising SEQ ID NO: 1"; and "A cDNA comprising SEQ ID NO: 1" implicitly recite specific structures such as promoters, enhancers, coding regions, and other regulatory elements in the preamble which must be sufficiently described in the specification so as to show the applicant was in possession of the claimed inventions.

In contrast, use of less specific, generic preamble language, such as "composition," "nucleic acid," "DNA," and "RNA," does not typically present a written description problem. These terms are sufficiently general that one skilled in the art can readily envision a sufficient number of members of the claimed genus to provide written description support for the genus.

A claim such as "A gene comprising SEQ ID NO: 1," can be viewed as a species claim in which the preamble recites a combination and the body of the claim recites a subcombination: The "gene" is the combination and "SEQ ID NO: 1" (which is a fragment of the gene) is the subcombination. Written description of only the subcombination (in this example the fragment SEQ ID NO: 1) normally does not put one in possession of the combination (in this example the gene).

Likewise, generic claims to sequences can be viewed as a genus of such combination-subcombination claims. For example, a claim such as "A nucleic acid comprising SEQ ID NO: 1" can be viewed as a genus claim in which each member of the genus (each species) is itself a combination- subcombination: Each member of the genus "nucleic acid" is a combination containing the subcombination "SEQ ID NO: 1" (which is a fragment of the nucleic acid). Again, the generic term "nucleic acid" does not typically present a written description problem because one skilled in the art can readily envision a sufficient number of members of the claimed genus to provide written description support for the genus.16

C. For each claimed species, determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed

Written description may be satisfied through disclosure of relevant identifying characteristics, i.e., structure, other physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.17 What is well known to one skilled in the art need not be disclosed.18 If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.19

For each claimed species:

(1) Determine whether a complete structure is disclosed. The complete structure of a species typically satisfies the requirement that the description be set forth in "such full, clear, concise and exact terms" to show possession of the claimed invention.20 If a complete structure is disclosed, the written description requirement is satisfied for that species, and a rejection under 35 U.S.C. 112 1 for lack of written description must not be made.

For example, consider the following claim:

A probe for use in detecting nucleic acid sequences coding for enzyme Q from the genus Bacillus consisting of SEQ ID NO:

16.21

Considering the claim as a whole, it is a species claim covering the probe SEQ ID NO: 16.The specification discloses the complete sequence for SEQ ID NO: 16.Thus, this claim falls into the "safe harbor" described under C(1).

(2) If the complete structure is not disclosed, determine whether the specification discloses other relevant identifying characteristics, i.e., physical and/or chemical characteristics and/or functional characteristics coupled with a known or disclosed correlation between function and structure, sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. Disclosure of any combination of such identifying characteristics that would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. In such a case, a rejection for lack of written description under 35 U.S.C. §112 ¶1 must not be made.

For example, consider the following claim:

An isolated double-stranded DNA consisting of (1) a single- stranded DNA which has a molecular size of 2.57 Kb and is derived from golden mosaic virus, and (2) a DNA complementary to said single-stranded DNA, giving the restriction endonuclease cleavage map shown in FIG.2(a) and having no Mbo I restriction endonuclease site.

Although the specification does not disclose the complete structure for the claimed DNA, it does disclose sufficient identifying characteristics, i.e., size, cleavage map, and source from which the DNA is derived. Thus, while this claim does not meet the C(1) criteria because the complete sequence is

not disclosed, it does meet the C(2) criteria because one skilled in the art would recognize from the characteristics, e.g., size, map, source, that applicant was in possession of the claimed material at the time of filing.

The following protein claim also falls within the C(2) criteria: An isolated alginate lyase enzyme wherein said enzyme lyses alginate in the mucous substance produced in a patient with cystic fibrosis and wherein said enzyme has the N-terminal amino acid sequence SEQ ID No. 1, obtained from Flavobacterium pepermentium and has the following physicochemical properties: (1) Activity: lyses alginate to saccharides having a non-reducing end C4-C5 double bond and ultimately to 4-deoxy-5-ketouronic acid; (2) Molecular weight: 60,000 daltons; (3) Optimal pH: 8.0; (4) Stable pH:

6.0-8.0; (5) Optimal temperature: 70 degrees C; and (6) Substrate specificity: alginate.

In this example, the specification discloses the molecular weight, origin, activity, and specificity but does not disclose the complete structure for the claimed enzyme. Thus, this claim would not meet the C(1) criteria because the complete sequence is not disclosed. However, the claim meets the C(2) criteria because, although the complete structure is not disclosed, one skilled in the art would recognize from the disclosed physical characteristics-e.g., molecular weight, origin, activity, and specificity-that applicant was in possession of the claimed material at the time of filing.

In contrast, consider the following claim:

An isolated nucleotide sequence consisting of the sequence of the reverse transcript of a human mRNA, which mRNA encodes insulin.

The specification in this example provides the coding sequence for rat insulin but not that for human insulin. The description for the reverse transcript of human mRNA is limited to its function, encoding human insulin, and to a method for isolating the claimed sequence from its natural source. A sequence described only by a purely functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed species. In this case, even though a genetic code table would correlate a known insulin amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of human mRNA or its corresponding cDNA. Thus, the specification in this example does not provide adequate written description, either under the C(1) or C(2) criteria.22

Any claim to a species that does not meet the test described under C(1) or C(2) must be rejected as lacking adequate written description under 35 U.S.C. §112 ¶1.

D. For each claimed genus, determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed genus at the time the application was filed

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by relevant identifying characteristics, i.e., structure or other physical and/or chemical characteristics, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such

identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.23

A "representative number of species" requires that the species which are expressly described be representative of the entire genus. Thus, when there is substantial variation within the genus, it may require a description of the various species which reflect the variation within the genus. For example, a broadly drawn claim to a specific gene from ruminant mammals may require a representative species from cattle, buffalo, bison, goat, deer, antelope, camel, giraffe and llama.

What constitutes a "representative number" is an inverse function of the predictability of the art, as determined in IIA above. The number must be sufficient to reasonably identify the other members of genus. In an unpredictable art, adequate written description of a genus cannot be achieved by disclosing only one species within the genus. In fact, if the members of the genus are expected to vary widely in their identifying characteristics, such as structure and activity, written description for each member within the genus may be necessary.

Generalized descriptions alone, such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," fail to satisfy the written description requirement because they do not describe any members of the genus except by function without any known or disclosed correlation between function and structure.24 If the correlation between structure and function in the art would not have been known to one skilled in the art and the specification does not describe the correlation, the written descriptive support cannot depend on that correlation.

For each claim to a genus:

(1) Determine whether a representative number of species have been described by complete structure as in C(1) above.If a representative number have been so described, then the applicant has written description support for the claimed

genus and a rejection under §112 ¶1 for lack of written description must not be made.

For example, consider the following claim to a genus:

An isolated DNA probe for detecting HIV-X, wherein said DNA probe hybridizes to the nucleotide sequence set forth in SEQ ID NO:1 under the following conditions: hybridization in 7% sodium dodecyl sulfate (SDS), 0.5M NaPO4 pH 7.0,

1mM EDTA at 50 C.; and washing with 1% SDS at 42 C.

In this case, the specification discloses the sequence of the isolated DNA molecule consisting of SEQ ID NO: 1 and discloses several sequences that hybridize to SEQ ID NO: 1. Hybridization under the stringent conditions specified here requires that the claimed nucleic acid probes be structurally similar to the complement of the nucleic acid sequence disclosed as SEQ ID NO: 1. In this case, the description as a whole is sufficient to evidence possession of the claimed genus because the genus is defined by relation to the structure of the sequence provided as SEQ ID NO: 1, and because several species are disclosed that possess the hybridization property which further defines the genus. Thus, this claim to a genus meets the D(1) criteria.

(2) For each claim to a genus not supported as described under D(1), determine whether there is a representative number of adequately described species, as analyzed under C(2). The representative

number must permit one skilled in the art to reasonably identify the remaining members of the genus. If a representative number are so described, then the written description requirement is satisfied and, again, a rejection under §112 ¶1 for lack of written description must not be made.

For example, consider the following claim to a genus:

A monoclonal antibody which specifically binds to the novel cancer associated TAG-31 antigen but which does not substantially bind normal adult human tissues, wherein said monoclonal antibody has a binding affinity of greater than 3 times 109 M-1 for TAG-31.

Considering the claim as a whole, it is drawn to a genus of monoclonal antibodies. Although the specification does not disclose the complete structure of a representative number of species to support the claimed genus of antibodies, it does disclose multiple monoclonal antibodies which have the isotype claimed as well as the binding specificity and binding affinity characteristics recited in the claims. In this well-developed art, additional identifying characteristics for a substantial portion of the genus are well-known (e.g., number of chains, disulfide bonds, constant and variable regions, etc.). Thus, applicant's disclosure combined with what was known in the art are sufficient to describe the claimed genus of monoclonal antibodies in such full, clear, concise and exact terms to show applicant was in possession of the claimed antibodies. Thus, the claim meets the D(2) criteria.

As another example, consider the following claim to a genus: An isolated mutanase enzyme produced by Bacillus having the following physicochemical properties (1) to (9): (1) action: an ability to cleave alpha-1,3-glucosidic links of mutan; (2) substrate specificity: an ability to effectively decompose mutan;(3) optimum pH: pH 4 to 4.5 when reacting on a mutan substrate at 35 degrees C. for 10 minutes; (4) pH range for stability: pH 4 to 10 when kept at 25 degrees C for 24 hours; (5) optimum temperature: 50 degrees to 65 degrees C when reacted at pH 5 with mutan as a substrate; (6) thermal stability: enzyme activity remains stable below 50 degrees C after incubation at pH 5 for 10 minutes; (7) effect of metal ions: mercury and silver show inhibitory effect on a mutan substrate; (8) effect of inhibitors: p-chloromercurybenzoic acid shows inhibitory effect on a mutan substrate; and (9) molecular weight: about 140,000 to about 160,000 as determined by SDS-polyacrylamide gel electrophoresis.

Considering the claim as a whole, it covers a genus of mutanase enzymes. Although the specification does not disclose the complete structure of a representative number of species to support the claimed genus of enzyme compositions, it does disclose 3 mutanase species produced by different strains of Bacillus (mutanases A, B and C) which are identified by multiple relevant identifying characteristics, i.e., molecular weight, substrate specificity, optimum and ranges of temperature and pH for mutan cleavage activity, etc. In this well-developed art, these identifying characteristics are sufficient for a skilled artisan to recognize applicant had possession of the species from the identifying characteristics of the three mutanase species, to reasonably predict sufficient identifying characteristics of the other members of the genus and, thus, establish possession of the genus. Thus, the claim meets the D(2) criteria.

As another example, consider the following claim to a genus: A DNA comprising a novel DF3 enhancer and DNA encoding a heterologous gene but not encoding DF3 wherein said DF3 enhancer consists of SEQ ID NO: 1.

Considering the claim as a whole, it covers a genus of DNA. The specification does not describe a representative number of members of the genus by complete structure. Thus, the claim does not

meet the D(1) criteria. However, there is sufficient disclosure of identifying characteristics common to the members of the genus, i.e., DF3 enhancer, to meet the D(2) criteria. Because of the nature of the generic term "DNA," one skilled in the art could envision a sufficient number of the members of the genus to describe the invention in such full, clear and concise terms as to show possession of the invention at the time of filing.

In contrast, consider the claim:

An isolated nucleic acid comprising the structure of the reverse transcript of a mammalian mRNA, which mRNA encodes insulin.

Considering the claim as a whole, the claim covers the genus of nucleotide sequences encoding mammalian insulin. The specification only provides the coding sequence for rat insulin cDNA and a method to isolate the coding sequence from its natural source.25 This description does not meet the criteria of D(1) or D(2) and thus does not satisfy the written description requirement.

Also contrast the claim "A gene comprising SEQ ID NO: 1".

Although all genes encompassed by this claim share the characteristic of comprising SEQ ID NO: 1, and as such might appear to meet the D(2) criteria, there is insufficient description of the characteristics (e.g., promoters, enhancers, coding regions, and other regulatory elements) which identify the genes, as opposed to any DNA comprising SEQ ID NO: 1.

If sufficient identifying characteristics are not disclosed for a given genus, as described in D(1) or D(2), the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. §112 ¶1.

III. Complete Patentability Determination Under All Statutory Requirements and Clearly Communicate Findings, Conclusions and Their Bases

The above only describes how to determine whether the written description requirement of 35 U.S.C. 112 1 is satisfied. Regardless of the outcome of that determination, Office personnel must complete the patentability determination under all the relevant statutory provisions of the Patent Act.

Once Office personnel have concluded analysis of the claimed invention under all the statutory provisions, including 35

U.S.C. 101, 112, 102 and 103, they should review all the proposed rejections and their bases to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions and reasons which support them.

Specific to these guidelines:

A. For each claim lacking written description support, reject the claim under section 112, 1, for lack of adequate written description

In rejecting a claim, set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

(1) identify the claim limitation not described; and

(2) provide reasons why a person skilled in the art at the time the application was filed would not have recognized the description of this limitation in view of the disclosure of the application as filed.

When appropriate, suggest amendments to the claims which would bring the claims into compliance with the written description in the specification, bearing in mind the prohibition against new matter in the claims and corresponding description set forth in 35 U.S.C. 112 and 132.

B. Upon reply by applicant, again determine the patentability of the claimed invention, including whether the written description requirement is satisfied by performing the analysis described above in view of the whole record

Upon reply by applicant, before repeating any rejection under Section 112 ¶1 for lack of written descriptive basis, review the basis for the rejection in view of the record as a whole, including amendments, arguments and any evidence

submitted by applicant. If the whole record now demonstrates that the written description requirement is satisfied, do not repeat the rejection in the next Office action. If the record still does not demonstrate that written description is adequate to support the claim(s), repeat the rejection under 35 U.S.C. 112

1, fully respond to applicant's rebuttal arguments, and properly treat any further showings submitted by applicant in the reply. Any affidavits, including those relevant to the §112¶1 written description requirement, must be thoroughly analyzed and discussed in the Office action.

ENDNOTES (References from Appendices A and B):

1. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

2. 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993).

3. 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

4. E.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560, 19

USPQ2d 1111, 1115 (Fed. Cir. 1991).

5. In re Barker, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977).

6. 35 U.S.C. §132 & §251.

7. E.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in the cases is most often phrased as whether the original application provides "adequate support" for the claims at issue or whether the material added to the specification incorporates "new matter" in violation of 35 U.S.C. 132. The "written description" question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the newly added claims corresponding to the count at issue, i.e., whether that party can "make the claim" corresponding to the interference count. E.g., see Martin v. Mayer, 823 F.2d 500, 502, 3 USPQ2d 1333, 1335 (Fed. Cir. 1987).

In addition, early opinions suggest the Patent and Trademark Office was unwilling to find written descriptive support when the only description was found in the claims; however, this viewpoint was rejected. See In re Koller, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); In re Gardner, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973) (accord); In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) (accord). It is now well-accepted that a satisfactory description can be mined from the claims or any other portion of the originally filed specification.

These early opinions did not address the quality or specificity of particularity that was required in the description, i.e., how much description is enough.

8. See Eli Lilly, 119 F.3d at 1566, 43 USPQ2d at 1404.

9. See In re Smith, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ("Precisely how close [to the claimed invention] the description must come to comply with 112 must be left to a case-by-case development".); In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976) (inquiry is primarily factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure).

10. Wertheim, 541 F.2d at 262, 191 USPQ at 96.

11. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406 (written description requirement not satisfied by merely providing "a result that one might achieve if one made that invention"); In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming a rejection for lack of written description because the specification does "little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate").

12. See, e.g., In re Morris, 127 F.3d 1048, 1053-54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

13. See, e.g., Ex parte Davis, 80 USPQ 448, 450 (1948) ("comprising" leaves the "claim open for the inclusion of unspecified ingredients even in major amounts".), quoted with approval in Moleculon Research Corp v. CBS, Inc., 793 F.2d 1261, 1271, 229 USPQ 805, 812 (Fed. Cir. 1986).

14. See Pac-Tec Inc. v. Amerace Corp., 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention).

15. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572,

41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

16. E.g., Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1405-06.

17. A "relevant identifying characteristic" is one that would provide evidence that applicant was in possession of what is claimed. For example, the presence of a restriction enzyme map of a gene may be relevant to a statement that the gene has been isolated. One skilled in the art could determine whether the gene disclosed was the same as or different than a gene isolated by another by comparing the restriction enzyme map. In contrast, evidence that the gene could be digested with a nuclease would not normally represent a relevant characteristic since any gene would be digested with a nuclease.

Examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics can demonstrate the requisite possession. For example, unique cleavage by particular enzymes, isoelectric points of fragments, detailed restriction enzyme maps, a comparison of enzymatic activities, or antibody cross reactivity may be sufficient to show possession of the claimed invention to one of skill in the art. See Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997) ("written description" requirement may be satisfied by using "such descriptive means as words, structures, figures, diagrams, formulas, etc. that fully set forth the claimed invention").

However, a definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is". Eli Lilly, 119 F.3 at 1568, 43 USPQ2d at 1406. See also Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen).

18. See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

19. See, e.g., Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1116; Martin v. Johnson, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in ipsis verbis to be sufficient").

20. 35 U.S.C. §112 ¶1. Cf. Fields v. Conover, 443 F.2d 1386, 1392, 170 USPQ 276, 280 (CCPA 1971) (finding a lack of written description because the specification lacked the "full, clear, concise, and exact written description" which is necessary to support the claimed invention).

21. The examples contained within these guidelines are not intended to represent the minimum requirements necessary to comply with 35 U.S.C. §112 ¶1.

22. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

23. See id. at 1568, 43 USPQ2d at 1406.

24. Cf. Eli Lilly, 119 F.3d at 1567, 43 USPQ2d at 1405 (stating that "The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning itself".).

25. See id. 1568, 43 USPQ2d at 1406. June 9, 1998

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Assistant Secretary of Commerce and Commissioner of Patents and Trademarks DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. 980605148-8148-01]

FOOTNOTES

(1) This practice is codified in 37 C.F.R. §1.475: Unity of invention before the International Searching

Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(2) This is explicitly stated in the Commissioner's Notice: The Commissioner has decided sua sponte to partially waive 37 C.F.R. §1.475 and §1.499 et seq. to permit applicants to claim up to ten (10) nucleotide sequences which do not have the same or corresponding special technical feature, without the payment of an additional fee. The PCT permits inventions which lack unity of invention to be maintained in the same international application for the payment of additional fees. Thus, in international applications, for each group for which applicant has paid additional international search and/or preliminary examination fees, the PTO has determined that up to four (4) such additional sequences per group is a reasonable number for examination. Further, claims directed to the selected sequences will be examined with claims drawn to any sequence combinations which have a common technical feature with the selected sequences. Nucleotide sequences encoding the same protein are considered to satisfy the unity of invention standard and will continue to be examined together.

(3) In re Brana, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995).

(4) Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881 (C.C.P.A.

1980). Although the Brana court did not expressly rely on this case, it is extensively relied upon in the guidelines. (5) Doll, John, "The Patenting of DNA, Science Magazine, Volume 280, Number 5364 (May 1, 1998), p. 689.

(6) U.S. patent applications 07/716,831, filed June 21, 1991, 07/837,195, filed September 25, 1992, and 07/952,911, filed February 12, 1993, all filed in the name of Craig Venter, et al. and assigned to the National Institutes of Health.

(7) See Rebecca S. Eisenberg and Robert P. Merges, "Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences," 23 AIPLA Q. J. 1 (1995).

(8) This potential defect could, theoretically, be avoided by adding a further limitation: A protein, except as existing or occurring in nature, comprising:

(A) all or part of the amino acid sequence set forth in SEQ. ID. NOS. 1, 2 or 3;

(B) an amino acid sequence at least 50% homologous with an amino acid sequence defined in (A), said protein having the in vivo biological property of stimulating the production of enzyme Y, and said protein having an amino acid sequence which differs from the sequence of any known polypeptide.

In other words, the inventor here is effectively seeking to claim any non-naturally occurring, non-biologically inactive, non-anticipated, enzyme Y-inhibiting protein.

(9) In re Fisher, 314 F.2d 817, 137 U.S.P.Q. 150 (C.C.P.A. 1963).

(10) Young v. United States, 179 U.S.P.Q. 801 (US Cl. Ct 1973):

Moreover, a single means-plus-function claim does not particularly point out and distinctly claim the invention as required by paragraph 1 of § 112, since it fails to recite any structure whatsoever. As stated in Ex parte Bullock, 1907 C.D. 93, 127 O.G. 580, a "single means" claim:

... is clearly indefinite and functional. No structure by which the function stated is accomplished is set forth in the claim. The claim is not for a combination of which the "means" for the purpose mentioned is an element, but is merely for means as an element and covers all possible means for accomplishing a certain function regardless of structure. 179 U.S.P.Q. at 808.

(11) See Genentech v. Wellcome

The independent claims at issue in the '075 and '330 recombinant patents contain no definition for the DNA isolate other than that it encodes human t-PA. Such a claim, defining a substance only by its function, encompassing all substances that accomplish that result, is akin to a single means claim, which might fail to satisfy the definiteness requirement of 35 U.S.C Section 112.31 U.S.P.Q. 1172.

Fiers v. Revel

Because the count at issue purports to cover all DNAs that code for b-IF, it is also analogous to a single means claim, which has been held not to comply with the first paragraph of section 112.25 U.S.P.Q. 1606.

In re Hyatt

The long-recognized problem with a single means claim is that it covers every conceivable means for achieving the stated result, while the specification discloses at most only those means known to the inventor. See O'Reilly v. Morse, 56 U.S. 62, 112 (1853). Thus, the claim is properly rejected for what used to be known as "undue breadth," but has since been appreciated as being, more accurately, based on the first paragraph of §112.218 U.S.P.Q. 197.

In Hyatt, the objectionable claim read:

A Fourier transform processor for generating Fourier transformed incremental output signals in response to incremental input signals, said Fourier transform processor comprising: incremental means for incrementally generating the Fourier transformed incremental output signals in response to the incremental input signals.

(12) Fiers v. Revel, 984 F.2d 1164,25 U.S.P.Q.2d 1601 (Fed. Cir. 1993).

(13) A means-plus-function claim has at least the following statutory advantages under U.S. patent law:

- A written description is inherently present, as long as at least one corresponding structure for each means is found in the patent specification.

- Enablement for the full scope of the claim is necessarily present, so long as at least one corresponding embodiment in the specification is enabled.

- The claim is definite, notwithstanding that it literally encompasses both disclosed structures and "equivalent structures" that are not expressly defined in the patent specification.

- The claim can be enforced both literally and under the doctrine of equivalents, further expanding the claim to subject matter performing substantially the same function in substantially the same way to achieve substantially the same result.

(14) A proper "means-plus-function" claim format would appear on its face to be relatively easy to perfect for DNA, i.e., a claim to a combination of two or more functionally- defined DNA sequence limitations. Consider the following claim format:

An isolated DNA compound useful for expressing a protein characterized by:

- a first sequence of DNA bases constituting a means for encoding a polypeptide that is effective to stimulate enzyme Y in vivo and

- a second sequence of DNA bases, operatively positioned with respect to said first sequence, constituting a means for promoting expression of said first sequence.

This claim according to 35 U.S.C. § 112, sixth paragraph reads both DNA for expressing the disclosed proteins, SEQ. ID. NOS. 1, 2, and 3 as well as equivalent structures performing the same function.

(15) A corresponding protein product claim can be fashioned from the DNA claim, at least in product-by-process terms:

A protein product of the process of expression in a transfected cell of an isolated DNA compound characterized by:

- a first sequence of DNA bases constituting a means for encoding a polypeptide that is effective to stimulate enzyme Y in vivo and

- a second sequence of DNA bases, operatively positioned with respect to said first sequence, constituting a means for promoting expression of said first sequence.

(16) 63 Fed. Reg. 32639-32645 (June 15, 1998). (17) University of California v. Eli Lilly and Co., 43

U.S.P.Q.2d 1398, 119 F.3d 1559 (Fed. Cir. 1997). The district court decision is reported at 39 U.S.P.Q.2d 1225 (DC S.Ind. 1995).

(18) Doll offered an economic rationale for broad patent claims in addition to the legal analysis. The economic rationale appeared as follows:

However, in the USPTO's view, new areas of technology do not create the need for a whole new specialized patent law. In many ways, the arguments currently being used for DNA sequence technology resemble those voiced 30 to 40 years ago when polymer chemistry was an emerging technology. At that time, people argued that if broad generic claims were granted on the building blocks of basic polymers, it would devastate the industry. In fact, no such disaster occurred. For example, the issuing in 1965 of a basic patent broadly claiming a vulcanizable copolymer of aliphatic mono-olefins and unsaturated bridged-ring hydrocarbons (3) did not preclude the later issuing of patents to different inventors for several copolymers of this type (4). These patents represent early examples of ethylene-propylene-diene monomer (EPDM) rubbers, which are highly weather- and ozone- resistant, stable to thermal aging, and have good electrical insulating properties. These EPDM rubbers have been commercially important as components in tires, weather stripping, radiator hoses, wire insulation, impact modifiers, and roofing.

EPDM copolymers were assembled from three basic building blocks that could be combined in many different ways and, as such, generic and specific claims to these copolymers are analogous to claims that may be issued to DNA inventions. Just as the issuing of broad product claims at the early stages of this technology did not deter development of other new vulcanizable copolymers, the issuing of relatively broad claims in genomic technology should not deter inventions in genomics. Two relevant examples of this in the field of biotechnology are the polymerase chain reaction (PCR) and the human immunodeficiency virus (HIV) protease, which were patented and then widely licensed to permit the biotech industry to continue to grow and benefit from these inventions.

Again, the comparisons being drawn are inapt. The monomers were chemical compounds, vended as chemical compounds. The persons owning patents on these compounds and their

uses were clearly entitled to patents; the inventions they made were starting materials or intermediates that were used in a variety of useful end products. EST's, in contrast, are neither. They are £ at best a part of the structure of a compound that might later be discovered and used as one means of making a protein product yet to be identified. (19) The appealed claim read in full: 4. An adrenocorticotrophic hormone preparation containing at least 1 International Unit of ACTH per milligram and containing no more than 0.08 units of vasopressin and no more than 0.05 units of oxytocin per International Unit of ACTH, and being further characterized as containing as the active component of [a?] polypeptide of at least 24 amino acids having the following sequence from the N terminus of the molecule; Serine, Tyrosine, Serine, Methionine, Glutamic Acid, Histadine, Phenylalanine, Arginine, Tryptophan, Glycine, Lysine, Proline, Valine, Glycine, Lysine, Lysine, Arginine, Arginine, Proline, Valine, Lysine, Valine, Tyrosine, Proline. [Emphasis supplied.]

PAPER: FLO/1.3 by Jerry D. Voigt

Interference with the United States – A Proceeding of Growing Interest to Multinational Companies

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Introduction

Most of the world has a "first to file" patent system. If two or more inventors discover the same patentable device, compound, process, etc., the one who files the first patent application will receive the right of excluding others from using the invention. The United States, in contrast, has a "first to invent" patent system. Patent protection on the same invention in the United States, the one who invented first has the superior right to the patent.

Because it awards patent rights to whoever invents first, the United States needed to develop a system for resolving the inevitable conflicts that arise when two or more parties claimed patent rights to the same subject matter. Congress established this procedure in § 135 of the patent laws by delegating to the Commissioner of the Patent and Trademark Office (PTO) the authority to declare an "interference" when "an application is made for a patent which…would interfere with any pending application, or with any unexpired patent…"1

Until very recently, under the laws of the United States, inventors outside the United States could not use their non-U.S. activity to prove they were the "first to invent". The best they could do was rely on the earliest filing date of their non-U.S. patent applications. But the recently enacted legislation implementing GATT and its accompanying TRIPs agreement abolish this geographic distinction. On and after January 1, 1996, inventive activity outside the United States may be used to prove who was the "first to invent" a particular invention. Because of this dramatic change in U.S. patent law, non-U.S. inventors must now become acquainted with the concepts and procedures of the United States "patent interference".

Subject Matter of Interferences

An interference occurs when an application claims subject matter that is the "same patentable invention" found in the claims of another application or issued patent. It is sometimes useful to look at an interference as a contest to determine which of two competing sets of claims should act as patent- defeating prior art against the other. The PTO uses this prior-art approach to define the subject matter of an interference--the "same patentable invention"--as follows:

Invention "A" is the "same patentable invention" as invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a "separate patentable invention" with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". 2

Claims in different applications or patents may be directed to interfering subject matter, that is, they may constitute "the same patentable invention," even though they do not actually and identically

overlap. For example, a claim requiring "chlorophenyl" could be directed, under proper circumstances, to the same patentable invention as a claim requiring "fluorophenyl" in an already-issued patent.

Furthermore, both of two interfering claims do not have to be patentably indistinct from each other; an interference can be declared if a claim in an application is patentably indistinct from a claim in the patent, even if the reverse is not true, i.e., the patent claim is patentably distinct from the application claim. At least in theory, an invention can be both the same patentable invention as another invention and a separate patentable invention with respect to the other invention. To illustrate, invention "A" could be directed to a genus (e.g., halophenyl) while invention "B" is directed to a species (e.g., fluorophenyl), subsumed within the genus of invention "A". Invention "A" is the same patentable invention as invention "B" because invention "A" is the same as (i.e., anticipated by) invention "B". At the same time, invention "B" (species) could be a separate patentable invention with respect to invention "A" (genus) because a species is not always anticipated by a subsuming genus and, under appropriate circumstances, a species can be patentable over a genus that totally encompasses the species.

The Concept of "Counts"

As part of the procedural mechanism for resolving interferences, the PTO prepares one or more "counts". These counts define the scope of the subject matter (invention) in dispute.

The count, initially drafted by the PTO, looks very much like a claim in a patent application or patent. Indeed, the count often derives directly from a claim in the application or patent of one or both of the parties to the interference. The count should encompass all the interfering subject matter; that is, all patentably indistinct, but otherwise patentable, subject matter of the applications and patents involved in the interference. Thus, in some instances, a count will actually be broader than the disclosure and claims of any single party.

For example, one party might disclose a process requiring a temperature between 60°C and 100°C. Meanwhile, the other party discloses substantially the same process at a temperature between 75°C and 125°C. In the ensuing interference, the count would pick up the low end of one party's range and the high end of the other, and recite a temperature range of 60°C to 125°C, even though neither party disclosed this range. Such a count is known as a "phantom count".

When the claims involved in an interference are particularly complex, the PTO faces the dilemma of drafting a count suitably broad to encompass the entire common invention. To meet this challenge, the PTO often fashions the count by taking the broadest claim from each side and connecting it with an "or". This technique, which has proven most satisfactory, gives each side the benefit of a count written in terms the party has chosen to define its invention. It also ensures a count of sufficient breadth to subsume the broadest allowable subject matter of each party.

Interferences, at least as initially declared, are usually based on a single count. An interference may involve multiple counts, but each separate count must be directed to a different patentable invention. Priority is decided separately for each count.

When the PTO declares an interference, it designates the claims in the applications or patents that "correspond to the count". If a claim does not define an invention that is patentably distinct from the invention defined by the count, then it corresponds to the count. Claims corresponding to a

particular count interfere with one another and any priority judgment as to a particular count governs all corresponding claims. A patentable claim not designated as corresponding to any count is not at risk in the interference; the party asserting such a claim will be entitled to obtain a patent containing the claim, regardless of the outcome of the interference.

The Date of Invention

In interference proceedings, the party determined to have invented first will receive an "award of priority". To receive this award, a party must establish an earlier "date of invention" than the opposing party. When determining this date, the PTO will consider both aspects of the inventive act, "conception" of the invention and its "reduction to practice".

On January 1, 1996, R&D labs throughout the world must take note of a significant change in U.S patent law: non-U.S. inventors will be able to prove dates of invention on the basis of non-U.S. inventive activity. Thus, all R&D labs should reevaluate the way they track their research and record its results. The records of this activity are essential for proving dates of invention. Those that fail to reconsider their research recordkeeping procedures may one day in the not-too-distant future find themselves congratulating the opposition in some interference proceeding.

Proving Conception

"Conception" can be likened to the proverbial light bulb turning on above the inventor's head. It is the mental part of the inventive act, the idea for the invention. But a legally sufficient conception, one that is relevant to the "date of invention," must be more than just a general idea. In traditional interference practice, an invention is conceived of when the inventor has in mind a complete idea of the invention of the count.

In most instances, claims--and counts--cover a number of different embodiments of an invention. To have a conception of the invention of the count, the inventor need not have thought of all possible embodiments. Just one embodiment is sufficient to prove conception of the count. However, the inventor must have in mind all the aspects of an embodiment of the invention embraced by the count. The inventor must also have in mind how to make or practice the invention so that the only thing left to do is the physical making of the invention.

The classic, and still accepted, definition of conception appears in the case of Mergenthaler v. Scudder:

The conception of the invention consists in the complete performance of the mental part of the inventive act. All that remains to be accomplished in order to perfect the act or instrument belongs to the department of construction, not invention. It is, therefore, the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice that constitutes an available conception within the meaning of the law.3

Proving Reduction to Practice

A party will not succeed in proving a date of invention merely by showing conception of the invention. After conception, the inventor must have reduced the invention to practice. This the inventor may do in one of two ways: (1) actually reducing the invention to practice by making the invention work or (2) constructively reducing it to practice by filing a patent application.

To achieve an actual reduction to practice, the inventor must actually make a tangible embodiment and demonstrate a practical utility. For example, if the invention is a machine, and the inventor has conceived of the idea of that machine, the inventor could reduce the invention to practice by building and testing the machine to show that it operates in the way intended.

A successful reduction to practice requires a showing of operativeness or practical utility. The invention need not reach the stage of perfection required for commercial exploitation; but the inventor must be able to show that the invention does indeed operate, even if poorly, in its intended functional setting.4 As with conception, however, reduction to practice can occur with a single embodiment within the count.

Under U.S. law, an inventor has a second option in showing the required reduction to practice, a relatively simple procedure obviating the need to produce a working model: “constructive reduction to practice”. A constructive reduction to practice occurs when the inventor files a patent application describing the invention, teaching how to make and use it, and explaining the best mode of practicing it.

The U.S. patent laws, in § 112, set forth the requirements for a complete and sufficient disclosure of an invention in a patent application. Filing a patent application meeting those requirements constitutes constructive reduction to practice.

Determining Priority: The Importance of Diligence

The first party to conceive of the invention and reduce it to practice is deemed the “first to invent”. If one party conceives of the invention first but reduces it to practice after the second party, he or she may still be considered the first inventor. Priority is awarded to the party establishing either of two sequences of events: (1) the earlier date of conception and the earlier date of reduction to practice or (2) the earlier date of conception, but a later date of reduction to practice, coupled with a reasonably diligent effort to reduce the invention to practice from just before the other party’s date of conception until reduction to practice is ultimately achieved. In either case, the reduction to practice may be actual or constructive.

If the party is first both to conceive of the invention and to reduce it to practice, then the other party’s diligence is irrelevant. Diligence becomes a factor only when a party is first to conceive of the invention and second to reduce it to practice. As a corollary, the date of conception has significance only when a party is second to reduce to practice and attempts to show conception and diligence from a time before the other party’s date of conception.

Several examples will illustrate these crucial requirements needed to prove a date of invention and hence priority: “conception,” “reduction to practice,” and “diligence”. Suppose that party A conceived of the invention on March 1, 1985, and reduced it to practice on April 1, 1985. Further, assume that party B conceived of the invention on March 15, 1985, and reduced it to practice on April 15, 1985. In this case, party A was first to conceive of the invention and first to reduce it to practice. Party A wins the interference and receives the award of priority.

Diligence plays no role in this example. Even if party B was diligent and party A was not, the result does not change. Whenever a party proves that it was both first to conceive of the invention and first to reduce it to practice, that party is the first to invent and is entitled to the award of priority.

Diligence only becomes relevant when party B conceives of the invention before party A. Thus, in our example, still assume that party A conceived of the invention on March 1, 1985, and reduced it to practice on April 1, 1985, just as before. Now, however, suppose that party B conceived of the invention a month earlier on February 1, 1985, instead of March 15, 1985, as in the previous example, but still assume that party B reduced the invention to practice on April 15, 1985. In this new situation, party B was first to conceive of the invention, but last to reduce it to practice. Diligence now becomes a key issue.

To succeed in this new example, party B (first to conceive, second to reduce to practice) would have to prove diligence from just before the conception date of party A, March 1, 1985, until the reduction-to-practice date of party B, April 15, 1985. If party B cannot prove diligence, then party A will be considered the first inventor on the basis of the reduction-to-practice date of April 1, 1985, some two weeks earlier than the April 15, 1985, date for reduction to practice by party B.

Proving Diligence

To establish diligence between conception and reduction to practice, a party must show conduct meeting well-established guidelines of the PTO Board of Patent Appeals and Interferences:

The party chargeable with diligence must account for the entire period during which diligence is required…The standards for finding reasonable diligence are harsh. The public policy favors early disclosure,…and thus the law is reluctant to displace an inventor who was the first to disclose to the public his invention...

During this period there must be “reasonably continuous activity”.5

As is apparent, an inventor seeking to rely on diligence during the critical period faces a heavy burden. While minor periods of inactivity, i.e., a few days may be forgiven or overlooked, as a general rule, to satisfy the requirement for “reasonable diligence,” a party must show virtual daily activity directed toward reducing the invention in issue to practice.

To show this necessary activity, the party must be prepared with evidence of what acts occurred as well as the specific dates when those acts occurred.6 This means that the party asserting diligence must establish what was done and when it was done.7 It is not sufficient merely to state that there were no weeks or months where the inventor was not diligent or that the inventor was diligent during the entire critical period.8

Under appropriate circumstances, absence of diligence may be excused. To be excused, parties usually must show that circumstances beyond their control prevented them from working on the invention and, but for those circumstances, they would have been working on the invention.

In interference practice, diligence usually is not an issue.

When it is, it can be quite difficult to prove. Accordingly, in the majority of interference cases, the party who was first to reduce the invention to practice, either by actual or constructive reduction to practice, will prevail.

The Importance of Corroboration

When seeking to prove that an invention was conceived of or reduced to practice on a given date, an inventor must be able to point to some corroboration of his or her own testimony. The inventor's word alone about conception and reduction to practice is simply not enough: Some evidence independent of the inventor, proving that the activities of the inventor actually occurred, must corroborate the story. This "corroboration" is sometimes difficult to establish, for it can be challenging to find witnesses who can corroborate all aspects of conception and actual reduction to practice.

The corroboration requirement only applies where an inventor tries to prove conception and actual reduction to practice. When a party relies on the effective filing date of the patent application, that party is not required to put on any corroborating witnesses or provide any documents other than the patent application itself, and any earlier application, such as a convention priority application, on which the party is relying.

How Interferences are Declared

During the pendency of a U.S. patent application, the application materials are kept in the strictest confidence by the PTO. Thus, often one patent applicant has not the slightest hint that another patent applicant is simultaneously seeking a patent on the same subject matter. By the same token, the holder of an already-issued patent may be totally unaware that a patent applicant seeks to obtain patent protection on subject matter already patented.

Because of this secrecy, interferences are often initiated by the PTO when a patent examiner becomes aware of two conflicting patent applications, which neither of the respective applicants knows about. In other words, a patent applicant may only learn that another applicant seeks patent protection of the same subject matter when notified that the PTO has declared an interference.

In other situations, a patent applicant may initiate an interference. For example, a patent applicant may learn of an already-issued U.S. patent and seek to have an interference declared between the application and the patent. This may involve amending the claims of the application or adding claims directed to the subject matter claimed in the patent.

Presumably the vast majority of interferences will come about because provoked by a party if prompt publication is adopted in the U.S.

Lastly, a U.S. patent applicant may learn that another U.S. patent application exists by seeing the publication of a foreign counterpart. In such a case the applicant may call the patent examiner's attention to this fact and request that the examiner investigate the possibility of declaring an interference with a potential corresponding U.S. application.

When Interferences Are Declared

When the PTO learns that two or more patent applications interfere with one another, the patent examiner looks at the effective dates of the applications. As a rule, if those dates come within six months of each other, the PTO will declare an interference unless the inventions are of a relatively simple nature. With relatively simple inventions, interferences are not declared between applications unless the filing dates are within three months. In situations where the filing dates are outside these guidelines, the PTO issues the earliest-filed application and applies the resultant

patent as prior art against the later application. Any interference that may ensue will involve the issued patent and the application.

When an application and an issued patent contain interfering subject matter, and the application has the earlier effective filing date, an interference is declared without regard to the difference in filing dates. When, however, the patent has the earliest effective filing date, an interference will not be declared unless the applicant establishes that there is a basis upon which the applicant could prevail. If the effective filing dates are within three months, the applicant need only file an affidavit or declaration alleging that there is a basis upon which he or she could prevail. No explanation is needed.9

If the difference in effective dates exceeds three months, a more detailed showing of possible success is required before the PTO will declare an interference. In this case, the party with the later filing date, known as the junior party, must actually show that he or she can overcome the effective filing date of the earlier party, known as the senior party.10 This showing almost always involves providing evidence that the junior party's invention was made before the senior party's filing date,11 but the junior party might also try to prove that the senior party is not entitled to a patent, for example, because of lack of patentability. However, the PTO will not declare an interference unless the party trying to provoke the interference has at least one allowed claim. Thus, the showing of unpatentability must apply to the senior party only, a somewhat unusual circumstance.

If the proper circumstances exist to permit an attack on patentability--such as a senior party's patent containing broad claims and a junior party's application containing narrow claims--an interference can provide an attractive forum for attacking patentability, for it is the only inter partes proceeding in the PTO where patentability can be contested.

The Interference: A Procedural Overview

Patent interferences consist of three phases, the first running from the declaration of the interference through the motion period; the second, from the decision on motions through the trial stage; and the third, from the close of testimony through final hearing. The interference begins when the PTO sends to the involved parties a notice advising them that an interference has been declared. The notice completely identifies the applications or patents of all opposing parties. If the PTO has determined that an involved application or patent is entitled to the benefit of the filing date of an earlier application, the Notice of Interference so indicates. Parties normally are not afforded the benefit of the filing date of foreign priority applications at the time interferences are declared, particularly if the priority application appears in a language other than English.

The Notice of Interference also includes (1) at least one count, (2) a listing of the claims in each party's case that have been designated as corresponding to the count, (3) the name of the PTO Administrative Patent Judge responsible for the interference, and (4) the due date for filing initial papers, i.e., a Designation of Lead Attorney, Preliminary Statements, and Preliminary Motions. Usually, parties have about two weeks to designate their lead attorney and about three months to file the first substantive papers, i.e., the Preliminary Statements and Preliminary Motions.

Preliminary Statements

A Preliminary Statement contains allegations of relevant dates the parties believe they can establish in the interference. But Preliminary Statements are mere allegations: They do not constitute proof.

Furthermore, nothing untoward will occur if a party alleges dates earlier than the ones the party ultimately establishes. By the same token, a party is normally not permitted to establish dates earlier than those alleged in the Preliminary Statement.

A typical Preliminary Statement alleges the date the invention was conceived, a date the first drawing was made (if any), the date the invention was first described in writing, the date the invention was first disclosed to a noninventor, the date the invention was first actually reduced to practice, and the date after conception when diligence toward reduction to practice began. If the inventor described the invention in writing, then the party must file that description with the Preliminary Statement.12

A party must make these allegations only when trying to prove a date of invention in advance of that party's filing date. When a party intends to rely solely on the filing date of an earlier application, such as a priority application, the Preliminary Statement merely needs so to state and identify the earlier application. Nothing further is required. Indeed, if a party intends to rely on its actual U.S. filing date, or the date of an earlier application to which benefit has been accorded in the Notice of Interference, no Preliminary Statement is required at all.

A party must complete the Preliminary Statement and file it with the PTO in a sealed envelope by the date specified in the Notice of Interference. The party must also serve a notice on the opponent, stating that the Preliminary Statement has been filed. At this time, however, the opponent does not receive a copy of the Preliminary Statement. Instead, the parties will receive their opponents' Preliminary Statements at the end of the motion period.

Preliminary Motions

The motion period is an extremely important stage of an interference proceeding. During this time, the parties raise issues that will be contested throughout the interference. As a general rule, if a party can raise an issue during the motion period and fails to do so, that party will not be permitted to raise it later. Thus, it is critical that all issues important to a case be addressed during the motion period.

Also, during the motion period a party may try to obtain a position that will be advantageous in later stages of the interference. Often, the outcome of the interference will be determined by positioning that takes place during the motion phase. The motion period further offers an opportunity to attempt to terminate the interference without a trial phase. In other words, certain motions, if granted, can be dispositive of the interference. If such a motion is brought successfully, the party then has no need to go through the time-consuming and expensive trial.

Finally, the motion period provides a time to define the issues the parties must contest in the interference. As in all legal contests, framing the issues can often determine ultimate outcome.

Preliminary Motions: The Crucial Ones

The types of preliminary motions that may be brought in an interference are set forth at 37 C.F.R. § 1.633 (Rule 633). A review of the rule shows a wide variety of possibilities. Furthermore, these possibilities are not exhaustive. 37 C.F.R.§ 1.635 provides for filing motions "relating to any matter other than a matter which may be raised under § 1.633... ". Motions under § 1.635 may be brought at any time, including during the motion period. The PTO is receptive to motions requesting anything

that a party is clever enough to think of, provided the action requested makes sense under the particular facts of the case.

Motions for Judgment on Grounds of Unpatentability

One of the dispositive motions available in an interference is a Motion for Judgment on the ground that the claims in the opponent's case are not patentable (37 C.F.R. §1.633(a)). Such a motion, of course, provides a very attractive option because it can end the interference quickly without ever reaching priority issues.

Motions for Judgment on grounds of unpatentability need to be considered carefully. Remember, interfering subject matter by definition is subject matter that is not patentably distinct. Thus, in most instances, an attack on patentability of an opponent's claims corresponding to the count also represents an attack on the patentability of one's own claims. A successful attack on an opponent's claims on the basis of prior art that is also prior art against one's own application or patent, often will result in neither party's receiving a patent. In many instances, however, this can provide a satisfactory outcome.

In some instances a party can attack the patentability of the opponent's claims without at the same time defeating the party's own claims. In such instances, Motions for Judgment on the ground of unpatentability are particularly attractive.

For example, a particular reference may be prior art against one party to the interference, but not to the other. In addition, one party's claims may be much narrower than the opponent's claims. A successful attack on broad claims does not necessarily defeat narrower claims. Furthermore, one party may have or can obtain claims not designated as corresponding to the interference count. Such claims would not be adversely affected by a finding that claims corresponding to the count are unpatentable, because claims designated as not corresponding to the interference count are by definition patentably distinct from the subject matter of the interference.

Motion to Dissolve on the Ground of No Interference- in-Fact

37 C.F.R. § 1.633(b) provides for Motions for Judgment on the ground there is no interference-in-fact. Such motions are proper when the claims in each party's case are patentably distinct. In situations where a party is content to allow the opponent to obtain a patent containing the opponent's allowed claims, and the party also would like to obtain the claims in its own application or patent, a Motion for Judgment on the ground there is no interference-in-fact may be desirable. A Motion for Judgment founded on no interference-in-fact can be coupled with a Motion for Judgment on the ground that an opponent's designated claims are unpatentable. If successful on both motions, the opponent will lose the claims in its application or patent, while the successful moving party will be able to obtain its allowed claims.

Motions to Redefine the Interfering Subject Matter

Under 37 C.F.R. § 1.633(c), a wide variety of motions to redefine the subject matter of the interference are available. For example, a party may move to add or substitute an interference count. Similarly, a party may amend a claim corresponding to the count or add a claim to be designated as corresponding to the count. Such motions can become crucial, for they ensure that the count and corresponding claims correspond to a party's priority proofs.

A party may also move to redefine the interfering subject matter by designating claims as not corresponding to the count. Such a motion urges that a particular claim defines a patentably distinct invention from the interference count. For example, the interference count could define a generic class of compounds, while the moving party's claims disclose a specific compound particularly effective for the intended purpose. If the opponent does not disclose the particularly effective compound, the moving party will likely want to bring a motion to designate as not corresponding to the count claims directed to that compound.

If a claim is designated as not corresponding to the count, that claim is not in issue in the interference. The applicant or patentee retains the claim after termination of the interference, regardless of the outcome of the interference. Thus, parties should always consider the possibility of bringing these motions.

Motion for the Benefit of the Filing Date of an Earlier Application or to Deny Previously Accorded Benefit of the Filing Date of an Earlier Application

Parties to an interference, under appropriate circumstances, are entitled to the benefit of the filing date of earlier-filed applications, including foreign priority applications. In many instances, the benefit of the filing date of earlier applications is accorded by the PTO at the time the interference is declared, obviating the need to move for priority benefit. In such a case, of course, it is possible to move to have the benefit accorded an opponent denied.

In most instances, however, date benefit is not accorded to foreign language priority applications at the time of the interference is declared. As a practical matter, at that time the PTO has no way of determining whether an applicant or patentee is entitled to priority benefit. Thus, a foreign application applicant will nearly always move for priority benefit.

The requirements for receiving benefit of the filing date of a previously filed application in an interference context are somewhat different than in the context of avoiding prior art. An intervening reference is only avoided by a prior application if that application supports the full scope of the claim in issue. In contrast, in an interference setting, it is enough that the prior applications support an embodiment within the scope of the interfering subject matter. For example, if the interference count is directed to "halophenyl," a party is entitled to the benefit of a foreign priority application disclosing "chlorophenyl".

The embodiment relied upon in an earlier case, including a foreign priority application, must comply with the requirements of 35 U.S.C. § 112. That is, the specification must (1) contain a written description of the embodiment relied upon, (2) must enable one skilled in the relevant art to make and use the relevant embodiment, and (3) disclose the best mode contemplated by the inventors. Nevertheless, the application need not describe the full scope of the interfering subject matter.

Other Motions

Rule 633 recognizes other motions, such as motions to substitute the earlier-filed application for the application involved in the interference, motions to declare an additional interference, and motions to add a reissue application. Moreover, inventorship may be corrected under Rule 634. Such motions may be important in specific factual settings, but they are not as common as the motions discussed above.

Discovery

Unlike the discovery available in federal district courts in the United States, the scope of discovery in interferences before the PTO is quite narrow. Generally, discovery is initially limited to discovery of information by the junior party from the senior party. Moreover, to be entitled to that information, the requesting party must have some basis for believing that it actually exists. Further, the party seeking discovery can only ask for relevant information and may not use the discovery mechanism as a "fishing expedition" to find out whether certain information is available for attacking the opponent's position.

The legislation recently enacted to implement the provisions of GATT and TRIPs specifically refers to discovery abroad relating to dates of invention. The GATT legislation amended § 104 of the U.S. patent laws so that it will read as follows:

To the extent that any information in a NAFTA or WTO member country concerning knowledge, use, or other activity relevant to proving or disproving a date of invention has not been made available for use in a proceeding in the Patent and Trademark Office, a court, or any other competent authority to the same extent as such information could be made available in the United States, the Commissioner, court, or such other authority shall draw appropriate inferences, or take other action permitted by statute, rule, or regulation, in favor of the party that requested the information in the proceeding.13

This provision requires the PTO or a court to "draw appropriate inferences" when evidence relevant to the date-of- invention issue is not obtainable from an entity in a WTO member country. At this time, the practical effect of this change is unclear.

Quite likely, if a party to an interference declines to provide required discovery, the PTO will assume as fact precisely what the party seeking discovery hopes to prove. Indeed, the PTO can grant judgment against a party for failure to provide discovery ordered by the PTO. Thus, the PTO has ample power to motivate parties to comply with discovery orders. But the drawing of adverse inferences or the granting of a judgment provides no incentives for nonparties to provide discovery. Using inferences fairly when a nonparty declines to provide discovery may prove difficult. But this potential problem will not often arise, for discovery in interferences is narrowly circumscribed, and discovery from unrelated third parties rarely becomes necessary.

Testimony and Exhibits

In the trial phase of an interference, called the "testimony period," the parties present evidence in the form of testimony of various witnesses. The parties may supplement this testimony with exhibits, consisting of documents of all kinds, including laboratory notebooks, internal reports, publications, and the like. Anything relevant to the issues in the interference may be introduced as an exhibit.

Recently adopted rule changes require presentation of direct testimony of witnesses in the form of affidavits or declarations. However, the direct testimony will not be received by the PTO unless the witness is produced for cross- examination by attorneys representing the adverse party. Cross-examination occurs before a court reporter. Though the scope of cross-examination can be rather broad, at least in theory it is limited to issues presented by the direct examination.

The PTO sets the length of the testimony period allotted to each party. The junior party, i.e. the party with the later filing date, goes first, presents testimony, and introduces exhibits. Then the senior party, i.e. the party with the earlier filing date, has a period for presenting testimony and introducing exhibits.

As a result of this sequencing, the senior party enjoys the advantage of seeing the junior party's entire case before the senior party must identify witnesses and documents. Because the senior party will win the interference on the basis of an earlier filing date if the junior party cannot prove the earlier date of invention, the senior party can choose to offer no testimony and documentary evidence, and that decision need not be made until after the junior party's testimony period has ended.

Often, after the junior party presents testimony and introduces exhibits, the PTO finds the proof insufficient to establish conception and reduction to practice. In that event, the senior party can win the interference whether or not he or she provided testimony or documentary evidence.

Briefing and Final Hearing

After introducing their testimony and exhibits, the parties will compile the evidence and file the resulting record in accordance with PTO rules. Then the time has come for the final phase of the interference: briefing and final hearing.

In this phase, the parties to the interference submit their briefs on the relevant issues and, after briefing, appear before a three-member panel of the PTO Board of Patent Appeals and Interferences. At this hearing, no witnesses appear before the Board. Instead, the final hearing consists solely of oral argument by counsel for the parties. After the final hearing, the Board considers the case and ultimately renders its decision.

Other Ways to Prevail in an Interference

Proving earlier conception or reduction to practice is neither the only aspect of an interference nor the only way to win. Interferences can be decided without any testimony about the date of invention. For example, as previously noted, a party might prevail by successfully attacking the patentability of the opponent's invention without even offering proof of his or her own conception or reduction to practice.

Abandonment, Suppression, or Concealment

In the United States, an inventor is not entitled to an invention if he or she abandons, suppresses, or conceals it between the time of invention and the time of filing an application for patent. Thus, suppose an inventor discovered the invention in 1990 but waited until 1994 to file a patent application. Meanwhile, another inventor invents the same invention in 1993 and immediately files for a patent. When both applications are pending, the examiner discovers the conflict and declares an interference.

In the interference, the 1993 inventor might prevail over the 1990 inventor by proving that the four-year delay between invention and filing constituted abandonment, suppression, or concealment. If the PTO agrees, then the 1990 inventor cannot rely on the evidence about making the invention in 1990. To avoid this result, the inventor must provide a sufficient excuse for the delay in filing the application, such as by showing that there was reasonably continuous activity relating to the

invention during the period in question. If the inventor cannot show such an excuse for the delay, he or she will be limited to the 1994 filing date and will lose the interference to the 1993 inventor, who also filed a patent application in 1993.

Under United States law, priority of invention is awarded to the first to invent, but early disclosure of the invention to the public forms an important part of the American system. Although there is no fixed time for how long the patent applicant can wait after he or she actually makes the invention to file a patent application, the cases on abandonment, suppression, or concealment show that when that period of time begins to exceed two years, the PTO will assume abandonment, suppression, or concealment, and thus require proof of an excuse.14

Derivation

Section 102(f) of United States patent laws states that an applicant cannot be granted a patent if "he did not himself invent the subject matter sought to be patented".15 Under this provision of the statute, a party to an interference might be able to invalidate the other party's patent by proving that the other party is not the true inventor. One way to do so is by proving "derivation".

By proving "derivation," a party (we'll call this person the "inventing party") can obtain an award of priority regardless of whether he or she was first or last to reduce the invention to practice. To establish derivation, the inventing party must prove that he or she conceived of the invention and communicated the conception to the other party (we'll call this person the "deriving party").

Proof of derivation will require witness testimony and documentary evidence, and usually will require documents in the possession of the deriving party. Ordinarily, the opponent's documents are difficult to obtain in interferences. However, if the inventing party can show that he or she communicated the invention to the deriving party, the PTO typically will grant access to the relevant documents in the possession of the deriving party.

If the inventing party proves conception and communication of that conception to the deriving party, then the deriving party is not considered an inventor and is precluded from obtaining a patent.

Introducing Patent Claims More Than One Year After the Patent Issues

According to § 135(b) of the U.S. patent laws, claims introduced into a patent application to provide a basis for an interference with a patent of another party must be added within one year of the issuance of the patent. For example, if a patent issues and a patent applicant does not introduce the subject matter of the patent claims into the application's claims until more than one year after the patent issues, the applicant can be prevented from getting into an interference with the owner of that patent. The inventor thus would not be entitled to the claims that would otherwise be in interference because of the one-year bar in § 135(b). This would be true even if the applicant actually made the invention before the patentee.

Under U.S. practice, the applicant need not introduce the exact patent claims into the application within the critical one-year period. It is enough that the application's claims are patentably indistinct from the patent claims.

Settlement of Interferences

Throughout the interference proceeding, the parties at any time might decide to resolve the conflict through a settlement agreement. Settling an interference, however, differs in some respects from the settlement of other disputes.

In settling an interference, the parties must provide for determining who would be entitled to the award of priority under U.S. law. If one or both of the parties has evidence of actually making the invention before the respective filing date, a common settlement procedure is to supply the other party with the documents showing conception and reduction to practice and then try to decide whether that evidence proves an earlier date of invention. If there are other issues involved, such as compliance with § 112 or patentability over the prior art, the parties could also try to work these issues out between themselves.

Often, parties to a settlement agreement will include license agreements providing for the licensing of the losing party by the winning party. These license agreements may include payment of royalties. It should be noted that such agreements could be entered into even if the parties choose to allow the PTO to make the decision of which party was the first to invent.

The rules permit a party to file voluntarily what is called a “concession of priority”. In this statement a party concedes priority to the other party, and when the PTO receives such a paper, it will award priority of invention to the other party and terminate the interference.

To end an interference voluntarily the parties might also file an “abandonment of the contest”. Similar to an express abandonment of a patent application, this document abandons the interference and any rights to the subject matter of the counts of the interference. Again, such an approach will prompt the PTO to terminate the interference in favor of the other party.

When parties choose to end an interference voluntarily, they usually will include in their settlement agreement either an abandonment of a pending application or a disclaimer of one or more claims of a patent. Most settlement agreements will require one or more of the parties to submit a concession of priority, abandon the contest, or take some action disclaiming a patent or abandoning an application.

If the parties reach any agreements that contemplate ending or settling an interference, they must file them with the PTO under § 135(c) of the patent laws. The PTO will, if asked, keep these agreements, which would include a settlement agreement and any associated license agreements, in a separate file not available to the public under ordinary circumstances. (The U.S. Government, however, does have access to these agreements if it wishes to investigate any possible violations of federal antitrust laws.)

Finally, § 135(d) provides for arbitration of interferences. In a settlement agreement, for example, the parties might agree to submit the interference to arbitration and be bound by the result of the arbitrator. This route is often chosen when the parties cannot agree on who is entitled to priority.

Summary

The valuable patent rights associated with some of the most important technological advances in world history have been determined through United States patent interferences. At least for the foreseeable future, these proceedings will continue to provide the forum for determining the ownership of U.S. patent rights when two or more inventors claim the same subject matter. Now, in

light of GATT and TRIPs, virtual worldwide inventive activity will become the focus of interference proceedings. No longer will non-U.S. inventive activity give the U.S. inventor a leg up in the interference battles of the future.

Because of these dramatic changes to U.S. patent law, it is entirely appropriate, indeed vital, that all applicants for United States patents understand the basic terminology and concepts discussed in this paper so that they can anticipate the events that will arise in a typical patent interference in the United States. As of January 1, 1996, all non-U.S. R&D labs must begin to pay careful attention to their methods of keeping laboratory notebooks so that in some future U.S. patent interference they will be ready and able to prove their date of invention through conception, reduction to practice, and diligence toward that reduction to practice. Failure to develop adequate procedures could cause the loss of very valuable patent rights come the day when a patent interference is declared by the U.S. Patent and Trademark Office.

Footnotes

(1) 35 U.S.C. § 135. As is apparent from the face of the statute, § 135 is limited to interferences between “an application” and any other interfering application or unexpired patent. The authority granted to the PTO by § 135

does not extend to interferences involving only issued patents; at least one application must be involved. Though rare, interferences among two or more issued patents may proceed in United States district courts under 35 U.S.C. § 291.

(2) 37 C.F.R. § 1.601(n).

(3) 11 App. D.C. 264, 276, 1897 C.D. 724, 731.

(4) Field v. Knowles, 183 F.2d 593, 601, 86 U.S.P.Q. 373, 379 (C.C.P.A. 1950).

(5) Liang v. Borger, 214 U.S.P.Q. 368, 372-373 (Bd. Pat. App. & Int. 1981), citations omitted; see also Moller v. Harding, 214 U.S.P.Q. 724, 729 (Bd. Pat. App. & Int. 1982).

(6) Kalnoki-Kis v. Land, 214 U.S.P.Q. 636, 641 (Bd. Pat. App. & Int. 1982).

(7) Gould v. Schawlow, 150 U.S.P.Q. 634, 643 (C.C.P.A. 1966).

(8) Id.

(9) 37 C.F.R. § 1.608(a).

(10) 37 C.F.R. § 1.608(b).

(11) A sample of the type of showing required is included in Appendix K.

(12) 37 C.F.R. § 1.623.

(13) Uruguay Round Agreement Act, Pub. L. No. 103-465, 108 Stat. 4809 (Dec. 8, 1994).

(14) As noted in the previous Section (Amended § 104), the PTO will take the position that these principles apply to foreign applicants proving dates of invention in advance of their filing date, although there is no clear statutory basis for doing so.

(15) 35 U.S.C. § 102(f).

PAPER: FLO/1.4 by Robin NOTT

Consequences of the International Specification

The question which has been raised is "How does one draft a patent specification in a form to meet the requirement of all the countries?"

I am a qualified English lawyer, a solicitor, and my practice is focused on post-grant matters, validity, infringement, litigation and post-grant amendment. While I have been involved in discussions on amendments to patent specifications pre-grant, that has only happened on one or two occasions in my career and I cannot describe myself as an expert on it. I therefore propose to consider the problems that can potentially arise to an English specification (whether granted through the EPO or through the UK Patent Office) when it gets to court. (I also have one suggestion on drafting claims.) I shall also touch very briefly on the position as I understand it in the Netherlands and Germany. No doubt I shall throw myself open to comments from the floor from my Dutch and German colleagues and I shall be very happy to have any misconceptions that I have corrected for the benefit of you all.

The English court's approach

As you know the patent judges in the English courts are former barristers with technical skills and many years of practice at the Patent Bar; and that is true in the High Court and the Court of Appeal. In the House of Lords we have Lord Hoffmann who has sat as one of the patent judges and is very knowledgeable and understanding about technology. The English Courts have always tried to adopt a very pragmatic approach to specifications and their approach can be broadly summed up by the comments made by Mr Justice Jacob in Raychem Corporation's patent in which he said, in summary:-

In all cases, and no matter what the nature of the attack on validity or arguments on infringement, the court must identify the inventive concept embodied in the claims. A properly drafted claim would state that concisely. The court was not required to substitute its own language for that of the patentee if the later was clear. But where the claims were prolix and obscure the court should break free of the language and concern itself with what they really meant.

Within wide limits a patentee could use what language he liked to define his invention. But it was the substance of the patentee's alleged technical contribution, rather than the form and language of the claims, that must impress the court.

Selection of a group of compositions by reference to an essentially arbitrary parameter having little technical significance did not involve any inventive step. Although it might not be obvious, in the common use of that term, to limit a claim by reference to some particular meaningless and arbitrary parameter, that had nothing to do with patentability. The selection of a group of compositions by reference to such a parameter does not involve any inventive step. Parents were not given for skill in inventing technical meaningless parameters.

If the patent claim consists of no more than a product or process selected by reference to a set of obviously desirable parameters, then the technical contribution was the selection of those parameters. Since the selection was obvious, so was the claim.

This approach has been confirmed by the Court of Appeal in Hoechst Celanese Corporation v BP Chemicals Limited (The Times, 27th July 1998) where the court was asked how it should approach the meaning of technical words in a patent specification. The court concluded that:-

It would be wrong to start the task of construction with any preconceived idea.

Having obtained the knowledge of the notional skilled man, the specification has to be read as a whole to ascertain its meaning and from that the court has to decide the ambit of the monopoly claimed using the guidance in the Protocol on the Interpretation of Article 69 of the Convention on the Grant of European Patents. The correct approach was a purposive construction, namely ascertainment of the meaning having regard to the purpose of the word.

The court then rejected a close textual analysis of the words in the specification as being the "literal analysis" that had been rejected by Lord Diplock in Catnic Components v Hill Smith Limited ([1982] RPC 237), the leading case in the UK on the construction of patent specifications and their claims.

However, while saying that the English courts are pragmatic in their approach to the interpretation of UK patent specifications and their claims it is worth remembering that national courts will have to apply their own rules to any alleged infringement because, under the European Patent Convention (EPC) the court must interpret the patents according to their own views so that the position may vary from country to country.

The requirements of an UK patent specification

What are the requirements for an UK patent specification? Under Section 14 of the Patents Act 1977:-

The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art (3); and

The claim or claims shall:-

(a) define the matter for which the applicant seeks protection;

(b) be clear and concise;

(c) be supported by the description; and (d) relate to one invention or to a group of inventions which are so linked as to form a single inventive concept (5);

following Articles 83 and 84 of the EPC.

The sufficiency of the description has to be at the date when the specification is filed, a point established by the House of Lords in Biogen v Medeva ([1997] RPC 1) in 1996. It follows from the decision that if a priority document is relied on the priority document itself must also be sufficient. In order to be sufficient, as appears from sub-section (3) the specification must allow a person skilled in the art to perform the invention, a so called "enabling disclosure" as referred to in Asahi's Application ([1991] RPC 485 (CA)). Note two things. Some correction may be possible to obvious mistakes. For example in Helitune v Stewart Hughes ([1991] FSR 171) the addressee of the specification would have appreciated that the specification contained an error; the court decided

that he would notionally and automatically have corrected the error; and this would have rendered the specification sufficient. Accordingly the specification was held sufficient.

Secondly it is important to note that there is no requirement for a "best mode" disclosure. However "best mode" remains an important requirement for the United States so that the best mode needs to be included in any specification which is to be used as the basis for an application there, and any other country where the "best mode" is required.

Note also that, as I understand the position, the US requirement of "best mode" is at the date of actual application, not the priority date. Contrast this with the UK position where, if priority is to be claimed, the application must be sufficient at the date of priority.

Thirdly, although it is not a point of great importance in relation to the UK, the form of the claim is immaterial. The old British style "one part" claim is allowed in the UK Patent Office. Alternatively the conventional European two part claim may be used. Reference numbers, as in the EPO style claims, are allowed. However the Comptroller has allowed a patentee to delete the reference numbers, to add an omnibus claim and to delete the French and German translations of the claim from the UK granted specification of an European patent. (Philips Electronics Patent. ([1987] RPC 244)).

A further point - the UK courts do not normally concern themselves very much with formal questions as to the name of the inventor or the name of the proprietor and, assuming there is no dispute raised by anyone the court will normally accept the position. If there is a dispute, save in cases where the patent has been obtained, ie stolen, the court is normally very pragmatic about allowing corrections to be made at any time.

Claim interpretation and infringement

As you all know, interpretation of claims under European, and therefore UK patents, is on the basis of Article 69 of the European Patent Convention and the Protocol. The idea of "equivalents" as such is dead in the UK. The rule of "purposive construction" must be adopted which I have referred to briefly above in relation to interpretation of technical terms in patent specifications above.

In summary the current view in England is that in considering whether or not an alleged infringement falls within the claims of a patent the court must answer the following questions laid down in the Improver case (Improver Corp v Remington [1990] FSR 181):-

Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no -

Would this (ie that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes -

Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

(In passing, I find even "purposive construction" difficult to square with the requirement in the Protocol that there should be "a reasonable degree of certainty for third parties". How is there to be any certainty for third parties if the courts can widen the claims in what must, in fact, be an arbitrary fashion, dependant on the court's view of the situation and the merits of the invention in the

context of the art at the time of trial. See for example the Court of Appeal's decision about rotary and reciprocating knives in Kastner v Rizla ([1995] RPC 585).

The current position in England seems to be a willingness to read claims more widely, and doubtless at some stage someone will call a halt and we shall start the cycle again.

Procedure for international applications

As I have said, I am not a practising patent attorney so that my experience of patent application and prosecution is, in effect, non-existent. However I will pass on to you one tip which I had recently had from a practising patent attorney.

His company was having great difficulty with translations into Japanese, for linguistic reasons which I will not bother you with. The solution was simple. Their attorneys are all instructed to draft patent claims in the old English-style single part form, and not in the two part European form. This is appropriate for the US; makes the translation easier for the Japanese and is appropriate there; and can be relatively easily amended by European attorneys used to European practice to comply with the two part claims required in the EPO. (He did not say anything about attempting to try to persuade the EPO to adopt single part claims, so I assume that he has not thought that worthwhile!)

The result is that the length of the claim initially is halved, the cost of translation into Japanese is halved, as is the cost of translation into any other country where "English-style" claims are allowed. The US claims are simple to draft. The conversion into European claims is, as I have said, relatively straightforward so that it has apparently led to considerable savings and, perhaps most important of all in relation to Japan, where protection was (and frequently will be) regarded as very important, to reliable claims there.

Amendment

I thought it would be useful if I talked very briefly about the opportunities for amendment of UK patents. Under Section 72(1) of the Act a UK patent can be revoked:-

(c) if it does not disclose the invention sufficiently clearly (ie does not comply with Section 14(3) of the Act (Article 83 EPC));

(d) if the matter disclosed in the specification extends beyond that disclosed in the application for the patent as filed [or the priority application as filed];

(e) if the protection conferred by the patent has been extended by an amendment which should not have been allowed.It is important to note that a pre-grant amendment may widen the scope of protection given by a claim provided that there is no added matter under Section 76 of the Act. (A.C. Edwards v Acme Signs ([1990] RPC 62 and [1992] RPC 131 (CA) and Southco v Dzus ([1990] RPC 587 and [1992] RPC 299 (CA)). However under (e) a post-grant amendment may not extend the protection given by the patent.

However even if a patent is invalid under (d) or (e) a patentee may still be able to amend, even though it will have been the patentees conduct that caused the prohibited amendment. The court appears to accept that amendment should be allowed apparently on the basis that the amendment sought by the patentee will have been approved by Comptroller or the court (Harding's Patent [1988] RPC 515).

However it is important to remember that the right to amend a patent is in at the discretion of the court or the Comptroller.

The power to amend is granted by Section 75 of the Act under which the Court "may, subject to Section 76 below, [which deals with the question of added matter and claim widening after grant] allow the proprietor to amend the specification of the patent ... as the court ... thinks fit". (75(1)).

This right to amend is discretionary. (The words "may allow".) The court will always take account of the public interest and not allow the patentee and an opponent to "carve up" the amendment.

As part of that, the court will be reluctant to allow amendment if there is substantial delay in seeking amendment and may refuse to allow amendment if it considers that the delay has been unreasonable.

However it normally draws a distinction between an amendment designed to validate and invalidate a claim and an amendment designed to allow enforcement of a valid claim.

So that, if claim 1 is invalid and claim 2 is valid, the court will normally allow claim 1 to be deleted and the consequential amendment of claim 2 (possibly a mere re-numbering of claim 2 as claim 1, or the incorporation of the texts of claim 1 into claim 2) to allow the old claim 2 to be enforced.

One other point to remember in UK proceedings is that the applicant for amendment will normally be expected to make very full discovery of all relevant documents and it is incumbent on the proprietor to make full disclosure of the background to the drafting of the invalid claim. It is likely that a proprietor will have to waive any professional privilege that he may otherwise have claimed if he is to be allowed his amendment.

When considering questions of amendment the Comptroller for many years refused to take account of EPO decisions but this seems to have been changed following the decision of the Patents Court in B & B Relay's Application ([1985] RPC 1) in which the Patents Court indicated that an attempt should be made to give the same meaning to any provision of the Act as that given by the relevant EPC provisions. This comment has been reinforced by the comments of the Patents Court in Bristol Myers Squibb Co v Baker Norton Pharmaceuticals ([1998] All ER (d) 415) in which the Patents Court said that "in future, save in the rare event of a specific contention that a provision of the 1977 Act has a different meaning from a corresponding provision of a convention it will be better for all concerned with patent matters in the United Kingdom (and hopefully throughout Europe) to work on the basis that the corresponding provisions of the conventions are of direct effect".

Test of added matter

In Bonzel v Intervention (No. 3) ([1993] RPC 553) the test for examining whether amendment had involved added subject matter was stated to be:-

(1) to ascertain through the eyes of the skilled addressee what is disclosed, explicitly and impliedly, in the original application;

(2) to do the same in respect of the patent as granted; and

(3) to compare the two disclosures and decide whether any subject-matter related to the invention has been added whether by deletion or addition, this comparison being strict in the sense that

subject-matter will be added when such matter is clearly and unambiguously disclosed in the application either explicitly or impliedly".

In this case, the court also stated that it is concerned with "what is disclosed, not what have been described".

The Comptroller has also stated that "the fundamental principle in determining additional subject-matter is to decide whether any document presents the informed reader with information relevant to the invention which the other document does not". (Van de Lely's Application ([1987] RPC 61); which is a similar test to that used in Bonzel. However in Southco v Dzus the Court of Appeal made it clear that while the main claim of the patent granted was worded differently from the application filed, the Court of Appeal held that the new wording did not add "fresh subject-matter", so that the claim was valid, even though the claim allowed was possibly broader than that originally filed (but not granted).

As an example of the problems of amendment and of implicit disclosure in Protoned's Application ([1983] FSR 110) an amendment to change "mechanical compression spring" to "mechanical spring" was refused on the basis that the deletion of the word "compression" widened the scope of the claim.

Finally on amendment, if an omnibus claim has been allowed (see above) deletion of descriptive matter must, necessarily, widen the claim (Shoketsu's Patent No. 3 (Sris 0/60/91 (76.09)).

The situation in Germany and Holland

It is at this point that I find myself treading on dangerous ground. However from brief discussions that I have had with German and Dutch lawyers it does appear that, at least in infringement proceedings, the courts in both countries will take a pragmatic view in exactly the same was as Mr Justice Jacob did in Raychem (above). The court will do its best to work out what the patent and the claims mean; and provided it can come to a clear conclusion will then enforce the resulting claims.

As I have indicated above, that seems to me a very sensible approach and much more satisfactory to all concerned than a formalistic, legalistic view of patents and patent claims and patent infringement.

Note: There is a detailed commentary from the National Groups of the AIPPI on "Breadth of Claim, Support by Disclosure and Scope of Protection of Patents" in the Yearbook for Question 142 for the AIPPI Congress in Rio de Janeiro in 1998 (AIPPI Yearbook 1998/IV).

PAPER: FLO/1.5 Bruce Murray

Summary of presentation

The previous speaker has provided some details of the important provisions of the draft treaty. I would like to question their usefulness, challenge the audience to identify the beneficiaries, and provide possible answers to some of these.

1. Filing date (Article 4)

Any filing which only meets the minimum requirements is arguably of little value to an applicant. If so, is there any value in these provisions. Does the applicant become the decision maker rather than the Office? Can issues of new matter be resolved simply by reference to a priority document? Is it useful to make a filing simply by reference to some document filed earlier elsewhere?

2. Application (Article 5)

If form and content requirements of national offices can be avoided by filing under the PCT, why not do that? In any case electronic filing will solve all form and content requirements. Can offices exclude paper filings, and would it not be better if all offices were required to accept electronic filings? While offices cannot require evidence of any matter unless they reasonably doubt the truth of what has been stated, is that not always the case? How useful is a translation of a priority document prepared by the applicant, especially where a competitor wants to attack patentability.

3. Representation/address for service (Article 7)

Can an applicant appoint a representative and if so when? What does an office do before and after that appointment? Can you identify circumstances where an office must not require a local representative and is there an advantage for the office in having one appointed? Surely it would be of advantage to the applicant? What would an office do if it received incoming mail directly from the applicant?

4. Signatures (Article 8)

Why should offices be able to require notarisation or certification of a signature? Are there any circumstances where it could add value? How frequently is it required, and how easily obtained?

5. Correcting mistakes (Article 12)

Mistakes can only be corrected according to national law – if no national provision then no correction available. Why is there no minimum obligation required of all offices? – are mistakes so infrequent that it is of no concern? If so, why bother with any provision at all?

6. Extensions of time (Articles 13-15)

Why should offices be able to deny a reasonable request for extension of time? Why should you have to prove your intentions? Why not for long periods, especially if you ask for the extension before the existing time limit expires? If a competitor took advantage of the invention after it was advertised lapsed or ceased, surely they are entitled to intervening rights if it is restored? Why

include provisions on intervening rights if there is no requirement to provide for them in national law.

7. Priority claims (Article 16)

How much extra time should be available to claim priority or to file a subsequent application? Are these provisions different to the extension of time provisions of Articles 13-15? If that is so, why is this provision more onerous? Why not merge them for simplicity?

8. Conclusions

I will conclude with some observations about whether it is only a Procedures Treaty, whether it has helped the harmonisation process, and whether offices will sign up.

PAPER: FLO/2.2 by Andrew PARKES

Searching, Signs and Designs

Following up on Jan van Barel's talk, I am asked to discuss searching from a practical user's point of view. I will be using a private practitioner's terminology in talking about the "client" but I think that many of you in industrial practice now are also required to regard the companies in your group as "clients".

In preparing for this talk, I made up a word trade mark and a simple device mark to go with it. I sent a Questionnaire to a number of colleagues who are members of the Trade Marks Group of the FICPI CET. I have summarised their answers in a number of tables which are included with the written papers for this meeting. I would like to thank the colleagues who responded to my Questionnaire and I must apologise also to those members or countries which I omitted. I wish to make it clear that I am responsible for the summaries, which may not fully convey the information which was set out by the person answering the Questionnaire. I am aware also that even within some countries the approach to searching can vary from one professional firm to another and therefore the answers which I received could have been different if I had addressed the questions to another colleague in that country. Nevertheless, I hope that the results will be helpful for the discussion of this morning's topic.

The trade mark which I invented is OLDCASTLE for cheese. It is to be used by a cheese manufacturer in the small town of Oldcastle, north of Dublin. The company has developed a flavoured cheese product which is expected to be popular internationally, particularly for children's lunch boxes. The proposed trade marks are shown on the attached representation sheet:

1. Word mark OLDCASTLE, which will mainly be printed in a Celtic form of script.

2. Castle device, which will be used alone or with the word mark OLDCASTLE printed across it.

3. The 3-dimensional shape of each portion of cheese which will simulate a castle as shown in the representation.

I expect that most people in this audience are familiar with the searching of word marks. I will therefore be concentrating on "signs and designs" other than words. But I recognise that many device marks have words used alongside them or incorporated into them, as in the case of my castle device mark. The word may also describe the device itself or at least one of its major features. So we have to think about word marks as well as devices. By the way, I am using the term "devices" in this talk, rather than "designs" because at a later stage I will be discussing possible searching through registered designs, or designs and models, which takes us into a different field of Intellectual Property Rights. Instead of using the term "device marks" I could of course have referred to "figurative marks" or "pictorial marks".

The initial question in today's topic as set out in the Working Programme is: "Is there a needle in the haystack?".

In every Search, we have to try to answer that question. However the task will obviously be much easier if the needle has a piece of bright red thread attached to it and the client can show us where the thread is lying on the surface of the haystack. Indeed we may not really be searching for a needle

at all but for the sword of Damocles which is hanging by the thread over the client's head and which the client has known about from the outset. The first essential step therefore in preparing for a Search is to get the right information from the client.

INFORMATION TO BE OBTAINED FROM THE CLIENT

There are some basic questions to be asked:

1. Is this a preliminary screening operation, for which there is a "shopping list" of proposed marks? This is often the case with word marks, much rarer with devices.

2. What is the origin or derivation of the mark? In the case of OLDCASTLE, the word mark is derived from the name of the town where the client is based. The device mark and the 3-dimensional shape are based upon an old drawing of a castle which existed in the same area of the country until about two hundred years ago. These sound like good bona fide reasons for adoption of the word and device marks. However we may have to question whether the local geographical and historical features are merely convenient excuses for using a mark which is intended to climb on the back of some other trader's reputation.

3. What are the existing products or services with which the client's product or service is intended to compete? What does the competitor's product or printed material look like? These are particularly important questions in the case of device marks, 3-dimensional marks and get-up.

4. Has the client copied all or part of the mark from another source, either within or outside the field of competition? In the OLDCASTLE case, the client is aware that a leading international chocolate manufacturer sells chocolate products in the shape of a castle having four round turrets at the corners. This chocolate product has been on sale, particularly to children, for about seven years in some countries. The client says that the idea of making cheese portions in the shape of a castle came to him first, and he discovered the chocolate product on the market subsequently.

5. Even if there has been no element of copying, is the client aware of a business in a different field which uses a similar mark and which enjoys a reputation? In my invented case, there is an investment banking firm on Wall Street in New York which has used the name OLDCASTLE for many years and which has a leading reputation in the field of financial services. As my client is based in the town of Oldcastle, he has good cause for using that name and it seems unlikely that his use will take unfair advantage of, or be detrimental to, the distinctive character or the repute of the banking firm's name. Nevertheless, the knowledge that the banking firm exists directs us towards a possible area of trade mark searching outside the field of food products.

The client may be reluctant to answer our questions, particularly concerning the nearest products of competitors and the possibility that the mark may have been consciously or unconsciously copied. But we have to get the client to understand that a well-directed search is the best search. It may be substantially cheaper if it enables us to do a name search for marks owned by a particular competitor or indeed to search for registrations of a particular mark or design which is already known to the client. There is no point in carrying out a comprehensive and expensive search in order to uncover information which the client really knew from the outset.

But let us not be negative. The client has a good mark and a novel device which to the best of our knowledge is not copied from or taking advantage of someone else's product. The next step is to decide on the geographical spread of the search.

WHAT TERRITORIES NEED TO BE COVERED?

The client may want world-wide clearance for the proposed mark. For word marks, a World Identical Screening Search can be done but it has limitations, particularly because it does not extend to similar marks. For device marks, a world-wide search would be prohibitively expensive, so we have to be realistic about the countries which can be covered.

We start with the home territory, and other territories in which the client is already active and for which it has a potential marketing interest in the foreseeable future. We can take a step-by-step approach, looking at certain key Registers first and then expanding the search if the mark is not knocked out in the early stages. For example, for an Irish company we would probably do Ireland, Community Trade Marks and the UK initially, and then move on to International (Madrid) Registrations and key continental countries such as Germany, France and the Benelux. If there is even a small possibility of the product going to the United States or being offered via mail order catalogues or on-line shopping, we need to carry out full Searches there, including Federal, State and Common Law Searches. The penalties for neglecting to search in the US can be severe if litigation arises later.

We have to think also that offers to trade on the Internet may reach into every country on the globe. We have to assess the risk/cost balance, which will be discussed later in this presentation.

HOW RELIABLE CAN SEARCHES OF REGISTERS BE?

In my Questionnaire to colleagues, I asked whether a Search for word marks would be carried out on an on-line database and I also asked how reliable are the records in which Searches are carried out. As you will see from the summary table, the majority of the respondents indicated that a database would be used, although in some cases the database would be available on a CD-ROM rather than being on-line. The real issue as Jan van Barel has pointed out is whether the search parameters, for example to determine phonetic similarity, are applied as part of the computerised system or are devised by the Searcher in order to extract the relevant information from the database. We can easily do an initial screening for identical marks in such a database, and the answers which I received from my colleagues indicate that in most cases they regard the reliability of the databases as high. However the reliability of a full search result depends upon the searcher, whether it be computer or human, and ultimately on the analysis of the search results.

DEVICE MARKS

When we look at searches for device marks, it is an entirely different situation. Device marks can be held in a database as digitised images and the classification of the elements of the device can be stored in a manner which facilitates retrieval. However the on-line delivery of digitised images is extremely slow and it seems at present that distribution of device marks on CD-ROM is the most practical option.

Good CD-ROM systems are available for the Community Trade Mark and also for UK Trade Marks. The images can be blown up on screen and are reasonably good if the device is not too complex in

its details. Before publication of a mark in the Bulletin, this is the only image which is available; after publication one can go to the printed version in the Bulletin also.

Jan van Barel has mentioned the Vienna Classification for the Figurative Elements of Marks. This is the system used by a substantial number of countries, even though they may not have formally ratified the Vienna Agreement. The Vienna Classification is based on 29 categories, each of which is split into divisions which in turn are split into sections. In the case of the castle device of my Questionnaire, we would be looking at the following:

Category 7: Constructions, structures for advertisements, gates or barriers.

Division 7.1: Dwellings, buildings, advertisement hoardings or pillars, cages or kennels for animals

Section 7.1.1: Castles, fortresses, crenellated walls, palaces. The OHIM uses the Vienna Classification down to section level and it is ideal for a simple device such as a castle.

However the sections are very narrowly defined and at least one of the CD-ROM products only classifies CTM device marks down to division level so that, for example all device marks for buildings are brought up by entry of the search parameter.

While access to images on a practitioner's desk is very useful and an initial screen can be performed by using the Vienna Classification, I think it is clear that device searches need to be carried out by expert searchers who are familiar with the classification and the mind-set of those who allocate the divisions and sections to elements of marks.

3-DIMENSIONAL MARKS

3-dimensional marks are included within the same classification system as device marks. The guide to the Vienna Classification contains an interesting set of examples of bottles and flasks which are allocated to division 19.7 and various sections of that division. The Community Trade Mark system provides for the identification of a mark as being 3-dimensional but this does not necessarily indicate that the distinctive character is associated with the shape of the product. The representation may show a distinctive get-up applied in a 3-dimensional manner on a product or package of conventional shape. It would be helpful in these cases if the OHIM would make greater use of article 38.2 CTMR and request a disclaimer of any exclusive right to non-distinctive elements of the mark so as to reduce the doubt as to the scope of protection. However that is another topic.

When the trade mark really does consist of the shape of goods or of their packaging, then the scope of searching may have to be extended beyond that of device trade marks. Many of you will probably be familiar with the recent case of Yakult v. Danone in the District Court of The Hague [1998] E.T.M.R. 465, which was concerned with small bottles for holding a fermented milk drink. The Japanese company Yakult Honsha had not only registered the shape of the bottle as a trade mark in class 29 but they had also protected it under the Uniform Benelux Act on Designs or Models. The case was decided on the basis of infringement of Yakult's right in the 3-dimensional trade mark, not the design registration, because in that case there were doubts about the novelty of the design at its date of registration. Nevertheless the case illustrates the overlap between trade mark protection and design protection for 3-dimensional packaging or products of this kind.

In my sample case, I suggested that cheese portions would be made in the shape of a castle and that the client already knew that a chocolate product was being marketed in a similar shape. The

majority of the respondents to my Questionnaire indicated that it would be advisable in this case to carry out a search through Registered Designs, although this would not generally be part of a trade mark clearance. In a number of countries design searching is done in the Registry, and no search facilities exist for outsiders. Other countries do provide a database, although the problem of providing images of the registered designs is obviously even more acute than with device trade marks. Designs can be classified under the Locarno classification, with 32 classes, each divided into sub-classes, which is suitable for computerisation.

COMMON LAW RIGHTS (Unregistered Marks in use)

The need for searching word marks which are used but not registered clearly varies substantially from country to country. In the United States, a Common Law Search is almost automatically a part of a trade mark Availability Search. In the event of litigation, the absence of a Search may be very costly to the defendant, in terms of damages or of attorney's fees. I understand that a case on this issue between International Star Class Yacht Racing Association and Tommy Hilfiger, Inc. [1998 U.S. App LEXIS 10642 (2nd Cir. 1998), extracted in INTA Bulletin, Vo. 53, No. 15] is still oscillating up and down between lower and appellate courts with no end in sight. In that case, Hilfiger's attorneys had screened the mark STAR CLASS for clothing in the Federal Register only. They advised the client of the need to conduct a full search but it was not done until after the Association sued for infringement of its unregistered mark. The courts are considering whether Hilfiger acted in bad faith, giving rise to an award of damages and attorney fees.

Systems are well established in the US for doing Common Law Searches, with considerable help from on-line databases. Internet Searches can also be carried out to find occurrences of particular words in association with specified goods or services. However it should be recognised that Internet Searches are far from conclusive because they depend upon the extent of coverage of the particular Search Engine used, which may be only one half of the total number of pages on the Web.

Common Law Searches are also recommended in other countries which recognise rights in marks arising from use, but they are carried out less frequently than in the USA and less information is available on databases, although Internet Searches can of course be done from anywhere. Company Name Searches will generally form part of a Common Law Search and they are also recommended for most of the other countries covered by my survey. However from a Practitioner's view point, Company Name Searches are difficult to assess if little information is given about the nature of a company's business or whether it is actively trading.

Domain names are the subject of another session at this Forum. It is sufficient now to say that domain name searches should be included on the same basis as Company Name Searches but with the greater convenience that Domain Names can be searched world-wide (at least on an identical basis) by a simple and economical computer search.

For Device Trade Marks and 3-Dimensional Marks, there is no practical way of carrying out Common Law Searches by computer. One has to go back to the basic questions to the client, and ask for information about competitors or traders in other fields who are known to be using devices or get-up which could be regarded as similar. Internet access can then be used to review the websites of the other traders to see whether their logos and product get-up can be seen. However ultimately it will probably come down to a survey of the market, carried out by an Investigator or, at least initially, by the client itself.

WHAT DO RECENT IMPROVEMENTS IN ACCESS TO DATABASES MEAN TO THE PRACTITIONER?

For searching word marks, life has become much easier because searchers do not need to spend time in the Trade Mark Office. Initial scanning of word marks can be done from a practitioner's own desk. For device marks and 3-dimensional marks, databases on CD-ROM are a great convenience as a screening tool. Internet searching can also be done but it is likely to require too much time and to produce too much information for the Practitioner's needs. Searching and analysis by specialist searchers are still, in my view, to be preferred.

WHERE IS THE RISK V. COST BALANCE?

For Trade Mark Searches you have to decide how many classes to cover. In my OLDCASTLE example, it is clear that a full Search is required in classes 29 and 30. Some colleagues added classes 32 and 33 for beverages, and class 42 for "providing of food and drink". Others included class 36 for "financial affairs" because of the investment banking firm called OLDCASTLE. An identical Search in all classes is recommended. This is feasible for word marks, but extremely expensive for device marks.

You also have to decide on the number of countries or regions to which the Search should be extended. This can be done on a step-by-step basis but the client will probably want to know the likely overall cost for a satisfactory Clearance Search.

In some cases, you may recommend that an application should be filed in order to get the results of Official Searches. In the United Kingdom, for example, search results are now available within a few weeks after the filing date. Search Reports on a Community Trade Mark application also provide useful information, although they can scarcely be regarded as Clearance Searches and at present they suffer from a long delay.

If the client knows the market well and provides good information about it, Common Law Searches may not be necessary except in the United States. Searches in Registered Designs and Models will only be required in the case of a product or packaging whose outer shape or ornamentation appeals to the eye.

The risk to the client depends on the circumstances in each individual case. Ultimately the cost to the client can be the withdrawal of the product from one or more markets and the need to redesign all packaging, labelling and advertising material. But search costs will not usually be regarded in this way, but will be considered as a proportion of the funds available for developing and launching a new product or service.

Clearly if the client is planning to do a marketing campaign in a particular country, to appoint a distrubutor or even to set up a subsidiary company, then full searches in that country need to be done. On the other hand, if the client is merely hoping that the product might eventually find customers in a country, then it is reasonable to omit searching at the initial stage. As I have mentioned, particular problems now arise with products or services which are to be traded over the Internet. No one can guarantee that a mark is clear in every country of the world.

I understand if an unexpected conflict does arise, it may be possible to restrict access to the client's website from a particular country where there is a prior right so that goods/services are not supplied via the website to users in that country. If the client wishes to continue selling into that country via the Internet, the consequence and resulting cost could be the need to rebrand the product/service

(and redesign its packaging, labelling and advertising material) with a non-conflicting mark and to set up a separate area on the website specifically for users from that country from where the goods/services with the non-conflicting mark are supplied. Whether the mere availability of the client's website in the problem country can constitute an infringement is a separate question. If it is an infringement, the possible ultimate cost to the client could be the cessation of trading under the mark via the Internet altogether. Obviously, these questions involve an area of great legal complexity and uncertainty which will depend on the applicable law in a particular case and further detailed discussion is outside the scope of this paper.

The cost/benefit ratio in searching for device marks is very much higher than it is for word marks, but the risks of confusion between device marks are less because no question of phonetic similarity arises. The more complex and unusual the device, the smaller is the chance that it will run into a conflict.

Ultimately the client has to make the decision. It is a matter for the practitioner to make it clear to the client:

(a) What Searches have been done and the limitations of those Searches e.g. time delay in entry of marks in the Search records; Convention applications which could be filed later; and possible errors or subjective classification decisions in the search records.

(b) What further Searches could be carried out and whether these are recommended in the circumstances of the case.

QUESTIONNAIRE and Survey RESULTS

PAPER: FLO/2.4 by Jonathan COHEN and Victoria CARRINGTON

Domain Names: In Whose Domain?

Questions to panelists at session 2.4 on domain names

The following questions are intended to provide structure and form a starting point for the discussion among the panelists and audience at Session 2.4. Background information is given below to provide a context for the questions and the discussion.

1.

a) As the Internet has its origins, development, infrastructure and major investment in the U.S., is it not appropriate that NewCo be American and that the

Board contain numerous American representatives, and that effective control of the DNS should remain in the U.S.?

b) Is it therefore not reasonable, that if we have one international dispute resolution system and the preponderance of the world is going to use .com, if it comes down to conflict of laws, that such system should be grounded in U.S. law?

2.

a) Should there be an international domain name dispute resolution system that comprises an efficient, online, inexpensive alternative to traditional litigation and which overcomes the problems associated with multi-jurisdictional conflicts of laws issues?

b) Should there be an international Internet intellectual property Treaty or Memorandum of Understanding that covers domain names and other IP disputes to facilitate the implementation and administration of a dispute resolution system as outlined in a) ?

3.

Are domain names truly different? Are they sui generis, or are they merely just another form of trade-mark?

(i.e.: are all these discussions merely a “flash in the pan” - are the types of disputes we are currently experiencing in relation to trade-marks and domain names all going to be resolved satisfactorily using national trade-mark and unfair competition laws?)

BACKGROUND INFORMATION

4) Brief History of the Internet

The origins of the Internet trace back to at least 1969, when the United States established a decentralized computer network (DARPANET) intended to provide reliable communications for the U.S. military and Department of Defence, even in the event of partial destruction through military hostilities. The academic community quickly realized and took advantage of the staggering implications of the Internet for free and instantaneous information exchange between scientists and

researchers. By the mid-80's, the National Science Foundation (NSF), an agency of the U.S. government, began funding creation of new research networks all linked together into a high speed network which eventually replaced the U.S. Department of Defence network. Gradually, other similar developing networks around the world were also linked up to NSF's network, creating the Internet as we know it today. Commercialization of the Internet began to occur in the early 1990's, when NSF granted an exclusive contract to Network Solutions, Inc. (NSI) to register domain names in the generic top level domains. In 1993, there were less than 10,000 registered domain names. By 1996, this had grown to over 300,000 registered domain names, and by 1997, the number had more than tripled again. NSI is currently registering between 100,000 to 200,000 domain names monthly. In addition to the generic top level domains, each country has its country code domain name. Without exception, the registrars and registry structures in individual countries are more or less voluntarily administered, and again, with few exceptions, the country top level domains are not nearly as popular as .com.

Currently, commerce on the Internet is estimated at $ 5 - 7 billion per year, and the market size is said to double every 18 months. By early in the next century, the Internet will probably represent approximately $ 50 billion in sales.

5) Important events in the change in DNS Governance - 1996 to present

Issues related to Internet use and access include problems involving dissemination of hate literature, child pornography, security, copyright and other intellectual property rights, most notably trade-marks. Until now, the preponderance of intellectual property disputes in the context of trade-marks and domain names have involved cybersquatting, cyberpiracy - and more recently metatags and hyperlinks. In the United States, there is a large and ever-increasing body of jurisprudence developing on these issues, such that they are becoming well (if not completely) defined in that country. Other recent jurisprudence in the U.K. and elsewhere indicates that cybersquatters and cyberpirates can be effectively dealt with by finding such conduct unlawful under national unfair competition and trade-mark laws.

There remain a number of undecided questions of law in many countries where little or no litigation involving domain names has taken place. Therefore some basic questions with respect to the interface between trade-mark law and domain names remain unsettled in many countries. (See AIPPI Q143)

In light of the foregoing, one important question is how big a problem are intellectual property issues on the Internet? To date the answer seems to be that IP issues are not of overwhelming importance given the ratio of disputes to Internet users. This is so even in the United States where the heaviest volume of cases has occurred, and notwithstanding the recent surge of international publicity surrounding trade-mark / domain name conflicts. Part of the reason for the widespread interest in such conflicts was that they highlighted the inevitable tension that was caused by the Internet's shift in focus from purely academic to primarily commercial. This was exacerbated by NSI's virtually non-existent initial dispute policy for .com, where domain name disputes occurred most frequently. In response to widespread international criticism and the fact that NSI was sued virtually every time a domain name conflict occurred, NSI's dispute policy was redrafted several times. The current policy is still not considered ideal, moreover the uncertainty created by the numerous revisions has attracted further criticism.

In September 1996, with little more than one year to go of NSI's monpoly, IAHC / IPOC was formed at the initiative of the ISOC and at the request of IANA, which manages the root of the DNS. IAHC consisted of eleven members representing a relatively broad range of interests both substantively and geographically, including representatives from WIPO, INTA and ITU. WIPO was approached to assist IAHC/IPOC in the development of an internationally acceptable process for the administration and expansion of the top-level DNS to succeed NSI / IANA. The result was the Generic Top Level Domain - Memorandum of Understanding (gTLD-MoU) which established an international Council of Registrars (CORE) with harmonized standards, a plan for the introduction of seven new gTLDs, and a formal dispute resolution process using Administrative Challenge Panels (ACPs) to be administered online under the auspices of WIPO.

WIPO held international consultations in Geneva in May and September 1997 (attended by Jonathan Cohen on behalf of FICPI), as well as further online consultations, on which basis several drafts of the Rules and Guidelines respecting ACPs were developed. Each successive draft responded quite significantly to comments and criticism received from around the world, including recommendations on each draft by

FICPI, and by late 1997 a viable dispute resolution process, albeit one that required still further refinement, had been developed.

Despite all the time, effort and international input in respect of the IAHC / WIPO gTLD-MoU initiative, on January 30,

1998 (not unexpectedly) the National Telecommunications and Information Administration (NTIA) of the United States Department of Commerce released a Green Paper that proposed an alternative to the IAHC / IPOC / WIPO initiative which focused almost exclusively on the technical aspects of Internet governance after the expiry of NSI's monopoly. The purpose of the Paper was to set forth a plan to implement the U.S. government's stated intention to withdraw from and privatize Internet governance. The key aspect of the U.S. proposal was that management and control of the DNS was to remain in the U.S. and be administered through a not-for- profit corporation (NewCo) to be located in the U.S.

However, the Board of Directors was to comprise members from around the world representing a wide spectrum of interests. Plans to add further gTLDs, as well as the institution of a comprehensive international Internet dispute resolution system were clearly rejected. The reality of the situation, i.e.: the origins of the Internet, source of capital investment and location and control of the majority of the root servers all being in the United States, resulted in the Green Paper effectively ending the IAHC / IPOC / WIPO initiative. (A summary of the Green Paper appears in Appendix I).

Prior to the drafting of the Green Paper, no significant international consultation on the scale of that conducted by WIPO had taken place other than hearings in the U.S. A request for comments on the Green Paper was issued to which FICPI responded. Our recommendations are summarized as follows:

1. NSI's contract should be extended for at least a further six months to one year in order to preserve the .com status quo during the period of uncertainty in other areas;

2. Representatives of the Department of Commerce should contact POC and WIPO, to determine if the two proposals, which represent somewhat polarized approaches to the problem, cannot be reconciled in some way;

3. The Department of Commerce should contact the Registrars of ISO country codes in all countries, to see if they can somehow be linked to the proposal;

4. A series of meetings or discussion groups should be organized, to which representatives of the intellectual property community, the telecommunications community and members of the Internet community, together with the ISO country code Registrars, WIPO representatives and any other parties considered to be interested be called to discuss specific topics and seek specific recommendations, including:

- the cost and format of alternative dispute resolution of domain name and possibly other Internet disputes,

- the precise criteria required for obtaining a domain name,

- an effort to determine if some international consensus can be reached regarding famous marks and how they should be dealt with, with respect to TLDs,

- a careful and in depth look be taken at the problems involved in jurisdiction and enforcement in relation to domain names and intellectual property infringement on the Internet (given that the vast majority of Internet community members are no longer American)

NSI's contract was extended until the end of September, 1998 and on June 5, the U.S. Secretary of Commerce released its White Paper. This document took into account some of the criticism received in response to the Green Paper, but there was little change with respect to the main issues (the changes set out in the White Paper are also summarized in Appendix I). One change of note is the provision for the formation of an initial Interim Board of Directors to run NewCo and, among other things, develop policies for the selection, appointment and election procedures of the final Board, as well as studies relating to the expansion of TLDs.

According to the timetable in the White Paper, the implementation of the significant elements of the U.S. proposal, namely the incorporation of NewCo (frequently referred to rather tellingly as the "New IANA") in the U.S. and the selection of its Interim Board of Directors was to take place by the end of September, 1998. This left little more than three months for such sweeping changes to be effected. A flurry of international meetings and consultations ensued as concerned stakeholders scrambled to use the brief allotted time to formulate positions and recommendations.

Most Recent Developments

One of the main currently ongoing consultation processes is that of WIPO. In dismissing the importance of trade- mark/domain name conflicts, the White Paper had defined WIPO's role as merely that of advisor on the narrow issues of cybersquatting and cyberpiracy. Accordingly WIPO was asked to undertake a study of these issues with a view to providing recommendations to the Interim Board of NewCo. In response, WIPO has initiated a series of RFCs (Requests for Comments), in which it is seeking international input on a range of issues far broader than that set out in the White Paper, including the question of what the international Internet community considers WIPO's role to be in the new system, and the steps that WIPO should be taking in respect of these issues.

RFC-1 was issued on July 8, 1998 with a deadline for comments at the end of August. The received comments (including that of FICPI) have been posted on WIPO's website (www.wipo.org). RFC-2 is currently in the comment solicitation stage and the deadline for responses is the end of October. This will be followed by a third RFC.

Concurrently, WIPO has also appointed an international panel of experts which is presently conducting a series of regional hearings and consultations on the issues which were determined to be within WIPO's mandate by the response to RFC-1. The list of experts as well as the schedule of regional hearings, which extends into early spring of 1999, is posted on WIPO's website. The first two such consultations have already taken place, in San Francisco (September 23) and Brussels (September 29) respectively. As of the time of writing, transcripts of these meetings had not yet been posted on WIPO's website.

Progress of NewCo Implementation

In the U.S., IANA and NSI have been working together to formalize arrangements for NewCo in accordance with the provisions of the White Paper. Following a series of draft Articles of Incorporation and Bylaws which were each subjected to and revised according to public comment (on an accelerated timetable), a not-for-profit corporation known as ICAAN (Internet Corporation for Assigned Names and Numbers) has been incorporated in California with a head office in Los Angeles. On October 2, 1998, IANA submitted a proposal to the Secretary of Commerce for his review, outlining the details of ICAAN's incorporation, the list of individuals who have agreed to serve on the Interim Board of Directors and enclosing the Articles of Incorporation and proposed Bylaws. The proposal states that the Board has not been formally elected yet, nor have the Bylaws been adopted pending review by the Secretary of Commerce. Of particular significance is that of the nine proposed Interim Board members, at least three, possibly four individuals are from the U.S.

FICPI's Activities in the DNS Reorganization Process

Submissions re: WIPO's Draft ACP Guidelines and U.S. Department of Commerce Proposals

As detailed above, FICPI has been active in the process from the beginning, including representation by Jonathan Cohen at WIPO's 1997 Consultative meetings in Geneva, and the submission of recommendations for the successive drafts of the ACP Rules and Guidelines, and the Department of Commerce proposals.

Joint U.S. - Canada - U.K. Meeting at Mont Tremblant - July, 1998

At the meeting at Mont Tremblant, Jonathan Cohen and Helmut Sonn personally reported to the EXCO with respect to what FICPI's role in the process should be. A panel discussion on trade-marks and domain names was also held at that meeting.

FICPI Meeting on Domain Names - Washington D.C. - September 19, 1998

As a consequence of the suggestions made by Mr. Cohen and Mr. Sonn at Mt. Tremblant, a meeting was organized in Washington by Mr. Cohen, Mr. Sonn and John Orange, which was attended by the following representatives:

NSI	Phil Sbarbarro

WIPO	Christopher Gibson
AIPLA	Mark Partridge, M. Kirk
AIPPI	Dennis Prahl
Nominet UK	Dr. William Black
USPTO	Tim Trainer
Industry Canada	Brian Dillon
ECTA	Paul Fields
GTE Service Corporation	Len Suchyta
AT&T / ICC	Marilyn Cade
MCI / INTA	Susan Anthony
Bell Atlantic	Sarah Deutsch
Virtual Networks	John Graves
Bell Communications Research, Inc.	Nicholas Lordi, Jr.
The Regis Group	Marc Chinoy, Mark Lardieri. (facilitators)

This broadly representative group was asked to develop recommendations in response to a series of questions relating to WIPO's role in the new DNS administration, the adequacy of existing national laws to deal with domain name/trade-mark conflicts on the Internet, the possibility of an international cooperation or treaty to resolve the situation and the role of the new not-for-profit corporation. (The text of the questions and meeting agenda comprise Document EXCO/IT98/CET/1106 at page CET(70)).

One purpose of the Washington meeting was for FICPI to obtain input from other IP groups in order to better formulate its own position. A second objective was to determine whether the potential exists to form a permanent liaison of major IP organizations, such as AIPPI, AIPLA, INTA etc. that would come together in developing recommendations for steps to be taken as the process for DNS administration evolves. Such a cooperative effort could extend in the future to other intellectual property issues on the Internet.

The meeting was well received and constructive, and it was unanimously agreed by all attendees that a second meeting should be planned.

WIPO Consultation Process

FICPI has made submissions to WIPO in response to RFC-1, which are included in these Working Papers as Document EXCO/IT98/CET/1104 at page CET(38). A submission should also be made by FICPI on RFC-2, the deadline for which is October 31, 1998.

APPENDIX I

Brief Summary of the U.S. Dep't of Commerce Green Paper (dated January 30, 1998) with changes by White Paper (dated June 5, 1998) in italics by: Dr. Victoria Carrington June 11, 1998

PRINCIPLES FOR A NEW SYSTEM

1. Stability- US government should pull out of the Internet number and address systems without sacrificing stability

current technical management not viable in the long run, needs to be improved as soon as possible, but not so fast as to destabilize the Net

2. Competition - success of the Internet depends on the maintenance of the current decentralized system which emphasized individual freedom and innovation, and this is best done with competition driven market mechanisms

3. Private, bottom-up coordination- where technical administration requires coordination, flexible private, rather than cumbersome government, control is preferable

4. Representation - need international input in decisionmaking

- *has not changed*

TWO GROUPS OF NAME / NUMBER FUNCTIONS

5. Those to be coordinated by a representative, not for profit corporation

management of number addresses

management of root server network (on a policy level at least)

maintenance / dissemination of addressing protocol parameters

authority to say when new TLDs can be added

6. Those to be privatised

the system for registering SLDs and management of TLD registries registration should be competitive, registries probably should not - has not changed

THE NOT FOR PROFIT CORPORATION

would have a CEO with corporate background funding from domain name and IP registries

US government would gradually transfer control of IANA functions and root systems to it by Sept/98, but policy oversight until Sept/2000

diverse, balanced board to represent key Internet stakeholders and users - 15 members: 3 from the regional registries (RIPE, APNIC and ARIN), 2 from IAB, 2 from domain name registries and registrars, 7 from "user" group, CEO

transparent decision-making, decisions open to public etc

will act as standard-setting body

- this has essentially not changed too much: there were submitted comments about composition of the board not being broad enough, i.e. trade-mark holders not adequately represented, but the response was essentially that you simply cannot represent everyone

- representation issues can be addressed later, and the 7 "user" seats can reflect additional types of interests, although they really only meant to suggest a guideline for Board composition

- now recommends starting the corporation with an Interim Board with full access to legal counsel in corporate, competition, IP and Internet law - these people will not be on the final Board, but will work out a system for electing the Board members from appropriate international groups, such as the ones in the original plan

- BUT: who are these people? They are now saying that the "private" sector is to be responsible for the formation of the corporation and its Interim Board without US government involvement, but who exactly is the private sector? The US private sector?

- they kept the time frame intact

CREATION OF NEW gTLDs

did not have enough information yet to be sure how to proceed (when the Green paper was drafted)

the U.S. government now no longer believes it should set out a plan or criteria for competition among registries and registrars - this is more appropriate for the corporation to do

recommended 5 new gTLDs at outset

in general, the U.S. still supports competition, but it has completely pulled out of setting it up

although many parties want to be in the registry or registrar business, the US should ideally wait until the new corporation has been established before setting out a plan for competition

the U.S. government also now states that it doesn't believe any new TLDs should be introduced pursuant to its own initiative - this responsibility too should be that of the new corporation

- however, this would take at least until September 1998, and it is preferable to introduce competition into the DNS earlier, during the transition to the new corporation, according to the following plan laid out in the Green Paper

TRADE-MARK DILEMMA

trade-mark holders should be given the same rights they have in the physical world

on-line dispute resolution mechanisms as inexpensive &

efficient litigation alternatives suggestions:

temporary name suspension if trade-mark owner responds shortly after registration of a name

jurisdiction concerns: registrants must agree that disputes over their name are to be settled in the registry's jurisdiction, or where the database or the "A" root server is maintained

"clearing" trade-marks, especially famous ones across a range of gTLDs

instead of a "monolithic" trade-mark dispute resolution process, each registry should have minimum dispute resolution process

study of the effects of new gTLDs and dispute resolution processes on trade-mark and IP right-holders, results to be used by the corporations in deciding how to proceed

registries should indemnify the corporation against legal expenses

- sets out criteria for the following:

1) Minimum Application Requirements and up to date ownership info

- expanded contact info

- certification as to entitlement and intent to use

2) Searchable Database Requirements

- certain info to be included in all registry databases and available to everyone that has Net access

3) ADR of Domain Name Conflicts

- readily available, convenient process without registrar involvement

- registries/registrars to abide by the results of the process or decision of court of competent jurisdiction

- temporary suspension if objection to registration raised within 30 days of domain name registration

the comments predominantly disagreed with the registries having varying dispute resolution measures, albeit with certain common criteria - a uniform approach was preferred

temporary name suspension at the request of a trade-mark owner was also unpopular and was seen to unnecessarily expand trade-mark owner's rights

expectedly, only U.S. commenters liked the idea of voluntarily attorning to U.S. jurisdiction - pretty well everyone else did NOT

so, now the U.S. government says it will seek international support to ask WIPO to develop uniform dispute resolution process to recommend to the corporation

specifically, they are now saying that they are not

trying to resolve jurisdiction problems in these policy papers

they now concede that having parties subject themselves to a neutral ADR process, such as that of WIPO, will be less controversial than requiring attornment to a specific national jurisdiction the new corporation's dispute resolution (that is binding on registrars and registries) should be limited to cybersquatting and cyberpirating, not situations where legitimate competing rights are involved, which should go to the appropriate court - BUT how can this be determined in advance without going through some form of process? Is not a hearing of some form required to determine the existence of cybersquatting, or legitimate rights? Essentially they are just passing on the issue without really doing anything meaningful on this very important question

- they do provide the other following suggestions in the white paper though:

1. Domain registrants pay registration fees at the time of registration or renewal and agree to submit infringing domain names to the authority of a court of law in the jurisdiction in which the registry, registry database, registrar, or the "A" root servers are located - again, how will "infringing" be decided before having a hearing on the question? Presumably, registrants will not voluntarily assume the status of infringer!

2. Domain name registrants would agree, when registering or renewing, to abide by processes adopted by the new corporation that exclude, either pro-actively or retroactively, certain famous trade-marks from being used as domain names (in one or more TLDs) except by the designated trade-mark holder (who will determine, and by what criteria, which marks qualify as "famous"?)

4. Nothing in the domain name registration agreement or in the operation of the new corporation should limit the rights that can be asserted by a domain name registrant or trade-mark owner under national laws

THE TRANSITION

- lists 6 steps to be taken to implement the suggestions in this paper:

1) establish and choose board of the new corporation - *which is now specifically stated to be the private sector's responsibility*

2) form membership associations for a) registries

& registrars and b) Net users - *this is not really mentioned in the new paper*

3) US government and IANA to agree on transfer of IANA functions to new corp - *to be done after the private sector establishes the new corporation*

4) US government and NSI to agree on how NSI is to evolve into one competitor among many registries, and level playing field established

5) new corporation must establish processes for determining whether an organization meets the transition period criteria for prospective registries and registrars - *not specifically addressed or changed*

6) set out process to make root server system management more robust and secure, and transferring it from U.S. government to new corporation - *U.S. government is to cooperate with IANA, NSI, IAB and other relevant organizations (both public and private) in studying the problem of*

improving the root server system, and its recommendations are to be implemented during the transition phase by the corporation when it develops a security strategy for DNS management and operations

both the U.S. government and the private sector have to take certain steps during the transition phase - i.e. the private sector has to actually set up the corporation and its Interim Board - once that's done, the U.S. government can work with the corporation in transferring administrative functions to it

The NSI Agreement

- what should go into the ramp down agreement between the U.S. government and NSI:

1) NSI to completely separate its registry and registrar businesses - NSI to continue to operate .com, .net & .org on a fully shared registry basis - NSI will transfer .edu to a not-for-profit entity

2) During the transition, NSI will make it technically possible to share the registration of its TLDs with other Registrars as soon as possible

3) NSI gives U.S. government a copy etc. of all data, software and licenses to other IP generated under the cooperative agreement, for use by the new corporation for the benefit of the Net

4) NSI will turn over control and management of the "A" root server and the root server system when U.S. government requests it

5) NSI agrees to meet registries' and registrars' requirements

the plan still calls for the cooperative agreement between the U.S. government and NSI to ramp down in order to introduce competition - NSI is to agree to take certain actions to facilitate this and recognize the new corporation and its role in implementing and administering the domain name system - the new plan is not quite as specific as the green paper, however

The .us Domain

- presently administered by IANA, but has a very cumbersome locality-based system

- U.S. government will start working with the private sector and state/local governments to simplify and make it more attractive

- no change

- the white paper also states explicitly, that the U.S. Department of Commerce has now determined (as a matter of administrative law requirements and in response to public comment),

that all it really should do is issue a general statement of policy, instead of imposing substantive regulatory provisions, which is what it initially set out to do in its Green Paper - therefore, the white paper is not a substantive rule, has no mandatory provisions, and does not have the force or effect of law

APPENDIX II List of Acronyms

ACP - administrative challenge panel ccTLD - country code top level domain CORE - Council of Registrars

DNS - domain name system

gTLD - generic top level domain (.com, .org, .net, .gov, .edu,

.mil and .int)

gTLD-MoU - Generic Top Level Domain Memorandum of Understanding

IAHC - International Ad Hoc Committee

IANA - Internet Assigned Numbers Authority

ICAAN - Internet Corporation for Assigned Addresses and Numbers (NewCo)

INTA - International Trade-mark Association

IPOC - Internet Policy Oversight Committee (succeeded by

POC - see below)

ISOC - Internet Society

ISP - Internet Service Provider

ITU - International Telecommunications Union

NSI - Network Solutions, Inc.

NTAI - National Telecommunications and Information Administration (of the U.S. Department of Commerce)

POC - Policy Oversight Committee (successor of IPOC) TLD - top level domain

Prepared by: Jonathan C. Cohen, with the assistance of Dr. Victoria Carrington

Status of NSI's contract with the United States Government

The contract between the U.S. government and NSI which established NSI's monopoly over the gTLDs and was scheduled to expire at the end of September, 1998 has been amended as of October 7, 1998 to extend the contract until September 30, 2000. This amendment to NSI's contract was purportedly made to comply with the provisions of the White Paper which set out the actions to be taken by the U.S. government, NSI, IANA and the private sector during the transition period which would gradually transfer DNS management and management functions to the private sector (NewCo).

The amendment has already attracted criticism for seeming to extend NSI's monopoly for two more years, especially in light of the wording of the White Paper which referred to the "ramp down" of NSI's cooperative agreement by the U.S. government. However, the fact remains that NewCo is still not in a position to take over the DNS management or addressing functions currently under the

control of NSI. In addition, other tasks to be undertaken by NSI during the transition, such as the development of a shared registry system (as a consequence of which NSI would become one competitor among many) and an enhanced searchable database containing domain name registration data, still remain to be done. Further, it is clearly important to the stability of the Internet to have a concrete arrangement in place pursuant to which the root server system continues to be maintained during the transition period, until NewCo is able to take over this responsibility from NSI.

Accordingly, the amendment specifies a timeline for the development of a Shared Registry System that would permit multiple registrars (other than NSI) to provide registration services within the gTLDs and which would see the first 5 new accredited registrars making registrations in .com, .net and .org by March 31, 1999 (Phase 1). Phase 2 involves the expansion of the new system by June 1, 1999, with all licensed accredited registrars having access to registry services by October 1, 1999. NSI's proposals for the enhanced searchable database are to be submitted to the U.S. government by November 1, 1998.

The amendment further specifies that both the U.S. government and NSI recognize NewCo, and that as the U.S. government gradually turns over DNS responsibilities to NewCo, NSI's corresponding obligations under this cooperative agreement will be terminated or covered in a contract between NSI and NewCo where applicable.

The practical effect of this amendment to NSI's contract is that we now have a more definite idea of the time frame available for consultations and formulation of recommendations to be submitted to NewCo and/or NSI in respect of all the issues canvassed earlier in this paper, as well as an indication of when the appropriate time is to make submissions concerning particular issues.

PAPER: FLO/2.5 by D. CARTER

Trademark Licences or Goodbye Goodwill

Background

In common law jurisdictions where the law is based on English law, it is only in relatively recent times that the concept of authorising the use of a trademark, or licensing the trademark has become accepted. Earlier this century it was regarded that the licensing of a trademark placed the validity of the trademark registration in jeopardy, even to the extent that a license automatically made the trademark incapable of remaining validly on the Register. The law in most common law countries has gradually changed, firstly to permit the authorisation of use of a trademark which is registered by someone other than the proprietor, by providing for the registration of the user as a Registered User, to the position we are at today, where the concept of licensing is so wide spread and well understood that few restrictions remain. In a great number of jurisdictions it is now possible to license unregistered trademarks and to license registered trademarks in respect of goods or services not specifically covered by the registrations. Licensing restrictions that we must still take account of are not based on difficulties associated with the licensing per se but are generally associated with consumer protection laws, anti-competition laws and the anti-monopoly laws which we must take into consideration when advising our clients particularly concerning multi-territory licenses.

License Categories

Trademark licenses fall into a number of distinct categories. Firstly, there is the manufacturing type license where the licensee acts as a manufacturing and/or distribution arm of the trademark owner, possibly to extend the territory covered by the trademark or to provide the manufacturing and/or distribution facilities which the trademark owner may not have. However, there are many other reasons why a trademark owner would enter into a license agreement of this type.

The second type of license is the promotional license, which may be associated with merchandising and often, involves a sporting organisation or a personality. With this type of license, a large range of manufacturers may be licensed to apply particular trademarks, such as football team logos, to a large range of products ranging from caps items of clothing to memorabilia to food and any other product.

A third type of licensing is known as franchising and we are all well aware of this form. Franchising is a way of enabling the distribution of goods (or services) by controlling the use of the trademark. A trademark owner can expand his business through franchising without the expense of his own separate business. Generally, although not always, the franchisee provides the business premises, staff, and everything else to run the business. The franchiser provides the trademark, and probably advice, training, business plans, advertising programs, and even suppliers of product or raw materials.

A fourth type of trademark license is that which is included in a technology license agreement, relating to, for example, the license of patents, industrial designs, or other industrial property, where the use of the trademark is part of the total package. Many patent licenses, for example, are combined with authority to use a trademark as part of a technology package license.

The licensing of certification trademarks is a fifth form of licensing which is associated solely with a trademark used to certify a quality, accuracy or some other characteristic, including origin and method of manufacture, of goods or services. Certification trademarks may be applied under license in accordance with the rules governing the use of the certification mark. In Australia, a distinction is drawn between an authorised user of a normal trademark and an "approved user" of a certification trademark. The rules governing the use of certification trademarks generally require provisions concerning who may certify the goods and/or services to which the mark is to be applied, the conditions under which an approved user is allowed to use the trademark, the use of the certification mark by the owner in the case where the owner is also a user and provisions governing settlement of any disputes arising from a refusal to allow the mark to be used. The registration of and control of use of a certification trademark is a subject of itself and I will not cover that in detail in this paper.

While these different types of licenses require differing structures, they all have in common the necessary legal requirements of licensing.

Legal Fundamentals

To grant a license is to authorise the use of property for which the grantor has a right, either by proprietorship or some other claim. It is therefore fundamental to licensing, and particularly trademark licensing, that the ultimate licensor has a property right which is able to be the subject of the intended license.

Property Rights

Registered Trademarks

The property right in a registered trademark is usually conferred by ownership of a trademark registration. It is not necessary for the purpose of the right to exist that the trademark be used or that there be a reputation in relation to particular goods or services. The registration itself creates the property, which can then be the subject of the license agreement. Of course, in some countries, the registration cannot be achieved without use of the trademark in relation to the goods of the registration. In most countries, however, all that is required is an intention to use a trademark in order to establish the property right by registration.

Once the property right is established, and in many cases even before the registration has been obtained, while an application is still pending, the owner can authorise another to use the trademark in relation to the goods or services which are or are to be covered by the registration.

Unregistered Trademarks

The property right in the trademark may be conferred solely by the use of the trademark such as to establish a reputation and goodwill in relation to the goods or services in respect of which the mark is used. In this case, the property right which exists is not the trademark as an entity, but the combination of the trademark with the reputation and the goodwill developed through use of the mark. Often, the license of an unregistered mark is associated with the license of a registered trademark, as was the situation in the United Kingdom GE case [(1969) RPC 418] which concerned the use of trademarks in relation to goods outside the scope of the registration. In this UK case, it was held that licensing of the registered mark could extend to the goods outside the scope of the

registration, thus giving rise to a license in respect of a trademark for goods for which the mark was not registered.

Of course, the whole question of licensing an unregistered trademark, and the validity of such licenses, is still being debated. In many jurisdictions the licensing of an unregistered trademark is not permitted. In Malaysia, for example, an unregistered trademark cannot be licensed. However, an applicant for a registration may appoint a registered user prior to the trademark application proceeding to registration. If the mark is subsequently refused then the license becomes invalid. In Taiwan, it is not possible to license an unregistered mark and, further, any license of a registered mark must be recorded with the Trademarks Office.

In the People's Republic of China, only proprietors of trademarks which have been registered in China are able to license other entities to use the trademark. It is mandatory for the trademark license agreement to be submitted to the Trademarks Office for recordal. This must be done within three (3) months of the date of execution of the license otherwise the administration may impose a fine or even request the Trademarks Office to cancel the registration of the trademark. While these legal requirements have been in place for some time, it appears that they have not been consistently enforced by the Chinese authorities. However, I would strongly recommend that any trademark license agreement in relation to a Chinese trademark registration be recorded although it is probably best to adopt a minimalist form of license agreement for this purpose.

These countries are just three examples to show that universal acceptance of licensing un-registered trademarks is not yet with us. I do not know the position in all European countries, but given the changes we have seen in licensing trademarks in the past 70 years throughout the world, from the time when it was not possible to license a registered trademark, to today, where we see rampant commercialisation and character merchandising, and the lifting of bans in various countries in relation to "trafficking" in a trademark, the wide acceptance of licensing unregistered marks appears to me to be inevitable.

Coming back to the initial point of legal fundamentals, the first legal requirement of licensing, therefore, is that the licensor has a property right which is capable of being licensed in the relevant territory

Where the licensor is not the owner of the trademark, licensing rights can be derived from an agreement with the trademark owner, such as in a Head License Agreement which allows the grant of sub-licenses. Licensing rights can also be conferred by legislation. In some countries, such as Australia, unless the license agreement contains specific provisions to the contrary, the legislation permits the licensee (Authorised User) to give permission to any person to apply the trademark to the goods, or in relation to goods or services, in respect of which the mark is registered. It is therefore most important in Australia that a trademark license agreement contains specific reference concerning whether or not the licensee is authorised to grant sub-licenses in respect of the trademark. Obviously, the question of control by the trademark owner must be a major consideration in the granting of a license which permits sub-licenses.

Control

The second fundamental requirement for current trademark licensing is that the owner of the trademark rights has control over the use of those rights. Not only must the owner have the ability to control the use, the owner must also exercise that ability or risk misuse of the trademark by the

licensee even to the extent that the licensor may be held not to have fulfilled its obligations and duties under the license.

In Australia, the Trademarks Act states that use of a trademark by an authorised user is authorised use to the extent only that the user uses the trademark under the control of the owner of the trademark. The words, "to the extent only that the user uses the trademark under the control of the owner ...". is a specific statement that actual control is required. It is not enough that the authorised user agreement, or license agreement, contains the usual provisions "the user may only use the said trademark in respect of the said goods if such goods conform to the standards of manufacture and quality laid down, given or approved from time to time by the licensor"., and "On request by the licensor, the licensee hereby agrees to supply the licensor, at all reasonable times, samples or specimens of all wrappers, packaging and literature in use by the licensee relating to any of the goods of permitted use offered for sale by the licensee, and the licensee further agrees that the licensor or its duly authorised representative or agent has the right to inspect the goods for which the said trademark is to be used and to inspect the methods of making the said goods on the premises of the licensee or on the premises of any sub-contractor to the licensee"..

While clauses of this type may be essential in a license agreement between arms-length parties to provide the basis for control, if the licensor abdicates its responsibilities and does not actively and adequately police the use of its trademark it runs the risk of the trademark being misused and therefore becoming liable to revocation or devaluation at the very least. Further, if the user does not use the mark "under the control of the owner", in other words, if the owner does not exercise the control, then the use of the mark by the user may well be disregarded in infringement or removal proceedings where use is being relied on to establish reputation and distinctiveness.

The issue of control is vital to current trademark licensing, and in those jurisdictions in which licensing is embodied in the legislation, quality control is usually an essential element.

This is so particularly in the United States, Canada, most if not all Europe, most of Asia and the pacific regions. Again referring to the Australian Trademarks Act, a person is defined as an Authorised User if the person uses the trademark under the control of the owner of the trademark. In Australia, the control is considered effective in two (2) circumstances. Firstly, if the owner of the trademark exercises quality control over goods or services the use of the mark is taken as being under the control of the owner. It will be seen that this form of control is control of quality of goods or services in relation to which the trademark is used. Such quality control may be embodied in an agreement between the parties having clauses along the lines of those referred to above, and the owner must then exercise that quality control as I have previously indicated.

There are many areas of trademark usage which may be subject to quality control. Bearing in mind the need to be seen to exercise control rather than simply be capable of controlling, trademark proprietors should look carefully at the following areas:

Standards of Manufacture

The qualities of raw materials, manufacturing tolerances and methods of production can be specified. It may even be possible to specify that the licensee purchases certain materials from the licensor, or another source, provided that the source is the only means of maintaining the necessary quality specification laid down by the licensor.

Preliminary Samples

It is desirable that samples of the product be checked and tested prior to commercial release.

Continuing Samples

A continuous program of obtaining and checking product samples should be in place. However, care should be exercised to ensure that the task is not too onerous, which could lead to a sampling requirement being ignored.

Labels

All labels, packaging, tickets and all other forms of using the trademark on or in relation to the goods must be approved before use.

Inspection of Premises

The licensor must have the right to inspect the premises where the goods are being manufactured, be that the licensees premises or those of a sub-contractor. The inspection should be able to be carried out by a representative of the licensor, preferably a person skilled in the goods the subject of the license.

Marketing

Promotional material to be used by the licensee should be checked by the licensor. It may be impractical for the licensee to provide the licensor with all samples of printed material preferably prior to publication. It will be understood, however, that it may be impractical for the licensee to provide pre-publication copies of every advertisement and the like in all territories.

Records

The licensee must maintain records of all products manufactured and/or sold and must provide access to these records at all reasonable times. Of course, when royalties are being paid (which may not be the case in all license agreements), the provision of records is of utmost importance.

Failure to provide adequate facilities in the license agreement to enable proper control over the use of the trademark to be achieved may well lead to the dire consequences referred to above if the licensee misuses the mark.. Inadequate exercise of control may also lead to conflict between the licensor and the licensee which can result in expensive and time consuming litigation. Inadequate control may also lead to product liability difficulties. The area of product liability is very unsettled, but there is a strong argument for suggesting that inadequate exercise of quality control by a licensor may be a basis on which the licensor may be held at least partially responsible in the case of injury caused by a defective product. This aspect has/will be covered by my colleague, Ms Beryl Green.

The second form of control is the exercise of financial control by the owner of the rights over a person dealing with the goods in relation to which the mark is used. In this case, the User is taken to use the trademark under the control of the owner. It will be apparent that financial control applies particularly to related companies, and it has long being the practice in Australia that a shareholding of more than 50% will be sufficient to establish a financial control. This may well be different in other

countries, such as in the United States, where control based on a non-wholly owned subsidiary might be rejected without additional evidence of the nature of the controlled use, such as by written agreement or otherwise.

The financial control referred to in the Australian Trademarks Act extends well beyond the corporate boundaries of related companies. Financial control can extend to financial agreements between parties through which the control may be exercised over the licensee's relevant trading activities. Such agreements will not necessarily enable the licensor to control all aspects of a licensee's business, and it is possible for such an agreement to be in place whereby the licensee has control over only certain defined business functions which relate to the trademark use. In this case, while the licensor may have partial financial control in relation to the licensee's business, it does not necessarily have control over all the business of the licensee.

The concept of control being a requirement for trademark licensing separates trademark licensing from licensing of other forms of intellectual property. For example, a patent license does not necessarily have any built-in form of control by the proprietor of the patent over the quality of the licensee's product. Of course, many patent license agreements will have such conditions in-built, but they are not essential to the patent license. However, at the present time, control by the trademark owner over use of its mark is an essential feature of a trademark license. This sets the trademark license apart from a mere consent to use. A consent to use may be given by a trademark owner to another person who wishes to use the or a similar mark in relation to particular goods, generally not comprised within the trademark owner's registration. Such a consent is not a license, royalties are not usually paid and no formal agreement apart from the consent notice is required. Where consented use comes under the watchful eye of the trademark owner that consent becomes a license and the control becomes a prerequisite.

ALTERNATE VIEWS

While I have indicated that control is a fundamental requirement for trademark licensing, this view does not necessarily have universal support. In the article "'naked is not a four- letter word: debunking the myth of the "quality control requirement" in trademark licensing", by Kevin Parks in The Trademark Reporter, Vol 82, 531, Mr. Parkes suggests that quality control should not be a requirement for trademark licensing. Mr. Parkes believes that the requirement for quality control of the products of a licensee imposes an obligation of quality maintenance on the licensee which the proprietor does not have. He suggests that the public has no right to demand goods of a particular quality from a licensor, and they should therefore not have that right in relation to goods of a licensee. Mr Parkes further argues that by requiring quality control, an inconsistent treatment exists between licensing trademark owners and non-licensing trademark owners. He suggests that non-licensing trademark owners will be able to produce goods of a whole range of different qualities while the licensing owners will need to exercise quality control over the licensed product or risk abandonment of the licensed mark.

I believe Mr Parkes has confused the issues of "quality control" with the issue of the trademark owner being enabled and required to exercise control over the use of his trademark. Notwithstanding, however, I do agree with Mr. Parkes that the commercial sophistication and reality of the usage of trademarks has moved in the direction where trademarks are now often more an indication of identity than an identification of quality. This is particularly the case in merchandising trademarks, such as cartoon characters, sports men and sports women and people famous for other

fields of activity or endeavour, sports teams and even sporting events. The purpose of such trademarks is very often primarily one of association and promotion of a commercial activity in which the greatest interest of the purchasing public is in the identification with the trademark owner rather than any expectation of a particular quality of goods. In fact, it is often the case that goods of varying qualities are licensed goods.

It follows that with these marks, the connection in the course of trade between the consumer and the trademark owner is not for the purpose of identification of the source of goods, nor is it necessarily for the purpose of identification of a particular quality or characteristic of goods. The connection may be purely one of promotion of the trademark owner and nothing else. Of course a large number of trademarks are used to identify quality. Everyone who buys a can of Coke expects it to be of a known quality. The person who buys an Olympic Games cap, however, may simply be wishing to identify with the Olympics rather that being assured of a cap of a particular quality. The "Olympic Games" trademarks are not used for purposes of indicating quality so much as to promote the Games thus providing a "source" connection as distinct from a "quality" connection. We are all aware of the Walt Disney cartoon characters such as Donald Duck, Mickey Mouse, Goofy and so on being used in a trademark sense. It is, I think, doubtful that these trademarks are used to indicate a quality of goods as distinct from providing some connection with the intellectual association of fun and games which the cartoon characters engender.

However, while quality control may no longer be necessary in all types of licensing agreements, the key is that the use of the trademark by the licensee maintains a commercial connection between the goods (or services) and the trademark proprietor by some form of control exercised by the proprietor over the user whereby the proprietor is able to ensure that the trademark is used in accordance with the proprietor's wishes. Some form of control must be in place to also satisfy the public interest requirement and prevent the mark becoming deceptive or confusing. That control may be unrelated to "quality", and the license may merely provides a connection of identity between the licensee and licensor to indicate source as distinct from quality.

The requirement for quality control might be appropriate in one category of licensing, i.e. Category 1 relating to manufacturing, but not appropriate to another category, i.e. Category 4 relating to merchanidising. Perhaps there will need to be a change in the way license agreements are drafted and in the way they are understood by trademark authorities which recognises different types of agreements for different types or categories of license.

Also, at the present time, license agreements require a form of control either quality control or financial control. For certain categories of trademark licensing, the exercising of that control is very important, although such exercise is perhaps not so important where the control is purely financial and/or the trademark licensing category is in the merchandising area. If quality control ceases to become an essential feature of trademark licensing, the function of a trademark license will change in the future perhaps to a system where the source of control of use of the trademark is more relevant than the actual quality of the goods produced by the licensee. It remains to be seen how any such change will effect the advantages that licenses provide such as the ability to control parallel important and franchising.

LAWFUL CONTRACT

Another fundamental of legal requirements of licensing a trademark is that there is a lawful contract which grants defined rights, such as the right to use the trademark, the right to apply a trademark,

the right to sub-license, the right to issue infringement proceedings and the like. Although a lawful contract does not need to be in writing in most major jurisdictions, without a written contract or agreement, the evidentiary requirements for establishing the nature of the control are insurmountable. Accordingly, in practice, the lawful contract needs to be in writing and it needs to set out all the conditions and restrictions which apply to the particular license.

LEGAL LIMITATIONS OF TRADEMARK LICENSING

Apart from the limitations concerning the licensing of unregistered trade marks in some jurisdictions, the principle limitations in licensing trademarks today derive from the need to avoid restrictive and anti-competitive trade practices. There are many and varied forms of anti-competitive and fair trading legislation around the world and there are many countries without legislation which is as effective as we might like to see, notwithstanding TRIPS. This therefore, clearly flags the need to have professional input from experts in all countries for which an agreement is to be prepared.

In Australia, like many countries, it is illegal under our Restrictive Trade Practices Act for a license agreement to have provisions which fix prices and which ties a licensee to a particular supplier of goods (unless such is required for quality control purposes). The Australian Act prevents companies entering into anti-competitive agreements in much the same way that similar legislation applies to license agreements in the United States and throughout Europe. However, there are differences. For example, in Australia, it is not illegal for an agreement to include a clause which prevents the licensee challenging the validity of the trademark. Also, we do not have a provision corresponding to Article 85(2) of the Treaty of Rome. Consequently, if a clause of an agreement was found to contravene the Trade Practices Act, it may well be that only that clause would be effected, not necessarily the whole agreement.

THE BLOCK EXEMPTION

I do not profess to be an expert on European licensing laws or the Block Exemptions. Most of you will know more than I on this topic. I will therefore comment only briefly on the Block Exemptions as I understand them.

The European Union's anti-trust laws stem from Articles 85 and 86 of the Treaty of Rome. Article 85 prevents companies entering into anti-competitive agreements, while Article 86 prohibits abuse of a dominant market position. Article 85(1) prohibits certain terms in an agreement the effect of which reduces, prevents or otherwise restricts competition unless the agreement has been exempted by the European Commission. If an agreement contains prohibited clauses, Article 85(2) says that no part of any such agreement may be enforced. An exemption is provided by Article 85(3) if the agreement resulted in some benefit to the consumers, including economic improvement or technical improvement.

Agreements which otherwise would have been notifiable to the Office of Fair Trading may be exempt under one of several Block Exemptions relating to technology transfer, franchising or distribution. The Technology Transfer Block Exemption enables the Commission to grant exemptions to blocks of agreements which relate to, for example, to patent licenses, know-how licenses or combinations thereof. If such an agreement incorporates trademark licensing, specific provisions in the Exemption extend the scope of the regulation to such ancillary trademark licensing, and relate to

matters such as not using the trademark license to effectively extend a patent license beyond the life of the patents.

The definition of franchise in the regulation refers to a package which includes industrial or intellectual property relating to trademarks, trade names, signs, utility models, designs, copyright, know-how or patents. While Block Exemptions cover franchising, in which the trademark license is part of a wider business agreement, there is no specific block exemption for pure trade mark licenses. However, the franchise exemption does provide an indication of what might be prohibited in a trademark license. For example, it is permitted to grant to the franchisee an exclusive licence which will exclude the franchisor operating in the franchisee territory. It is possible to require the franchisee to obtain goods or services from a designated party in certain circumstances. Various forms of quality control are permitted, including inspection of premises, use of specified equipment, complying with presentation methods, and the like. Therefore, the franchising block exemptions will provide a clear indication as to what will be allowable and what will be unacceptable in a straight trademark license agreement.

There are also block exemptions in relation to exclusive distribution and purchasing agreements, but that it is a separate issued.

The block exemptions, if applicable to an agreement, include lists of terms which are automatically exempted from the operation of Article 85(1) (the white list), those terms which are specifically not exempted (the black list) and a list of other provisions which may or may not be exempt depending upon the circumstances (the grey list).

In the United States, franchising is a commonly used method of distribution of goods based on the use of the franchisor's trademark. Franchising is regulated by the Federal Government (FTC) as well as by some individual states. If a franchise exists in the United States, the FTC requires that a disclosure statement be provided to ensure that the franchise agreement conforms with the applicable federal laws. State laws may also require the submission of agreements for approval. It is not the purpose of this paper to examine the US franchise laws in detail. I would recommend, however, that before entering into any licensing or franchise agreement in the United States the views or advice of an attorney specialising in this area of the law should be obtained well in advance.

Australia has recently adopted a mandatory Franchising Code of Conduct, similar to that of the United States, after attempting to self-regulate. The new Code became effective on 1st August 1998.

Other limitations of licensing in many countries include the need to specify whether a trademark license is an exclusive or non-exclusive license. The terms usually used are whether the user of the trademark is to be a sole user or a non-exclusive user. If the user is to be a sole user then this will exclude the owner of the trademark using the mark in the licensed territory. The sole user will usually have rights to sue for infringement and be able to join the owner of the mark as a defendant if the owner refuses to take action in relation to infringement.

Recordal

In many countries throughout the world, a license agreement in respect of a registered trademark, often referred to as a Registered User or Authorised User agreement, was required to be registered to obtain the benefits conferred by the relevant legislation. These benefits included the statutory acknowledgment that use by the user inured to the benefit of the proprietor and the right to take

infringement action. Of course, registration of the agreement was not mandatory in most countries, although it is mandatory in some as I have indicated above. In relatively recently enacted legislation in Australia, United Kingdom and Canada, the recordal of authorised users has been abolished, although in Australia at least, a recordal of an interest in a mark may still be made by a user.

Because of the need for or desirability of recording an agreement with the relevant Trade Marks authority, when agreements are prepared for many jurisdictions, it is often preferable to prepare specific agreements for individual countries which can be used in those countries for recordal purposes.

What Of Goodwill

One of the fundamental advantages of licensing a registered trademark is that the use of the mark inures to the benefit of the trademark owner and not the user. This fundamental is the corner stone on which licensing of trademarks is built. As a result of this, the goodwill developed through use of the mark also vests with the owner when the license is correctly prepared and monitored for the relevant territory. Factors affecting the goodwill include:

Exercising the necessary control;

Recording the license in those countries where recordal is necessary, such as Malaysia, and Thailand;

PARALLEL IMPORTS

as a result of recent developments in Europe concerning exhaustion of rights, a major advantage of trademark licensing has become the ability to use a license to exercise contractual control over use of the mark thus preventing parallel importation of goods into the European Community. This provides a huge benefit to manufacturers outside the Community who can license use of their trademark within Europe and through those licensees, prevent the importation of goods originally marketed outside Europe. Similarly, the European company is able to license use of the trademark in territories outside the Community and prevent parallel importation from those territories into the Community. You will all be familiar with the recent Silhouette case which, while not explicit in this regard, provides the clearest implicit indication that the Community does not recognise worldwide exhaustion of rights. Licensing into and out of Europe, therefore, will become a tool to be used by trademark owners world-wide to counteract the exhaustion of rights principles which otherwise apply prevent parallel imports.

In Australia, some trademark owners have been able to use copyright to prevent importation of goods properly marked by the trademark owner overseas. However, recent amendments to the Australian Copyright Act will prevent this act being used to restrict trade. these amendments will come into effect in about 15 months time.

PAPER: FLO/3.2 by Michael STEWART

Conflict of Interest (Topics for Discussion provided by FICPI)

(1) The search reveals a trademark prosecuted to registration by the firm. Does it make any difference whether the relevance is remote or the last contact with the former client was 10 years ago?

The facts of this hypothetical situation set forth a potential conflict rather than an actual conflict. There is no indication that the newer client will apply for a mark, that the mark will be granted, or that the older client will oppose the mark. Thus, the attorney is in the difficult position of trying to anticipate a conflict.

In the United States, a practitioner is bound by nine ethical canons, which are incorporated into the Model Rules of Professional Conduct and the Code of Federal Regulations, which apply to practitioners before the USPTO.

Ethical Canon 9 applies to this hypothetical and states that "[a] lawyer should avoid even the appearance of professional impropriety".

Whether the relevance of the trademark of the former client is remote to the current search plays an important part in the analysis for an appearance of impropriety. As a general rule, a conflict arises if the representation of the new client is in a matter adverse to another/former client and if the subject matter of the current representation is substantially related to the subject matter of the prior representation.

This is the "substantial relationship test". Under this test, the closer the client's interests are to being "directly" adverse, the more likely an impermissible conflict will occur.

Ethics rules strictly prohibit concurrent representation of clients with directly conflicting interests. Unfortunately, this rule raises many questions of interpretation without much guidance. For example, what is "directly" adverse? When might an attorney have a reasonable belief that the representation is permissible? How much of a conflict does it take to adversely affect the relationship?

If the matter is potentially adverse to the first client, and the first client does not agree to your representation of the second client, the representation will likely be impermissible. Thus, in this type of situation, the practitioner is forced to decide whether the potential conflict will become an actual conflict.

The duty to preserve a client's confidences survives the termination of the attorney-client relationship (or, in the context of this topic, a dormant trademark file). The "substantial relationship test" is used in this context as well. Courts focus on whether the attorney would have or reasonably could have learned information in the first representation that would be of significance in the second.

Other than any effect on the relevance of the search to the trademark, the timing of the last client contact should not become a factor in determining a conflict. The key question is still whether the attorney should expect a potential conflict.

The Seventh Circuit set forth a three-step test for determining substantial relatedness. First, the court will try to recreate the actual scope of the prior representation. Secondly, the court will ask what confidential information a reasonable client would have given to a reasonable attorney in the course of such representation. Finally, after the first two inquiries, the court will presume that the client did share any information a reasonable client would have given his attorney, and ask whether this information is relevant to the second representation. If the information is relevant, the Court will find that the attorney had an improper conflict of interest in representing the second client.

One way to handle the matter is by seeking the informed consent of both parties, particularly if the chances of a potential conflict becoming an actual conflict are remote. A written consent agreement should fully inform the parties of the potential conflict and the risks involved. Most conflict of interest problems can be waived by the affected parties (the only exception is where the conflict is so great that an impaired relationship with one of the parties is inevitable).

(2) The inventor asks your advice when a similar concept was the subject of an application handled by one of your partners last year.

Rule 1.10 of the Model Rules of Professional Conduct establishes a two-step analysis for attorneys associated in a firm. The first step (a) is to decide whether an attorney practicing alone would be barred from taking on a matter under the conflict of interest rules. If so, the second step (b) is automatic. The same bar applies to all attorneys who are associated in the same firm. No distinction is made between partners, associates, or “of counsel” attorneys.

A “firm” as defined in the Rules can be interpreted as a private firm, an organization’s legal department, or a legal services organization. The key is the exact nature of the relationship; the relationship is decided on a case-by-case basis. Relevant factual inquiries could even include attorneys sharing the same office space, libraries, or secretaries.

The purpose of this rule is to prevent an attorney who is barred from representation from simply handing the matter over to a partner or associate. “The exact relationship is immaterial, so long as they were in some way associated in the practice of law”.

Illustrative Example

An attorney in Chicago represented a major corporation in litigation against several oil companies. An attorney in the firm’s Washington, D.C. branch office was preparing a lobbying effort for the same oil companies. The matters were substantially related, and neither attorney knew of the other’s involvement. The court applied the automatic bar rule and considered the firm’s large size, separate offices, or the fact that the attorneys did not talk to one another as irrelevant facts. Once the relationship was discovered, the firm had to

take remedial action and withdraw from the case. A client had already paid the firm $2.5 million in fees, resulting in a suit against the firm by the shareholders of the client.

In some cases, because of the timing of the notice of the conflict, judges have refused to disqualify the firm when balancing the conflict and potential damages to the client with the hardship it would impose on the client if the relationship were to be severed.

(3) You take a partnership in a firm acting for the opponent in an opposition handled by you at your previous firm.

Canon 4 states that "[a] lawyer should preserve the confidences of his client".

Disciplinary Rule 4-101 and 37 CFR 10.57 indicate that the "confidences" that should be preserved relate to information that would be protected by the attorney-client privilege. "Secrets" refers to other information that the client has requested be kept secret or which would be embarrassing or detrimental to the client if disclosed.

The law is quite clear that the new partner (or a new associate) is prevented from representing the former client's opponent (the new client at the new firm) in an action that involves matters substantially related to the attorney's former relationship.

The basic inquiry is whether it reasonably could be said that the attorney, in the former relationship, acquired privileged information relevant to the new firm's representation against the former client. Since the facts of this hypothetical indicate that the attorney was directly involved, the answer will be in the affirmative. The court will find that a substantial relationship existed between the former and present representation. Thus, the second relationship will be improper unless the former client consents that the attorney, as a member of another firm, may represent the opponent.

A more difficult variation of the above hypothetical is if the entire new firm can be disqualified from representing the new attorney's former opponent as a result of the new attorney's disqualification.

If the new attorney is disqualified, there exists a rebuttable presumption that the new attorney shared confidences with the new firm. If the new firm fails to rebut the presumption, the firm will be vicariously disqualified from representing its client.

In order to rebut the presumption of shared confidences, it is necessary to demonstrate that sufficient institutional mechanisms have been set up to prevent the flow of confidential information. The factors a court will consider are: (1) the size of the firm (small firm or large firm with the new attorney in a different practice group or branch office), (2) likelihood of contact with attorneys handling the representation, (3) whether the attorney shares in fees from the litigation, and (4) internal rules which prevent the attorney from gaining access to litigation information.

The bottom line is that when a firm makes a lateral hire, the firm should make sure that mechanisms are in place to assure that the new attorney is isolated from any matter even remotely connected with the attorney's prior employment.

Illustrative Example

A law firm hired a judge's law clerk who was assigned to an infringement case that the law firm had handled. However, the court refused to disqualify the firm because the firm had established a "Chinese Wall" around the new hire. Before the new hire started, the firm notified all of its attorneys that a "Chinese Wall" had been established around the new hire. The firm placed locks on the doors of offices and storage rooms where files relating to the case were kept. Furthermore, documents related to the case were stored separately from the main file room. In view of these and other precautions, the firm was not disqualified.

(4) You are appointed Patent manager in a company, the main rival to your previous employer for whom you were Patent Officer.

As an attorney for the company, the company takes the role of the client. Thus, the attorney would be under the same duty to maintain the confidences of the company as an attorney who changed law firms.

Courts have applied the concept of "substantially related matters" in this situation.

In Guzewicz , the court ruled that a former general counsel for a corporation may represent stockholders in a derivative action against management where the claim does not involve matters substantially related to the attorney's prior work in the corporation.

In addition to conflict of interest situations, non-competition and/or confidentiality agreements may apply in the corporate setting.

An interesting corporate-related case discussing conflicts of interest occurred in Telectronics v. Medtronic. In Telectronics, an attorney was in-house counsel for Corporation A. The attorney obtained a patent for an employee's invention who assigned the rights to Corporation A. The employee later left Corporation A for Corporation B. The attorney left Corporation A for Corporation C. Years later, Corporations B and C both thought that they had rights to the original patent through a license. Corporation B sued Corporation C for infringement. Part of Corporation C's defense was to attack the patent. Accordingly, the attorney who helped procure the original patent was now attacking his own work product. In the suit, Corporation B tried to have the attorney (who now worked for C) disqualified based on the "former client" status of Corporation B and Employee.

The Federal Circuit stated that Corporation B and the employee were never clients of the attorney (the attorney/client relationship as to the attorney and Corporation A was not disputed, and A waived the privilege). The Court ruled that an assignment of a patent does not transfer an attorney-client relationship. Also, the Court ruled that Corporation A was the client, not Employee. Employee could not have expected his confidences to be withheld from Corporation A. Thus, the attorney/client privilege runs to the client, not the patented property or the attorney's work product.

ADDITIONAL HYPOTHETICALS

(A) Should there be minimum standards set forth for an IP firm's trademark and patent due date docketing system?

Discussion: Yes. The more difficult question is what those standards should be. To be safe, a firm should use a standard that exceeds the normal "due care" malpractice standard. Firms should have a dual docketing system in which all important dates go into both a central docketing system (some firms have "group" or "office" systems), and into individual calendar systems maintained by each attorney involved in a matter. Some large full-service firms use a separate (and more extensive) docketing system for their IP groups, because of the heightened importance of the docketing system in the IP practice area.

(B) You agree to act as an expert in a patent case. You state an opinion as to law and certain facts. A few years later, your Client A (represented by you) is on the reverse side of the identical issues. Should you advise Client A as to your prior "on the record" position? What if you do not?

Discussion: If the position that you have taken is material to the outcome, the safest course is to inform the client. ABA Formal Ethics Opinion 93-377 holds that if a law firm takes different positions

on the same legal question for two separate clients, and it is likely that the firm's position in one could adversely affect the contrary arguments in the other case, a Model Rule 1.7(b) conflict exists, requiring disclosure and consent by each client. Here, it is arguable that Client A should be informed that opposing counsel might cite your testimony against you (particularly if there is reason to believe they may become aware of it). Some ethics attorneys disagree with 93-377, and some would probably distinguish the "expert testimony" situation, but caution suggests disclosure would be advisable. At a minimum, there is a potentially serious business conflict that would be exacerbated by non-disclosure.

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PAPER: FLO/3.4.1. by Francis AHNER

"Fishing for evidence" in France

I. THE BURDEN OF PROOF

The patentee does in fact have the burden of proving the infringement of which he claims to be the victim. This is a general principle watered down by two exceptions, the scope of which is, however, limited. In certain cases, in fact, it is provided that it is possible to demand from the defendant a certain co-operation in the production of proof.

1. In application of Article 10 of the Civil Code and Article 11 paragraph 2 of the New Code of Civil Procedure (in annexes 1 and 2), each of the parties is obliged to assist the legal process with a view to the demonstration of the truth, and, in principle, an injunction may be issued against one of the parties to produce an element of proof which is held by that party.

Such a measure, which is infrequently applied by the French Courts, can, however, be contemplated only in the case where the patentee has already adduced an initiation of proof which the defendant may be compelled to supplement. In no circumstances can the defendant be compelled to prove anything entirely in the place of the petitioner and thus to make good his deficiency.

2. There is a second exception relating to the reversal of the burden of proof within the context of a process patent. This principle has been formalised in Article 34 of the agreement on TRIPS (in annex 3) which specifically provides that "any identical product manufactured without the consent of the holder of the patent will, subject to proof to the contrary, be considered as having been obtained by the patented process if:

a. the product obtained by the patented process is novel; or if

b. there is a high probability that the identical product was obtained by the process, and the holder of the patent has not been able, despite reasonable efforts, to determine which process was in fact used".

The final paragraph of Article 34 provides that, in the event of the submission of proof to the contrary, the legitimate interests of the defendants appertaining to the protection of their manufacturing and commercial secrets shall be taken into account.

We shall encounter in this instance the same difficulties of preservation of secrecy and of confidentiality as on the occasion of infringement seizure operations, to which we shall refer subsequently.

II. THE MEANS OF PROOF

To adduce proof of infringement, the patentee may have recourse to any means. This principle is expressly stated in Article L-615.5 (in annex 4) of the Intellectual Property Code (IPC).

These means certainly include avowal, presentation of the article complained of, presumptions and expert assessment.

It is certainly the case that all these elements of proof may be contested by the adduction of proof to the contrary. For this reason, French legislation has established specific means for adduction of proof, namely the infringement seizure procedure.

It is of interest to note that the infringement seizure was authorised in France for the first time on 7 January 1791 by the Constituent Assembly.

Such a procedure, which is specifically intended to establish the substantive nature of the alleged infringement, is not obligatory. In practice, it is nevertheless observed that, given that this procedure is implemented under the control of a judge, the courts tend to give a certain preference to this mode of proof.

Article L-615.5 of the IPC introduces the principle of the infringement seizure, the details of implementation of which are prescribed by the Decree of 15 February 1969.

In accordance with this procedure, the proprietor of a patent or of a patent application is entitled to cause the execution, by any bailiff, of the detailed description, with or without actual seizure, of the products or processes alleged to be infringing.

To execute such a seizure, it is necessary to obtain in advance an order from the President of the Court of the place of the alleged infringement.

In practice, such an order is obtained without any difficulty just on production of an official copy of the patent, of an extract from the National Register of Patents confirming ownership of the property right, and of a statement of payment of the annual fees certifying that the property right is in force.

It should be noted that this procedure is likewise open, under certain conditions, to concessionaires of an exclusive right of exploitation, as well as to holders of a licence of right, of a compulsory licence or of an official licence.

To execute such a seizure, the bailiff is generally assisted by an expert, who in most cases is an Industrial Property attorney chosen by reason of his knowledge of the cited patent.

In practice, the order submitted to the President of the Court is drafted by the counsels of the patentee and, depending upon each particular case, it is accordingly customary to specify in detail what will have to be the precise task of the bailiff.

It is important to note that the alleged infringer is never warned either of the precise location or of the time when the seizure operations will be implemented. The effect of surprise is therefore intentional, to prevent any attempt at dissimulation of elements of proof on the part of the party against whom the seizure is executed.

The order issued by the President of the Court in general authorises the bailiff, accompanied by the expert, to gather all the elements of proof which are necessary for the purpose of demonstrating to the Judge the origin, the nature and the extent of the alleged infringement.

III. THE DIFFICULT BALANCE BETWEEN PROOF AND SECRECY

Accordingly, it is readily understood that this draconian procedure has necessarily raised practical problems, as it was necessary to preserve a balance between, on the one hand, the need to be able

to adduce proof of the infringement and, on the other hand, the need to preserve the secrecy of the business of the party against whom the seizure is executed.

A first measure permitting the immobilisation of certain papers necessary for the proof of infringement consists in having them visaed “ne varietur” by the bailiff so as to be certain that it will be possible to relocate them subsequently without risk of modification or of substitution, for example in the course of an investigation by expert auditors which is initiated for the purpose of evaluating the amount of the loss suffered by the patentee.

It is clear that the bailiff may likewise visa in this way any type of technical document such as plans, manufacturing data sheets, control records of raw materials or manufactured products, etc.

The Industrial Property attorney who accompanies the bailiff in order to assist him in his task does in general take the more active part in the selection of the documents, papers or products to be retained or to be set aside. Accordingly, it appears logical that the expert accompanying the bailiff, most frequently an Industrial Property attorney, should not belong to the company of the patentee and should be subject to an obligation of confidentiality or of professional secrecy.

In these circumstances, certainly, the French legal practice, with regard to this specific question of the balance to be maintained between the need to apply a sanction to the infringement by adducing proof of the latter and the need to preserve the secrecy of the business of the party against whom the seizure is executed, has noted hesitations, and has perhaps unfortunately been incorrectly inspired by certain other foreign procedures which are more demanding and more onerous, without necessarily being more effective.

In the course of the seizure operations, in the event of disagreement as to the choice of the papers to be retained, the practice has become oriented towards the placing in a sealed envelope of the papers adjudged to be necessary for the proof by the bailiff and the attorney, but considered as secret by the party against whom the seizure is executed.

These papers, the core of the dispute, are then delivered to an expert appointed by the court, which has entrusted to him a very precise task for the purpose of determining the fate of the papers seized.

It is clear that the persons present in the course of the seizure operations and the subsequent expert assessment appertaining to the qualification and the destination of the papers, will have to be subject to secrecy and confidentiality.

In France, the professional secrecy of Industrial Property attorneys is governed by Article R.422-54 of the IPC, Article 12.3 of the Decree of 29 July 1997 and Articles 226-13 and 226-14 of the New Penal Code (in annexes 5 and 6).

In practice, the expert appointed by the Court will conduct his expert assessment without the presence of the parties, but with the assistance of the barristers and Industrial Property attorneys of each one of the parties.

Accordingly, the expert has as his task to organise the confidentiality of this procedure.

A plurality of solutions have been contemplated:

1. A judgement dated 6 December 1996 of the Court of Paris accepted the principle of the pre-eminence of confidentiality, that is to say that the expert had as his task to sort between the confidential papers and the non-confidential papers, only the latter being capable of being utilised for the purpose of adducing proof of infringement.

Such a solution is certainly subject to criticism in numerous ways.

(BARKATS v. FRANCE TELECOM)

2. On 4 July 1997, the Court of Paris had considered that the party effecting the seizure must have access to all the documents likely to contribute to proof of the infringement and only to those documents. The Court added that the responsibility for qualifying as confidential or not confidential the documents found in his factory should not, under pretext of confidentiality, be left just to the tolerance of the party against whom the seizure is executed. Accordingly, the Court invoked the principle of the pre-eminence of the need for proof of infringement. In other words, a paper useful for proving infringement has lost its allegedly confidential nature.

(SERME v. SYNTHESIA)

3. A third solution was adopted within the context of an order in chambers dated 24 November 1997 by the Court of Paris. This order specified in particular that, “In order to preserve the possible confidential nature of the papers seized, the expert shall open the envelope [in which the bailiff put the seized documents] and make a selection between the documents in the presence only of the barrister and Industrial Property attorney of each one of the parties, whose identity shall have to be communicated, before the first expert assessment meeting, to the expert and to the parties, all these persons being committed to an obligation of confidentiality”.

The order then specifies that, “If the documents retained by the expert as being necessary for the proof of the alleged infringement do nevertheless have a confidential nature, only the above-named persons shall be able freely to have access thereto”.

(M.S.D.-CHIBRET v. SEARLE & MONSANTO)

4. A very recent decision of the Court of Paris dated of September 30, 1998, is also of interest. In this case B.M.S. manufactured its product Taxol outside of France and imported it in France. The Court validated the seizure procedure carried out at the Agence du Médicament, which is the national institute having delivered the authorisation to put the product on the market. The seized documents were concerned with the preparation process of the active substance.

The Court confirmed that R.P.R. can use under its own responsibility in the framework of foreign law suits the documents considered by the Expert as necessary to prove the infringement.

(RHÔNE POULENC RORER v. B.M.S.)

5. Other similar suggestions have likewise been advocated with regard to the fate of these evidential papers which are necessary but confidential. It is in fact possible to prescribe a restriction of access to a limited number of persons of a business who shall be caused to follow the procedure, while prescribing appropriate measures to prevent disclosures to other persons.

It is likewise possible to prescribe a limitation of use of the papers, in the present case use only for the infringement proceedings appertaining to the particular patent cited before the Court before which the matter has been placed.

These restrictions of access and/or limitations of use do however raise a certain number of difficulties in French legal practice.

First of all, in order that such limitations should be strictly respected, it will be necessary to have sanctions effectively applied.

Then, according to French practice, it is moreover necessary to comply with two essential principles: the first being the principle of the respecting of the hearing of arguments from all interested parties (respect du principe du contradictoire) and the second being the maintenance of the public nature of hearings.

Finally, the provisions of Article 24 of the Brussels Convention (in annex 7) specify the principle of the free use of the means of proof in various proceedings conducted in different States of the European Community, a principle which seems to be in conflict with any restriction of access or limitation of use.

In consequence, an effective solution might consist in organising the confidentiality of the papers seized within the context of an expert assessment initiated by the judge and carried out in the presence only of the barristers and Industrial Property attorneys of the parties, these being committed to the obligation of confidentiality.

In the event of disagreement between these various representatives of the parties, the expert shall have to refer to the judge responsible for the conducting of the expert assessments in order finally to lead to a final sorting between only two types of documents:

a. the documents which are genuinely necessary for the proof of the infringement (having thus lost any confidential nature), and

b. the other documents, which shall purely and simply be returned to the party against whom the seizure is executed, and definitively removed from the debates.

At the conclusion of such an expert assessment, the judicial expert should be able to provide the court with at least an initial motivated opinion, regarding the substantive nature of the infringement.

Annex 1: Article 10 of the French Civil Code

Art.10 (Law No. 72-626 of 5 July 1972) Each party shall be obliged to give its assistance to the legal authority with a view to demonstrating the truth.

Any person who, without just cause, fails to comply with this obligation when he has been lawfully required to do so may be compelled to comply therewith, if necessary under penalty of a default charge or of a civil fine, without prejudice to damages.

Annex 2: Article 11 paragraph 2 of the French New Code of Civil Procedure

Art. 11 The parties shall be obliged to give their assistance in measures of preliminary examination, it being left to the judge to draw any conclusion from an abstention or from a refusal.

If a party holds an element of proof, the judge may, upon the petition of the other party, enjoin him to produce it, if necessary under penalty of a default charge. He may, upon the petition of one of the parties, request or order, if necessary under the same penalty, the production of all documents held by third parties if there is no lawful obstacle.

Annex 3: Article 34 of the Agreement on Trade Related of Intellectual Property Rights (T.R.I.P.S. Agreement)

Art. 34 Process patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different form the patented process.

Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

a. if the product obtained by the patented process is new;

b. if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

Annex 4: Article L-615.5 of the French Intellectual Property Code

L.615-5: The owner of a patent application or the owner of a utility certificate application or the owner of a patent or of a utility certificate shall have the possibility of furnishing proof by any means whatsoever of the infringement of which he claims to be a victim.

He shall further be entitled, on an order given by the President of the First Instance Court of the place of the presumed infringement, to direct any bailiffs, accompanied by experts of his own choice, to proceed with a detailed description, with or without effective seizure, of the allegedly infringing articles or processes. Such order shall be provisionally enforced. It may be subjected to a security on the part of the plaintiff. In that same order, the President of the Court may authorize the bailiff to carry out any enquiry required to ascertain the origin, nature and scope of the infringement.

The same right shall be enjoyed by the licensee of an exclusive right of working under the conditions laid down in the second paragraph of Article L.615-2 and in the fourth paragraph of Article L.615-2, by the holder of a license of right, a compulsory license or an ex-officio license in accordance with Articles L.613-10, L.613-11, L.613-15, L.613-17 and L.613-19.

If the petitioner fails to institute proceedings before a Court within a term of 15 days, the seizure shall automatically be void, without prejudice to any damages.

Annex 5: Decree of July 29, 1997

12.3 Professional secrecy.

Industrial property attorneys are bound by professional secrecy, advice on any subject sent by an industrial property attorney to his client, or intended for the client, and correspondence exchanged between the client and his industrial property attorney are covered by professional secrecy.

The industrial property attorney must, because of the professional secrecy by which he is bound:

refuse to give evidence of what he may know about his

clients or professional matters except in those cases laid down by law;

refuse to produce his clients' documents and files to

any person other than the parties themselves, their heirs or assigns or authorized representatives, or any person authorized by law or by a decision of a court, on proof of their identity and standing.

Professional secrecy cannot be cited against persons who are statutorily empowered to carry out judicial, administrative or customs inquiries, or against the courts.

In the event of enquiries by police or magistrates and judicial, customs or disciplinary procedures, especially searches and seizures, relating to his professional activity, the industrial property attorney shall notify the Chairman of the company so that the latter, or his representative, can provide assistance and endeavour to ensure respect for professional secrecy, especially within the framework of the provisions of the Code of Criminal Procedure.

Annexes 6:

Article R.422-54 of the French Intellectual Property Code

Art. R.422-54. The Industrial Property attorney:

2. Shall observe professional secrecy: such secrecy shall extend, in particular, to the professional advice which he gives to his client, to the professional correspondence exchanged and to all documents prepared in connection therewith;

Articles 226-13 and 226-14 of the French New Penal Code

"Art. 226-13. The disclosure of information of a secret nature by a person who is the depository thereof by status or by profession or by reason of a temporary function or task shall be punished by a term of imprisonment of one year and a fine of 100,000 F".

"Art. 226-14. Article 226-13 shall not be applicable in cases where the law demands or authorises the disclosure of the secret".

The Court of Cassation shall apply Article 226-13 in cases where it is necessary to guarantee the security of the confidences which an individual has to impart to a person whose profession demands that secrets are entrusted to him.

Now, this is so in the case of industrial property attorneys upon whom the law confers the monopoly - which they share with barristers - "to advise, assist or represent third parties with a view to obtaining, maintaining, exploiting or defending industrial property rights".

French bilateral professional Convention signed on 17 September 1998

Convention confirming confidentiality upon all correspondence between barristers and Intellectual Property attorneys, signed on 17 September 1998;

This convention prohibits any disclosure by the addressee and any utilisation by anyone of the correspondence communication between barristers and Intellectual Property attorneys.

Annex 7: Article 24 of the Brussels Convention Provisional, including protective, measures Article 24

Application may be made to the courts of a Contracting State for such provisional, including protective, measures as may be available under the law of that State, even if, under this Convention, the courts of another Contracting State have jurisdiction as to the substance of the matter.

PAPER: FLO/3.4.2 by Annika Ryberg, Director and Legal Counsel, Astra AB

Fishing for Evidence

OUTLINE

1. The basic rules on evidence in the TRIPs Agreement

2. Different principles for some types of evidence

2.1. Pre-litigation

2.1.1. Saisie and similar proceedings

2.1.2. Anton Pillar Order

2.2. Litigation

2.2.1. Discovery countries

2.2.2 Non-discovery countries

3. Discovery - a company perspective

3.1. Non-U.S. discovery

3.2. U.S. discovery

3.2.1 Documents

3.2.2. Interrogatories

3.2.3. Depositions

4. Privilege rules and discovery

5. Evidence in a future European judicial system for patent litigation

5.1. Documents

5.2. Experts

PAPER: FLO/1.2 by Jürgen Betten

IP and the Internet

1. Introduction

The Internet is about 30 years old and has its origin in the year 1968 when a project group of the Department of Defence of the USA proposed - for defence purposes - the ARPANET (Advanced Research Projects Agency). In the early 1970's the Internet developed from the ARPANET.

The Internet can be described as a global network connecting millions of computers and which uses a common Transmission Control Protocol, the TCP/IP. In order to get access to a particular internet computer, the Internet Protocol (IP) address is used.

The most important service of the Internet is the World Wide Web (WWW or 3W) which was developed in 1993 in the CERN in Geneva, Switzerland. It has a special transmission protocol, the http (Hyptertext Transfer Protocol) with a special language HTML (HyperText Markup Language) to describe the documents (websites or web pages) stored on servers throughout the world. It is estimated that more than 100 millions of web pages exist with exploding tendency.

The other main service of the Internet is the electronic mail or e-mail. It is estimated that there are more than 70 millions of e-mail users with yearly increase rates of at least 110%.

The success of the Internet was mainly due to the fact that almost no rules exist, that it is free of charge, easy to use, and meets the requirements of the young generation to explore the world through the computer.

At the very beginning when the Internet was mainly used by governmental and university people it was considered as an area free of law. But it turned out quite fast that the existing laws also cover the Internet and that the Internet does not give rise to really new IP problems, if you take into account the broadcasting or radio transmission or the satellite transmission.

In this workshop we want to discuss only a few problems, mainly in the field of trademarks and patents. Nevertheless, we know that there are also a lot of problems in the copyright field.

As far as copyright is concerned you should keep in mind that the international conventions, such as the Berne Convention for the Protection of Literary and Artistic Works, and the National Copyright or Author's Protection Laws mention only an unlimited list of protected works. Further, it is the primary function of the copyright law to let the author have a share in the fruits of his work, i.e. any use of the work.

Therefore, and this was purported by a member of the competent senate in the German Federal Supreme Court some weeks ago in a conference of lawyers and patent attorneys specialized in the computer law, that it is quite clear that the judges will find ways to protect the rights of an author also in the Internet with the copyright law as it stands. Of course, it would be better - for clarification purposes - to have a so-called transmission right besides the right to reproduce or copy. Nevertheless, the copyright law can successfully be used in the Internet already now.

One last general remark. Please make it clear to your client that the website or homepage is a very sensible publication which can easily be accessed from all over the world and that he should not only entrust the computer freaks in this firm with the design of the homepage, but it should be checked by the management, the law department, or attorneys as with usual publications.

2. Trademarks

2.1 System of Signs Designating Products or Companies

We have heard yesterday in the workshop 2.4 more about domain names. If you look at the IP in general, we have to ask how the domain names fit into the system of trademarks, service marks, trade names (commercial names) and the like.

All these "signs" are considered equal rights and the priority is decisive which sign prevails over the other sign. The general opinion as to domain names is that they are at least some kind of trade names so that they are to be considered to some extent equal rights to trademarks and trade names.

The generic top level domains (gTLDs) like

.com, .edu, .gov, .int, .mil, .net, and .org

and the two-letter top level domains (TLDs) like

.ca, .de, .tm (Turkmenistan), .tv (Tuvalu), .us etc.

are registered on a first-come, first-served-basis and are accessible throughout the global Internet.

Opposite thereto the trademarks and trade names are, due to the principle of territoriality, protected by national laws only for one country. In the great majority of countries the trademarks are also registered on a first-come, first-served-basis and the prior use is relevant only in exceptional cases, whereas in the US and some other countries the trademark must normally be used before granting it protection.

This means that for trademarks only in a few countries the prior use has some influence on the priority, whereas in most countries the priority is determined by the application date.

With trade names, in most countries the first use of the trade name in the corresponding country determines the priority, whereas the registration in the company register is more of declaratory nature.

In view of the fact that the domain name is considered as a trade name, it can only be enforced in a country against a younger national trademark or trade name, if it has been used in this country. For this it is in my opinion, however, not sufficient to prove the "use" by showing that someone from this country had access to the web page of the domain name owner. The domain name should be used in commerce of this country, i.e. on advertisements, leaflets, business papers or in connection with the product, if the product can be distributed

- like a computer program - through the Internet.

2.2 Protection of Names of Computer Programs (German Speciality)

In this connection a German speciality should be mentioned which is quite unknown outside Germany or even with German lawyers and patent attorneys, namely the protection of names of computer programs as "title". From a personal survey I know that this kind of protection might be available also in other countries, at least on the European continent.

Just as in some other countries of the world, the title of literary and artistic works, such as books and films, is protected in Germany. This protection used to be provided for by the Unfair Competition Law. Since January 1, 1995 this protection is provided for by section 5 of the new Trademark Law. This kind of protection, which does not require a registration, but only the use of the title in Germany, was extended in the last years by the German Federal Supreme Court to the names of games, computer games, and computer programs, if they were distinctive. According to the grounding of the decision "PowerPoint" this new kind of protection can also be used for other "intellectual products" for which a name is used. This may help in those cases where a company A forgot to register the name of the computer program as a trademark in Germany, and a company B registered a trademark after the name of the computer program of company A was used in Germany.

If you can show e.g. that you have offered the new computer program in the Internet and that some programs carrying the name had been shipped immediately thereafter to Germany and are usable in Germany, your program is protected as "title" in Germany as from the date of offering the product in the Internet, without registration as trademark.

2.3 Does incorporating a trademark in a web page fulfill the "use" requirement for a trademark through the Internet?

In most countries where the use of the trademark is compulsory either before registration (as in the USA and Canada) or after a grace period of - in most countries - five years after registration, the trademark can only be enforced if the "use" requirement has been fulfilled.

In most countries the trademark must be used in connection with the goods or services in respect of which it is registered. Some trademark laws even prescribe the use on the goods or on the packaging or wrappings and consider the use of the trademark only in advertisement not sufficient use to maintain the trademark right.

In the USA the trademark owner must establish that the mark was used in commerce of the USA, that the mark was affixed to the goods, and that the use in commerce was considerable and not only de minimus use.

To use the trademark only on the website in the Internet, i.e. on the display, will most probably not be considered sufficient use in all countries from which the website could be accessed.

I have also doubts whether it will be considered sufficient use if you only prove by a log file that your website has been accessed by users from that country.

In my opinion the product (or the packaging or wrapping thereof) containing the trademark must be shipped to the country in which the priority of the trademark is claimed.

2.4 Special Internet Problems in connection with Trademarks

2.4.1 Meta-Tags

I have already mentioned in the introduction the HTML (HyperText Markup Language) which defines the logical structure of the document or web page, not the layout. Its commands are designated as "Tags" and written between acute brackets <>. One special command is the <META> command or Meta-Tag which contains information about the document (author, key words, abstract of the document etc.)

This information is used especially by search engines to find the document and to determine the degree of relevancy of the document. With this it is possible to use trademarks as key words, your own trademark or - and this is more important for us - also the trademark of a competitor. You should realize that these key words cannot be seen by the end user without special efforts and this explains why it is possible that you hit upon a document which does not contain the key word for which you were searching.

Let us assume that a competitor of "Coca-Cola" uses the trademark "Coca-Cola" as Meta-Tag. If now somebody is looking for "Coca-Cola" he will get a list of hits which contains also the homepage of the competitor. If the competitor optimizes this by multiple insertion of "Coca-Cola" as a Meta-Tag, he can even come up as number one or two on the list of say 3500 hits. Since most probably only the first hits of a search will be looked up, this would mean that it is possible to misuse a trademark of another company by Meta-Tagging.

In some countries, at least on the European continent, this might be considered unfair competition. Some persons doubt whether this hidden use of someone other's trademark is considered a trademark infringement, because the trademark is hidden and not used as a trademark.

According to Art. 5 No. 1(a) of the European Trademark Harmonization Directive "the proprietor of a trademark is entitled to prevent all third parties using in the course of trade any sign" - i.e. even an invisible sign - "which is identical with the trademark in relation to goods or services which are identical with those for which the trademark is registered". If we assume that the web page relates to identical goods or services, the use of the Meta-Tag could probably be seen as an infringement of Art. 5 No. 1(a) of the European Trademark Harmonization Directive.

In Art. 5 No. 3(b) of the European Trademark Harmonization Directive it is made clear that it may be prohibited "using the sign on business papers and in advertising", i.e. on the web page.

In the USA this was considered unfair competition because of confusion or misleading representation. Stephanie Chong of Canada questioned in an article, "whether the end-user might be confused by trademark usage which he or she cannot see. The end-user may not be confused once the list of hits is perused and each site examined. If, however, you have a long list of hits and only the first ones are examined, the risk of confusion might be high if the wrong webpage is at a prominent place".

2.4.2 HyperLinks

We distinguish between normal "links" or "outline links" and so-called "inline links" or "embedded links". With the outline links you will jump after a click to a remote webpage.

In the case of the embedded link the object (the other or remote webpage or part thereof) will be integrated in the base webpage you see in the moment. If this integrated part contains someone else's trademark, this might be a trademark infringement. The same might be true if by a normal

(outline) link a special page of someone else is addressed, without seeing the first or home page so that, if a trademark of someone else is used on this (special) page, this might be considered as use of the trademark in the base website.

A special case of the embedded link is the so-called framing, where the embedded parts of remote webpages of other parties are framed. Apart from an infringement of the copyright act also trademark infringement could arise.

3. Patents

3.1 Preliminary Results

Concerning the patent protection of computer programs which was a topic on the last Forum I would like to make a preliminary remark.

In view of the practice of the last two to five years and the developments in the USA, Japan, Korea, and in Europe, it can be said that you can get a patent in principle for all computer programs (including business methods) which are new and inventive and for which it makes sense to invest the high costs for filing a patent application. This is at least valid for the USA, Japan, Korea, the EPO, and the GPO. In this connection I would like to mention only a few decisions: “In re Alappat” (US-CAFC), “Sohei” (Technical Board of Appeal of the EPO) and now “State Street Bank” (US-CAFC).

You probably know from the Annual Report 1997 of the EPO that the applications concerning data processing had in 1997 the highest growth rate of 28%. It seems to be that even the UK Patent Office might find some ways in the future to come along the still negative court decsions or to induce a new positive court decision in the UK.

Taken this, it is clear that also for all Internet technologies patents are granted to a great extent. According to a report of an American search company over 500 PCT patent applications were published in 1997 by WIPO for technologies concerning the Internet such as: browsers, data compression, e-commerce, interfaces, Java applications, multimedia, payment, protocols etc. For quite a lot of these PCT applications the regional phase with the EPO was entered. Therefore it seems to be worthwhile to have a closer look at how a patent application could be better prepared to meet the requirements of a use of the patent in the Internet world.

3.2 Claim Drafting

3.2.1 Program Product or Media Claims and Internet Claims

In the moment the hottest topic in the field of patent protection of computer programs is the protection of “program product claims” or “media claims” - in the USA also named “Beauregard” claims. Such “media claims” read as follows:

A computer program product comprising:

a computer usable medium having computer readable program code means embodied ... or

A computer readable storage medium containing a program to execute a process A, a process B, a process C ... using a computer ... or

Computer program product comprising:

a machine readable code stored on a program storage device and/or readable by a machine

and/or capable of being transmitted by a computer,

said code causing the machine ...

The intention of such media claims is to enforce the patent against direct infringement, i.e. to protect the product which is commercialized or put to the market, whereas you can enforce your method claims only under contributory infringement.

Such kind of claims are granted by the USPTO, the Japanese and the Korean Patent Offices. With the EPO and the GPO it is not yet clear whether and in which form such kind of claims are granted.

In my opinion it is not a question of amendment of the EPC or the EPO Examination Guidelines, but only a question of finding convincing arguments according to which such kind of claims are necessary for sufficient protection of the invention.

It is generally accepted that the enforcement against direct infringement is easier to establish than against contributory infringement. Further, infringement of a European patent is dealt with by national laws, which are still not harmonized. Further, it would be discriminative in comparison with other technologies to grant only method claims and not claims directed to the actual product being commercialized. Therefore a need exists to have protection against contributory (indirect) and direct infringement.

According to the German law adapted to the EPC, it is up to the applicant to decide for what kind of claims he wants to have protection. The same is valid for the EPC.

For the Internet you need claims that would read not only on storage mediums, but on the transmission and electronic distribution or such kind of claims like computer program readable by a computer system ... computer program storable into a memory of a computer system ...

With such “Internet claims” you could stop someone who is offering the computer program stored on a server outside the patented area and could be downloaded in a country where a patent exists.

According to a not yet published decision of a Technical Board of Appeal of the EPO in principle the media claims and the Internet claims are admissible. It is now up to the Examination Division to decide which form such kind of claims should have. The German Patents Court will most probably decide on this question during the next year.

3.2.2 Apparatus and Use Claims

In case of distributed computing on different places of the world by using one inventive and protected method, apparatus and use claims might be helpful, besides the method claims. Let us take a multi-user system in global environment distributed all over the world and a patented system (covered by method and system claims) which is run partly on a workstation in Tokyo, on a workstation in Paris, and a workstation in New York.

In this case you need not only method and system claims to protect the invention, but also apparatus claims directed to the individual workstation or use claims (use of a workstation for carrying out the method or part thereof).

3.3 Protection of Data Structure

The protection of data structures, not of the data or the content itself, is especially important for protection of inventions in the database field. In view of the fact that in the Internet a lot of databases are stored all over the world, the database can easily be stored on a server in a country without patent protection.

According to the US-CAFC ("In re Lowry") data structures imply a physical organization of data and are therefore considered patentable. This data structure can also be considered as the frame of the data making it a physical entity and is therefore independent of the content or the data in the data structure.

This approach of the US-CAFC was taken over by the Japanese and the Korean Patent Offices and according to the new Japanese and Korean Examination Guidelines data structures are explicitly protected. Such a "data structure claim" could have the form:

Computer readable storage medium which contains data having a structure A, a structure B, a structure C ...

If the data structure of the database could be protected by patent claims, the essence of the database is protected. In this case a further claim should be directed to the use of the data structure, e.g. for access to the database or downloading of a part of the database, so that you can stop the use of the patent in a country with patent protection, even if the database is stored on a server in a country without patent protection.

For the time being data structures can be protected as a patent claim in the USPTO, Japan and Korea, but not yet in the EPO. This seems to be - in view of the EPO decision "BBC/Colour Television Signal" - only a question of time, as it was the case with the program product claims.

4. Infringement of IP rights

4.1 Is offering of protected products an infringement?

For the Internet the act of "offering" of protected goods or services is most important. According to Art. 29 (a) of the European Community Patent Law and Art. 5, 3.(c) of the European Trademark Harmonization Directive the "offering" of goods or services could be prevented as a separate act. The same is valid for a lot of other countries outside the EU.

It should, however, be mentioned that in some countries, probably in Switzerland, the offered goods or services must also be present in this country or in this jurisdiction. In the UK the offering must take place in the UK jurisdiction and I was told that it is not yet decided whether the offer through Internet is in the UK jurisdiction.

In case of doubt you still have the possibility to order the product through the Internet so that the product will enter the corresponding country.

One possibility to avoid an infringement by offering the protected product seems to be to use a disclaimer, such as "not for sale in UK" or the like, if the product is only protected in UK.

4.2 Enforcement of IP rights

It is my opinion that the main problems the Internet causes are not so much the IP laws, but the international enforcement of rights, namely

to identify the infringer,

to identify the place of infringement,

to determine the applicable law, i.e. the jurisdiction over the subject-matter and

to enforce foreign judgements.

Such problems were the subject matter of workshop 3.1 and are therefore not dealt with in this workshop.

5. Conclusion

In my opinion the existing IP laws are well prepared to solve the problems in relation to the Internet, even if they have to be stretched or extensive argumentation as to relevancy must be put forward, but we do not need a new IP Cyberlaw as some Professors are proposing. What we need is an improvement of the Treaty concerning Enforcement of Foreign Judgements and a harmonization of enforcement which was discussed in workshop 3.1.

PAPER: FLO/3.7.1 by Mogens Kring, Director General of the Danish Patent Office

National Patent Offices: To be or not to be

Ladies and Gentlemen,

Thank you for giving me the opportunity to take part in this very interesting FICPI Open Forum.

Opening remarks

I have been invited to say something about national patent offices and their prospects of survival. As I represent such an office and as we at my office have thought a good deal about this particular question, it is quite interesting for me to be able to present our considerations at this FICPI Open Forum.

When FICPI held its international conference in Copenhagen last year, I gave a speech at the opening of the conference. My main theme then was that – regardless of the emergence of new systems in the patent sector, including a Community Patent – it is important to preserve the national patent offices.

I suggested that some of the work with European patents might be delegated to those NPOs, that need such work in order to maintain a proper size, provided that they are qualified, and willing to do that work.

I will focus on European national patent offices. Should any of my remarks prove interesting or relevant in a wider geographical context, I would naturally be pleased.

Overview of the problem (Overhead)

This overhead shows the different strategies, which may be pursued by various NPO's in order to serve their industry. Several EPO member states have chosen strategy I. These countries have chosen not to build up in-house expertise for performing substantial search. If such a search is required as part of the grant procedure, it will be carried out by the EPO.

The necessary services for pursuing this strategy can be provided by the NPO's in a qualified manner more or less independent of the size of the NPO. It is my opinion, therefore, that countries which have chosen this strategy will not have any difficulty in maintaining their NPO at a level of competence suitable for their purpose.

Strategy II applies to the member states, which carry out search, and examination work on their own. This can only be done in a qualified manner if staff number exceeds a critical mass. The question of survival of NPOs of countries pursuing strategy II depends, therefore, to a large extent upon the size of the country - or more exactly, on the size of national patent activity of the country.

Mr. Bruce Alexander of Boult Wade Tennant, London, wrote an article in the magazine "Patent World" in March this year titled "Wither National Patent Offices?" I believe that he especially had "strategy II" offices in mind. I quote:

"Those NPOs which may face problems in future are the NPOs of all other countries of Europe which at present only handle a limited amount of national patent applications and grant patents on the basis of substantial search and examination at EPO level in house and whose clients want their NPOs to continue to offer this service together with commercial services including substantial searches".

The Danish NPO is in exactly this category. But also other NPOs in EPO member states are more or less in the same situation. Since I am most familiar with my own circumstances, I shall explain the problem as it relates to the Danish Patent Office.

Relations between customers and the Danish Patent Office

The Danish Patent Office has primarily customers from Danish trade and industry, patent agents, public and semi-public institutions, university researchers and independent inventors. We play a dual role in relation to the customers. On the one hand, we act as an authority; on the other, we conduct services on a commercial basis.

Our activities as an authority include the granting of patents, registration of utility models, trademarks and designs, and the general communication of know-how in this connection. This part of our work currently accounts for approx. 90% of turnover and is fully fee-financed, without any support from the Government.

Since our accession to the EPO in 1990, we have seen the authority-related part of our patent activities change quite dramatically. The number of applications from Danish applicants has remained unchanged: approximately 1,200 per annum. The number of foreign applications has, however, dropped from 5.800 to 300 per annum.

Our commercial activities consist of services sold to the Danish business community on market terms. At present these activities account for about 10% of turnover. Also these activities are of course fully paid for by the customers.

Typical examples of our commercial services related to patents are listed in the next overhead. They are:

Technical searches Profile analysis Surveillance

Training courses / education

Participation in projects

Companies use our commercial service for novelty searches, investigation of existing techniques, the legal status of rights in technical fields, etc. This enables them to estimate trends in development. The quality and applicability of these services depend very much on the Danish Patent Office having staff who are highly trained in both search and examination procedures.

To be somewhat more specific about the commercial services, I will give you the reasons why searches are so important. They lend inspiration to the solving of a technical problem reveal at an early stage whether other people have already thought of the same idea identify existing rights and make it possible to avoid infringing them show what other people are doing in the field provide a sound basis for a patent application.

The material accompanying the manuscript explains in more detail the nature of the various services. Two examples are given from our commercial activities, which are patent- related, and which require that the staff must be highly qualified patent engineers, skilled in search and examination work comparable to the EPO level. The examples serve to illustrate how the Danish Patent Office participates in co-operation with Danish companies and innovation centres, with the objective of improving their innovation activities.

The relationship between the Danish Patent Office and its customers is very flexible and unbureaucratic and the success is to a large extent based on our informal and frequent dialogue and interaction with the customer. In many ways our commercial service acts as an extra desk function for the companies using this possibility.

This is true when speaking of our commercial activities. But there is also a corresponding relationship between applicants and the Patent Office in our activities as an authority, which makes the Danish Patent Office attractive to the Danish applicants.

I hope that my explanation and the examples showing how the Danish Patent Office enters into working relationships with its customers can serve as useful illustrations. Danish companies

– even the largest ones – and innovation centres have expressed the clear desire to co-operate with an NPO that is capable of performing substantial search and examination at EPO level. The individual customer expects local knowledge and an insight into the local cultural background. He wants the service delivered in the form of a dialogue. He expects the process to be conducted in Danish. And one final but important detail is that he expects to get such a service at a reasonable price.

If Danish industry is deprived of such a service in future, it will be seen as a deterioration of the terms under which Danish companies compete on international markets.

Developing the business basis of the Danish Patent Office

Why exactly is Danish industry in danger of losing the present level of service which is provided by the Danish Patent Office as a patent authority and service provider?

The simple fact is that within the next few years we shall find ourselves in short of work. This will happen as we gradually reduce the backlog of patent applications still with us from the old days, and as information technology enables us to become even more efficient and productive than we are at present. It will then be necessary to look for new tasks, which are sufficiently demanding in order to enable our highly qualified examiners to maintain and develop their skills. Otherwise we shall not be able to maintain the crucial mass of approximately 50 examiners that we consider necessary to be able to work reasonably efficiently with our innovation-related activities.

We are, therefore, actively and seriously engaged in expanding our volume of work by three measures, all of which involve the expertise of our examiners.

Firstly, we are encouraging Danish industry and Danish researchers to engage more fully in patent activity. A side effect of this will be more work for our examiners.

Secondly, we are actively engaged in developing new commercial services, which our customers are requesting – and which require the assistance of our examiners.

However, even if we succeed in generating some expansion in these fields, we do not think it will be sufficient to maintain the necessary staff of about 50 examiners.

And thirdly, therefore, we believe that the Danish Patent Office should be a resource for the EPO on a sub-contractual basis. Both with regard to work involving European patents and work on future Community patents.

Our motivation is not job creation at the Danish Patent Office. If it were, we would not get the support of the Confederation of Danish Industries. Our reason for taking these steps is to maintain in Denmark a qualified NPO as a framework condition for Danish industry. Danish industry is very much in favour of this objective. Appended to my manuscript you will find a copy of the statement to this effect made by the representative of the Confederation of Danish Industries at the European Commission hearing in Luxembourg last November on "The Green Paper on Patents".

A rhetorical question – and an answer

In the light of these considerations, I would like to put a rhetorical question – and attempt an answer: (Overhead) Considering that:

all of us – supported by the Commission – take a deep interest in the innovation capacity of Europe some member states (and Denmark is certainly one of them) find that a qualified NPO is an essential framework condition for industrial innovation this may be hard to maintain without transferring qualified patent work from EPO to these NPOs on a contractual basis such a division of labour is technically possible today - then what prevents us from working positively towards making this an element of the future European patent system? Thus ensuring a system based on the Principle of Subsidiarity which is an essential element in the functioning of the European Community!

The idea has been used before, when the EPO was starting up although at that time for different reasons. And I assume it is merely a matter of letting the idea mature. Before too long we shall hopefully all be in general agreement that the idea adds a healthy and positive element to the design of the European patent system, which the Commission and all the member states work positively towards.

My own answer is: Nothing prevents us – provided that it is done in a proper manner. And there are several good reasons why it should be done. Allow me to be a little more specific about what I believe constitutes "a proper manner". I draw three points to your attention:

There must be a solid legal foundation

Subcontracting will not change the fact that the patents will still be European patents granted by the EPO. But I am fully aware that subcontracting as such will require EPO member states to support this model at a diplomatic conference. There are, however, other pressing issues as well, which will require amendments to the Convention in the early future and which will necessitate such a conference. So we should include it on the agenda for that event.

The level of quality must be high

It would certainly be unacceptable if sub-contracting were to produce a lower quality of work than that supplied by the EPO with its own resources. But industry throughout the world uses the concept of sub-contracting to become even more competitive. And it makes sure that the quality produced

by its suppliers is first class. What is to prevent the EPO from organising a similar quality-control system? The EPO, of course, can do it – if it so decides.

In this connection it is important that the quality system should be planned in such a way that it is independent of the President of the EPO – just as the Appeal Board system is independent of the President. Clearly, it would be unacceptable if a member state whose NPO did not meet the quality standard could put political pressure on the President.

The volume of sub-contracting work must be no more than required to ensure the preservation of the NPO's critical mass

An NPO must not be permitted to request more sub-contracting work than necessary to maintain its "critical mass" of technical staff in order – with reasonable efficiency – to provide its national industry qualified patents work. Guidelines would have to be drawn up for the determination of calculation of "critical mass".

At the DKPTO we are presently preparing documents on these three subjects. It is the intention that these documents should provide a basis for the further discussions at EPO level.

To avoid any misunderstanding, we are not talking of any disintegration of the EPO.

The bulk of work should be maintained at the EPO thus enabling it to set the standards. Where the limit should be, I do not know exactly. I have the feeling that at the present time the EPO should not outsource more than 20% of its work to sub-contractors – maybe the limit should be lower.

Concluding remarks

We can probably all agree it is a vital and basic condition for European industry that in each country there is an effective infrastructure to provide the protection of industrial property rights. There are different strategies for achieving this, and each country should, of course, choose the strategy best suited to its particular situation. I find that the EPO has an obligation to assist in ensuring such an infrastructure - especially for those countries, which are at the outskirts of Europe and whose mother tongue is not one of the three official EPO languages.

This is a job for the EPO, which seems to me to be as relevant as a task which it already shoulders – namely, the task of assisting relevant non-member states to develop a healthy infrastructure in this field. I am thinking here of many East European countries – but also, for example, of China.

For some member states, such as Denmark, one of the most efficient and relevant ways of offering assistance will be to subcontract some search work. I would like to add, however, that such a system of sub-contracting offers another benefit: it would help to improve the EPO's own flexibility in the event of a fluctuating workload. Moreover, the salaries paid by sub-contractees are normal national salaries – not the salaries of international agencies.

I first launched these ideas almost a year ago at the FICPI Congress in Copenhagen and a short time later at the Conference of the International Chamber of Commerce in Paris. The feed back and positive backing that I have received still convinces me that the ideas has a lot of merit.

Nevertheless, I think it would be highly desirable if FICPI would consider giving the idea additional support. It is necessary; since it takes a lot of power to turn a European supertanker like the EPO.

Anyone interested in learning more about the idea can order from the Danish Patent Office a copy of our memorandum of January 9, 1998, entitled “How to create synergy between the EPO and the NPO”, plus the appendix of April 3, 1998.

Thank you for your attention!

PAPER: FLO/3.7.2 by Jean-Jacques MARTIN, Président de la Compagnie Nationale des Conseils en Propriété Industrielle

Les Office de Brevets Nationaux – Le Cas de l'INPI Français

1. PRESENTATION GENERALE

Le problème des offices nationaux responsables de l'enregistrement, de la délivrance et du maintien en vigueur des brevets, qu'il s'agisse de brevets nationaux, ou de validation de brevets européens, se pose aujourd'hui avec une acuité nouvelle.

En effet, dans tous les pays de la Convention de Munich, on constate :

les brevets nationaux sont de moins en moins nombreux et les validations européennes de plus en plus prédominantes.

dans le cas d'un brevet national, les offices nationaux ont une activité procédurale considérable qui, en France, comporte notamment un examen, un rapport de recherche et des formalités de délivrance, alors que les validations ne comportent que la réception de traductions mises à la disposition du public.

les offices nationaux perçoivent des annuités sur les validations d'origine européenne, et en versent 50 % à l'Office Européen ; on dit que la "clé de répartition" est de 50 %. Les annuités de validation représentent un montant important (environ 1/3 des recettes de l'INPI français, dont la moitié est versée à l'OEB).

Une taxe de validation est perçue par l'INPI (230 FF) pour chaque dépôt de traduction.

Les réformes actuellement envisagées peuvent-elles remettre en cause la situation ci-dessus ?

Il existe un projet de dépôt centralisé des validations européennes, selon lequel toute les traductions correspondant à un brevet européen seraient déposées de façon centralisée.

Si la centralisation se fait dans l'office national du déposant, il n'y aura statistiquement rien de changé. Mais si le dépôt centralisé se faisait auprès de l'Office Européen de Munich, alors les offices nationaux perdraient leur activité d'offices récepteurs pour les traductions et les taxes de validation qui ne représentent qu'une part faible (moins de 2 % des recettes).

Rien ne permet de supposer un changement proche de la clé de répartition.

L'hypothèse du brevet communautaire, dont il faut souhaiter la création, tant il est lié à l'unification européenne, diminuerait encore évidemment le rôle des offices nationaux, puisqu'ils n'auraient alors vraisemblablement plus rien à faire dans le processus de délivrance et de maintien en vigueur des titres communautaires.

Y aurait-il alors la même répartition ?

2. L'Exemple de l'Institut français : les nouveaux rôles des offices nationaux. Missions de l'INPI.

L'INPI a depuis 1990 ses missions définies par la loi.

L'article 411-1 du Code de la Propriété Intellectuelle énonce :

L'Institut national de la propriété industrielle est un établissement public doté de la personnalité civile et de l'autonomie financière, placé auprès du ministre de l'industrie.

Cet établissement a pour mission :

1. De centraliser et diffuser toute information nécessaire pour la protection des innovations et pour l'enregistrement des entreprises, ainsi que d'engager toute action de

sensibilisation et de formation dans ces domaines ;

2. D'appliquer les lois et règlements en matière de propriété industrielle, de registre du commerce et des sociétés et de répertoire des métiers ; à cet effet, l'Institut pourvoit, notamment à la réception des dépôts de demandes des titres de propriété industrielle ou annexes à la propriété industrielle, à leur examen et à leur délivrance ou enregistrement et à la surveillance de leur maintien ; il centralise le registre du commerce et des sociétés, le répertoire des métiers et le Bulletin officiel des annonces civiles et commerciales ; il assure la diffusion des informations techniques, commerciales et financières contenues dans les titres de propriété industrielle et instruments centralisés de publicité légale ;

3. De prendre toute initiative en vue d'une adaptation permanente du droit national et international aux besoins des innovateurs et des entreprises ; à ce titre, il propose au ministre chargé de la propriété industrielle toute réforme qu'il estime utile en ces matières ; il participe à l'élaboration des accords internationaux ainsi qu'à la représentation de la France dans les organisations internationales compétentes.

Analyse des missions de l'INPI

Si l'on se réfère à ces dispositions, on voit clairement se dégager trois conclusions :

l'alinéa 2 prévoit les missions classiques de tout office de la propriété industrielle dans la création, le contrôle, le maintien en vigueur et la publicité des titres de propriété industrielle ;

l'alinéa 3 prévoit des activités paralégislatives de toute première importance. Dans la période de transformation rapide de la propriété industrielle, c'est l'INPI qui est le moteur principal de l'adaptation des dispositions internationales, communautaires, européennes, au droit et à la pratique français.

mais c'est le point 1 de l'article 411-1 qui doit retenir notre attention : l'Institut français a une mission de diffusion d'informations, de sensibilisation et de formation, ce qui a été, en 1990, une innovation considérable par rapport au système ancien.

Les actions présentes de l'INPI :

a. l'INPI, dont le centre est à Paris, a dix délégations régionales (Bordeaux, Grenoble, Lille, Lyon, Marseille, Nancy, Nice, Rennes, Strasbourg, Toulouse) qui reçoivent les dépôts, diffusent l'information et organisent la sensibilisation, le plus souvent en coopération avec la profession libérale, c'est-à-dire la Compagnie Nationale des Conseils en Propriété Industrielle dont j'ai

l'honneur d'être le Président. Une nouvelle délégation régionale va être créée à Nantes, pour une ouverture en prochaine.

b. l'INPI a lancé en 1998 un appel à propositions vers les groupements professionnels en vue de subventionner des actions de sensibilisation et de formation. Près d'une centaine de réponses ont été reçues et leur instruction est en cours.

c. l'INPI organise une sélection d'entreprises innovantes et décerne aux meilleures d'entre elles des Trophées, d'abord des Trophées régionaux au niveau local, puis des Trophées nationaux.

d. l'INPI, en liaison avec les services du Ministère, élabore en ce moment un guide d'évaluation des dommages et intérêts pour la contrefaçon de brevets.

e. l'INPI participe activement à des études sur la mise en place d'un système d'assurance litige sur lequel les professionnels de la profession libérale et de l'industrie ont été largement consultés.

f. l'INPI et la CNCPI sont partie prenante dans la réforme du Centre d'Etudes Internationales de la Propriété Industrielle (CEIPI) à Strasbourg.

g. des diagnostics d'évaluation des besoins et de audits de propriété industrielle sont proposés aux PME, avec la participation de la CNCPI.

h. une politique active de promotion des brevets va être lancée en direction des entreprises de 200 à 2000 employés dans trois secteurs (matériel médical, manutention-emballage, instrumentation-métrologie).

i. des programmes de formation pilote à la propriété industrielle sont mis en place dans diverses Ecoles des Mines, qui sont parmi les plus prestigieuses écoles d'ingénieurs françaises.

j. en coopération avec l'Office Européen des Brevets, un outil de recherche documentaire est installé sur le site de l'INPI, et il est prévu une mise en réseau avec les autres instruments de recherche installés sur les sites des offices des pays membres de l'Office Européen.

k. enfin, et le rôle de l'INPI est ici évidemment incontournable, il faut signaler que la France va demander la réunion d'une conférence intergouvernementale des pays membres de l'OEB pour étudier les principaux thèmes d'une révision de la convention de Munich et les conséquences d'une éventuelle ouverture aux pays d'Europe centrale et orientale.

[Ce point sera développé au cours de la conférence si je suis autorisé à le faire par les autorités françaises.]

CONCLUSION

L'exemple de l'évolution de l'Institut National de la Propriété Industrielle français montre que le rôle des offices nationaux est bien loin d'être terminé.

Pour aider les déposants européens à mieux comprendre l'importance stratégique de la propriété industrielle et le maniement de cet outil et pour aider l'industrie européenne, notamment la petite et moyenne industrie, face à la concurrence non européenne, il et indispensable que les pouvoirs publics, en coopération avec les professionnels libéraux que nous sommes, aident à la sensibilisation et à la formation.

En l'état actuel de la construction européenne, dans l'état actuel de l'utilisation des langues, ce rôle ne peut être tenu que par un office national.

Sous l'impulsion de son Directeur Général, Daniel HANGARD, l'INPI, en coopération active et confiante avec la CNCPI, prépare efficacement l'avenir.