

# Intellectual Property



## Note from the Editors

Welcome to the Summer issue of our *Intellectual Property Newsletter*. In this issue, we examine current topics involving intellectual property law, including:

- potential legal implications and business considerations for technologies involving human embryonic stem cells in Europe and in the U.S.;
- choosing the right strategy for fast-tracked prosecution, resulting from the USPTO's new rules relating to the Requests for Continued Examinations;
- and a summary of data exclusivity and patent term provisions in certain key countries in Asia and South America.

We hope you find the articles interesting and helpful to you and your company.

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# Legal Implications and Business Considerations for Technologies Involving Human Embryonic Stem Cells in Europe and U.S.

By Brian A. Donahue and Terri Shieh-Newton

The future may be getting brighter for stem cell researchers in the United States as restrictions for funding of stem cell research have been loosened, but efforts to commercialize stem cell technologies have faced a new hurdle with a recent decision by a European court regarding the patentability of human embryonic stem cells. In October 2011, the Court of Justice of the European Union (CJEU) issued a decision ruling that inventions related to human embryonic stem cells are unpatentable in the European Union.<sup>1</sup> An aspect of the court's decision that is particularly troublesome to stem cell practitioners is the court's ruling that even if claims in a patent application do not require destruction of a human embryo *per se*, if the claim is construed to use cells that had to have been obtained by the destruction of a human embryo, then the claim is not patentable. The court ruling does not prohibit stem cell research in Europe but limits patent protection for human embryonic stem cells, methods that use human embryonic stem cells, and cells that are derived from human embryonic stem cells. This European court decision will have major implications for stem cell companies when formulating a global patent protection strategy and should be considered as part of the business plan.

## The European court decision

The current CJEU decision stems from German Patent DE197586864 awarded to Oliver Brüstle of the University of Bonn. Claims of the Brüstle patent are generally directed toward populations of neural precursor cells derived from embryonic stem cells and are potentially useful

for the treatment of neurodegenerative diseases such as Parkinson's disease. It is noteworthy that the claims of the Brüstle patent do not specifically recite the use of human embryos to obtain human embryonic stem cells. Greenpeace brought the Brüstle patent to the German courts citing that the Brüstle patent was against the morality provisions of German patent law.

...EFFORTS TO  
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The German court held that the Brüstle patent was invalid in so far as it covers precursor cells obtained from human embryonic stem cells and processes for the production of these precursor cells. Brüstle appealed the German court decision. The German court stayed the proceedings and instead referred the case to the European court on the premise of an article of the Convention on the Grant of European Patents (CGEP) which states that "European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States."<sup>2</sup> Although

the Convention provides for the patentability of any invention, in all fields of technology, it should be noted that ethical or moral principles supplement the standard legal examination under patent law regardless of the technical field of the invention.<sup>3</sup>

## Three questions posed to the European court

In passing Brüstle's appeal to the European court, the German court posed three questions to the CJEU with regard to the patentability of human embryonic stem cells and with regard to the scope of human embryonic stem cells that might fall under such a ban. The answers to these questions provide insight into how the European court views the patentability of human embryonic stem cells. These insights should be taken into account by stem cell practitioners when developing strategies for protection and commercializing their technology in Europe.

**Question 1** – The first question answered by the European court dealt with what is meant by the term "human embryos." The German court provided some examples in an effort to help clarify the question.<sup>4</sup>

The European court answered that based on its interpretation of directives issued by the European parliament, any human ovum must, *as soon as fertilized*, be regarded as a human embryo.<sup>5</sup> The court made it clear that this classification also applies to a non-fertilized human ovum into which a cell nucleus of a mature human cell has been transplanted and this classification applied to a non-fertilized human ovum that has been stimulated to division and development by parthenogenesis.<sup>6</sup> With this approach, the court has essentially encompassed any cell capable of commencing to the development

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of a human being in the court's definition of "human embryo."

As such, the European court has included a broad range of cells that fall under the scope of human embryo. Essentially, the court is including *any* totipotent cell that has the capacity to differentiate into a human being as a human embryo. This would include totipotent cells that are not generated by fertilization of an egg. Examples of potentially totipotent cells that may fall under the European court's interpretation of a human embryo include stem cells generated by parthenogenesis, a method by which an egg is stimulated to replicate in the absence of fertilization, and cells generated by nuclear transfer, a process where the DNA of an egg is replaced with the DNA of a mature somatic cell.<sup>7</sup> Nuclear transfer, referred to as Somatic Cell Nuclear Transfer (SCNT), is the process that was used to make Dolly the sheep. Clearly, the definition of a human embryo put forth by the European court will impact the scope of cells that fall under the guideline of cells that require the destruction of a human embryo or the previous destruction of a human embryo. In this regard, any technology that utilizes totipotent stem cells may be interpreted as utilizing human embryos.

In posing its first question, the German court specifically asked about cells obtained from a blastocyst, a stage at which stem cells are often obtained from embryos.<sup>8</sup> The European court ruled that it was up to referring the court (*i.e.*, the German court) to ascertain if cells derived from human embryos at the blastocyst stage are capable of commencing the process of development into a human being and therefore are included in the concept of "human embryo" within the meaning and for the purposes of European law.<sup>9</sup> It is unclear

if human egg cells, stimulated to replicate by parthenogenesis or nuclear transfer, are capable of forming a human being. Moreover, it is unclear how "commencing" the process of development of a human being will be defined. For example, how far along a development pathway will cells still be considered to be capable of developing into a human being? It will be interesting to see how the referring court rules on this issue. Clearly, this ruling will shape what sorts of stem cells will or will not be patentable in Europe.

...THE USE OF HUMAN EMBRYONIC STEM CELLS MAY BE INCLUDED IN THE USE OF HUMAN EMBRYOS FOR INDUSTRIAL OR COMMERCIAL PURPOSES INCLUDING SCIENTIFIC RESEARCH.

**Question 2** – The German court asked the European court what is meant by the expression "uses of human embryos for industrial or commercial purposes"? Specifically, does the use of human embryos for industrial use include *any* commercial exploitation within the meaning of Articles of the European convention, especially the use of human embryonic stem cells for the purposes of scientific research?<sup>10</sup>

The court answered that the use of human embryos for industrial or commercial purposes also covers the use of human embryos for purposes of scientific research.<sup>11</sup> As outlined in the answer to Question 1, the use of human embryonic stem cells may be included in the use of human embryos for industrial or commercial purposes including scientific research. This answer may have implications for

a wide variety of stem-cell-based patent applications ranging from applications directed toward therapeutics to diagnostics to research tools.

The court suggested that the only use of human embryos that may be patentable is for therapeutic or diagnostic purposes where the embryo is kept alive.<sup>12</sup> This use would include human embryonic stem cells, for example, a use by which stem cells are removed from an embryo, treated *ex vivo*, and put back into the embryo for the treatment of genetic disorders.

This leads to an interesting possibility where certain human embryonic stem cells, or cells derived from human embryonic stem cells, may be patentable. Dr. Robert Lanza of Advanced Cell Technology has proposed a process to establish human embryonic stem cell lines by removing a single cell from an embryo during an *in vitro* fertilization.<sup>13</sup> The embryo is not destroyed in this process, but rather, can be implanted in a mother.

**Question 3** – Arguably the most important question asked of the European court is whether a stem cell technology is unpatentable pursuant to the court's Directive even though the use of human embryos is not explicitly claimed in the patent, but the use of human embryos is a necessary precondition for the application of that teaching. For example, if the patent concerns a product whose production necessitates the prior destruction of human embryos, or because the patent concerns a process for which such a product is needed as base material. As noted above, claims of the Brüstle patent did not recite any cells or methods explicitly requiring the destruction of human embryos, but rather, relied on embryonic stem cell lines.

The court answered that the Directive excludes an invention from patentability where the technical teaching of the patent application requires the *prior* destruction of human embryos or their use as a base material, whatever the stage at which that takes place and even if the description of

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the patent application does not refer to human embryos.<sup>14</sup>

It will be interesting to see how broadly the European courts interpret the meaning of requiring the prior destruction of human embryos. For example, would a cell line be considered unpatentable if it *could* be generated by a process where embryos are not destroyed, for example, the process proposed by Dr. Lanza? Similarly, is the use of a gene unpatentable by the mere fact that the gene was identified in a human embryonic stem cell even if one can practice the use on other types of cells (e.g., induced pluripotent stem cells or adult stem cells)?

## The impact of the European court decision on the European Patent Office

A key question that remains is how the European Patent Office (EPO) will react to the European court's decision. The European Patent Office was formed as a result of the European Patent Convention and is not a part of the European Union. As a result, unlike the EU member nation courts, the EPO is under no obligation to follow Directives of the European court. Thus far, the EPO has not issued any directives in response to the European court's decision. This could potentially lead to a bizarre situation where a stem-cell-related patent may issue from the EPO but will not be enforceable in most European nations.

In the past, the EPO has allowed patent applications directed toward differentiation of pluripotent stem cells to more mature phenotypes in cases where one could start with the established human embryonic stem cell lines. The EPO has taken the stance that human embryonic stem cells were publically available on or after May 9, 2003, the earliest date that human embryonic stem cells were deposited with the United

States National Institutes of Health. Therefore, the EPO has allowed stem-cell related patents that have a priority date on or after May 9, 2003. For example, under current EPO practice, a patent application filed in January of 2004 and directed toward differentiation of human embryonic stem cells to a mature phenotype, such as a liver cell or a neuron, may be considered patentable if the invention could have been practiced with an established human embryonic stem cell line at the filing date of the application. Under the European court's decision, however, such a patent application may be considered unpatentable because obtaining the starting material, a human embryonic cell, would have required the destruction of a human embryo at some point in time.

## How will the European Patent Office react to the Brüstle decision?

It is hard to predict how the EPO will react to the European court's Directive, but one can get a glimmer of the EPO's thoughts on this matter by looking at the EPO's "WARF Decision."<sup>15</sup> The WARF decision is based on a European patent application filed by the Wisconsin Alumni Research Foundation (WARF) and naming James Thomson as inventor. The patent relates to Dr. Thomson's development of methods to culture human embryonic stem cells. In the WARF decision, the Enlarged Board of Appeal of the EPO ruled that a patent application filed by WARF was unpatentable in view of Article 6 of the European convention which states that "European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States." This is the essentially the same legal standard held against Brüstle.

It is noteworthy, however, that the WARF patent application was filed before the May 9, 2003 date when established human

embryonic stem cells were publically available. As such, cells recited in the claims of the WARF patent required the destruction of human embryos, and the WARF decision does not contradict current EPO practice. But given the European court's Directive, particularly with regard to the unpatentability of cells that required prior destruction of human embryos, it is quite possible that the EPO will no longer allow human embryonic stem cell cases filed after May 9, 2003.

We note that European patent examiners are requiring provisos to the effect that claimed stem cells are not derived from human embryos or are not human embryonic stem cells. For example, the EPO granted a patent to Dr. Brüstle based on the German patent, but the claims include the phrase "with the proviso that the method does not include the destruction of human embryos."

## What about patent protection for other types of stem cells and stem cell technologies?

On a more positive note for stem cell scientists and practitioners, the European court decision impacts only human embryonic stem cells. It does not cover a number of other types of stem cells, such as induced pluripotent stem cells (iPS) and adult stem cells. iPS cells are generated by taking mature somatic cells and forcing them to dedifferentiate to pluripotent cells. For example, skin cells from a patient can be dedifferentiated to produce pluripotent stem cells which, in turn, can be differentiated into a different type of cell such as a liver cell. As no embryos are involved in this process, iPS cells do not fall under the directive of the European court decision. All in all, iPS cells show great potential as an alternative to human embryonic stem cells.

Adult stem cells also do not fall under the Directive of the European court. Adult stem cells are cells that are obtained from non-embryonic sources, like adults, and are pluripotent and/or multipotent for a particular subclass of cells. For example, blood stem

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cells are cells that can differentiate into any of the many types of blood cells including red blood cells, T cells, B cells, etc. Other adult stem cells that show promise for the development of therapeutics include liver stem cells, pancreatic stem cells, skin stem cells, and neural stem cells.

It is important to note that the European decision only affects human embryonic stem cells. Other stem cell technologies, such as mouse embryonic stem cells, do not fall under the court's Directive.

Additionally, the European decision arguably does not affect the ability to patent the technologies themselves that are needed for effectuating human ES cells into treatments, provided that the claims are carefully crafted to be directed to these technologies themselves. These types of technologies could include cell culture media, growth factor formulations, incubators, and other equipment for growing cells.

## Patentability of human embryonic stem cells in other countries

Although the prospects of earning protection for human embryonic stem cell technologies in Europe does not look very promising, the protection of human stem cell technologies is available in a number of countries including the United States, Canada, and Australia. Patent protection for stem cell technologies also is available in Japan, although Japanese patent law does include morality limitations. So far, the patentability for human embryonic stem cells has not reached the courts in Japan. In China, on the other hand, human embryonic stem cells are not patentable according to Chinese patent laws.<sup>16</sup>

In the United States, three patents awarded to WARF were challenged using the United States Patent and Trademark Office's reexamination procedures. These patents

are based on Dr. Thomson's work and correspond to the technology that was subject to the EPO's WARF Decision. Two of the WARF U.S. patents survived the reexamination procedure with relatively few changes. The third WARF U.S. patent was deemed invalid during the reexamination procedure and is now under appeal by WARF. It is noteworthy however, that in the U.S., the WARF patents were challenged based on prior art rather than for morality issues.

## Moving forward in the EU

The CJEU decision is sure to have an impact on companies wishing to commercialize stem cells. Stem cell patentees will have to reassess their portfolios as the national courts and EPO react to the CJEU decision. Stem cell practitioners should consider alternatives to embryonic stem cells, such as iPS cells. On a broader note, stem cell companies will have to assess their business strategies in view of weaker patent protection in Europe compared to other jurisdictions where patents directed toward human embryonic stem cells are permitted, such as the U.S. and Japan. Chris Mason of the University of London has even suggested that the European decision may be a "boon" for stem cell science by lifting restrictions on the use of certain cells or methods.<sup>17</sup> In the meantime, stem cell practitioners should keep a watch on how the European national courts treat the CJEU decision and what changes the EPO will make in view of the CJEU decision.

## Moving forward globally with other alternatives

Companies and investors who are involved with stem cell technology should weigh the varying degrees of patent protection available for human embryonic stem cell technologies in different countries when developing a legal and business strategy for commercializing human embryonic stem cells. Is it better to practice the technology in a jurisdiction that affords strong protection or is it better to practice the technology in a jurisdiction where there are few intellectual property restrictions? Where is the market

demand for this particular stem cell technology? Would it be better to rely on trade secret as a way to protect the stem cell technology, particularly when dealing with manufacturing processes? If trade secret protection is available in that country, then patent filings (and subsequent publications) in other countries could jeopardize trade secret protection.

Other alternatives to patent protection exist to create market hurdles for competitors as well. One such alternative is to use the data protection afforded by a regulatory agency to create a barrier to market entry. For example, in Europe, eight years of data exclusivity is afforded to the innovator after the innovator's product is authorized for sale in the EU before others can apply for authorization based on the innovator's clinical data. An additional two years will pass before others can market their product in the EU state.

Thus, companies and investors who are seeking to develop and/or invest in stem cell technologies, including human ES cells, should confer with their patent attorneys to develop a comprehensive global strategy that aligns the scientific discoveries with the business interests while maximizing legal protection for the discovery.

<sup>1</sup> Brüstle v Greenpeace (C-34/10).

<sup>2</sup> Brüstle, 3.

<sup>3</sup> Brüstle, 3.

<sup>4</sup> Brüstle, 23.

<sup>5</sup> Brüstle, 35.

<sup>6</sup> Brüstle, 36.

<sup>7</sup> Brüstle, 38.

<sup>8</sup> Brüstle, 23.

<sup>9</sup> Brüstle, 36.

<sup>10</sup> Brüstle, 23.

<sup>11</sup> Brüstle, 39 and 41.

<sup>12</sup> Brüstle, 44.

<sup>13</sup> Chung, Y. et al. (2008) *Cell Stem Cell* 2:113-117.

<sup>14</sup> Brüstle, 47.

<sup>15</sup> G2/06, November 2008.

<sup>16</sup> Section 4.3.2.2, Chapter 1, Part II, *The Chinese Guidelines for Patent Examination*.

<sup>17</sup> Callaway, E. (2011) *Nature* 478:441.

# The Expedited Request for Continued Examination – Choosing the Right Strategy for Fast-Track Prosecution

By Terri Shieh-Newton, Matthew D. Show, and Gladys H. Monroy

The United States Patent and Trademark Office (USPTO) has announced new rules relating to the inclusion of Requests for Continued Examination (RCEs) into its Track I program for fee-based expedited examination. As the name suggests, RCE applications qualifying for inclusion into the expedited examination program are examined out-of-turn based on priority status. The new RCE rules complement the Track I program for expedited examination available to patent Applicants that was put in place following the passage of the Leahy-Smith American Invents Act (AIA) last September. The new rules also offer patent Applicants a new tool for decreasing the overall time an application spends in prosecution.

## Background: A Potential Solution to the “Backlog”

The new expedited examination rules were implemented in part to help relieve the several-year backlog of applications which are waiting to be examined at the Patent Office. According to the most recent statistics available for the end of February 2012, there were 83,632 applications waiting to receive an Office Action following the filing of an RCE. This large number is due, in part, to new procedures instituted by the USPTO in late 2009. Prior to this, RCE applications were placed in an Examiner’s “Amended Docket,” which is the same docket used for applications that have received a response or an amendment after the issuance of a non-final rejection and are awaiting either a final rejection or a Notice of Allowance. Examiners are required to respond to applications on their Amended

Docket within two months.

However, in November of 2009, procedures instituted by Director Kappos resulted in RCE applications being

...ACCORDING TO YEAR-END STATISTICS PROVIDED BY THE USPTO, AN RCE CURRENTLY AVERAGES ALMOST FIVE MONTHS FROM FILING UNTIL THE ISSUANCE OF THE NEXT OFFICE ACTION.

directed to the Examiner’s “Special New” application docket instead of the Amended Docket.<sup>1</sup> The Special New docket also includes Continuation and Divisional applications, in addition to applications accorded special status under 37 C.F.R. § 1.102. The rationale underlying this change in policy was to give Examiners greater flexibility in managing their workload. In essence, the policy alleviated the need for Examiners to act on an RCE within two months of filing, as is the requirement for applications on the Amended Docket. The end result of this policy change has been to slow prosecution of RCE applications considerably, which has no doubt contributed to the aforementioned backlog of applications awaiting the

issuance of an Office Action. Indeed, according to year-end statistics provided by the USPTO, an RCE currently averages almost five months from filing until the issuance of the next Office Action. Essentially, therefore, the new expedited RCE program is an effort to restore some of the speed of the RCE that was the *status quo* prior to the Directive issued by the Director in late 2009.

## Standard Track I Examination

The USPTO has been planning on initiating a three-track program for utility patent prosecution whereby Applicants will choose the track that best fits their overall prosecution strategy.<sup>2</sup> Track III will permit applicants to delay paying certain fees by deferring examination for a period of time. Track II will resemble the current standard procedure for prosecution and it is expected that most Applicants will continue to choose this track as the format for prosecution. Following passage of the AIA last September, the USPTO began accepting requests for prioritized examination of patent applications through the Track I Program. For a fee, Track I allows inventors and businesses to have their patent applications processed to completion within 12 months. No examination support documents or other admissions are required.

Track I is available for new, original (*i.e.*, non-reissue) nonprovisional utility or plant applications filed under 35 USC § 111(a) as well as Continuation or Divisional applications filed on or after September 26, 2011. Track I is not available for

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design applications or national stage applications, but could be sought for U.S. national stage applications by filing a “bypass continuation” application instead.<sup>3</sup>

A request for standard Track I examination must be filed accompanying the patent application and the application must be filed as a complete application with all requirements of 37 CFR § 1.51(b) met at the time of filing. Additionally, all papers associated with the application must be filed electronically (via EFS-WEB). The application must contain no more than four independent claims and no more than 30 total claims, and no multiple dependent claims. An application accepted into Track I will be given “special” status throughout prosecution until a “final disposition” within a year.<sup>4</sup> However, if an extension of time is taken for any response, Track I processing will be lost. Additionally, Track I status will be lost if the application is amended to include more than four independent claims, more than 30 total claims, or any multiple dependent claims at any time during prosecution.

As of March 12, 2012, 1,903 petitions have been granted under the Track I program, 631 are pending, and 45 have been dismissed. On average, the first office actions are being sent approximately one month after the petition’s approval of the petition. The first Track I petition application to issue as a patent was awarded on January 10, 2012. The application was filed on September 30, 2011, accompanied by a Track I request. The USPTO granted the request on November 1, 2011. During prosecution, the Applicant filed an IDS and a proactive terminal disclaimer associated with the application’s parent

case. The case was handled by a primary Examiner who had handled the parent case and who allowed the claims with Examiner-proposed amendments following an interview—all in a little over three months after filing.

**...WHILE THE NEW EXPEDITED RCE PROGRAM DOES NOT APPEAR TO AFFECT THE WAY THE USPTO WILL CALCULATE PTA, APPLICANTS SHOULD CONSIDER HOW IMPORTANT PTA IS FOR THE SUBJECT MATTER BEING PROTECTED BY THE CLAIMS.**

## Requirements for the Expedited RCE Program

In order to qualify for the new Track I RCE expedited examination program, the request must be in an original utility or plant nonprovisional application that has been filed under 35 U.S.C. § 111(a) or that has entered the national stage under 35 U.S.C. § 371. The request for prioritized examination of the RCE must be filed via the USPTO’s electronic filing system (EFS-Web), except in a plant application (for which the request must be filed on paper prior to the mailing of a first Office action after the filing of the RCE). The application must contain no more than four independent claims, no more than 30 total claims, and no multiple dependent claims. No examination search report is needed to apply to the program. The request for prioritized examination may either be filed concurrently with, or subsequently to, the filing of a request for

continued examination. It should also be noted that only a single such request for prioritized examination accompanying an RCE may be granted during the pendency of an application.

Once the request is accepted, the application is supposed to reach a final disposition within 12 months of prioritized status being granted. “Final disposition” in the context of an expedited RCE is defined as any of the following: (1) mailing of a notice of allowance; (2) mailing of a final Office action; (3) filing of a notice of appeal; (4) completion of examination as defined in 37 C.F.R. § 41.102; (5) filing of a subsequent request for continued examination; or (6) abandonment of the application.<sup>5</sup> It should additionally be noted that an application under prioritized examination would not be accorded special status throughout the entire course of an appeal or interference before the BPAI, or after the filing of a subsequent request for continued examination.

Similar to Standard Track I Examination, adding more than four independent claims, more than 30 total claims, or a single multiple dependent claim will end prioritized examination. Additionally, Applicants must respond within the shortened statutory period (*i.e.* three months). Should an Applicant take any extensions of time, then the application is no longer accorded a “prioritized” status, leading to the application being relegated to the Examiner’s regular docket instead of the special docket. However, the new prioritized RCE program differs from the standard Track I program in at least two ways. First, a request for admission into the prioritized RCE program can be filed *after* an RCE has been filed, whereas in the standard Track I program, the request must be filed accompanying the application. Second, U.S. national stage applications are eligible for this program while these applications are not eligible for the standard Track I program.

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## Effects on Patent Term Adjustment

In general, patent term adjustment (PTA) is an attempt to ensure, despite delays caused by the USPTO during prosecution, that each allowed patent retains a term of about 20 years from the earliest nonprovisional priority date. Under the current rules, the statutory 20-year term can be increased for certain USPTO-related delays and is decreased for Applicant-related delays. Most patent term adjustments concern what the USPTO refers to as "A-type" delays or "B-type" delays. In general, A-type delay relates to administrative delays caused by the USPTO during the course of prosecution and include such things as failure to send a first Office action within 14 months after filing, failure to issue another Office action following an Applicant's responsive filing or an appellate decision within four months, and failure to issue the patent within four months of the issue fee payment. B-type delay relates to failure of the USPTO to issue a patent within three years of filing.<sup>6</sup> For every day the USPTO goes over these statutorily set time limits, an extra day is added to the patent term. However, for every day an Applicant delays in responding to a USPTO action during a statutorily prescribed time, a day of PTA time is removed.

As with the filing of a standard RCE, filing a Request for Continued Examination under the new Track I program will toll the clock for accrual under B-type delays. For the A-type delays, it should be noted that the USPTO has not issued any official announcement about how PTA will be calculated for the time accrued up to the time that the Track I request is filed. Given the relative rapidity for issuance of office actions and responses associated

with the new expedited RCE program, it appears unlikely that the Applicants will accumulate any more A-type delay due to USPTO delay. Therefore, while the new expedited RCE program does not appear to affect the way the USPTO will calculate PTA, Applicants should consider how important PTA is for the subject matter being protected by the claims.

**...A PHARMACEUTICAL OR BIOTECHNOLOGY COMPANY CAN CHOOSE TO UTILIZE THE TRACK I PROGRAM ACCORDING TO THE PRODUCT CYCLE OF ITS DRUG OR PRODUCT AND ALSO EXTERNAL MARKET ACTIVITIES.**

## Impact on Different Industries

The considerations for requesting expedited prosecution may be different depending on the industry in which the Applicants practice. These considerations include PTA time, scope of claim coverage, and subject matter being covered by the claims. For example, in the software and electronics industry where technology evolves rapidly, the value of patents in these fields may be greater earlier in the patent term compared with other fields such as the pharmaceutical or biotechnology industry. Thus, obtaining extra PTA time at the end of the patent term may not be as important in the software and electronics industry where the technology turnover is faster and where the technology could be outdated by the end of the 20-year patent term.

In contrast, in the pharmaceutical or biotechnology industry, drug development and regulatory approval can take many years in the beginning. Thus, it may not be advantageous to expedite prosecution to obtain a patent quickly when testing is still being done to determine the leading candidates for the drug since Applicants would want more time and flexibility when trying to draft claims that would provide specific coverage for the eventual commercial product(s). Once the drug gets approved, becomes more established in the medical profession, is used by hospitals and clinics, and is generating revenue daily, then the value of extending the patent term by additional PTA days increases significantly. In this situation, Applicants may choose to forego requesting expedited prosecution since they may need additional time at the beginning of the patent prosecution to develop and test their leading drug candidates. They can capitalize on the patent term adjustment that may accrue to their advantage when their drug is being used in the market. In other situations, a pharmaceutical or biotechnology company may want to consider expediting patent prosecution based on market activity, such as the activities of third-party competitors. A pharmaceutical or biotechnology company may want to expedite patent prosecution quickly to obtain a patent to enforce against a third-party infringer. Thus, a pharmaceutical or biotechnology company can choose to utilize the Track I program according to the product cycle of its drug or product and also external market activities.

In the renewable energy industry, government regulations and incentives can be a factor in considering whether to expedite prosecution. As with the electronic and pharmaceutical industries, renewable energy companies may want to protect their current commercial interests with specific coverage in issued patents. However, the renewable energy industry is relatively new compared to electronics

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and pharmaceuticals. Many states have enacted mandates on the percentage of fuel for vehicles that must come from renewable sources. Federal mandates may also arise in the future. Additional transportation mandates require increased fuel efficiency standards for engines and even requirements for biojet fuel blending. In states such as California, mandates have been enacted which dictate that a given percentage of the energy generated in the state must come from renewable sources such as solar, wind, and other renewable technologies. Some of these mandates will not come into effect for a few years to more than a decade from now. Thus, for an Applicant whose patent involves technology associated with renewable energy, such as the development of biofuels, maximizing the amount of PTA time could increase the value of their patents as the renewable energy industry matures and the various government mandates take effect. This, however, must be balanced against the effect of issued patents.

Applicants who are considering applying for the expedited program should think about how it would affect the overall strategy for prosecution for the subject matter being covered. From a strategic point of view, Applicants may wish to consider enrolling in the expedited program if the prosecution of their application is likely to conclude favorably for the Applicant with issued claims that are of value to the business. Another consideration for Applicants is whether the new expedited program makes sense for applications in their portfolio from the perspective of the life cycle of the Applicant. For example, either of these programs may not be the best idea for a

small biotechnology or pharmaceutical company still in the “start-up” phase, as most early applications from these types of entities cover their basic “proof of concept” that they will further develop with increased funding. For these types of entities, rapid patent prosecution is not always a priority or even an advantage. However, the same company later on in its “midlife” when trying to attract either the attention of a larger company for purposes of partnering or even further funding, may wish to have a tangible IP asset to attract investors or potential partners or acquirers. Finally, a large pharmaceutical company may wish to speed prosecution as much as possible, particularly when the activities of regulatory agencies, such as the FDA, come into play.

According to the Federal Register Notice announcing the new expedited RCE program, requests will count towards the 10,000 request “cap” that the AIA places on all requests for expedited examination, which means that both the standard Track I program and the new expedited RCE program will be included in tabulating this figure. While, as of March 1, 2012, only 1,903 Track I petitions have been filed for the current fiscal year which began on October 1, 2011, Applicants potentially wishing to avail themselves of either of these programs should expect that the inclusion of expedited RCE requests has the potential to substantially increase this number in a short period of time. Applicants who are considering utilizing this expedited prosecution program should consult with their patent attorneys for a careful assessment of their situation and strategize about how this program can be used to maximize the value of their patent portfolio.

routes. One common route is national stage entry off of a PCT application (designating the U.S.) under 35 U.S.C. §371. This is similar to national stage entry in other countries. Alternatively, an Applicant may also file a continuation application under 35 U.S.C. §111(a) as a “bypass” method from U.S. National Stage Entry. Since U.S. patent law treats an international application which designates the U.S. as having the same effect as a pending U.S. application with the International Application filing date, bypass continuation applications represent a second way for a PCT application to enter prosecution in the U.S. (See MPEP 201.11(a).)

<sup>4</sup> For purposes of Standard Track I Examination, “final disposition” refers to any of (1) mailing of a notice of allowance, (2) mailing of a final Office Action, (3) filing of a notice of appeal, (4) declaration of an interference by the Board of Patent Appeals and Interferences (BPAI), (5) filing of a request for continued examination, or (6) abandonment of the application. “Changes to Implement the Prioritized Examination Track (Track I) of the Enhanced Examination Timing Control Procedures,” 76 Fed. Reg. 6369, 6370 (Feb. 4, 2011).

<sup>5</sup> See “Changes to Implement the Prioritized Examination for Requests for Continued Examination,” 76 Fed. Reg. 78566, 78566 (Dec. 19, 2011).

<sup>6</sup> See 37 C.F.R. § 1.705.

<sup>1</sup> See “Notice of Change to Docketing of Requests for Continued Examination” at [http://www.uspto.gov/patents/law/notices/rce\\_docket.pdf](http://www.uspto.gov/patents/law/notices/rce_docket.pdf).

<sup>2</sup> “Enhanced Examination Timing Control Initiative,” 75 Fed. Reg. 31763-31768 (June 4, 2010).

<sup>3</sup> An Applicant can enter U.S. Prosecution by various

# Patent Term Extensions and Regulatory Exclusivities for Pharmaceuticals in Asia and South America

By Cary Miller

Patent protection for pharmaceutical products has an impact on the pharmaceutical market and innovation. As pharmaceutical products require regulatory approval before commercial use, and because regulatory approvals commonly issue after a relevant patent's statutory term has begun, drug products typically have less than the full patent term remaining at the time the drug is launched. In the United States, the "Patent Term Restoration" portion of the Hatch-Waxman Act remedied this situation by affording NDA holders the opportunity to extend the life of one patent for up to five years, depending on the period of exclusivity lost due to the regulatory approval process.

Regulatory exclusivities prevent potential generic competitors from filing an application seeking regulatory approval for a competing generic drug product, or prohibit the FDA (or equivalent regulatory authority outside the United States) from approving the generic drug application. To obtain market approval, pharmaceutical manufacturers submit large amounts of clinical data to the regulatory authority. This data may cost hundreds of millions of dollars to produce. Generic drug manufacturers may later use that data to obtain approval of their generic versions of the drug product. Data exclusivity prevents generic competitors from relying on the clinical data submitted by the original pharmaceutical manufacturer for a certain period of time. The Hatch-Waxman Act awards a five-year data exclusivity period for drug products containing a new chemical entity.

The availability of such patent term extensions and data exclusivity periods varies in other countries. Being up-to-

date with the current requirements outside the United States is critical for successful drug development and for maximizing the commercial life of a pharmaceutical patent portfolio. Asia and South America present challenges due to frequent changes in the regulations and to the wide variability in approaches among neighboring countries.

This article provides a summary of the data exclusivity and patent term provisions in certain key Asian and South American countries.

## **China**

Chinese law provides for a data exclusivity period of six years for new chemical entities. Patent term extensions for regulatory delays are not available in China.

## **Hong Kong**

Data exclusivity and patent term extension for regulatory delays are not available in Hong Kong.

## **Japan**

Under the Pharmaceutical Affairs Law, the Japanese regulatory authority re-examines the safety and efficacy of drugs after drug approval in view of the data collected during the re-examination period. The re-examination period lasts from four to 10 years after drug approval. The data submitted to the regulatory authority is not available to generic drug companies during the re-examination period. Accordingly, the re-examination system effectively works as a data exclusivity system in Japan.

The re-examination system applies to new chemical entities and previously approved drugs that receive approval for new clinical indications. For new chemical entities, the re-examination

period used to be six years from the date of drug approval. Since April 1, 2007, the re-examination period for new drugs is eight years. Previously approved drugs that receive approval for new clinical indications are subject to a shorter, four-year reexamination period.

Patent term extensions for regulatory delays are available in Japan. The patent term can be extended for up to five years. Unlike in the United States, more than one patent can be extended in Japan.

## **Korea**

The United States-Korea Free Trade Agreement, which took effect March 15, 2012, amended the Korean Pharmaceutical Affairs Act. The revised Act and its implementing regulations include provisions for patent term restoration and data exclusivity for patented pharmaceuticals. These revisions apply to all members of the WTO pursuant to TRIPS.

Korea's patent term restoration provisions permit a patent term extension for up to five years to compensate for patent term lost to regulatory delays.

The new provisions provide for a five-year data exclusivity period that is similar to that provided in the United States. Generic companies are prohibited from submitting generic drug applications in Korea for at least five years from the original company's approval date for a new chemical entity.

## **Malaysia**

Data exclusivity is available in Malaysia. The term is determined by the director of pharmaceutical services and will not exceed five years for a new drug product

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# Regulatory Exclusivities

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containing a new chemical entity.

Under current law, patent term extensions based upon regulatory delays are not available in Malaysia. Patents with an effective filing date before August 1, 2001, are entitled to a patent term that is the longer of either 20 years from the filing date or 15 years from the issue date.

## **Philippines**

Data exclusivity and patent term extensions for regulatory delays are not available in the Philippines.

## **Thailand**

Thailand provides for a five-year data protection period that guarantees that the confidential data of a new drug applicant will remain confidential.

Patent term extensions for regulatory delays are not available in Thailand.

## **Vietnam**

Vietnam provides for a five-year data exclusivity period, unless the generic applicant has obtained the original manufacturer's permission to use its data. If the applicant requests that the data be kept secret, the Vietnamese regulatory authority is required to keep the data confidential unless the disclosure is

necessary to protect the public.

Patent term extensions for regulatory delays are not available in Vietnam.

## **Argentina**

Data exclusivity and patent term extensions for regulatory delays are not available in Argentina.

## **Brazil**

Brazilian law does not currently provide a data exclusivity period for human pharmaceutical products. The Brazilian Pharmaceutical Regulatory Agency can approve a generic drug application at any time after market approval of a new chemical entity.

Brazilian law does provide for market exclusivity rights for veterinary drugs. A veterinary drug receives a 10-year exclusivity period if it is a new chemical entity and a five-year exclusivity period if it is not a new chemical entity.

Brazil does not provide patent term extensions based upon regulatory delays.

## **Chile**

Chile provides a five-year data exclusivity period to new chemical entities as long as the drug application includes undisclosed data that is not publicly available and the filing of the drug application in Chile occurs less than a year after the drug has been approved outside of Chile. The nonpublication requirement has traditionally been difficult as Chile's regulatory authority has found publication

of abstracts and partial clinical results to be sufficient to deny data exclusivity. More recently, however, Chile's regulatory authority has found that publications must contain the clinical data in its entirety in order to deny data exclusivity. The requirement to file in Chile within the one-year window obligates pharmaceutical companies to prioritize the Chilean market, which may be challenging.

Chile permits patent term extension for regulatory delays. Unlike most countries, Chile does not place a time limit upon the extension.

## **Mexico**

Data exclusivity and patent term extensions for regulatory delays are not available in Mexico.

## **Conclusions**

Understanding and taking advantage of data exclusivity periods and patent term extensions are important in making global pharmaceutical marketing decisions. The availability and requirements of data exclusivity and patent term extensions outside the United States are in flux, particularly due to the requirements of TRIPS and the negotiation of trade agreements. As the availability of data exclusivity periods and patent term extensions differs for small molecules and biologics in certain jurisdictions, remaining aware of the changing data exclusivity periods and patent term extensions in different countries will continue to be important.

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