

Noli IP Newsletter

NOLI IP Solutions, PC

1/27/2016

January 2016 Edition

When is it advisable to file an Article 19 or an Article 34 and Demand under Chapter II for your PCT Application?

By Sergio Chacon-Hoffmann

When you file your Patent Cooperation Treaty (PCT) international application, you are filing one non-granting application that

among them, the time to market your application. Upon publication of the international

In summary, responding to the International Search Report and Written Opinion during the international period is both a money and strategy decision. Acting and taking no action are both options and your decision will depend on your own strategy for the international application. Consult with your patent attorney or agent once you get your International Search Report and Written Opinion.

will be active for 18 months from the international filing date or 30 months from the first priority application you claim. At present, it provides you the option, upon completion of its timeline, to file applications in up to 148 of its member nations.

The benefits of such an application are many,

application, the full disclosure becomes prior art worldwide. Provisional protection may begin on some countries.

Upon receiving your International Search Report and Written Opinion (ISR-WO) it is advisable to review if you wish to file an

Bring it on, 2016!!!

By Mariana Paula Noli

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It is hard to believe for me that we are already way into the New Year, in a few days it will be February 2016. 2015 came and went posing many challenges as well as fulfilling many of our dreams and goals for us at NOLI IP Solutions, PC. Looking back at this past year, I can only say that we have come a long way and we are looking forward to keep learning and growing to be better professionally and personally. We are ready for the journey ahead.



Thank you for continue to choose us as your counsel of preference and we highly encourage you to let us know how we can improve by contacting us with your suggestions and feedback at mail@noli-ipsolutions.com.

Article 19, where only claims can be amended, or an Article 34 and Demand, where amendments can be submitted on the totality of the application, provided you do not introduce new matter or go beyond the scope of the application as filed.

When do you file the Article 19?

Two (2) months from the date of transmittal of the international search report to the International Bureau and to the applicant by the International Searching Authority or 16 months from the priority date, whichever time limit expires later. There are no official fees to respond, only the fees of the professional handling your international application.

When do you file an Article 34 Amendment?

You should consider the value of (a) a Supplementary International Search and (b) Responding to the International Search Authority (ISA) by filing an Article 34 Amendment and

Demand under Chapter II. Filing such a response at this stage provides you the opportunity to formally rebut the findings in the Report and Opinion. The ISA must react and respond to your filing, most likely through the International Preliminary Report on Patentability (IPRP), the last document to issue in the international period. This latter step happens on month 22 or three (3) months from the issuance of the International Search Report.

Both of these steps are optional and your strategy may be to amend now or simply to wait and address the issues of the ISR/WO once you file national and/or regional phase applications. However, if money is an issue and you foresee filing more than four (4) applications based on the international application, you may wish to set aside the ISR/WO from becoming a first Office Action for that country application. Taking either of these steps will generate an expense during the international period.

If, on the other hand, you do not wish to give any indication to third parties of what corrections would resolve the objections by the ISA, you may wish to hold off until you file the national and/or regional applications to make any amendments attempting to set aside the ISA's objections. While this may cost a bit more if you have four (4) country applications and in each the ISR/WO is cited as a first office action, you may also find that some country examiners may not consider the ISA/WO and do their own search.

In summary, responding to the International Search Report and Written Opinion during the international period is both a money and strategy decision. Acting and taking no action are both options and your decision will depend on your own strategy for the international application.

Consult with our patent team once you get your International Search Report and Written Opinion.

Was it the End of Gene Patent World as We Knew It?

By Mariana Paula Noli and Monica Hernandez

The main purpose of a patent is to promote research and innovation and to allow the return of new beneficial results returned to serve society. The exclusivity granted to the inventor who can exclude others from using the invention is, however, limited in time.

A patent may be defined as *'a grant by the state (country) of exclusive rights for a limited time in respect of a new and useful invention, usually limited to the territory of the state granting the patent'*. It does not give a right to use the invention, but rather the right to prevent others from using it commercially. Use of the invention must comply with other relevant regulations.

Practically everything that is made by man is patentable. Patent claims can cover different subjects, including "Genes" as long as is not made in nature.

One could think that a genetic substance that can be reproduced by using artificial means, as with the

isolation and cloning of a gene could be considered a man-made invention, and therefore eligible for patenting. However, this view of "patenting life" has generated much discussions and conclusions vary from country to country.

In 1980 the US Supreme Court ruled in *Diamond v. Chakrabarty* that manmade, living organisms could be patented. In its decision, the Supreme Court urged a broad interpretation of patent eligibility, holding that *"anything under the sun that is made by man"* including living organisms, can be patented. Since then, other courts decisions issued expanded on patent-eligible subject matter, strengthening the rights of patent holders relative to potential infringers. Many patents have been issued on a range of biotech inventions, including patents related to human gene sequences.

However, in June 2013, the Supreme Court unanimously ruled, in case *Molecular Pathology v.*

Myriad Genetics Inc., that isolated naturally occurring sequences of genomic DNA (gDNA) cannot be patented. The Court, nonetheless, left open the possibility of patenting complementary DNA (cDNA) and novel methods of manipulating genes or applying the information contained therein. The Supreme Court granted certiorari only on a single question: 'Are human genes patentable?' In a short opinion written by Justice Thomas, the Court unanimously ruled that isolated gDNA does not constitute patentable subject matter eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring'. The Court stated that Myriad had 'found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention'.

Later, in *re. Kubin* (2009 Federal Circuit decision) was established that beyond the § 101 test at issue in Myriad, any DNA

claims still have to meet the other patentability requirements: novelty (§ 102), nonobviousness (§ 103), and sufficiently explicit description (§ 112).

In *Kubin* the Court set a stricter standard for the § 103 requirement, holding that significant existing knowledge about the (1) protein coded by a gene and (2) techniques necessary for isolating and sequencing the gene makes the gene itself unpatentably obvious. Under the *Kubin* standard, many of the isolated single-gene gDNA

patents struck down by *Myriad* might have already been invalid.



The Court noted that its decision in *Myriad* did not address method claims, ‘new applications of knowledge’ about genes, or ‘the patentability of DNA in which the order of naturally occurring nucleotides has been altered’. Still, *Myriad*’s

logic could have effects outside the Court’s intended scope; lower courts, for instance, could apply *Myriad* to product patents for isolated biological materials like cell lines and proteins.

If you have any questions about whether your or not, your work is patentable, do not hesitate to contact our patent experts or please send us an email at mail@noli-ipsolutions.com for more information about this topic.

WE ARE ALL ABOUT HELPING START-UPS!

WE BELIEVE IN INNOVATION, ENTREPRENEURSHIP AND PROGRESS. It is for that reason that all of us at Noli IP have been working with the start-up community one way or another.

- Ms. Monica Hernandez has represented us at a group meeting this past January 22, 2016 at the HubBog incubator in Bogota, Colombia.
- Ms. Mariana Noli will be participating of the mentoring program and job fair during the “**San Diego Startup Convergence**” from February 4-6, 2016.
- Ms. Luciana Noli will be teaching starting this March 2016, a series of educational sessions and workshops for entrepreneurs at the UCA in Buenos Aires, Argentina.
- Ms. Judit Marai has been in continuous discussions with many start-ups in Budapest, Hungary.



For more information about our start-up practice, please email us at mail@noli-ipsolutions.com.