IPO COMMITTEE NEWSLETTER

APRIL 2011

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THE NEW ARGENTINA SYSTEM OF DIVISIONAL PATENT APPLICATIONS

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I. INTRODUCTION

As had happened in Europe[1] and was attempted in the United States,[2] in 2010 Argentina amended its system of divisional patent applications. Although the changes were not as far-reaching as in the U.S.A., they were not as prudent as those made to the European patent, and the first amendment, which was somewhat sweeping, had to be toned down only four months later.

We shall address here the changes introduced by the successive changes made in 2010 and the best strategy to adjust to the current system.

II. DIVISIONAL PRACTICE IN ARGENTINA

1. The provisions in the law

Argentina's first patent law, in force from 1864 to 1995, had no provisions on divisional applications,[3] but they were widely accepted by the practice of the Argentine PTO.

On the other hand, the patent law enacted in 1995 (No. 24,481) did include one such provision, namely art. 17, which states that "the patent application may not comprise more than one invention only or a group of inventions so linked as to form a single inventive concept" and that "the applications which do not meet this requirement shall be divided as established in the regulatory decree". In turn, art. 17 of the regulatory decree states that "when the patent application comprises more than one invention, it shall be divided prior to its grant". We shall come back later to this provision from the regulatory decree.

2. Reasons for filing divisional applications

Prior to the changes introduced in 2010, divisional applications were filed in Argentina for two reasons: when the original application had more than one invention (lack of unity), or when it included more than one object and the Argentine PTO, while prepared to allow the patent for certain objects, would refuse to grant it until other objects were removed from the application.

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1 *See* the Decision of the Administrative Council of March 25, 2009 amending the implementing regulations to the European Patent Convention (CA/D 2/09).

2 *See* Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46716 (Aug. 21, 2007).

3 P.C. Breuer Moreno, TRATADO DE PATENTES DE INVENCIÓN, Abeledo-Perrot, Buenos Aires, 1957, vol. I, p. 286.

The lack of unity objection is no different in Argentina from what is elsewhere, and therefore does not require any special explanation. On the other hand, the second situation warrants a closer scrutiny, as in many ways it is peculiar to the Argentine practice and arises relatively often.

In many cases the Argentine PTO will issue an office action stating that some objects are allowable but the application may not proceed to grant until other objects are deleted. In some instances this objection involves *patentable subject matter*: the PTO is ready to grant the patent which refers, for example, to a patent for the DNA construct, the modified sequences and the essentially non-biological method for obtaining a plant, but not for the plant itself, or for the cells or seeds; the same can happen with pharmaceutical inventions, when the PTO will grant the patent for the compound, the composition and the process for obtaining or synthesizing compound and composition, but not for the method of treatment or the use protected in a main claim. Other instances involve *inventive activity*, as happens with claims where the unexpected advantages of the claimed compounds have not been pointed out. In some cases, finally, the PTO may object the *support* of certain claims and request that the scope of the application be limited to those claims it considers to be adequately supported by the specification.

In all these cases the applicant faces an insurmountable dilemma: to either delete the claims objected to by the PTO for the patent to proceed to grant, or keep them and face a certain rejection of the *whole* application (including the scope approved by the PTO), with the subsequent need to appeal from said rejection before the Federal Courts, with the attendant expenses, delay and uncertainty. Making matters worse, patent prosecution and judicial appeals can be lengthy in Argentina, thus detracting from effective protection inasmuch as the patent is granted for a term running from the date of grant up to the twentieth anniversary of the application date, and the Argentine patent law has no provisions on provisional protection[4] or term extension.[5]

And it was precisely the divisional practice which allowed applicants to cut this Gordian knot: the original application, limited to what had been agreed to by the PTO, would proceed swiftly to grant, unencumbered by the objectionable subject matter; while the latter would be included in the divisional application, which could be argued before the PTO or appealed before the courts, as the need arose, without jeopardizing the former. A broad and flexible system had thus developed, which adequately met applicants' needs without having to overhaul the whole patent prosecution process.

III. THE FIRST AMENDMENT: DISPOSITION No. 147/2010

Nevertheless, citing technical reasons and arguing that this procedure had led to a proliferation of unnecessary applications, on June 20, 2010 the Argentine PTO issued

4 On the subject of provisional patent protection under Argentine law, *see* Martín Bensadon, LEY DE PATENTES COMENTADA Y CONCORDADA CON EL ADPIC Y EL CONVENIO DE PARÍS, LexisNexis, Buenos Aires, 2007, p. 239 *et seq*.

5 On the patent term in Argentina, *see* Eugenio Hoss, *Duración de las patentes*, La Ley 2010-B, p. 786 *et seq*.

Disposition No. 147/2010,[6] which severely restricted the hitherto straightforward and simple divisional practice.

The main points of the new system set up by Disposition No. 147/2010 were the following:

(a) the divisional application could be filed only until notice of the substantive examination office action had been served (art. 1);

(b) once the substantive examination had begun, if there was no unity of invention the examiner would request that the application be divided within 30 days, under the condition that otherwise the application would be held as having been abandoned (art. 2);

(c) any divisional application filed after notification of the substantive examination would be rejected, unless it were filed in response to an explicit request from an examiner (art. 3); and

(d) all preceding applications, including the first application in a series of two or more successive divisional applications, would have to be alive and pending at the time the specific divisional was filed (arts. 4 and 5).

The new regulation was roundly criticized. First, the number of divisional applications was too low to cause the Argentine PTO's backlog: between 2003 and 2008 the yearly average of divisional applications did not exceed 2,2 %. Indeed, the new regulation could have the opposite effect, as it might trigger *preventive* divisional applications.[7] But the main criticism was made on constitutional grounds: Disposition No. 147/2010 was unconstitutional because it went far beyond a reasonable regulation of the prosecution process and adversely affected applicant's rights as it introduced a restriction absent from art. 17 of the regulatory decree (which states that the divisional application could be filed at any time until the grant of the basic application).

IV. THE SECOND AMENDMENT: DISPOSITION No. 198/2010

In the face of this criticism, on November 19, 2010 the Argentine PTO issued Disposition No. 198/2010[8] which repealed articles 1 and 3 of Disposition No. 147/2010. In the surviving system, divisional applications may now be filed in the following two situations:

(a) upon requirement from the examiner, during the substantive examination (compulsory divisional application); and

[6] Published in the Official Gazette (*Boletín Oficial*) No. 31939 on July 7, 2010.

[7] This happened to the European Patent Office in September 2010, just before the October 1 deadline for filing divisional applications under the old text of Rule 36 (on European divisional applications) of the European Patent Convention (*EPO Divisionals deadline causes surge in filings*, "Managing Intellectual Property", November 2010, p. 10).

[8] Published in the Official Gazette (*Boletín Oficial*) No. 32036 on November 26, 2010.

(b) at applicant's will, at any time prior to the resolution of the basic application (voluntary divisional application).

Regarding compulsory divisional applications, art. 2 of Disposition No. 147 (which is still in force as this provision was not repealed by Disposition No. 198) states that "once the substantive examination has begun, if the examiner ascertains that the application lacks unity of invention or is a 'complex application', he or she shall request that the application be divided within 30 working days, under the condition that otherwise the application will be held as having been abandoned". A strict reading of this provision might lead to the conclusion that the application will always be declared as having been abandoned if the applicant fails to divide it when charged to do so by the examiner. However, no notice of abandonment may validly issue, even if the divisional application is not filed, if applicant has nonetheless removed the objected subject matter from the basic (and finally only) application and thus complied with the rule of unity of invention. Furthermore, a divisional application may not be rejected for having been filed after the 30-day deadline set forth in Disposition No. 147, if it is nonetheless filed within the general term of art. 17 of the regulatory decree (i.e., as long as the basic application is pending).

A contentious issue is whether all applications must be pending in a series of successive divisional applications, from the first (basic) application up to the last divisional application. Article 5 of Disposition No. 147 (also not repealed by Disposition No. 198, and therefore still in force) unequivocally states that "if a divisional application (C) is filed, which originates from another divisional application (B) whose mother is (A), it is necessary for (A) to be pending at the time divisional application (C) is filed". Regardless of its cumbersome wording, the provision is clear in requiring that in a series of divisional applications, absolutely all of them must be "alive" (i.e. pending) at the time the last divisional is filed. This requirement is unconstitutional because it introduces a restriction –the pendency of a preceding divisional application other than the specific application being divided– noticeably absent from both the Patent Law and its regulatory decree, which prevail over any rules issued by the Argentine PTO. Notwithstanding this constitutional argument, for practical reasons art. 5 must be taken into account, as will be explained immediately below.

V. STRATEGIES

What are the practical consequences that may be drawn from the above analysis, and particularly which is the best strategy to take full advantage of the current divisional system in Argentina? Although the procedure set up by Disposition No. 198/2010 restored, to a great extent, the quite liberal *status quo* prior to the issuance of Disposition No. 147/2010, things now are not quite as they were before.

First, the requirement of art. 2 of Disposition No. 147 (i.e., the request from the examiner, issued in the substantive examination, that the application be divided) should not be taken lightly. That is precisely the point in time in which the applicant must study and decide if the original application is to be divided, and, if so, whether one or more divisional applications will be filed.

Secondly, although we stand by our contention that it is unconstitutional to require that all preceding divisional

applications (up to the original application) be pending, it must be nevertheless be reckoned with the fact that the Argentine PTO shall refuse a divisional application filed in a series where the “grandmother” (or more remote) application is no longer pending, which in turn will trigger the need to file an appeal against this rejection. Accordingly, when studying whether to file a divisional application, it is advisable to decide at the same time whether more than one divisional application will be necessary, so as to file all of them simultaneously.

Finally, since there is no notice of allowance in the Argentine procedure, applicants must be careful not to delay filing the divisional application(s) once the objectionable subject matter has been removed, because while they are pondering their decision the basic patent may issue, and thereafter no divisional application will be accepted.

THE PATENTABILITY OF BIOLOGICAL MATERIALS IN AUSTRALIA

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1. Introduction

The *Patent Amendment (Human Genes and Biological Materials) Bill* (2010) ("the Bill") is currently before the Australian parliament. It seeks to ban the patenting of all biological material that is "identical or substantially identical to such materials as they exist in nature". If passed, this legislation would represent a major shift in Australian patent law. It may also significantly jeopardize the biotechnology, pharmaceutical, medical and agricultural industries in Australia. This article sets out the proposed ban on patentable subject matter and discusses the ramifications of such a ban.

2. The *Patent Amendment (Human Genes and Biological Materials) Bill* (2010)

The *Patent Amendment (Human Genes and Biological Materials) Bill* (2010) was recently introduced into both houses of the Australian parliament. Although it has yet to be passed into law, it is highly contentious. The Bill was drafted despite a 2004 report by the Australian Law Reform Commission (ALRC) explicitly recommending against a ban on patenting of genes[10], and despite an Australian Senate Committee failing to make any recommendations on the patentability of genes and genetic technologies[11], and despite a 2010 report by the Advisory Council on Intellectual Property (ACIP) explicitly recommending against the introduction of specific exclusions for patentability[12], and despite any Australian court ever having provided *obiter dicta* or *ratio decidendi* on the patentability of biological materials.

Among other proposed changes, the Bill seeks to amend section 18 of the *Patents Act* (1990) as follows (shown in strikethrough for proposed deleted text and underline for proposed added text):

> (1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:
>
> (a) is a manner of manufacture within the meaning of section 6 of the

[9]. Vaughan is a legal practitioner admitted to the Supreme Court of New South Wales and a patent attorney registered to practice before the Australian Patent Office and the Intellectual Property Office of New Zealand. Vaughan is also a trade marks attorney registered to practice before the Australian Trade Marks Office. Vaughan practices with Pizzeys Patent and Trade Mark Attorneys: www.pizzeys.com.au;

[10]. Australian Law Reform Commission *"Genes and Ingenuity: Gene Patenting and Human Health"* (ALRC No. 99, 2004);

[11]. Senate, Community Affairs References Committee: *Report on inquiry into gene patents*, 26 August 2010;

[12]. Advisory Council on Intellectual Property Report, *Patentable Subject Matter*, 23 December 2010;

Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an inventive step; and

(c) is useful;

.....

~~(2) Human beings, and the biological processes for their generation, are not patentable inventions.~~

(2) The following are not patentable inventions:

(a) human beings, and the biological processes for their generation; and

(b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.

.....

(5) In this section:

biological materials, in section 18, includes DNA, RNA, proteins, cells and fluids.

The proposed ban on patenting of biological materials under section 18(2) is therefore far broader than the current ban, which is limited to "human beings and the biological processes for their generation". Proposed section 18(2)(b) bans from patentability all biological materials that are "identical or substantially identical" to those existing in nature. The ban therefore not only runs counter to the recommendations made by the ALRC and the ACIP, but it is also broader than the summary judgement of the New York District Court in *Association for Molecular Pathology v United States Patent and Trade Mark Office* [13] (the "*Myriad Genetics Case*"), given that the Bill makes no distinction on the basis of inherent "informational" characteristics of a biological material.

The legal definitional problems associated with the proposed language of section 18(2)(b) are numerous, and include (1) defining the scope of a "biological material", (2) defining the scope of a "component or derivative" of a biological material, (3) defining the scope of "substantially identical" and (4) defining the scope of "such materials as they exist in nature".

In relation to defining the scope of the term "biological material", some assistance is provided under section 18(5) which proposes a non-exhaustive inclusive definition including DNA, RNA, proteins, cells and fluids. Accordingly, it appears that any biological material from any naturally occurring biological system is proposed to be banned from patentability. Anti-cancer compounds such as paclitaxel, isolated from the Pacific Yew tree, would therefore be banned from patentability. Also, the ability to patent autologous cell therapies, the precise aim of which is to replicate

[13]. No. 09-Civ-4515 (SDNY), handed down on 29 March 2010;

biological material from a patient in need, may also be jeopardized.

The term "component or derivative" of a biological material even further broadens the scope of the ban on biological materials. On a literal interpretation, a "component" of a "biological material" (specifically defined as including DNA, RNA and proteins) arguably encompasses, for example, any one or more single nucleic acid residues or single amino acid residues. It is therefore difficult to know where to reasonably draw the line on the scope of the term "component". Equally problematic, the term "derivative" is commonly defined as a compound or molecule that is derived from a similar compound or molecule by some chemical or physical process. The term "derivative" can also be used for compounds that can at least theoretically be formed from a known precursor compound. Hence, it is difficult to know whether a "derivative" of a biological material, which may for example be a chemically altered amino acid that does not exist in nature, would nevertheless still fall within the proposed banned subject matter.

In relation to defining the term "substantially identical", it is noteworthy that section 44 of the Australian *Trade Marks Act* (1995) bars registration of a trade mark that is "substantially identical" with a prior filed trade mark. [14] Although the term "substantially identical" has therefore been subject to at least 15 years of interpretation in relation to Australian trade mark law, it is nevertheless difficult to see how any significant interpretive benefit may be translated over to issues of "biological material" as proposed under section 18(2) of the *Patent Act* (1990). Indeed, use of the term "substantially identical" would almost certainly result in prolonged and potentially expensive interpretation during patent office or court proceedings.

In relation to defining the scope of the phrase "such materials as they exist in nature", it is presumably necessary to attempt to define what biological material is naturally occurring and what is artificial. For example, how does one differentiate between the human intervention involved in artificially creating genetically modified cotton versus the breeding of animals and crops to suit human needs over thousands of years? At what point in time, or through what type of human intervention, can we differentiate between biological material that "exists in nature" and that which does not? Such issues are particularly pertinent for agriculture, where it is arguable that the continued release of genetically modified crops or animals for widespread use by farmers changes what defines "existing in nature" on a continual basis.

It is therefore clear that not only would the proposed ban on patenting of biological materials significantly change the scope of patentable subject matter in Australia, but the particular language proposed is overly broad, problematic and confusing.

3. Conclusion: Ramifications of the proposed bans on patentable subject matter

It is immediately apparent that if passed into law, the *Patent Amendment (Human Genes and Biological Materials) Bill* (2010) would have a profound affect on the biotechnology, pharmaceutical, medical and agricultural

[14]. Registration is only barred if the substantially identical or deceptively similar trade mark is sought to be registered in respect of similar goods or closely related services;

industries in Australia. Despite the recognized expertise of the ALRC, its recommendation that the *Patents Act* should not be amended to exclude genetic materials or technologies from patentability appears to have been ignored. In addition, the significant impediments to amending the *Patents Act* to exclude genetic materials from patentability, including a long history of patenting such inventions, international treaty obligations, and a biotechnology industry dependent on patents and inventions, has also been ignored.[15] Moreover, the approach taken goes directly against recommendations made by the ACIP that a specific list of unpatentable subject matter should not be provided, and that "no persuasive case has been made to introduce a specific exclusion to prevent the patenting of human genes and genetic products." [16]

From a legal perspective, it is important to note that Australia is a signatory to the Trade Related Aspects of Intellectual Property (TRIPS) agreement. Article (Art) 27(1) of TRIPS obliges member countries to make patents "available for any inventions, whether products or processes, in all fields of technology…". Various exceptions to this requirement are found in Art 27(2) and Art 27(3). Although the exclusions to patentability under Art 27(2) and 27(3) are potentially broad, it appears clear that the proposed exclusions under the *Patent Amendment (Human Genes and Biological Materials) Bill* (2010) are even broader. For example, the proposed Australian Bill clearly excludes patenting of micro-organisms, but Art 27(3)(b) of TRIPS disallows such exclusion. Proponents of the amendments to section 18(2) argue that TRIPS would not be contravened because the banned subject matter would not qualify as an "invention" and therefore would not be subject to Art 27.

In addition to Australia's potential contravention of its obligations under TRIPS, the commercial reality of banning from patentability all biological material that exists in nature could result in the biotechnology, pharmaceutical, medical and agricultural industries withdrawing investment in Australia. As a consequence, there is the potential for future difficulty in accessing medicines and associated problems in the provision of healthcare. This possible lack of investment could arise not only because of diminished returns on investments through a lack of patent rights, but also because of the remaining significant costs in obtaining regulatory approval. Indeed, sources indicate that the Australian Therapeutic Goods Administration, which is responsible for granting market approval, is planning on further increasing its charges to applicants.

The Bill is currently before parliament and is also the subject of a renewed Senate Inquiry. [17] Submissions from the public closed on 25 February 2011 and included a diverse range of opinions. The Australian Institute of Patent Attorneys, a professional body representing patent attorneys in Australia, was clear in its objection to the Bill. [18] The Senate Committee is now

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[15]. Australian Law Reform Commission *"Genes and Ingenuity: Gene Patenting and Human Health"* (ALRC No. 99, 2004);

[16]. Advisory Council on Intellectual Property Report, *Patentable Subject Matter*, 23 December 2010, page 14;

[17]. Senate, Legal and Constitutional Affairs Legislation Committee;

[18]. See http://www.aph.gov.au/senate/committee/

conducting hearings and is due to report on 16 June 2011.

Patent applicants seeking to claim biological materials in Australia are therefore strongly urged to closely monitor the progress of the *Patent Amendment (Human Genes and Biological Materials) Bill* (2010) through the Senate Inquiry at http://www.aph.gov.au/Senate/committee/legcon_ctte/patent_amendment/index.htm, which also provides a link to each of the 100 submissions received from academics, various professional bodies, pharmaceutical companies, patent attorneys, medical research institutes, and state and federal government.

legcon_ctte/patent_amendment/submissions.htm submission no. 49.

CANADIAN COMMISSIONER OF PATENTS ENDORSES BROAD MONOCLONAL ANTIBODY CLAIMS

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A recently published decision of the Commissioner of Patents in *Re Immunex Corporation Patent Application No. 583,988*[19] has provided prospective Canadian patentees of inventions relating to monoclonal antibodies with some long-sought clarity in this rapidly evolving practice area.

Background

Historically, written description and enablement requirements for antibodies – particularly monoclonal antibodies – have been quite high in Canada. This was due to the 1995 decision of the Commissioner of Patents in *Re Institute Pasteur*[20], wherein claims to monoclonal antibodies and related hybridomas were refused on the basis of statements taken from a scientific reference manual. These statements concerned certain unpredictable aspects of antibodies, and were arguably taken out of context. The Commissioner determined that, at the 1987 filing date, reference to "traditional techniques" for antibody production constituted insufficient description.

More recently, in 2008, Commissioner's decision #1283[21] considered an affidavit submitted by the scientist whose statements were relied upon in *Pasteur*. In the affidavit, Dr. James Goding stated

I do not support the proposition that, given a sufficiently purified protein, one would not expect that monoclonal antibodies could be produced... If my writings are cited in support of this proposition, then they are wrongly cited.[22]

The Patent Appeal Board conceded, stating

In light of this evidence, it appears there are concerns with Pasteur in so far as it may be relied upon as authority for the proposition that a patent specification is defective for lack of enablement because monoclonal antibody production was not a well developed methodology or merely because it fails to set out a detailed proposed protocol for the production of a monoclonal antibody to a given antigen.[23]

However, on the front lines of patent prosecution, Patent Office policy with regard to antibodies remained quite murky.

The Immunex Decision

The Immunex application was filed on November 28, 1988 and related to interleukin-1 receptors (IL-1R). Claim 29 was directed to "A monoclonal antibody immunoreactive with IL-1R polypeptide." Claim 54 was added during prosecution to specifically encompass an antibody directed to polypeptides defined by sequence, while claim 58 was a parallel product-by-process claim. The Examiner objected to these claims in a Final Action for being insufficiently supported by the description, citing a lack of specific examples of such an antibody, and no supporting biological deposit.

[19] (2011) 89 C.P.R. (4th) 34.
[20] (1995) 76 C.P.R. (3d) 206.
[21] (2008) Commissioner's Decision #1283.

[22] *Ibid.* at [119].

[23] *Ibid*. at [121].

The Applicant argued that the subject matter of the claims, though not specifically exemplified, was supported by a full, enabling disclosure of how to make and use the claimed monoclonal antibodies; the IL-1R protein had been fully described, and detailed protocols for making antibodies had been included. These methods were routine at filing, according to the Applicant.

In its decision, the Patent Appeal Board noted that U.S. and U.K. courts have recently recognized that no undue experimental burden is required to raise monoclonal antibodies targeted to a defined polypeptide. Broad claims to such antibodies have been allowed in these jurisdictions without specific exemplification, in view of the maturity of antibody production technologies.

Turning to the case at hand, the Board noted that two types of IL-1R polypeptides exist: Type I and Type II. The specification disclosed the construction, expression, and purification of an extracellular domain of a Type I IL-1R. Thus, the Board concluded that the specification was only enabling for antibodies directed to Type I polypeptides, while the claims in question encompassed both types. However, the Board was willing to allow the claims if the scope of the antibody target was limited to Type I IL-1R polypeptides, and invited the Applicant to effect the necessary amendments.

In arriving at its decision, the Board noted that the description taught the cloning and protein expression techniques required to prepare the immunogen. It also considered a 1989 (i.e. post-filing) publication from a third party, as well as an affidavit signed by one of the inventors, to support its conclusions that generation of monoclonal antibodies was sufficiently supported. Once the antigen was in hand, the work which followed did not, in the Board's view, involve undue experimental burden. The actual techniques used post-filing closely mirrored the general protocol taught in the description.

The Board stated

… the skilled person would appreciate that monoclonal antibodies can be adequately described based on a combination of a structural description of the antigen, functional identity [i.e. specific immunoreactivity] between the antibody and antigen, and knowledge of predictable production methods.

Of particular note, the Board seems to have indicated that a target polypeptide can be "fully characterized" by providing a complete amino acid sequence.

However, the Board cautioned that claims to antibodies having special functional attributes, such as diagnostic or therapeutic antibodies, may require correspondingly detailed support.

What does it mean for prospective patentees?

Publication of the Immunex decision in the *Canadian Patent Reporter* explains and clarifies a recently observed but, until now, somewhat mysterious[24] trend for Canadian

[24] The Immunnex application was filed before the Canadian Patent Act was amended on October 1, 1989 to allow publication of an application and its file history (which includes this Commissioner's decision) prior to issuance. Though the decision was handed down in 2010, the application has not yet issued and,

Patent Examiners to allow broader claims to monoclonal antibodies in some applications when novel antigens and epitopes are disclosed.

This decision sheds light on the underlying reasons for this change, and supports the argument that monoclonal antibodies can be routinely generated without undue experimentation when a well-defined target protein is disclosed, for example, by sequence and/or structure. It also highlights the importance of providing general protocols and prophetic examples in patent specifications for the purposes of support.

In drafting and prosecuting antibody-related applications in Canada, it may also be helpful to bear in mind the non-exhaustive list of considerations for support and enablement which were set out in Commissioners decision #1283 (and applied in the *Immunex* decision), briefly summarized and consolidated below:

whether there is more than merely a general description of the polypeptide, including an explicit description of specific epitopes;
whether there is a description of a paratope of a monoclonal antibody;
whether the scope of an antibody claim in respect of the polypeptide is appropriate;
the availability and/or ease of production of the polypeptide;
whether there are indications on record which suggest a requirement for undue experimentation or undue adaptation of the known methods;
whether an antibody was actually prepared, and whether the applicant was in a position to provide a biological deposit of a hybridoma; and
whether there are indications of success or failure on record.

What about other types of antibodies?

While claims to monoclonal and chimeric antibodies are now being entertained in the absence specific examples, claims to humanized antibodies are still being routinely objected to unless they have been specifically exemplified in the description.

A basis for this Patent Office policy may lie in the 2009 Commissioner's Decision in *Re Sloan-Kettering Institute for Cancer Research Patent Application No. 2,072,017*[25] in which the Board considered a claim encompassing humanized antibodies to be neither supported nor enabled because, amongst other considerations, few laboratories ("in the neighbourhood of ten") were active in the field of antibody humanization at the filing date (December 14, 1990), and because the steps to a humanized antibody were then "considerably more involved" than those involved in constructing a chimeric antibody.

The recent decision in *Re Immunex Corporation* should embolden prospective patentees to argue that the standards set forth therein should apply equally to other sub-types of antibodies, particularly in view of technological advancements since 1990.

hence, the decision has not been published by the Patent Office.

[25] (2009) 82 C.P.R. (4th) 33.

CHANGES AND IMPROVEMENTS IN CHILEAN PATENT LAW

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I. CHILE SHORT OVERVIEW – SOME FACTS AND FIGURES

President Obama has just completed a two days visit to Chile on March 21-22, 2011 confirming the good standing of the bilateral relations. The incredible success of the Free Trade Agreement FTA signed between the U.S. and Chile in 2003 has meant that the commerce has raised 164%, and in 2010 a year marked by the consequences of the earthquake and the reconstructions of large areas of the country, the bilateral exchange raised to more than 15 billion dollars.

Nearly 15 thousand companies among importers and exporters with more than 7 thousand different products participate in this exchange generating almost 4 thousand employments in the U.S., thus this treaty has proved to be an excellent instrument to develop a healthy commercial relationship between Chile and the United States of America.

Commercially speaking, Chile is the world's opened country, having in force FTAs and other commercial agreements with a large number of countries and regions within can be found the European Union, EFTA, China, India, Japan, Korea, Australia, Canada, Central America and Mexico among others.

Intellectual Property was one of the hot topics discussed in this visit as there are some issues included in the IP Chapter of the FTA that need some harmonization efforts to have full implementation.

Important to include in this short overview is the entrance of Chile to the Organization for Economic Co-operation and Development (OECD) in May of 2010, thus being the first South American country to be accepted in this exclusive club of developed countries. The above has meant an international recognition to our country after two decades of reformulations to the democratic and economic systems.

II. SOME HISTORY OF THE IP DEVELOPMENTS

The Chilean Industrial Property Law has undergone in the last years mayor changes aimed to modernize and improve the standards of protection to IP holders.

The first important change was produced in 1991 with the entrance into force of a completely new and modernized Industrial Property Law (CL IP Law), text which has been amended twice in the last years. New IP Law 19.039 issued on 30 September 1991 included such new articles as for instance the allowance to patentability of pharmaceutical products per se, which in does days was a revolutionary step forward for a Latin American country and the addition of Chile to the Paris Convention.

Following Chilean modernization standards, a first amendment to the IP law was made on 1st December 2005 with the issuance of Law 19.996 which in short terms upgraded the CL IP law to TRIPS standards and to some aspects of the EU and US FTAs. This first amendment included so radical concepts for those days such as the 6 months grace period term for disclosures made prior to the filing of the application.

Continuing with the modernization spirit and to complement some missing aspects of the FTAs with the EU and US, the Chilean

IP law was further amended in Law 20.160 dated 26 January 2007. This new amendment to law 19.039 included further improvements in the IP law as for instance the extension of the grace period from 6 to 12 months as well as others which are discussed herein below.

A once new modernization of the IP standards in the last years was the entrance into effect of the Patent Cooperation Treaty (PCT) as of 2 June 2009, which meant that any international application filed on or after June 2, 2009, Chile (country code: CL) is automatically designated, and as it is bound by Chapter II of the Treaty.

The PCT is in full force in Chile and international applications filed as of 2 June 2009 are already entering national phase within the 30 months term from the priority application.

Finally, it is important to state that Intellectual property issues in Chile are managed by two separate laws, the Industrial Property Law - which governs patents, trade marks, industrial designs and utility models, and the Copyright Law number 17,336 which governs copyrights and was recently amended to comply with TRIPS and FTAs standards as well.

III. NEW IP STANDARDS

3.1. NEW FORMS OF PROTECTION

In addition to existing forms of protection, such as patents, trade marks, utility models and industrial designs, the new IP law includes the following new forms:

Industrial Drawings: figures in a two-dimensional plane, for incorporation in an article of manufacture, with ornamental purpose. They must offer a novel aspect to the product. This kind of two-dimensional right is granted for a non-renewable period of 10 years from the application.

Schemes and Topographies of Semiconductor Products: protection of the three-dimensional shape of elements in an integrated-circuit semiconductor chip. Protection is for a non-renewable term of 10 years from the application or from its first commercial exploitation in any part of the world.

Trade Secrets: protection of trade secrets is defined as the knowledge of products or industrial processes, of which continued secrecy confers on the owner an improvement or competitive advantage.

Undisclosed Information: The undisclosed information refers to the data submitted to the national authority that grants sanitary registrations and marketing approvals to pharmaceutical products (in Chile the Public Health Institute -ISP), or the Cattle and Agronomic Service (SAG) for agronomic products. According to the new legislation this data shall be undisclosed and secret for five years for pharmaceutical products and ten years for chemical-agricultural products, during time the official agent cannot give commercialization licenses to third parties using the secret data. In order to be eligible for data exclusivity protection, security and safety data must refer to undisclosed studies. Law provides that “data are deemed undisclosed when reasonable measures have been taken to maintain them as such and if they are generally not known or not readily accessible by people belonging to circles inn which the information is generally uses”. The ISP has also stated that data will still be considered as eligible for protection when the disclosure refers to information provided to the authority in order to fulfil with legal requirements. Once data exclusivity

authorization is recognized, the ISP cannot rely on such studies to allow registrations for third parties who lack authorization from the owner of such data for a period of 5 years counted as form the date of issuance of registration of the protected product.

3.2. IMPROVED AND BETTER ENFORCEMENT

Formerly, criminal proceedings were the only effective way to enforce IP rights in Chile. This made it very difficult for rights owners successfully to seek remedies because winning such procedures requires the plaintiff to prove bad faith on the part of the infringer. Although civil actions were also possible, they were governed by the general legislation, which is inadequate for these kinds of matters. The amendments of the law maintained criminal actions but also established special civil actions to enforce IP rights. The law amendments were aimed at stopping infringement, obtaining compensation, and getting the necessary court-sanctioned measures to prevent repeat infringements.

The plaintiff may choose how compensation is evaluated, either using the traditional form of lost profits and emerging damages, or an alternative according to one of the following criteria: the profits that the plaintiff has ceased to obtain as a consequence of the infringement; the profit that the infringer has made by means of the infringement; and the payment of a royalty.

Precautionary and prejudicial remedies were also included in the law amendment in case of infringement of any IP rights and in general Criminal proceedings were simplified in a major general law amendment.

In civil cases concerning process patents, the court may establish the reversal of the burden of the proof, i.e. that the burden of proof falls on the defendant when the products directly obtained by the patented method are new.

Finally, it is important to state that patent term was extended to 20 years from the application date, compared to the prior 15-year term awarded from the date of grant.

3.3. COMPULSORY LICENCES

Former IP Law 19.039 allowed for compulsory licences in the case of monopolistic abuse, but in the amendment two main causes are added, namely reasons of public health, national security, non-commercial public use, national emergency or others of extreme urgency declared by the proper authority, and when the exploitation of a patent cannot be done without a previous patent when, for instance, the new patent covers an invention of a considerable economic importance.

The process and requirements for granting compulsory licences meet all TRIPs Agreement guarantees, and shall be overseen in the first instance by the Free Competition Court in cases of monopolistic abuse, and by the head of the National Institute of Industrial Property (INAPI) in cases of public health, emergency, urgent or non-commercial public use, and by the ordinary courts in the event of dependent patents.

The amended IP law also provided for the international exhaustion of rights for all IP institutions. This criterion is consistent with the free trade and open commercial policy that Chile has adopted in the past three decades. Further, this general concept is in

line with article 6 of the TRIPs Agreement, which refers to the exhaustion of IP rights.

Former law provided for a Special Court of Appeals to hear cases judged in the first instance by the Chilean Industrial Property Department, the members of this court were not IP specialists. Under the amendments, at least six of the 10 members of the court are selected from specialized IP lawyers. Additionally, the court will have more space, with two regular rooms instead of one, and even three in special circumstances. According to the new text of the law, the intervention of the Supreme Court as a last recourse is envisaged in all kinds of cases, whether administrative or judicial.

3.4. GRACE PERIOD

As discussed before, our last law amendment of 2007 extended the Grace Period disposition to 12 moths from first disclosure of the invention, provided that the public disclosure:

a) Was made, authorized or comes from the applicant of the patent, or

b) Has been made or arises from abuse or unfair practices of which has been an object the applicant or the inventor.

This special disposition has included an exception to the absolute novelty requirement permitting for instance the presentation of applications having an international filing date that is prior to the entrance of Chile to the PCT (2 June 2009) but a first disclosure (usually the international publication date) that is less than 12 months from the CL filing date.

3.5. SUPPLEMENTARY PATENT PROTECTION

The possibility of requesting the extension of the patent term has been included in the last modification introduced to the Chilean Industrial Property Law of 2007, stating that within 6 months as from the granting of a patent, the owner shall be entitled to request a term of Supplementary Protection, always provided that unjustified administrative delay has existed in the granting of the patent, and the prosecution term has lapsed more than 5 years counted as from the filing date of the application or 3 years counted as from the examination request, whichever is longer. The Supplementary Protection will last only for the accredited unjustified administrative delay.

The Supplementary Patent Term shall be also requested if delay is produced in the sanitary registration for a pharmaceutical product protected by a patent. Specifically, Art. 53 Bis 2 of the CL IP Law : *"Within the 6 months of obtaining a Sanitary Registration for a pharmaceutical product protected by a patent, the owner will be entitled to request a term of Supplementary Protection for that part of the invention containing the pharmaceutical product, always provided that unjustified delay has existed in the granting of the said registration. This Supplementary Protection may be requested by those owners which sanitary registration lasted more than 1 year counted from the application date. The Supplementary Protection will last only for the accredited unjustified administrative delay."*

3.6 PATENT EXCEPTIONS

The new Chilean Patent Law includes some exceptions to patent rights in very special cases, as for instance the right to prevent third parties from importing, exporting, manufacturing or producing the matter protected by a patent with the purpose of

obtaining a sanitary registration or authorization of a pharmaceutical product.

However, our law is very clear to say that such an exception does not enable for commercialization of said products without authorization of the holder of the patent.

IV. OTHER GOVERMENTAL EFFORTS

4.1. CREATION OF THE NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (INAPI)

The old Industrial Property Department (DPI), a public repartition depending from the Ministry of Economics was replaced by the much modern National Institute of Industrial Property (INAPI), still a governmental institution but having higher budget and capabilities which has permitted among other improvements, the shortening in the prosecution of patent applications in 21% with respect to 2008 as well as the reduction of timeframes in other administrative proceedings.

4.2. NEW IP SPECIALIZED POLICE FORCE

Among the efforts made by the Chilean government to improve the enforcement of IP rights, the Police (PDI) created in 2008 a specialized task force called BRIDEPI, which only objective is to conduct investigations in connection to IP crimes.

In the last years this specialized force has seized important amounts of counterfeited products as well as pirate software.

4.3. BORDER MEASURES

Border Rules for the Observance of Intellectual Property Rights have been created basically establishing regulations for clearance of goods suspect of infringing intellectual property rights.

This new Law establishes two types of procedures: 1) upon the request of the interested party; and 2) upon the request of the Customs Administration.

In this regard, Customs are authorized to suspend clearance of suspicious goods for up to 5 working days due to copyright infringement or trademark counterfeiting, without prejudice of the sphere of competence of the qualified judge.

According to our law, IP infringement actions can not be initiated ex-officio neither by the Prosecutor, Customs or the Police, the only way to seek the seizure and destruction of the infringing products is to file the corresponding criminal or civil action for the trademark infringement and/or counterfeit, requesting to the Court for the judicial seizure and finally, the destruction of the infringing goods.

This improvement goes beyond TRIPS standards as it comprises all IP issues including patent enforcement.

V. EXPECTED TO COME

5.1. ADOPTION OF UPOV 91 ACT

The current Chilean Law is being adapted as per UPOV 91 Act.

As a result of the above, the protection standards will be improved since (i) the fruit will also be protected, (ii) the protection deadlines will increase from 18 to 25 years in the case of trees and grapes varieties, and from 15 to 20 years for the rest; (iii) the provisional protection will cover from the publication date of the variety to the

granting date. Other improvements as stated in UPOV 91 Act will be available as from issuance of the new law which is expected to occur very soon.

5.2. APPROVAL OF THE BUDAPEST TREATY ON THE DEPOSIT OF MICROORGANISMS IN THE FINAL STEP

On September 14, 2010 the Chamber of Deputies of Chile approved the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, done at Budapest on April 28, 1977. Consequently, the text has passed its final stage in the Senate of Chile where it is expected to be approved within the next months.

The objective of the treaty is to allow or require the deposit of microorganisms for patent registration procedure on biological material to an "international depositary authority, whether such authority is located in or outside the territory of the State in question.

VI. CONCLUSIONS

As discussed before, the Chilean IP Law has been continuously improving its standards in the last years. This, mainly as a consequence of three major reason: i) the general modernization of the country in view of our general policy of an open market nation; ii) to fulfil the minimum standards imposed by the TRIPs Agreement; and iii) due to obligations incurred after the signature of a number of free trade agreements and other commercial treaties which have obliged us the harmonization of our laws and the adoption higher standards in this area.

However, there is still work to be done, as for instance the ongoing war against piracy, the further improvement of our IP legislation, the training of our specialized IP courts so as to have better enforcement are among others missing issues that our authorities and IP specialist are working on.

The amended IP law has meant that international IP holders have in Chile a country with known international standards, where options available for protection of IP rights equate to standards in developed countries, where enforcement is possible, and most importantly, where legislation is acquiring the significance that all of us wish to see. Now it is in the hands of holders of IP rights to demonstrate that the adoption of these high levels will also result in benefits for a developing nation.

AMAZON 1-CLICK: THE FLIP FLOP IN CANADA OVER WHETHER SOFTWARE AND BUSINESS METHODS ARE PATENTABLE

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The Amazon 1-Click case has been a rallying point in the debate over the patentability of software patents in the United States for many years.[26] For example, in 1999 Amazon.com, Inc. sued its rival Barnes&Noble.com (resulting in a settlement in 2002), and an *ex parte* reexamination in the U.S. lasted four years before ultimately upholding the patent in 2010.[27] The Amazon case has raised a similar debate in Canada about software and business methods and has pitted the Patent Office against the Federal Court in a fight that has the potential to radically reshape the landscape on patentable subject matter.

Software and Business Methods Initially Appear Patentable

In February 2005, the Patent Office amended two chapters of the Manual of Patent Office Practice (MOPOP) related to patentable subject matter: Chapter 12 ("Utility and Subject Matter"), and Chapter 16 ("Computer-implemented Inventions"). These chapters reflected a significant policy relaxation by the Patent Office that opened the door for the patentability of software and business methods. Specifically, the 2005 version of the MOPOP provided as follows.

Computer-related subject matter is not excluded from patentability if the traditional criteria for patentability are satisfied.

Software that has been integrated with traditionally patentable subject matter may be patentable.

The expression "business methods" refers to a broad category of subject matter, which often relates to financial, marketing and other commercial activities. These methods are not automatically excluded from patentability, since there is *no authority in the Patent Act or Rules, or in the Jurisprudence to sanction or preclude patentability based on their inclusion in this category*.

The Amazon.com patent application ("the '933 Application") describes purchasing items over the Internet using a single-action (e.g. clicking a mouse button) by transmitting a client identifier associated with information about the buyer, which may be stored in a "cookie".[28] Originally filed in 1998, the Canadian application was finally rejected by the Canadian patent examiner in June of 2004 on grounds that all the claims were both obvious and covered non-statutory subject matter. However, the subject matter of the '933 Application seemed fairly technical and based on the revisions to MOPOP in 2005, there appeared to be a good argument that the examiner was wrong, at least on the question of subject matter, and that the '933 Application would be allowed on appeal.

[26] The U.S. application issued as Patent No. 5,960,411 on September 28, 1999.

[27] Reexamination No. 90/007,946 resulted in an *ex parte* re-examination certificate being issued July 13, 2010,

[28] Canadian patent application no. 2,246,933, filed September 11, 1998 by Amazon.com, Inc.

The Patent Appeal Board Rewrites the Law on Patentable Subject Matter

The Patent Appeal Board (PAB) first heard Amazon's appeal in late 2005, after the revised chapters of MPOP had been released. However, the decision by the Board was delayed. In fact, in an unusual and somewhat controversial move, in July of 2008 the PAB informed Amazon that two members of that original panel had retired before the decision could be finalized. Therefore the case would need to be reargued at a second hearing in late 2008. Following this hearing, in March 2009 (nearly five years after the examiner's final rejection and more than ten years after the '933 Application was filed!) the PAB released its decision.[29]

The Board found that all claims of the '933 Application were inventive and therefore overturned the examiner's conclusions on obviousness. However, the PAB rejected all the claims as being directed to non-statutory subject matter, including both the method and system claims.[30]

The Board stated that it was necessary to separately consider both the *form* of the claims (e.g. whether each claim on its face appears to define statutory subject matter) and their *substance* (e.g. what has been discovered or added to human knowledge) when determining whether the claims fall into one of the defined statutory categories under section 2 of the *Patent Act*. A claimed invention *could not* be considered as statutory if the particular feature (or group of features) that made it new and unobvious fell into excluded subject matter. Furthermore, in order for an *art or process* to be patentable, it must "cause a change in the character or condition of some physical object".[31]

The Board also took a very hard line with respect to business method patents, and stated matter-of-factly that business methods are not patentable in Canada, relying on a dissenting judgment from the Supreme Court of Canada in *Monsanto v. Schmeiser*,[32] and several UK and US cases.[33] This was a surprising conclusion as it clearly conflicts with the position of the Patent Office as set out in the 2005 version of MOPOP,[34] and other previous PAB

[29] Decision #1290, *Re Application No. 2,246,933*, (March 5, 2009) online at:

http://patents.ic.gc.ca/opic-cipo/comdec/eng/decision/1290/image.html

[30] e.g. an art, process, machine, manufacture and composition of matter, see section 2 of the *Patent Act*, R.S.C. 1985, c. P-4.

[31] See *Lawson v. Commissioner of Patents* (1970), 62 C.P.R. 101 (Ex. Ct.).

[32] *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R., 2004 SCC 34, see Justice Arbour's dissent.

[33] Including the Federal Circuit decision of *In re Bilski* (2008), 88 USPQ2d 1385 (CAFC) which has since been overturned: *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

[34] See *Manual of Patent Office Practice*, Chapter 12.04.04 (Rev. February 2005), online at: http://www.cipo.ic.gc.ca/eic/site/cipo internet-internetopic.nsf/eng/wr00723.html#no12.04.04

decisions.[35] The Board also held that any non-technological subject matter would be rejected as being non-statutory, since each of the five categories of invention that are identified in section 2 of the *Patent Act* inherently relate to technology.

The Board ultimately concluded that all claims of the '933 Application were rules for carrying out an online order, and were therefore unpatentable since they *did not change the character or condition of any physical object*. The Board also stated that the invention claimed in the '933 Application was nothing more than a "method of doing business" and moreover was not technological, and for these additional reasons was also unpatentable.

The PAB Amazon Decision and the MOPOP

Overall the PAB decision conflicted greatly with the text of the 2005 version of the MOPOP. The decision took a very negative view on the patentability of software and business methods and moreover suggested that this view was rooted in the depths of Canadian law. This is quite simply incorrect and was in direct contrast to the permissive language of the MOPOP in force at that time, which clearly stated that there was no authority in the *Patent Act* or *Rules*, or in Canadian jurisprudence to preclude the patentability of business methods.

This inconsistency was resolved in a rather Kafkaesque fashion, as work was already underway to rewrite the MOPOP. By the end of 2009, which was about 7 months after the decision of the PAB, new versions of Chapter 12 on patentable subject matter and Chapter 13 on examination were in force.[36] These revised chapters incorporated the language of the PAB decision and completely flip-flopped on the question of the patentability of software and business methods. Soon after, a new draft of chapter 16 was also released,[37] which provided a narrow definition of "computer-implemented invention," and made it clear that a "technological solution to a technological problem" is required *in order for a computerized invention to be patentable*. Given the similarity of the language and concepts used in the PAB decision and revised Chapters 12 and 13, the PAB decision was probably written concurrently with, or with knowledge of, revised Chapters 12 and 13.

This flip-flopping is very troubling, and clearly shows that the PAB decision was not an isolated incident but rather was a symptom of a major policy shift that spans the entire Patent Office.

The Federal Court Responds and Soundly Rejects the Patent Appeal Board

Perhaps unsurprisingly, Amazon appealed. On October 14, 2010, the Federal Court

[35] See for example Decision #1272, *Re Application No. 2,298,467* (March 5, 2009) online at:

http://brevets-patents.ic.gc.ca/opic-cipo/comdec/eng/decision/1272/summary.html, which upheld claims to a computer system used for purchasing diamonds.

[36] Both available online at: http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00720.html

[37] *Ibid.*

released a harshly worded decision[38] overturning the PAB and chastising virtually every one of its holdings. Quite bluntly, the Federal Court made it clear that software and business methods *could be patentable subject matter in Canada.*

The tone of the decision was unbelievably strong for a Canadian Court. Justice Phelan explained that "the Commissioner's conclusions [on the question of "form and substance"] are *not supported by Canadian law*,"[39] since the *Free World* decision had made it clear that the claims of a patent *must be interpreted in a "purposive manner"*. Any "form and substance" approach had been explicitly rejected.[40] Moreover, the Patent Office simply *cannot* "parse the claims into their 'novel' and 'non-novel' components in order to evaluate patentability" as claimed by the PAB.[41]

The Court then explained that a "technological requirement" is not a part of Canadian patent law, and moreover that the Commissioner had *absolutely no authority* to introduce such a requirement. In any event, introducing such a "technological" requirement would do nothing but render the Canadian patent system overly restrictive and confusing, since "[t]echnology is in such a state of flux that to attempt to define it would serve to defeat the flexibility which is so crucial to the *Act*."[42]

Justice Phelan also unequivocally stated that business methods could be patentable, explaining that there is an "absolute lack of authority in Canada for a 'business method' exclusion." He also clearly took issue with the policy driven nature of the PAB decision, referring to it as a "test case" as evidenced by "the questionable interpretation of legal authorities in support of the Commissioner's approach to assessing subject matters[sic]."[43] In his opinion, the "misapprehension of the Commissioner and the Examiner as to the patentability of the subject-matter in these claims is a fundamental error of law."[44]

However, in spite of the scathing tone of his decision, Justice Phelan refused to order that a patent be granted for the '933 Application. Instead, he remanded the case back to the Patent Office for expedited re-examination now that (in his view) the subject-matter issue had been resolved.

The Battle Continues…

Predictably the Commissioner of Patents was not satisfied with Justice Phelan's decision and appealed. On March 3, 2011, the Commissioner filed a Memorandum of Law and Facts setting out the framework for the appeal.[45] According to the Memorandum, the PAB's approach to "parsing" the claims was not inconsistent with the *Free World* decision, but simply builds on it. In particular, when considering patentable subject matter, the Court must *first identify the "actual invention"*. This is

[38] *Amazon.com, Inc. v. The A.G. of Canada and the Commissioner of Patents*, 2010 F.C. 1011 (*FC Decision)*.

[39] *Ibid., para. 43*

[40] *Free World Trust v. Électro Santé Inc*., [2000] 2 S.C.R. 1024 (*Free World*).

[41] *FC Decision, supra* at para. 42.

[42] *Ibid*. 71.

[43] *Ibid.*, para. 78.

[44] *Ibid.*, para. 81.

[45] Available online at: http://www.ippractice.ca/files/AmazonAppellantMemo.pdf

done so that it can be determined whether the invention is a justified exception to the historical public interest prohibition against monopolies. According to the Commissioner, this approach goes beyond the approach to claim construction as required under *Free World* for invalidity and infringement analysis, and in some cases may require further analysis that leads to different "essential elements" being identified. Then, with specific reference to the '933 Application, the Commissioner argues that Amazon's "actual invention" is merely a set of instructions by which known elements are used to process pre-existing information. Since these do not result in any physical changes, the claims of the '933 Application cannot fall within section 2 of the *Patent Act* and should be held to be unpatentable.

The Financial Institutions Seek Leave to Intervene

Shortly after the Commissioner's Memorandum was submitted, the Canadian Life and Health Insurance Association Inc. ("CLHIA") and the Canadian Bankers Association ("CBA") submitted a request to be granted intervener status in the appeal.[46] Both parties represent financial intuitions, including a large number of banks and insurance companies both in Canada and abroad. In particular, the CLHIA was established in 1894 as a voluntary trade organization and represents the collective interests of nearly all life and health insurers across Canada, with total assets of over $475 billion. The CBA similarly works on behalf of over fifty domestic and foreign banks that manage close to $3.1 trillion in assets.

The CLHIA and CBA argue that the outcome of the Amazon appeal will affect not only the '933 Application, but many more business method patent applications in Canada. In their opinion, the net result of the Amazon decision would be to allow the patenting of ideas and mental steps, such as those involved in various financial sectors, and that all aspects of a bank or insurance company will be affected. In particular, CLHIA argues that business method patents will create:

"an elaborate thicket of permissions… whereby each bank and broker, regardless of institution or asset size, would need to negotiate a full portfolio of licenses in order to carry on business, or worse, perhaps would not even be able to obtain such licenses."

This would lead to increased costs for consumers and erect barriers to entry, stiffing competition and negatively impacting the financial services that would be available across the country.

Both the CLHIA and CBA are actively involved in government lobbying, and have been strongly advocating against business method patents since at least early 2008. Conveniently enough, this was around the same time that the PAB decided to hold its second hearing in the Amazon case and begin revising the MOPOP. It appears therefore that their lobbying efforts have borne fruit.

[46] Available online at: http://www.ippractice.ca/files/AmazonInterventionByCLHIAandCBA.pdf

Navigating the Subject Matter Waters During the Ongoing Battle

At the time of writing, Amazon.com has just responded to the Commissioner's Memorandum, however it will be many months before a hearing is held and even more before a decision is rendered. Moreover, many predict this dispute to end with an appeal to the Supreme Court of Canada, which means that a final resolution to the question of patentable subject matter in Canada is likely several years away.

It is now clear that companies around the world are watching this case closely, particularly by financial intuitions and software companies with an interest in Canada, as the outcome is likely to have a significant impact on the landscape of patentable subject matter. In the meantime, patent applications continue to be filed and prosecuted and Canadian patent agents work and develop new strategies and techniques for obtaining broad patent protection. While challenging, progress continues to be made and sophisticated applicants should consider speaking with experienced Canadian patent agents to seek advice on how to successfully obtain protection for their software and business method innovations in Canada.

As an interesting side note, the current Commissioner of Patents, Mary Carman, will be replaced on April 15, 2011 by Sylvain Laporte. Some speculate this may signal a shift in Patent Office policy, including the Office's approach to patentable subject matter, but only time will tell.

AUSTRALIA INTELLECTUAL PROPERTY LAWS AMENDMENT (RAISING THE BAR) DRAFT BILL 2011

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The Australian Government has unveiled its Intellectual Property Laws Amendment (Raising the Bar) Draft Bill 2011 ("the Bill") for public comment. The deadline for the responses ends on 4 April 2011.
The purpose of the Bill and the intended amendments to the current Patents Act which may flow therefrom is to improve Australian Patent Law to be more in tune with that of our major trading partners.

It is the hope of any resultant changes that the validity of any granted Patent will be stronger because of expanded grounds of objection being available to the Patent Examiner, the resolution of Patent Applications will be quicker and that genuine research and experimentation of a Patent will not be stifled.

Normally, Transitional Provisions operate to exempt pending Patent Applications from the impact of any new laws introduced after their filing date. Not so, with the present Draft Bill. A potential major downside is the proposal that the below new standards/requirements on inventive step, utility, support and sufficiency will apply to all pending Applications for which an Examination Report has not yet issued. Therefore, the goalposts may be shifted while the "game is in progress" and Applicants cannot control whether an Examiner's Report will issue on their cases before the new rules apply.

The following are some of the changes proposed in the Bill:

Inventive Step

The current Australian Patents Act 1990 requires that the invention is assessed by the person skilled in the art in light of the common general knowledge in *Australia*. The Bill proposes to remove this territorial limitation. This will allow experts from any jurisdiction to provide evidence on the common general knowledge of an invention as at the priority date of the claim.

Coupled with the international view on "common general knowledge", the present three (3) part test that the information under consideration by the person skilled in the art in assessing the patentability of the invention must have been 1. *Ascertained*, 2. *Understood* and 3. *Regarded* as relevant, is to be removed. That said, information which the skilled addressee would not have appreciated as being relevant would be excluded under the new test.

Formal Introduction of an Enabling Requirement and the Need to Describe the Invention Fully

There is no requirement under the current Australian Patents Act to describe the invention fully in the basic Application (only the nature of the invention has to be described). However, many of our trading partners require an enabling disclosure to be present in the basic Application. Given that an Australian basic Application (or as it is known in Australia, a Provisional Application) is usually relied upon to justify a priority claim in an Australian PCT Application or an overseas convention Application, Australian practitioners prepare their basic/Provisional Applications with the foreign enabling disclosure requirement in

mind. However, the draft Bill wants to ensure that any basic or Provisional Application contains a comprehensive enabling disclosure regardless of whether it is to be relied upon in Australia or in an overseas jurisdiction or not.

As a corollary thereto, the complete specification will be required to provide sufficient information to enable the claimed invention to be produced across the full scope of each claim. The "best method known to the Applicant of performing the invention" requirement remains intact.

Since these are already standards that have to be met by most foreign originating Patent specifications, we do not see that overseas practitioners have to alter their drafting techniques in the preparation of basic Applications.

Fair Basis Requirement Modified to a "Support" Requirement

The expression "Fair Basis" as used in Australia is proposed to be amended to a "support" requirement. This also follows on from the enabling requirement discussed above, since the present concept of "Fair Basis" does not require a degree of enablement. The new "support" requirement seeks to encompass that there must be basis in the description for each claim and that the scope of the claims must not be broader than is justified by the extent of description, drawings and contribution in the art.
Again, we find that for overseas practitioners their specifications already comply with such a proposed new standard.

Prior Use considered during Examination

Examiners will be permitted to consider all publicly available information, including documents and acts and thus any prior use of the invention anywhere in the world.
The present "Grace Period" provisions of the Australian Patents Act will be altered to also cover secret use.

Utility/Usefulness – Specific, Substantial and Credible

Utility or usefulness will be another new strike weapon for the Examiner. The present definition of "useful" is proposed to be replaced by the need that the specification discloses a "specific, substantial and credible" use for the claimed invention. The change is to reflect the meaning of "usefulness" as given by the U.S. Courts and the USPTO.

Modified Examination is OUT for the Count

Australia currently provides the Patent Applicant with a choice of two (2) Examination Routes. Normal Examination, which is self explanatory and the one most favoured by Applicants. The other less often elected option of Modified Examination, wherein the Australian specification must be brought into substantial word-for-word conformity (save for a few minor formalities) with a corresponding granted overseas Patent which had issued from prescribed country.
If an Applicant was to elect Modified Examination, Australian practitioners would generally counsel otherwise. It seems that our prayers will be answered by the Draft Bill in that the Modified Examination option will be removed.

Whole of Contents Considerations

The requirements for a Whole of Contents novelty objection to hold are being simplified, wherein the relevant information

only now needs to have appeared at filing in the cited earlier Patent specification. It was previously also required to have appeared in the cited Patent specification on its publication.

Amendments

Amendments which attempt to expand the disclosure or claim matter beyond that which appeared in the specification at filing will not be permitted. Amendments to correct a clerical error or obvious mistake will still be allowed.

Standard of proof for Acceptance

The current practice calls for the Patent Examiner to accept a Patent Application "unless it appears practically certain" that the Patent, if granted, would be invalid. The Bill recommends a new and lower standard of on the "balance of probabilities", which test already applies during litigation of a Patent.

Divisional Patent Applications

Divisional Applications will no longer be permitted to be filed during the post-grant Opposition period of an Application. Divisional Applications or the conversion of a standard Patent Application to be a divisional must take place within three (3) months of the date of advertisement of acceptance of the parent case.

It is believed by stopping the filing of Divisionals during a pre-grant opposition that this will lead to a speedier resolution of Patent Applications.

Re-Examination considerations Expanded

The Bill introduces all grounds for attacking the patentability of an invention which are available to the Patent Examiner can be used during re-examination by a third party. Currently, only novelty and inventive step of the invention can be contested at the re-examination stage.

Again, the burden of proof test will be altered to be determined on the "balance of probabilities".

Therefore, there is now to be alignment/consistency of the burden of proof and also the grounds of invalidity on which the invention whether it is covered in a granted Patent or still in a pending Patent Application.

Research and Experimental Activities Exempt from Infringement

Infringement exemption provisions have been provided for genuine research and experimental activities.

The Draft Bill includes a list of activities that are deemed to be experimental. The list is not exhaustive. The exemption is not intended to apply where the main purpose is to commercialise the invention or manufacture the invention for the purpose of sale or use for commercial purpose. Market research of a patented invention by making and using the invention to ascertain whether there exists and the level of commercial demand for it would be an infringement.

Spring-boarding Provisions to be Expanded and are Exempt from Infringement

The Bill expands the current spring-boarding provisions (presently limited to pharmaceutical Patents) to include inventions in all fields of technology for the purpose of gaining regulatory approval as not constituting an infringement of the Patent.

Gene Technology

Gene-specific technologies are not dealt with in the Draft Bill. Gene-specific issues are currently being considered separately by the Senate Legal and Constitutional Affairs Legislation Committee and by the Government.

Formality Matters

It is proposed that Patents will no longer be deemed invalid merely because the Patent was granted to a "person" who was not entitled to it. This has been a favoured ground of attack in pre-grant oppositions.

An opposed Patent Application will only be permitted to be withdrawn with the Commissioner's consent.

At last, the Commissioner will be allowed to revoke the acceptance of a standard Patent Application, if it is reasonable to do so in all the circumstances. It is contemplated such power would be used where an administrative error has occurred during the process of accepting an Application.

Final Verdict

We consider that the Draft Bill improves many aspects of the current Act and will make the Australian Patent System stronger. In addition, the Australian Patents Act will be more harmonious with our major trading partners, which brings with it better certainty for the Patentee in the validity of any granted Australian Patent.

It is however disappointing to see that there has been no real effort made to align the Patent laws of both Australia and New Zealand (there is also a Bill being pending in New Zealand), since the two countries announced in February 2011 their joint intention to have a single examination process for both countries.

Patent Protection in India
Enercon Indian Patent Invalidation

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Late last fall, the Indian IP Appellate Board revoked 12 Indian patents of Enercon GmbH, a German wind power company. As the need to dramatize is always found by the news media worldwide, the German newspapers drafted articles raising concerns about possible corruption and a biased decision from the Indian appellate board for "national interest", since these patents cover technology that can be used in the installation and operation of wind turbines in India. Enercon was viewed by the German news media as being targets to allow such technology to be used more freely in India without restrictions due to the energy needs of India.

Enercon India Ltd. (EIL), the company who brought the invalidity action, is a joint venture of Enercon GmbH (56% share) and the Indian Mehra Group (44% share). EIL currently employs 3500 employees and has about $550 million in revenue. EIL was established 1995, but in 2005 a dispute arose between the two parent companies. In this dispute Enercon GmbH filed a complaint against the EIL management for mismanagement of the EIL joint venture. An interim injunction was granted in Oct 2007 effectively limiting the authority of the EIL management to only perform day-to-day operations. Although 2 years past, it appears that in retaliation of this injunction by the German company, in January 2009 EIL filed a petition for revocation of 19 Indian patents of Enercon GmbH, that were actually used by the joint venture. (nothing like having your joint venture company try to invalidate your own patents. That's Gutsy!) The results of this, as mentioned, was the Indian Intellectual Property Appellate Board (IPAB) revoking 12 of the patents. The patents were invalidated mostly based on obviousness type rejections. Currently the other 7 of the 19 patent invalidity actions are still pending for a decision from the IPAB. As would be expected, Enercon GmbH appealed the 12 decisions of the IPAB to the High Court in New Delhi. Oral arguments have already been held but no decision from the court has been announced.

Once the decision on the invalidity of these 12 patents was published by the IPAB the headlines that appeared in the German Newspaper "Handelsblatt" on January 25, 2011 read;

"*Patents Gone with the Wind*" "…. This court [IPAB] declared the patent during the proceedings, India, national interest was' to evaluate higher than the rights of a company on its technology. The background to this argument: The wind power plays in meeting future energy needs of India's important role. "

On February 2nd 2011 another German newspaper, "Faz Net" wrote "*Coldblooded Outser from India"* " …the line of argument adopted by the patent Judge in the EIL case nevertheless makes one sit up and take note: India's national interest should be placed higher than the rights of any individual company to its technology. "With this justification, almost every patent could be annulled in future in the name of the development interests of India", is what Enercon is saying." The general conclusions of these articles ware that there seems to be a case of self-serving logic here, with government sanction. Of course this got the attention of many major European companies including Siemens who has its own wind power business and is also well know in the Indian market for many products.

We wanted to determine if the newspapers were correct in their own analysis of the situation so we embarked on our own investigation of these actions to either confirm that this may be a concern for foreign companies who are doing business in India operating under the assumption that they are protected by having Indian patents or was this just the news media making news on its own again.

Here is what we found out:

The order itself invalidating these patents states that;

14. […] This is a case of invention dealing with the wind power mills technology. The invention in this field are very much needed for the society, […] Every such technology needs to be protected and such protection kindles the fuel of interest in the inventor so as to come out with more such technologies, which are useful to the society. But the patent system is designed to strike a proper balance between the inventor's interest and the public interest. ….. 26. In view of the above findings we also feel and are of the opinion, that to avoid delay […], this matter shall be disposed of along with all the other points in the main matter when all the ORA's are being heard immediately, […], so as to have speedier justice in the matter, such that these alternate sources of production of electrical energy can be tapped and utilized for the betterment of society and the public at large, either by way of upholding the patent grant or in the alternative, throwing open the same technology to the concerned industries to utilize the same in an expeditious and benevolent manner for the benefit of the industry and the public as well as the nation." interim order 166-2010 of IPAB from 27th July 2010)

We did some investigating on the foreign counterparts for these invalidated patents and found the following:

- Several of corresponding EP patents have been revoked in oppositions at the EPO.
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- Two of the EP patents were unenforceable in UK because of prior art.
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- A review of one of the orders (for IN202947) found significant weaknesses in the patent.

Thus, at least the decision to revoke the patent by the IPAB is not obviously wrong and does have some merit. We did find out that there have been some patent cases in the past where there was some corruption at Indian courts. However, in this case it appears there is no evidence of corruption and there are some facts supporting the invalidity of the patents. Also, we must keep in mind that if the patents are valid then the high court will likely overrule the decisions. We will have to wait for the decision.

The news media in Germany may also be part of Enercon's campaign to increase political pressure from German authorities towards India. Another interesting fact is that this case was a hot topic at the IP conference in New Delhi, on March 10th & 11th 2011, which had high ranking Indian and German officials as participants.

Some other considerations of India's patent system should also be noted to understand some of the background for these cases, including:

- Indian patent act has a long history and was made TRIPS conforming in 2005.
- There is not much case law and practical experience with enforceability of patents in India.
- There is more experience with trademarks and decisions are made without much delay (recent Siemens case: ex-parte injunction within a few weeks).
- The Chief litigator of Roche in India has stated that compulsory license has not been relevant until now, although Roche has patents for which such license could be requested.
- The absence of case law can also be seen as an opportunity to be actively involved in creating jurisprudence in our favor.

With all this said it remains difficult to determine if there really is any merit to the German news media's conclusion on national protectionism by India and one can draw a conclusion for either side. One thing for certain is that when dealing with any emerging market that has not dealt consistently in the past or is just developing legal precedence, on IP matters, one can never be sure of the outcome, or real protection, that they can count on from the patents they have in these emerging markets.

EPO PETITIONs FOR REVIEW

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I. Introduction

One of the changes in the renewed European Patent Convention (also known as the EPC2000) was the introduction of a review procedure for decisions of its Boards of Appeal by the Enlarged Board of Appeal (EBA). This review procedure was adopted as the Petition for review and codified as article 112(a) in the EPC2000,.

The wording of article 112(a) implies that only fundamental procedural defects can form a basis for review. Only intolerable deficiencies occurring during the appeal procedure may be reviewed. It is neither intended to extend the appeal procedure nor to ensure uniform application of the law by the Boards of Appeal.

Since the EPC2000 became effective on 13 December 2007, more than 40 petitions have been reviewed. Merely in one case the petition was successful and consequently the decision of the Board of Appeal was set aside and the appeal procedure reopened.

The evident message is that this petition for review procedure is not a strategy for success. This article reviews decisions of such petitions by the EBA in order to identify relevant factors, and particularly failures.

II. The Boards of Appeal within the EPO

According to Art. 21 (2) EPC2000, the Boards of Appeal are hearing appeals from decisions of the Receiving Section, the Examining Divisions, the Opposition Divisions, and the Legal Division form the European Patent Office (EPO) . An appeal may only be filed by a party that is adversely affected by a decision

Approximately 2000 appeals are filed annually. These appeals are distributed among the 26 Technical Boards and the Legal Board. 1600 decisions are rendered each year, which occur – usually – at the end of Oral Proceedings that are held before the Board. The written decision follows at a later stage.

Both the EPC, and the Rules of Procedure of the Boards of Appeal (RPBA) specify principles in order to organize the appeal process that envisions procedural expediency while ensuring legitimate expectations of the involved parties. Those principles are:

1. The right to be heard: A decision may only be based on grounds or evidence on which the parties have had an opportunity to comment (art 113(1) EPC);

2. The restriction to the submitted request (such as the claims): the request is either acceptable or not acceptable (art 113(2) EPC); and

3. Time limits and form of the appeal (art 108 EPC); the full scope of the appeal must be presented in the grounds of appeal submitted within 2 months of the filing of the appeal (or in the respondent's first reply) (art 12 RPBA). Any later submission may be rejected as late-filed, unless it is a response to the other party or an opinion of the Board (art 13 RPBA).

4. In case of oral proceedings, the Chairman of the Board shall state the final requests of the parties and declare the debate closed prior to taking and announcing the decision. The board will ensure that a case is ready for decision at the conclusion of the oral proceedings (art 15 RPBA).

5. Minutes of Oral Proceedings will be drawn up, containing the essentials of the oral proceedings, including any relevant statement made by the parties (R 124(1) EPC).

It is the objective that the Boards apply the law in a harmonized manner. In case of conflicting decisions of Boards and for important points of law referral may be made by a Board of Appeal to the EBA. The average number of decisions rendered by the EBA per year is between zero and three. Currently, two referrals to the EBA are pending. The EBA has been made responsible for examining Petitions for review.

III. Petitions for review procedure

Article 112a(2) EPC2000, defines the five types of acceptable grounds on which a Petition for review can be based. These grounds include: (a) a member of the Board took part in the appeal decision, (b) the Board included a member not appointed as a member of the Boards of Appeal, (c) fundamental violation of article 113 EPC, (d) any other fundamental procedural defects, and (e) a criminal act may have had impact on the decision.

The petition is to be filed within 2 months from the notification of the decision for grounds (a) to (d), and 2 months form establishment of the criminal act (ground (e)), but not later than 5 years for the notification of the decision.

The petition fee is high, i.e. €2625, and is only refunded when the petition is accepted.

The petition is admissible only if the procedural defect was objected by the party during the appeal procedure and rejected by the board unless, such objection could not be raised during the appeal procedure, e.g. the defect occurs when the decision is announced at the end of the procedure or occurs in the written decision.

Statistics

To date 55 petitions have been filed since 13 December 2007. 42 petitions have been examined and decided. 1 petition (R7/09) has been accepted and is presently under review. Of the 42 concluded cases, 36 petitions related to appeals in opposition proceedings; the other 6 petitions related to appeals in the examination proceedings. Presently, 13 petitions are pending (http://www.epo.org/law-practice/case-law-appeals/eba/pending-petitions.html).

The ground (c) in relation to the fundamental violation of Article 113, in particular the right to be heard, is most frequently developed in the petitions. In relation to the ground (d), i.e., any other fundamental procedural defect, petitioners do not always take account the limitations set by Rule104. These limitations are failure to hold requested oral proceedings and not deciding on a party request.

Concluded review cases did not relate to ground (b) on a non- appointed member of the Board of Appeal, and not to ground (e) on criminal act.

Table 1: Summary of concluded petitions for review divided by the petition ground pursuant article 112aEPC, in relation to ground (6) a subdivision was made; some petitions were based on more than one ground

	(a)	(b)	(c)	(d)	(d)	(e)
Subject	partiality or exclusion of a Board member	Non-appointed board member	Fundamental violation of not being heard	no decision was made on relevant request	Other defect	Criminal act
Occurrence in petitions	2	0	32	9	8	0

Ground for the decision on the petition for review

Most petitions are dismissed as being "clearly unallowable". The decision usually appears to use the expression "clearly unallowable", in order to emphasize that the case for the petition was evidently not complying with the requirements.

Inadmissibility most frequently resulted from the fact that the petitioner has not made the objection during Oral Proceedings and/or that the minutes of the oral proceedings did provide no evidence for the alleged defect.

Table 2: Outcome of *petitions for review*

Outcome	Nr of petitions	Comments
Allowable	1	Party was not properly informed of the Board and was taken by surprise by the decision without having the chance to comment on the appeal filed
Clearly inadmissible	9	Petition not properly filed (fee paid too late etc), or no objection made during Oral Proceedings or not in minutes
Clearly unallowable	26	Material issue and/or no violation found or no causal effect between violation and decision
Withdrawn	6	Typically after a negative opinion of the Enlarged Board

IV. Discussion: relevance of Oral Proceedings

As stated above, most Petitions for review resulted from appeals in opposition proceedings in which generally oral proceedings have been held. The conduct in oral proceedings appears to be very relevant in relation to possible procedural violations. Here, the parties – and particularly their representatives – bear the primary responsibility. Many decisions concluded that no review of the appeal procedure was considered necessary in view of one of following reasons:

i. the party involved did not object against the procedural violation during oral proceedings when possible. Consequently, the violation was not entered into the minutes of the appeal proceedings as an essential statement, and hence there is a lack of basis for a Petition of review;

ii. the party involved had the opportunity to giving its arguments to support a request or even file a new request, but did not do so (at least did not identify the request that could have saved its patent), thus the decision was delivered on a party request;

iii. there is no procedural violation, but the party involved is not satisfied with the decision or the arguments therein of the board of appeal

A regular complaint formulated in petitions is an alleged surprise that the oral proceedings have been closed and the decision rendered earlier than expected. The Enlarged Board attributes the full responsibility (for the alleged procedural violation) to the party and its representative. It is moreover expressed that there is no right for the parties to be informed, in advance, of the reasoning that the Board will adopt ultimately in the written decision. Oral Proceedings give the parties the possibility to take a position on the facts and the decisive arguments, but nothing more than that. Furthermore, a Board will not generally provide guidance as to requests a party is to present.

Conduct for the party

Apparently, there is a need for the party to be prepared for oral proceedings and an understanding what to expect during oral proceedings. It is not surprising that the EPO looks here to the party (and the party patent attorney) first. A good understanding of the RBPA is highy relevant. Generally, a patent attorney attends a few oral proceedings per year, whereas a Board of Appeal renders on average 60 decisions, probably on the basis of a similar number of oral proceedings. Hence, a patent attorney appears less experienced and might not oversee during the appeal procedure and in particular during oral proceedings formal and procedural requirements and pitfalls, such as to oversee an (ultimate) opportunity to present his case or file a request.

Thus, in order to be avoid the occurrence of a defect forming a sound ground for ultimate review, or when such defect occurs, it is of eminent importance that the party brings such occurrence immediately to the attention of the Board of Appeal, When rejected by the Board, the party should request that the rejection is entered into the minutes of the proceedings. Operating this way, such defect may form a sound basis for review. Obviously, defects in the oral or written

decision by the Board are beyond the control of a party to the proceedings.

V. Conclusion

Yearly, about 1600 decisions are delivered by the Boards of Appeal. Not more than 55 petitions for review have been filed over the past 3.5 years. The number of petitions thus represents a low percentage. Apparently, the frequency of fundamental procedural defects in appeal decisions is low. Although, the low chance of success and the high burden of proof may have be factors which establish a high barrier of entry.

RECENT DEVELOPMENTS IN THE QUEST FOR AN EU PATENT

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March has seen two significant developments in the long-running saga of creating a unitary patent system for Europe as opposed to the current system governed by the European patent Convention (a stand alone treaty open to all countries in Europe irrespective of whether they are members of the European Union) in which a "European Patent" issued by the European Patent Office breaks down into a bundle of national rights enforceable by national laws after grant. On March 8, the Court of Justice of the European Union gave its opinion on whether proposals for a European Patent Court system complied with the EU's basic treaties. On Mach 10 the Council of the European Union endorsed a plan for 25 of the 27 members of the European Union to create a single multinational patent right for themselves.

The idea of a single multinational patent for at least part of Europe has been under consideration since proposals for Common Market Patent were first developed in the 1960s. However, two issues have bedeviled all attempts to accomplish this objective: 1) the issue of language and 2) the question of how to handle litigation relating to a community wide patent. On the first some countries have felt very strongly that any patent enforceable in their country had to be in their language. On the second industry has been fearful about giving national courts with little experience in patent matters the power to invalidate a patent across the whole of Europe. Feelings on the first were sufficiently strong that the most recent EU structural treaty, the Treaty of Lisbon provides for the EU to set up an EU patent by use of normal legislative means (which require a qualified majority of the member states to agree), however the language regime for such a patent would require unanimous agreement of the member states.

In 1975 the Community Patent Convention was signed by the then member states of the European Community to create a unitary right and define the rights given by a patent. It was revised twice to meet criticisms of the original text but never came into effect. In 2000, efforts where the European Commission proposed a regulation to bring this about has suffered a decade of frustration for its efforts.

The Commission proposals for reform of the European Patent System were based on the idea that the European Union could itself join the EPC by the European Union as a combined entity for which a single patent (to be called a Community Patent) might be granted.[1] Such a patent would exist in the one language in which the application had been prosecuted (i.e. English French or German) except for the claims which would have to be in English, French and German. Additionally, the Commission proposed that a new court system be set up to have jurisdiction over all patent disputes throughout Europe. These proposals evolved only slowly due to political difficulties. A common political position was adopted at the EU Competitiveness

[1] COM(2000)412 final issued on August 1, 2000. In addition to the proposals noted above, the Commission's proposal includes a definition of infringement of a Community Patent which is essentially the same as that on the 1975 Community Patent Convention noted above.

Council meeting of March 7, 2003.[2] The major features were as follows:

1) Community patents would be granted by the European Patent Office with pre-grant procedure essentially the same as at present. Within a reasonable time after grant, however, translations of the granted claims into a language of each EU state requiring such a translation would have been required

2) The European Patent Office would have been be required to allow applicants having a national language other than English, French and German to have the preliminary steps prior to examination (including searches in non-EPO official languages) carried out in a national patent office acting on behalf of the EPO. The EPO may also have national patent offices that function in English, French or German, carry out searching on its behalf.

3) Renewal of Community Patents would be effected by fees paid directly to the EPO, with the level of such fees being set at no more than the "average" cost of renewing European patents under the present system.

4) A unitary Court for the Community Patent would have been set up in Luxembourg, although it will be empowered to hold hearings in other Member States. This court wold have exclusive jurisdiction in "actions and claims of invalidity or infringement proceedings of actions for a declaration of non-infringement, of proceedings relating to the use of the patent or on the right based on prior use of the patent or requests for limitation, counterclaims for invalidity or applications for declaration of lapse, including requests for provisional measures." Appeals from the Community Patent Court would lie to the General Court (formerly known as Court of First Instance) of the European Communities. The Community Patent Court would sit in panels of three judges and be assisted by technical experts.

Significant parts of industry said they would not use such a system.

Revised drafts of a Regulation to implement the Common Political Approach were issued in the summer of 2003.[3] A number of interesting issues emerged from the drafts, for example a provision for the grant of compulsory cross licenses if exploitation of a later patent for "an important technical advance of considerable economic significance in relation to the invention claimed in" and earlier patent is blocked by that patent.[4] Another was a possible expansion of the definition of infringement to cover acts carried out in the EU to assist in carrying out the patented invention outside the EU,[5] a broadening of

[2]Available on line at http://register.consilium.eu.int/pdf/en/03/st07/st07159en03.pdf

[3]It appears that adoption of the regulation is contemplated as being carried out under Article 308 of the EC Treaty rather than the more usual route under Article 251. Proceeding under Article 308 reduces the involvement of the European Parliament in adopting the legislation but does require unanimity in the Council.

[4]Draft Regulation Article 21. The language seems to be TRIPS-compliant. TRIPS adopted such language to try to reduce the old "patent-flooding" problems in Japan

[5]Draft Regulation Article 8

the exemptions from patent infringement to cover acts authorized by certain other EU regulations and directives[6] and introduction of a statute of limitation for starting a patent infringement action of ten years from the infringement subject to a requirement that the action must be brought within five years of the date on which the patent owner knew or should have known of the infringement.[7]

At the March 2004 meeting of the EU's Competitiveness Council there were signs that adoption of the regulation might not be proceeding smoothly when disputes arose as to how to deal with errors in translation of claims that were found to have occurred when a patent came to be litigated. These differences widened at the May 2004 meeting.

Following a review of the situation in 2006, the Commission indicated that it would make one final effort to secure agreement for a Community Patent regulation, this time with reduced translation requirements and a litigation system having regional courts of first instance for patent infringement and validity trials but a common court of appeal for the entire EU.[8] Further attempts to resolve the differences between the member states continued and the European Commission took the precautionary step of submitting its proposals for a patent court system to the Court of Justice of the European Union for an opinion as to whether the proposals complied with the basic treaties governing the European Union.

By December 2010 it became clear that it was highly unlikely that Spain and Italy would agree to the Commission's proposals on the translation requirements and 12 European countries requested permission to work towards a single patent covering all of them under the EU's enhanced cooperation procedure rather than waiting for the political problems relating to a single patent for the whole EU to be resolved. Since then all other EU member states except Spain and Italy have joined this request.

Enhanced cooperation procedures have been available in the EU since 1999 and subject to certain requirements provide a mechanism to permit groups of at least nine countries within the EU to cooperate more extensively than is required under the EU treaties themselves. The only previous use of the procedure so far has been in the field of divorce law to try to settle issues of jurisdiction in divorce proceedings of transnational EU couples.

In order for enhanced cooperation to be permitted all of the Commission, the European Parliament and the Council must agree. The March agreement by the Council was the final agreement required. The Commission at the request of the original twelve countries seeking enhanced cooperation published its proposal for enhanced cooperation in December, and Parliament approved the enhanced cooperation route on February 15.

[6]Draft Regulation Article 9

[7]Draft Regulation Article 45

[8]See the European Commission's publication "Enhancing the Patent System in Europe" COM (2007) 29-03-07 available on-line at http://documents.epo.org/projects/babylon/eponet.nsf/0/028A3690A78A516FC12572C6003F5A7B/$File/communication_en.pdf

The main provisions of the proposal[9] are as follows:

(1) A proposal for a Regulation of the European Parliament and the Council creating
unitary patent protection. This would provide that

– The unitary patent protection should be optional to the users of the patent system and should co-exist with national and European patents. The unitary patent should be a specific category of a European patent, granted by the European Patent Office, designating the Member States participating in enhanced cooperation on unitary basis.

– Consequently, a single procedure in accordance with the EPC would apply to unitary patents and to all other European patents. Until the moment of grant, applicants would have the choice between (i) a European patent valid in the territories of the participating Member States for which this patent would have unitary character, (ii) a European patent valid in the territories of the participating Member States for which this patent would have unitary character but also designating selected other Contracting States of the EPC, or (iii) a European patent designating only selected Contracting States of the EPC.

– The unitary patent should be of autonomous nature and provide equal protection throughout the territories of the participating Member States. It may only be granted, transferred, revoked or may lapse in respect of those territories as a whole.

[9]See COM (2010) 790 final dated December 14, 2010

(2) A proposal for a Council Regulation on the translation arrangements for the unitary patent. This would include the following

– It is envisaged that the specification of the unitary patent be published by the EPO in accordance with Article 14(6) EPC. Without prejudice to any transitional arrangements deemed necessary, no further translations would be required. Any additional translation requirements under such transitional arrangements would be proportionate and required only on a temporary basis and not have legal value thus ensuring legal certainty for the users of the patent system. In any case, transitional arrangements would terminate when high quality machine translations are made available, subject to an objective evaluation of the quality.[47]

– Translations should not have legal value thus ensuring legal certainty for the users of the patent system

– In case of a dispute relating to a unitary patent, a full manual translation of the patent specification would have to be provided by the patent proprietor at his expense:
(a) into an official language of the Member State in which either the alleged infringement took place or in which the alleged infringer is domiciled (at the choice of the alleged infringer); and

[47] On March 24, 2011, the European Patent Office announced that it had made an agreement with Google to use Google Translate technology European Patents into into 28 European languages, as well as into Chinese, Japanese, Korean and Russian.. It is hoped that the project will be completed by the end of 2014.

(b) into the language of proceedings of the court hearing the dispute (at the request of the court).

– A scheme for compensating the costs of translating patent applications filed in an official language of the Union into an official language of the EPO at the beginning of the procedure for applicants based in the Member States which have an official language other than one of the official languages of the EPO, should be set up in addition to what is currently in place for other European patents, including financial and technical assistance for preparing those translations.

In its statement approving the adoption of enhanced cooperation, the Council noted that the requirements of Article 20 of the Treaty on European Union and Articles 326 to 334 of the Treaty on Functioning of the European Union in that Enhanced Cooperation had only been adopted as a last resort after attempts to deal with the issue on an EU-wide basis had failed, that the legal area in question was not one in which the EU had exclusive competence, that the proposal furthered the objectives of the EU by fostering the internal market and promoting scientific and technological advance andwas not discriminatory against members of the EU not participating in the cooperation and did not distort competition.

It will now be for the Commission to produce drafts of the two regulations that have been proposed. These will probably include features relating to the nature of patent infringement, exceptions from patent infringement and other "property law" aspects of patents as set out in the Community Patent Convention and the subsequent proposed regulations.

On the question of the proposed patent court system. The Court of Justice held that as they stood, the proposals were not in compliance with the EU treaties. The Commission's proposal is for a Patent Court open to all members of the European Patent Convention and having a court of first instance, comprising a central division and local and regional divisions, and a court of appeal, that court having jurisdiction to hear appeals brought against decisions delivered by the court of first instance. A third body of the Patent Court would be a joint registry. The proposal specifically permits the first instance patent court to refer any question of EU law to the Court of Justice of the European Union and requires that the Patent Appeal Court refers any such question to the Court of Justice of the European Union. These provisions are analogous to those which apply generally to national courts.

The Court of Justice held, however, that there was an important difference between its relations with national courts and its relation with the proposed Patent Court system in that whereas it was possible to take action against countries or national courts that did not follow the rulings of the Court of Justice of the European Union, no such remedies would be available against the proposed Patent Court. Furthermore by removing jurisdiction over patent matters from national courts, the proposed agreement would deprive the national courts of their right to refer questions of EU law in fields within the jurisdiction of the Patent Court to the Court of Justice for a preliminary opinion. The Court of Justice therefore concluded that, as proposed at present,

the envisaged agreement, by conferring on an international court which is outside the institutional and judicial framework of the European Union an exclusive jurisdiction to

hear a significant number of actions brought by individuals in the field of the Community patent and to interpret and apply European Union law in that field, would deprive courts of Member States of their powers in relation to the interpretation and application of European Union law and the Court of its powers to reply, by preliminary ruling, to questions referred by those courts and, consequently, would alter the essential character of the powers which the Treaties confer on the institutions of the European Union and on the Member States and which are indispensable to the preservation of the very nature of European Union law.

Consequently, the proposal is not compatible with the basic governing treaties of the European Union. The Commission has stated that it will analyze the Court's decision "very carefully with a view to identifying appropriate solutions".