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PRODUCT-BY-PROCESS CLAIMS: A JURISDICTIONAL COMPARISON

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Introduction

In some circumstances, particularly in the chemical and life sciences, it can be difficult or impossible to define a product solely by reference to its structural or chemical features. Indeed, in many cases the precise structure or chemical formula may not be completely known at the time a patent is drafted.

A solution in these circumstances is to use a form of product claim that characterizes the product by reference to the process that has been used to make the product. Examples of such claims include: "Product X produced by Process Y", "Product X obtained by Process Y", or "Product X obtainable by Process Y". The use of product-by-process claims has been described as a "rule of necessity" when the inventive product cannot be described in any other way.[1] But a wide range of claim formats can be considered "product-by-process" claims, including claims partially limited by process steps or even product claims with functional terms.[2]

Typically, such "product-by-process" claims are thought to extend protection beyond that conferred by process claims alone. Yet, the same claim may confer distinctly different protection depending on the jurisdiction in which it is prosecuted or enforced. Crucially, the language chosen can greatly influence the examination and enforcement of these claims across several important jurisdictions.

Europe

The EPO considers the terms "obtained", "obtainable", and similar terms to be equivalent and directed broadly to the product *per se*. A product obtainable by a process is a claim format that, when read literally, should encompass all products with the resulting characteristics imparted by the process. A claim to a product obtained by that same process simply includes the end point of the process.

In line with this construction, the European Patent Office examines product-by-process claims as directed to the product *per se* without limitation as to how the products are actually produced. The EPO also restricts the use of product-by-process claims to when there is no other information available that could enable an applicant to define the product satisfactorily by reference to its composition, structure or some other testable parameter[3].

For infringement proceedings, the authors understand that all signatories to the EPC will construe the claims for infringement as the EPO does for examination – *i.e*. as directed to the product *per se*.

USA

For examination, current USPTO practice construes these claims as directed to the product, irrespective of the process by which it is made. Examination asks initially if the product itself is novel. Process limitations play a role only if "the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product."

[1] *Abbott Labs. v. Sandoz, Inc*., 2007-1400, -1445 (Fed. Cir., 18 May 2009) (Newman J., Mayer, J., and Lourie, J., dissenting, at *3, *8).

[2] Mirabel cited by dissent in Abbott

[3] Case Law of the Boards of Appeal of the European Patent Office, 5th Ed., 2006: pp211-213, paragraphs 6.1 and 6.3

The USPTO focus on the patentability of the product often appears to result in claims reciting whatever structural or physical limitations might be available to at least partially describe the product in those terms. These are necessarily less than comprehensive in limiting the claim (else there would be no process limitations) but more than what may be required by the EPO. The net result in prosecution can be a marked distinction in claims that grant in the US from their counterparts before the EPO. US claims may appear as "hybrids" - reciting structural features along with process limitations.

Recently, the construction of these claims for assessing infringement was settled in the *Abbott Labs v. Sandoz*[4]. Sitting *en banc* on only this issue, the CAFC held that product-by-process claims in the US include the process steps as express limitations of the claim. Contrary precedent, including *Scripps Clinic*,[5] has been expressly overruled. While this decision appears to have settled divided precedent on the construction of these claims in infringement proceedings, it perhaps raises further questions about how such claims should be examined. Indeed, the dissent in *Abbott Labs v. Sandoz* suggests that "[f]or the first time, claims are construed differently for validity and for infringement." Certainly, the holding of *Abbott Labs* now puts a premium on the ability to claim without reference to process limitations.

Interestingly, in light of the practice in other jurisdictions, the Court's majority opinion in *Abbott Labs* dismissed attempts by counsel for Abbott to finely parse claims based upon a plain language interpretation of "obtainable" as opposed to "obtained". The Court found this argument unavailing, at least on the facts of the case.

Japan

In Japan, product-by-process claims are generally treated broadly as claims to the product, *per se*, without limitation as to how the products are actually produced[6]. Thus, the approach in Japan is similar to the approach adopted in the US and in Europe during examination.

It is the authors' understanding that the Japanese Patent Office does not allow claims written in the "obtainable" format, and construes the "obtained" format broadly as a claim to the product, *per se*.

Australia

In contrast to the approaches in the EU, US, and Japan, but in line with Australia's emphasis on plain language interpretation, Australian patent law makes a clear distinction between the "obtained" and "obtainable" formats of these claims. A product "obtained" by the process is presumptively limited by the process features. A product "obtainable" by a process is presumptively to the product itself, unlimited by the process, though characterized by it.

The Australian Examiner's Manual suggests that the "obtainable" claim format will only be possible where the chemical structure or composition of the product is undetermined, echoing EP practice. However, in the authors' experience this restriction is not strictly observed, depending of the facts of the case.

Also in line with the Australian emphasis on plain language interpretation, these claims will likely be construed by a court using similar principles, looking to the detailed language of the claims in the context of the entire invention described by the specification to

[4] *Abbott Labs. v. Sandoz, Inc.*, 2007-1400, -1445 (Fed. Cir., 18 May 2009).

[5] *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991).

[6] *F. Hoffman La Roche v Otsuka Pharmaceutical Co., Ltd et. al.* (Heisei 06 (ne) No. 2857) Tokyo High Court, 17 July 1997.

determine the scope for infringement determinations.

Enforcement

For most product-by-process claims, the lack of explicit structural or chemical features of the product-by-process can lead to difficulties in enforcement. While a product-by-process claim may be presumed to cover the product, *per se*, the issue will often be whether the allegedly infringing product is structurally or chemically identical to the claimed product.

Some jurisdictions create a statutory presumption that any equivalent product is presumed to have been produced by the claimed process in the absence of evidence to the contrary[7]. This reduces the evidentiary burden upon the patentee when asserting a process claim, particularly in jurisdictions where discovery is limited. In practice, a plaintiff will likely be required to identify structural or chemical characteristics/properties of the product which result from one or more steps in the claimed process, and which are present in the allegedly infringing product, and which distinguish it from prior art products. This is certainly now the case in the US after *Abbott v. Sandoz* and appears to present a substantially increased evidentiary burden on the plaintiff.

Equally, however, where product by process claims are construed as directed to the product *per se* for infringement (e.g. in the EU, Japan, and, depending on the language of the claim, Australia) it can be difficult for potential infringers to determine whether their product falls within the scope of a product-by-process claim. The question becomes whether the characteristics imparted by the process claimed can be imparted by a different process. Of course, the uncertainty surrounding such claims may have a deterrent effect to potential infringers, even if ultimate infringement is not initially clear.

In most jurisdictions, process claims are deemed to also cover the product that has been made by the claimed process[8]. This provides an important means of protection where there are no claims to the product, *per se*, where the claimed process is performed outside of the patent jurisdiction, and the resulting product is imported into the patent jurisdiction.

Of critical importance, of course, is whether a claim will be construed as a product-by-process claim at all. A large diversity of claims can be drafted to fit within the class and "...there may be differing results depending upon the exact wording of a claim at issue". [9] This issue is likely of much greater importance to modern chemical or biological products that to mechanical products. Careful attention must be paid to how each jurisdiction may construe these claims in examination and infringement.

Summary & Suggestions

1. Consider carefully the scope of protection provided by product-by-process claims in each jurisdiction and shape prosecution strategy appropriately. The same claim will likely be construed differently across jurisdictions. Of course, where a process results in a product which is both novel and inventive, then product claims should always be included in the application.

2. Wherever such a product is difficult to define in structural or chemical terms, then product-by-process claims should also be included. Even where the product can be readily defined in structural or chemical terms, there may be advantages to the patentee to also include product-by-process claims, depending upon jurisdiction.

3. If product-by-process claims are needed, the specification's description should include claims in at least the "obtained" and

[7] Japanese Patent Law Section 104, Canadian Patent Act Section 55.1

[8] See, for example, EPC Article 64(2); Japanese Patent Law Section 2(3)(iii); 35 USC Section 271(g).

[9] *Abbott Labs. v. Sandoz, Inc.*, Lourie dissent at *3.

"obtainable" formats, with additional options for defining the product included. The "obtainable" format should be used wherever possible (*e.g.* Europe and Australia), with the "obtained" format being used in countries where claims in the "obtainable" format are not allowable (Japan), but which nevertheless construe claims in the "obtained" format broadly as being directed to the product, *per se*.

EFFECT OF INDIA PATENT LAW ON THE PATENTING OF DRUGS

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Section 3 of the current Indian Patent Act includes a description of subject matter that is not patentable. One of the most controversial provisions of this section is paragraph (d).

the mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation:

For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

This provision is cited during prosecution before the various Indian Patent Offices, in oppositions and was at is issue before the High Court in Chennai in the infamous Novartis decision. In this controversial decision, the High Court ruled in favor of the validity of this provision.

At the present time the Indian Patent Office continues to reject applications and opponents have been successful in challenging applications on the basis that they do not meet the criteria of Section 3(d).

The Delhi Patent Office rejected GlaxoSmithkline's (GSK) application for ethane sulphonate salt of rosiglitazone because according to the Patent Office GSK did not establish that the efficacy of the ethane sulphonate salt of rosiglitazone was superior to that of rosiglitazone.

Torrent Pharma Ltd. was successful in its pre-grant opposition challenging the patentability of Pfizer's application for the drug CADUET® (combination of amlodipine or its pharmaceutically acceptable salt (amlodipine besylate) and atorvastatin or its pharmaceutically acceptably salt (hemi calcium salt of atorvastatin)). According to the Indian Patent Office, Pfizer did not establish the efficacy of the combination as compared to the known compounds.

Ranbaxy Laboratories was successful in its pre-grant opposition to Gilead Sciences Inc. application for crystalline adefovir diprivoxil (AD). Ranbaxy argued that what was claimed was a crystalline form of AD and that unless enhanced efficacy over the known compound i.e. amorphous AD was established, it should be considered to be the same as the known compound and thus not patentable. Ranbaxy acknowledged that Gilead had submitted evidence that the crystalline AD form has a good melting point and/or bulk density properties that facilitates manufacturing and formulation of compositions containing AD; at least 97% (w/w) purity; and enhanced dissolution rate. It was Ranbaxy's position that all of these relate to physical properties and do not establish efficacy.

Gilead argued that the crystalline forms differ from the known amorphous form, for example, having different melting points, anhydrous - crystalline form, hydrated form,

solvated form and salt form. Gilead also "submitted that the pharmaceutical formulations of the invention including the crystalline AD exhibits marked in vitro antiviral activity against both HIV and HBV and is substantially efficacious over the prior art compounds and formulations."

In his decision, refusing the patent, the Controller stated:

I have observed that the applicants have not provided a comparative data with respect to the amorphous/parent compound of the alleged invention. Also no improvement in the therapeutic efficacy of AD as compared to its parent compound (PMEA) has been provided. In fact both the compounds (AD) is [sic] used to treat viral infections which is also the activity shown by the parent compound (PMEA). In view of the above I state that the subject matter for application no. 712/DEL/2002 is not patentable under section 3(d). (Decision at page 22).

An applicant seeking to obtain a patent for salts, esters, ethers, polymorphs, metabolites, pure forms, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance must be prepared to show improved efficacy as compared to the known substance and should keep in mind the following provisions from the Indian Patent Office's Draft Manual of Patent Practice and Procedure when drafting an application for this subject matter. Particular attention must be paid to section 4.5.4 that states that the comparative data is required to be made at the time of filing of the application or priority date.

> 4.5.1 Mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance is not patentable. According to the proviso to this sub-section, a known substance in its new form such as amorphous to crystalline or crystalline to amorphous or hygroscopic to dried, one isomer to other isomer, metabolite, complex, combination of plurality of forms, salts, hydrates, polymorphs, esters, ethers, or in new particle size, shall be considered same as of known substances unless such new forms significantly differ in the properties with regard to efficacy.
>
> 4.5.2 In order to be patentable, any salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance, they must differ significantly in the properties with regard to efficacy. The requirement here that namely the new form must result in enhancement of known efficacy of known substance and that in order to be distinct from the known substance, the new form must differ in the properties with regard to efficacy.
>
> 4.5.3 The examiner makes comparison with regard to properties or enhancement of efficacy between the known substance and the new form of known substance. In case the new form is further converted into another new form, the comparison is made between the already existing form and another new form but not between the base compound and another new form.
>
> 4.5.4 The comparison with regard to properties or enhancement of efficacy is required to be made at the time of date of filing of the application or priority date if the application is claiming the priority of any earlier application but not at the stage of subsequent development.
>
> 4.5.5 The efficacy need not be quantified in terms of numerical value to determine whether the product is efficacious because it is not possible to have a standard numerical value for efficacy for all products including pharmaceutical products.
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> 4.5.6 In regard to 'efficacy' in pharmaceutical products, the Madras High Court observed: "*going by the meaning for the word "efficacy" and "therapeutic" …, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease/ having a good effect on the body? In other words, the patent applicant is definitely aware as to what is the "therapeutic effect" of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for." "Due to the advanced technology in all fields of science, it is possible to show by giving*

necessary comparative details based on such science that the discovery of a new form of a known substance had resulted in the enhancement of the known efficacy of the original substance and the derivatives so derived will not be the same substance, since the properties of the derivatives differ significantly with regard to efficacy." (Novartis AG v. Union of India W.P. 24760/06).

It is not known whether Section 3(d) will withstand further challenges but one should expect that claims for salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance will be examined for inventiveness not only in India but throughout the world and applicants should whenever possible include comparative data in an application.

THE IMPACT OF THE DEVELOPING COUNTRIES ON PCT REFORM

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PCT Background

For quite some time PCT Users have indicated that the PCT is not meeting its full potential. One of the main purposes of the PCT was to avoid duplication of work by having the work done during the International Phase being recognized by others. However, this is not taking place. There is a lack of confidence in the work that is done on international searches, as well as international examination. The reason generally acknowledged reason for this is that the quality of the international search may not be as good as the quality of national searching.

This situation is especially noted in the USPTO and the JPO. EPO, on the other hand, appears to have a strong commitment to PCT as it is a major part of their work. When the EPO does an international search they do not repeat the work upon entry into the regional phase.

As a result of the lack of confidence in the PCT work, challenges have appeared to the PCT system. Patent offices have supported the PPH system, the New Route System and other approaches to work sharing. The fact that the PPH product is accepted with more confidence shows that a quality search and examination can provide for work sharing. It is this type of confidence that Users are interested in introducing into the PCT system to make it more efficient and to be able to achieve some of its original purposes.

With this in mind, the International Bureau proposed a Roadmap of milestones to improve the quality and efficiency of the existing PCT system. It was specifically identified as not making any changes in the PCT system, but simply an exercise in encouraging patent offices to achieve the milestones in order to improve the efficiency and quality of the existing PCT to develop a more effective use of the current PCT system. The Roadmap included recommendations that patent offices should provide only one search, both for the international and national phase; patent offices should review their reservations under the Treaty to make the system more uniform; examinations should be more complete and relevant, and consideration should be addressed to a collaborative type of search.

Purpose Of PCT Working Group Meeting In May, 2009 In Geneva

The essential purpose of the Working Group meeting in May 2009, was to pass a resolution to support the Roadmap and have it presented at the PCT Assembly in the Fall. Indirectly, it was to be able to encourage US and Japan to improve the quality of their international work so that they should not duplicate the work that they have done in the international phase when applicants enter the national phase in that same country. Also, to improve such quality so other patent offices would gain confidence in making use of this

work product, to the extent that their national laws permit.

Political Background

Historically, in various Intellectual Property issues there has been a divide between the Developed and the Developing countries. This divide had appeared in connection with harmonization talks, and thus far has been one reason which prevented adoption of any SPLT (Substantive Patent Law Treaty). It has also stimulated what has been called the Development Agenda, where WIPO was to address the needs of developing countries.

The PCT had been immune to such split between Developed and Developing countries. Essentially PCT was looked at as a procedural system, not effecting any of the national systems, but simply providing extra services and benefits to all Users, as well as to all patent offices.

Also, historically, decisions within WIPO meetings had been based on a consensus. Consensus in the past was understood as a majority of the delegates agreeing. More recently, however, the concept of consensus as exists in WTO has crept into the proceedings in WIPO. This concept is that consensus requires unanimity. To the extent there are any objections, WIPO now takes the position that they cannot move forward on any matter.

Concerns Of Developing Countries

For the first time in any PCT Working Group, a deep divide appeared between the Developed and the Developing countries.

A large number of Developing countries attended the Working Group meeting and objected strenuously to the Roadmap, indicating that they looked upon this proposal as threatening their national sovereignty to issue patents.

While led by Brazil, Egypt and India, the concerns were voiced by many other countries including Senegal, Brundai (not even a PCT member) Sri Lanka, Indonesia, Philippines, El Salvador, Zambia, Mali, Barbados and others.

The Developing countries voiced concerns that the proposed Roadmap might pave the way towards an international agreement on substantive patent harmonization, a goal that they believe would impose the will of the Developed countries on their national laws.

To some extent, this general opposition to any PCT Roadmap proposal, may have been stimulated by a separate proposal put forward by the United States, calling for a comprehensive reform of the system through the negotiation of a new PCT, referred to as “PCT-II”. The proposal for the new treaty included the feature that applications receiving a positive patentability report during the international phase, would automatically issue as national patents, possibly under a Hague type system whereby the national office would have a specific period of time to issue a notification of refusal.

The idea of automatically granting patent protection for applications that receive a positive report concerned many countries, especially the Developing countries, believing that this would impinge upon their national sovereignty.

Initially, the Developing countries did not want any progress in the area of avoiding duplication of work, which suggests to them impeding the national work based upon international activities. However, after continued discussion and reassurances by the Secretariat, as well as continued pressure by User groups, the Working Group ultimately agreed to permit WIPO to study the various issues relating to delay and quality and identifying the problems in the existing systems, and then identifying possible solutions. However, there was no formal endorsement of the strategy to move forward on the Roadmap.

Analysis

It appears that further work by WIPO in moving forward on the Roadmap, while not fully stymied, will clearly be slowed down. In the future, greater attention will have to be paid to the Developing countries, even within the PCT System.

It also appears that WIPO will have to address areas in which PCT can play a more significant role to Developing countries. To the extent PCT can be made more attractive to the needs of Developing countries, there may be a greater prospect of success in getting their cooperation on moving forward to achieve the goals of PCT and improve its operational aspects.

At present, it may be that PCT improvements will have to take place either through the Trilateral, or through the Meeting of International Authorities (MIAs). To the extent the new Director of the USPTO will be interested in improving the PCT, USPTO will be able to join with the EPO, who is already favoring PCT, and then in the Trilateral urge Japan to join them with such improvement. It is believed that the Administration will place great pressure on the new USPTO Director to improve the delay time and reduce backlog. Work sharing through the PCT would be a good opportunity to achieve progress on these goals. However, improvement in the quality of the international searches and examinations is critical to getting the most out of work sharing.

Accordingly, while progress within WIPO may be difficult to achieve, progress through the Trilateral looks more promising.

NEW RULES FROM THE EPO: RAISING THE BAR AND INCREASING LEGAL CERTAINTY?

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The EPO has introduced significant changes to some of the Rules of the European Patent Convention. Many of these changes are causing concern, particularly those governing the filing of divisional applications and those relating to mandatory responses to Search Report Opinions. The new rules will take effect on 1 April 2010 and some transitional provisions will apply after this date. It appears that the EPO's motivation for the (somewhat hasty) introduction of these new Rules, is to both increase legal certainty for third parties, and raise the bar in terms of the quality of patents that it grants.

Divisional Applications

Presently, a divisional application may be filed from an earlier European patent application at any time whilst the earlier application is pending (i.e. not granted, withdrawn or refused). However, in addition to this requirement, the new Rules stipulate that divisional applications may only be filed within a time limit of 24 months from the Examining Division's first communication in respect of the earliest application for which a communication has been issued, or within a time limit of 24 months from any communication in which the Examining division has objected that the earlier application does not meet the requirements of Article 82 EPC (unity of invention), providing it was raising that specific objection for the first time.

It seems that the word "earliest" in new R36(1)(a) indicates that should an examination report be issued on a divisional application before the parent application is examined, the 24 month time limit is triggered for filing a

divisional from either the existing divisional or the parent. In other words, the first examination report on a divisional application does not trigger a further 24 month time period in which to file a second divisional from the disclosure of the first divisional.

The consequences of the new rules are far from clear. R36(1)(a) means that, in practice, an applicant for a European patent application must decide whether to file any voluntary divisional applications from that disclosure within 24 months of the date of the issuance of the first examination report under A94(3) communication under R71(3) EPC (intention to grant) if examination of the application raises no substantive or significant objections.

R36(1)(b) is intended to allow the filing of divisional applications in response to the first objection from the Examining Division to a specific lack of unity in the claims of an application. This time period can run independently from that set out in R36(1)(a). This would occur if the first Examination Report did not raise a lack of unity objection, but such a rejection was raised in a subsequent Examination Report.

A situation in which this second time limit might take effect is when, having filed a divisional application, the Examining Division issues an examination report under A94(3) on that divisional application that includes an objection that the claims do not meet the requirements for unity of invention. If that objection of a lack of unity is being raised for the first time (whether on the earliest parent application or on the divisional application) then the issuance of that examination report will trigger a separate period of twenty-four months in which to file a further divisional application. If the same objection has already been raised in a previous communication from the Examining Division, even if it was raised on the parent application of a pending divisional application, then the further time limit will not be triggered.

The presence of the word "specific" in new rule 36(1)(b) appears to indicate that if a subsequent lack of unity objection is raised against different subject matter in the same application, this will be considered to be the first time that the specific objection has been raised. In other words, a second objection under Article 82 will trigger a further 24 month time period in which to file a divisional application, provided that the second objection does not relate to the same non-unified subject as the first objection under Article 82.

If either of the time limits for filing divisional applications is missed there is no legal remedy for reinstating the right to file a divisional application.

Although on first reading, the two separate 24 month time periods seem fairly straightforward, upon further analysis the situation seems far from clear. The co-implementation of the new divisional rules with the other rules, unless strictly monitored, is inevitably going to lead to inconsistent application of the various time limits, raising lack of unity objections and the enforcement of new rule 62a.

Plurality of Independent Claims vs. A lack of Unity.

New Rule 62a is concerned with the presence in an application of a plurality of independent claims in the same category.

Currently, if the EPO considers that there is a plurality of independent claims in any one category, all such claims will be searched, and the Applicant will be requested to restrict the claims to one independent claim per category during Examination.

Under new Rule 62a, if the EPO considers there to be a plurality of independent claims in any one category, it will ask the Applicant to indicate which of those independent claims it wishes to form the basis of the search. A two month time limit will be given for the applicant to respond.

Consequently, due to the introduction of new Rule 62a, not all independent claims will

be searched, meaning that the subject matter of these claims cannot be re-introduced into the claim set during examination, since unsearched subject matter cannot be examined. It therefore seems, at present, that the only way to pursue such unsearched subject matter will be by way of filing a divisional application. The new time periods for filing a divisional application, of course, must be taken into consideration. An objection raised under new Rule 62a will not trigger a new time period for filing a divisional application.

It is worth taking note that other rule changes that will be implemented 2010 detailed below may influence the application of the new divisional rules, particularly the time period triggered by the lack of unity. New rule 62a, as discussed above, will require the selection of a single independent claim per category (product, process etc) before search, if raised. If such an objection is raised by the EPO, the likelihood of a lack of unity objection being raised during examination is clearly reduced (unless caused by a lack of novelty/inventive step in the unifying concept, which will be identified during the search).

It remains to be seen whether the EPO will issue more objections under Rule 62a and/or Rule 43 to avoid issuing further lack of unity objections and thus avoiding triggering additional time periods in which divisional applications can be filed.

Up-Front Prosecution

As well as the Rule changes already mentioned, there are others which it seems have been drafted with the intention of trying to raise the bar in terms of the quality of patents granted by the EPO, by "weeding out" the weaker applications at an earlier stage in prosecution. It appears that in its effort to do so, the EPO has placed a lot of emphasis on frontloading prosecution. Many of the decisions that could in the past be deferred for a number of years will now need to be dealt with early on in the prosecution process. Some rules apply to all European applications, whether filed directly with the EPO, or entering Europe from the International phase of the PCT, and others just to ex-PCT applications.

At least two of the Rule amendments will have an influence on which International Searching Authority an Applicant may choose.

Responding To Search Opinion

Amended Rule 161 affects the timing of amendment of the application in response to ISR or IPER. This change only affects PCT applications entering the European regional phase.

Currently, a response to the Written Opinion of the International Search Report (ISR) or International Preliminary Examination Report (IPER) is not obligatory. If the EPO acts as the International Searching Authority (ISA) or the International Preliminary Examining Authority (IPEA), the first communication issued by the Examining Division of the EPO upon entry into European regional phase will generally be a reiteration of the written opinion of the ISR or IPER.

However, new Rule 161 means that if the EPO was the ISA or the IPEA, a response to the Written Opinion must be filed within of the time period set by the communication under Rule 161, to amend claims/pay excess claims fees. This communication is issued shortly after the publication of the ISR or shortly after entry of the application into the European regional phase, whichever is later. This significantly reduces the time period between entering the European phase and having to respond to substantive objections. Currently, such objections do not need to be addressed for time periods of anything up to three years after entering the European regional phase.

Therefore, for International applications where the EPO is the ISA (or IPEA) the Applicant should consider the objections raised in the Written Opinion prior to entering the EP regional phase. This may seem particularly harsh, in that if the decision to enter the European regional phase is taken very close to

the deadline for doing so, the Applicant is not left with very much time to consider and respond to the EPO Examiner's objections.

Using the EPO as ISA: Frying Pan or Fire?

However, before deciding never to nominate the EPO as ISA in view of the new Rule 161, Applicants should consider the effect of the new Rule 70a, relating to the mandatory response to the Extended European Search Report (EESR). The EESR is issued on all "direct filed" EP applications including all divisional applications, and on ex PCT applications that have entered the European regional phase, where the EPO was not the ISA.

Currently, it is optional to file a response to the Extended European Search Report (EESR), which consists of a European Search Report together with the Written Opinion of the Searching Examiner. If no response is filed, the opinion accompanying the EESR is re-issued as the first Examination Report.

New Rule 70a means that a response to the EESR opinion will be required by the EPO.

Consequently, it seems that the EESR should be treated as the first examination report insofar as all objections of the Searching Examiner must be addressed. The time period to respond to the EESR for an ex-PCT application is the same as that given for responding to the communication inviting the applicant to confirm that it wishes to proceed with the application, which is usually 2 months from the date of that communication. This communication normally issues shortly after the issuance of the EESR. For a direct convention European application, the period for response is within 6 months of publication of the EESR. The application will be deemed to be withdrawn if no response filed, in both situations.

It is worth noting that, in view of the new Rule governing the filing of divisional applications, although it may contain substantive objections, the EESR is unlikely to be considered to be the first communication from the Examining Division as it is currently issued by the Search Division. This remains to be clarified, however, once the Rules are implemented.

Therefore, in view of new Rule 161 and new Rule 70a, the Applicant may wish to nominate the EPO as ISA, as although the response to any objections raised by the European Search Examiner must be addressed earlier in the prosecution process, the Applicant will actually have a longer time period in which to address the objections.

Meaningful Search

Amended Rule 63 is concerned with the situation that occurs , if the EPO considers it impossible to carry out a meaningful search on some or all of the claims of an application (due to unpatentable subject matter, unclear claims, or a large number of embodiments). Currently, the EPO will draw up a search report as far as it can or it will issue a reasoned statement as to why a meaningful search cannot be carried out.

The amendment to Rule 63 means that if the EPO considers a meaningful search to be impossible, it will ask the applicant to provide a statement of the subject matter to be searched. If not provided, or if the statement is considered to be insufficient, the EPO will conduct a search to the extent that it can, or will issue a reasoned statement as to why no meaningful search can be carried out. Once the application has proceeded to examination, the Examining Division will request that the claims are restricted to searched subject matter. The unsearched object matter will only be able to be pursued in a divisional application. The time period for filing such a divisional will be dictated by new Rule 36(1) EPC.

Consequently, due to the amendment to Rule 63, the applicant will now have a chance to respond to an objection of the EPO that no meaningful search can be carried out. This should result in the searching of claims that may currently be unsearched by the EPO. This seems to be a sensible new rule from the EPO to try and minimize the number of applications in which it is not clear what is the invention. If the

Applicant clarifies the subject matter prior to a search, it should enable the correct invention to be examined.

Identifying Amendments

Amended Rule 137, related to amendments made to the application. Currently, the applicant may amend the description, claims and drawings of his own volition in response to the European Search Report and again after receipt of the first examination report. Any further amendments are only admissible at the discretion of the Examining Division.

As a result of new Rule 137 the applicant may amend the description, claims and drawings of his own volition only in response to the European Search Report. Any further amendments (for example, in response to any communication for the Examining Division) will only be admissible at the discretion of the Examining Division. Furthermore, any amendments made to the description, claims and drawings must be identified and basis in the application as filed must be provided.

Consequently, the applicant has only one chance, as of right, to make amendments to the application. All bases for amendments must be given. If basis is not provided or if the requirement is not met, the EPO will request that the Applicant corrects this deficiency within one month. This new Rule appears to have been implemented to ensure that applications do not proceed to grant and then subsequently fall at opposition due to the presence of "added matter". Many applications fall foul of the inescapable trap of having an unallowable amendment that cannot be removed during opposition due to broadening the scope of the granted claim if such an amendment is removed, which is unallowable. By identifying amendments as they are made during prosecution, the Applicant should be able to rest assured that any granted patent is less likely to fall on the "added matter" ground.

It will remain to be seen whether the bar will indeed be raised, or whether the new Rules will merely speed up the grant of patents, strong and, weak. As for legal certainty for third parties, this will only come to light once all the tricks in the book, and undoubtedly some new tricks, have been used to try and circumvent the new Rules. All we can do for now is watch, wait and perhaps be creative.

SUPPLEMENTARY INTERNATIONAL SEARCH

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Introduction

On January 1, 2009, the International Bureau of the World Intellectual Property Organization (WIPO) introduced a new element into the PCT system: supplementary international search (SIS). SIS is an optional service that allows a PCT applicant to receive one or more extra searches during the international phase in addition to the usual search performed by the applicant's International Searching Authority (ISA). New Rule 45*bis* of the Regulations under the PCT[10] establishes the SIS ground rules, which, like most of PCT, are somewhat complex and require some getting used to.

SIS was born out of the failure of the PCT system to provide sufficiently thorough international searches that reveal the full extent of the relevant prior art. International search is plagued by the tendency of ISAs to focus on prior art in languages with which the ISA examiners feel competent, while overlooking art in languages with which they are not familiar. By providing applicants with the opportunity to

[10] *See* http://www.wipo.int/pct/en/texts/rules/r45bis.htm for the text of Rule 45*bis*. For a PDF version of the complete Regulations under the PCT (as in force on January 1, 2009), *see* http://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct_regs.pdf.

request searches by more than one ISA, the goal of SIS is to increase the breadth of the languages being searched and thereby to produce a richer, more reliable, and more linguistically diverse means for discovering the relevant art before applicants have to make costly national/regional phase decisions.

SIS is expensive and is therefore not intended for routine use. It is, however, a tool that may prove to be both helpful and effective in prosecuting applications for commercially important inventions where significant prior art is known to exist in a language in which the main ISA lacks search capacity.

Main Features Of The SIS System

PCT applicants may request SIS from any ISA that offers it, but the ISA that carries out the main search may not also carry out the SIS. Applicants must file their requests for SIS with the International Bureau – not the receiving office or the ISA – within 19 months of the priority date, and they must pay supplementary international search and handling fees *in Swiss francs* within one month of filing the request. In light of the PCT requirement of unity of invention, if an application claims more than a single inventive concept, the supplementary authority will identify and search only one invention claimed in the application. The result of the SIS procedure will be the establishment of a supplementary international search report, which will generally issue 28 months from the priority date.

SIS is currently offered by only three ISAs: the Nordic Patent Institute (a "virtual ISA" that consists of the Danish, Icelandic, and Norwegian patent offices); the Russian Federal Service for Intellectual Property, Patents, and Trademarks; and the Swedish Patent and Registration Office. In addition to searching the PCT minimum documentation, the Nordic Institute searches documents in Danish, Icelandic, Norwegian, and Swedish; the Russian office searches documents in Russian and some other languages of the former Soviet Union or members of the Commonwealth of Independent States; and the Swedish office searches documents in Swedish, Danish, Finnish, and Norwegian. This is admittedly a narrow list of languages for the time being, but the Austrian, European, and Finnish offices are expected to begin offering SIS within the next year or two, with other ISAs considering joining the system sometime thereafter.

Mechanics Of The System

As mentioned above, the deadline for requesting SIS is 19 months from the priority date, a deadline that is predicated on the expectation – or at least the hope – that applicants will already have the benefit of the main international search. The deadline is binding, however, even in cases where the main international search report has not yet issued. The selected ISA will usually begin to carry out SIS upon receipt of the request and a copy of the main search report from the International Bureau, but where the main search report has not yet been established, the supplementary authority will begin SIS no later than 22 months from the priority date. The ISA has a 28-month deadline for establishment of the supplementary search report in order to ensure that applicants have sufficient time to study and react to the report before they have to enter the national/regional phase.

Applicants must use a particular form (PCT/IB/375[11]) to request SIS. The form allows applicants to specify the supplementary authority they have chosen to carry out the search and, in cases where the PCT application does not meet the requirement of unity of invention, to identify the claims relating to a single invention that the applicant wishes the authority to search. While the main ISA is generally bound to search the first claimed invention in cases of lack of unity of invention, the supplementary authority may focus on a different claimed invention if the applicant so requests. The supplementary authority is also free to disagree with the main authority's unity

[11] *See* http://www.wipo.int/export/sites/www/pct/en/forms/ib/editable/ed_ib375.pdf for an editable PDF version of the form.

of invention finding and determine that an invention possesses unity when the main authority found that unity was lacking, or vice versa.

The current ISAs offering SIS all accept and perform searches on applications written in English. Where the language of an application is not one that the authority searches, however, an applicant seeking SIS must translate the application into a language that the authority does accept. In the same vein, if an application contains a sequence listing, the applicant must submit a copy of the sequence listing in electronic format.

ISAs carry out SIS on the basis of the claims as filed in the PCT application. Consequently, any Article 19 or Article 34 amendments that an applicant may have filed will not be taken into account for the purpose of SIS. Furthermore, if an ISA does not normally search particular subject matter in accordance with Article 17(2) of the PCT, it need not do so when carrying out supplementary searches. So if the national law of an ISA does not permit the patenting of business methods or methods of treatment of the human or animal body, the ISA may refuse to carry out SIS. Similarly, if the ISA determines that the description, claims, or drawings are so unclear as to render a meaningful search impossible, it may refuse to perform SIS just as it may decline to perform the main search.

It is up to each ISA to determine the scope of the SIS that it is willing to undertake. The ISA will usually make such a determination at the time it declares its willingness to perform SIS. An ISA may declare, for example, that for each request for SIS, it will undertake a new search of the PCT minimum documentation as well as a search of documents in other languages held by that authority. The Swedish Patent Office and the Nordic Patent Institute have both agreed to such a broad scope. An ISA may decide to carry out SIS on the basis of a more restricted scope, however. For instance, an ISA may agree only to focus on language-specific documentation held by the authority. This is the case with respect to the primary scope of search offered by the Russian Federal Service; however, if an application relates to methods of treatment of the human or animal body and the main ISA has refused to carry out a search, the Russian Service will undertake SIS on a broader, all-inclusive scope. [12]

The fee for SIS consists of a supplementary search fee, which each ISA is free to set, and a supplementary search handling fee of 200 Swiss francs (CHF 200), which is set by WIPO. Requests for SIS may be withdrawn any time prior to the issuance of the supplementary international search report or declaration by the ISA that no report will be established, but the SIS fee will only be returned if the International Bureau has not yet transmitted the request for SIS to the ISA.

The Supplementary International Search Report

The result of SIS is the issuance by the ISA of a supplementary international search report (form PCT/SISA/501). The supplementary report resembles the main international search report, but it eliminates some elements that would be duplicative, such as the classification of the invention and the list of prior art citations included in the main report (unless the citations have a bearing on the findings of the supplementary report). The supplementary report also differs in that it is not accompanied by a written opinion, although the supplementary report may contain more detailed explanations than the main report regarding the references cited and, particularly where the supplementary authority had to carry out the SIS without the benefit of the main search report, it may include a fuller description of the scope of the search performed.

The ISA transmits copies of the supplementary international search report to the

[12] For a table outlining the requirements, fees, and scope of services offered by the three current SIS authorities, *see PCT Newsletter*, December 2008, available at http://www.wipo.int/edocs/pctndocs/en/2008/pct_news_2008_12.pdf.

applicant and the International Bureau of WIPO. In cases where an ISA does not establish the supplementary report in English (for example, where a Russian applicant requests SIS for a Russian-language application from the Russian Federal Service), the International Bureau will produce an English-language translation. It is also the responsibility of the International Bureau to send copies of the supplementary report to all designated offices once the application has entered national/regional phase and to make the report publicly available by posting it with the application file on the WIPO Patentscope® database.

Conclusion

It is far too early to judge the impact of SIS, especially since few applicants have availed themselves of the service so far. But if it serves the purpose for which it was intended, SIS should help applicants evaluate the likelihood of successfully prosecuting their applications in the national/regional phase and give designated offices greater confidence in the results of international search, thereby limiting the need to duplicate searches. The end result could be savings in time and efficiency for applicants and offices alike.

PCT-NATIONAL PHASE ENTRIES IN BRAZIL AFTER THE 30-MONTH TIME LIMIT

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Diverging from some national IP laws or Patent Office practices in other jurisdictions the Brazilian Industrial Property Law, henceforth referred to as BIPL and the rules of the Brazilian Patent and Trademark Office, henceforth referred to as BPTO do not contain time extension provisions for actions that could still be taken to avoid the loss of rights on paying a supplemental fee.

As a matter of fact, the BIPL and the BPTO rules (also known as the Normative Acts) do explicitly provide for the loss of rights or the definitive shelving of the application without right to appeal for formal deficiencies, while in other jurisdictions these deficiencies can be remedied with the reinstatement of the application on payment of a prescribed fee. By way of example, in BR such formal deficiencies entailing the definitive shelving of patent, trademark, and industrial design applications are:

(i) The Power of Attorney is not filed within 60 (sixty) days counted from the practice of the first act by the party, independently of a notification from the BPTO to the applicant or his patent attorney;

(ii) A reply is not filed to an office action within 90 (ninety) days independently of a notification from the BPTO to the applicant or his attorney also;

(iii) Non compliance with the requirements set out in an office action issued to an industrial design application, even if a timely reply was filed;

(iv) Non-payment of the final fee at grant and again, independently of a notification from the BPTO to the applicant; and

(v) National phase entry after PCT Article 22 time limit of 30 months.

It is also true that Chapter III Section 221 of the BIPL defines the legal remedy for excepting the failure to observe the respective time limits in (i), (ii), (iii), and (iv). As to (v), the failure to observe the 30-month term, at first glance, it could be inferred that Section 221 would also serve as basis for a request for the further processing of the national phase entry beyond said 30-month term but there are some limitations of legal and practical nature.

The Normative Act intended to rule the PCT National Phase Entry is as old as 1997 and until April 30, 2004 said Normative Act provided for national phase entry of PCT either chapter I and chapter II, i.e. 20-month and 30-month, respectively. The filing of the Demand within 19 months from the earliest priority was a legal requirement to benefit from the 30-month term, otherwise the BPTO would refuse the application which in turn was deemed to be withdrawn with respect to Brazil. Also, the failure to enter the Brazilian Phase within the 20 months term entailed the withdrawal of the international application as explicitly provided for in said BPTO rule. No remedy.

In addition, Section 221 dealing with time limits is silent as to the prescription time for the applicant to evidence legitimate reasons for the failure to observe the time limits defined in Brazilian IP practice. So, the BPTO adopted the 5 (five)-day term as provided for in the Civil Procedure Code (CPC), in Section 185 which is counted from the date on which the unforeseen event that prevented the party to take action in due time ended. Collision with PCT!

On September 27, 2008 Brazil, one of the seven PCT founding members which adopted English as the official language, became the 14th national ISA and IPEA counting with the support of 33 members. From that date on the BPTO has taken steps with a view to act as such by hiring and training examiners, enjoying cooperation agreements with Patent and Trademark Offices in examining countries and conforming the BPTO rules to the PCT rules.

On May 14, 2009 the BPTO laid down Resolution 212/09 which provides for national phase entries *after* the expiration of the 30-month statutory time limit as provided for in Art. 22 of the PCT when the failure to comply with the 30-month term is evidenced by unforeseeable circumstances or *"force majeure"* reasons *(ipsis litteris).*

Two new time limits are established in this resolution, e.g.:

- 2 (two months) counted from the date on which the unforeseen event that prevented the Brazilian phase entry in due time ended; or
- 12 (twelve) months counted from the expiration of the 30-month time limit, *whichever expires first*.

As also provided for in Article 24 (1) (iii) of the PCT, the international application shall be considered to be withdrawn with respect to Brazil according to Article 3 by the instant resolution.

The resolution goes further in stating that the application shall be examined on formalities. If the acts or occurrences alleged by the applicant as unforeseeable circumstances or *force majeure* are recognized as such, the request shall be accepted and the application shall be allowed to proceed to national phase entry.

Conversely, applicant's request shall be refused if he fails to evidence the unforeseeable circumstances or *force majeure* of his allegation in support of the belated PCT phase entry.

Applicant has the right to appeal within a period of 60 (sixty) days counted form the publication date against the decision that refused the processing of the national phase entry. Appeals shall be decided by the President of BPTO thus ending the administrative instance.

It is worth to reflect in practical terms:

First, Brazilian examiners are versed with concepts like legitimate reasons, *force majeure*, and act of God that have been cited by applicants as defense under the rule of impossibility to prevent the insurmountable loss of rights under normal conditions which is the spirit in the aforementioned Section 221 of the Brazilian Patent Law of 1996.

In view of long years experience any allegations lacking clear evidences shall be refused.

Diverging from the 5 (five) days term under Section 221 provisions the instant

resolution provides for a 2 (two) months term to take action. Time enough for obtaining pieces of evidence.

The instant resolution does not cite the department competent to decide on the allegations or evidences in support of the unforeseeable circumstance or *force majeure*. Allegations and evidence deemed controversial which at the end can be challenged on legal grounds by third parties mainly the competitors or the society in broad terms, shall be redirected within BPTO to the Attorney General Division of the BPTO.

Presently neither the BPTO nor the Attorney General Division is bound to time limits to render a decision.

Therefore ***it is the duty of care*** which shall count to the officers in the Patent Office, and that shall be evidenced by the applicant or the foreign associate instructing the case, when natural disasters are not the reason, aiming at acceptance of the unforeseeable circumstance or *force majeure*.

As a try of an unforeseeable circumstance or *force majeure* let us imagine that the PCT applicant instructs in due time his patent agent by e-mail but the patent agent does not receive in his inbox the instructions due to a failure on the provider's side. In turn, the patent agent in Brazil does not receive the corresponding order and fails to meet the 30-month term. The unforeseeable circumstance that prevented applicant's patent agent from instructing the patent agent in Brazil shall be evidenced by the event tracker or event log which e-mail providers have readily available. In another situation, when instructions followed by mail applicant or foreign associate shall evidence that the registered mail went astray.

As in all situations dealing with an exception to comply with a statutory time limit, the acceptance of the request for further processing of the PCT national phase shall be argued on a case by case basis with strong evidence.

Concluding, lack of a standard of reasonable care while facing deadlines that could even remotely but still foreseeable jeopardize applicant's expectations and to leave the final outcome to the discretion of the Patent Office is not an option.