

## HOW TO IMPROVE (DELAY) THE NATIONAL/REGIONAL PHASE ENTRY OF A PCT APPLICATION

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The PCT application became a reality in 1978. In the same year it was also possible to apply for European patents. And much earlier, in the 19<sup>th</sup> century, the right of priority had been created through the Paris Union Convention (1883). The main purpose of all these tools is to facilitate the protection of an invention in different territories.

A good protection strategy consists of filing a European priority application with the EPO in English, followed by the filing of a PCT application at the end of the priority year with the EPO as the receiving office, and the entry of the PCT at the end of the established period (30-31 months) at the national (US, JP, CN, etc.) or regional (EPO, etc.) offices of the territories of interest. Previously, at the end of the priority year, it must be assessed whether there is interest in any of the countries that have not signed the PCT, such as Argentina or Taiwan.

### Diagram 1

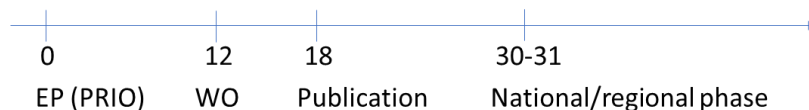


Diagram 1 summarizes this strategy, which is particularly advantageous for European applicants, but is also useful for all applicants who wish to take advantage of the following benefits, among others:

- Use of English in the drafting of priority and PCT applications, and as the language that will be considered the authentic text in the different territories where the PCT enters, with consequent savings in translation in the initial stages.
- Obtaining a search and opinion of patentability within the priority year, prepared by the EPO, which helps to adjust the subsequent PCT application, with respect to the priority application, if necessary.
- Possibility of adding new subject matter or amending claims in the PCT application.
- Possibility of using the PCT-Direct if the opinion of patentability is negative, being the EPO the only major office that offers this possibility at the moment (see <http://www.zbm-patents.eu/en/pct-direct-a-great-tool-in-patent-prosecution-strategy/>).
- Possibility to wait until 30-31 months to enter national/regional phase.

While the above is one of the most common and advantageous strategies used by applicants, there are other possibilities that can bring significant advantages in specific circumstances. In particular, the withdrawal of the priority claim during the PCT phase can be of great interest. This possibility and some of the options it offers are discussed below.

In accordance with PCT Rule 90bis.3(a) (Withdrawal of Priority Claims):

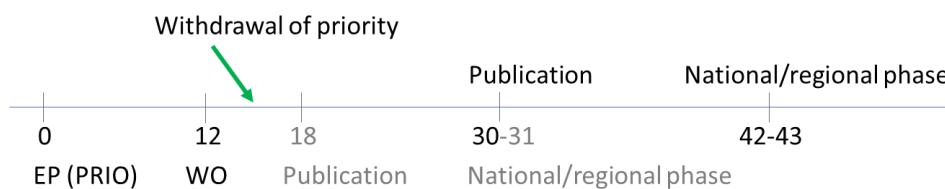
(a) The applicant may withdraw a priority claim made in the international application under Article 8(1) at any time before the expiration of 30 months from the priority date.

Paragraph d) of that Article provides that:

(d) Where the withdrawal of a priority claim causes a change in the priority date, any time limit calculated from the original priority date which has not yet expired shall, subject to paragraph (e), be calculated from the priority date resulting from the change.

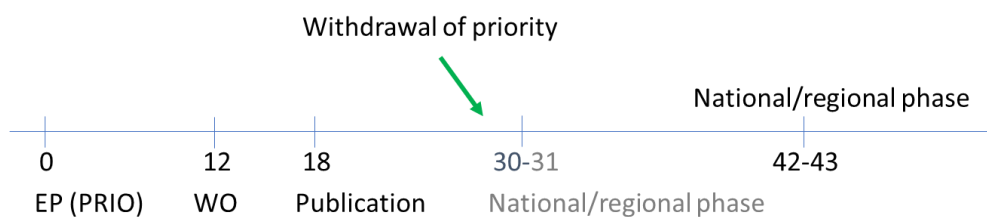
This Rule allows for two different scenarios. In the first, the withdrawal of priority is made prior to the publication of the PCT (strictly before the technical preparations for the PCT have been completed, which is usually 15 days before), thus postponing this publication until the 18th month from its filing date (i.e., until the 30th month from the date of the withdrawn priority). The deadlines for entry into the national/regional phase are also postponed. This is illustrated in Diagram 2 (in grey are the deadlines that do not apply after the withdrawal of priority).

Diagram 2



In the second scenario, the withdrawal of priority takes place between the publication of the PCT and the deadline for national/regional phase entry, as illustrated in Diagram 3, thus only postponing the national/regional phase entry (the deadlines that do not apply after the withdrawal of priority are greyed out).

Diagram 3



This second scenario is usually the most interesting option.

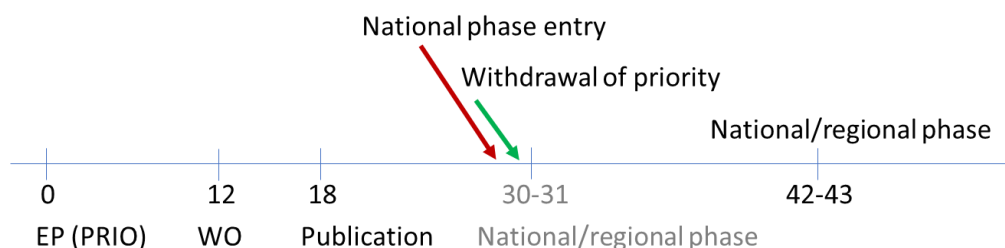
In no case is it possible to withdraw PCT priority to make up for missed deadlines, so this cannot be done once the deadline for national/regional phase entry has been exceeded.

There is a mixed version between the normal strategy, with entry into all the territories of interest at the end of the 30-31 months from the priority, and late entry in all the territories after withdrawal of the priority. In this new proposal, before the withdrawal of the priority, some territories are entered in the usual way. For these first territories the priority will be valid, even if it is later withdrawn for other territories, under paragraph (a) of PCT Rule 90bis.6 (Effect of withdrawal), which reads:

(a) Withdrawal under Rule 90bis of the international application, any designation, any priority claim, the demand, or any election shall have no effect in respect of any designated or elected Office which has already started to process or examine the international application under Article 23(2) or Article 40(2).

Thus, the national/regional phase entry for the first territories must be made in time for the respective applications resulting from this entry to begin prosecution or examination before priority is withdrawn before the 30th month. This situation is illustrated in Diagram 4.

Diagram 4



Any withdrawal of priority in the PCT only makes sense if the European priority application is not published, for which it must be withdrawn prior to publication. Otherwise, the publication of the priority application would be prior art against novelty under Art. 54(3) EPC against a possible Euro-PCT application without priority. In most countries, any disclosure made by the applicant before the PCT filing date would also be prior art.

Clearly, there are advantages in postponing the publication of the PCT and its national/regional phase entry. Nevertheless, the withdrawal of priority also involves an important risk, since there may be some prior art documents between the priority date and the PCT application date that affects patentability, there may even be a patent application from a third party filed in that time period.

However, this risk is minimal if, prior to the withdrawal of the priority, a complementary search is made to check that there is no prior art that may affect the patentability of non-priority claims.

Any relevant disclosure as prior art in the case of withdrawal of priority, should have been made public before the 12<sup>th</sup> month in the previous diagrams, so that it would be retrieved in a search carried out around the 30<sup>th</sup> month, when the withdrawal of priority should take place.

In the case of a patent application from a third party, the situation is more conflicting. In the worst case scenario, it could have been filed one day before the PCT (month 12 - 1 day). This would imply that the publication of the third party application would take place approximately in month 30, which is when the PCT priority should be withdrawn. In this situation, there would be only a small window of a few days during which a relevant third party application would not be accessible through the databases.

Ultimately, if a thorough search is made prior to the withdrawal of the priority to locate possible relevant documents prior to the PCT filing date, the risk of withdrawal of the priority due to prior art is minimal.

Finally, some risks that may affect specific countries should be noted. Many countries include in their national laws the obligation to file the priority application with their national patent office, when the invention has been made in the country, to review its possible interest for defense. This situation occurs, for example, in Spain, where, in the case of an invention made in Spain, the corresponding European application or PCT would not produce effects in this country if the priority application was not filed with the Spanish Patent and Trademark Office. In Spain, this requirement can be fulfilled by filing the priority EP application in English (with a Spanish translation of only the abstract) through the SPTO, which acts as a mailbox for the EPO. The PCT application can then be filed in English at the EPO.

If a Spanish applicant has used the above strategy, and subsequently withdraws the priority of the PCT application, the latter would literally not comply with the requirement set out by Spanish law (PCT with priority filed in the SPTO), although in reality the invention would have been initially reviewed by the Spanish authorities. It is difficult to foresee what a Spanish judge might decide in this situation. In any case, this type of problem would be specific to one territory and would not affect the overall strategy.

The practical implementation of the above strategies may have different objectives. Some of the most interesting ones are illustrated below.

### **1. Extend the time window of protection of the PCT application**

Many PCT applications do not enter the national/regional phase. Many public research institutions and universities, as well as start-ups, face a critical decision at the end of the 30 months from the priority date. It is true that sometimes these 30 months have been sufficient to rule out the commercial interest of an invention. On the other hand, this period has often not been sufficient, and patent rights are lost due to lack of economic resources to enter the PCT in some territories.

In the latter situation, the withdrawal of priority, as illustrated in Diagram 3, may be a good solution, as it allows practically a year's protection to be gained in all territories, at little cost, but with the aforementioned risk.

If the risk is to be minimized, the strategy in Diagram 4 can be used. For example, the PCT can enter the EPO and the United States with priority, in order to ensure a sufficient market to make the transfer of technology viable; and, subsequently, depending on the success of the transfer, extend protection to other countries with the PCT already without priority.

**2. Postponing the decision on protection in some territories**

Virtually all applicants, even with the decision taken to extend protection, have doubts about the benefits of protecting or not protecting in some territories. In the 30-month period offered by the PCT system there is not always time to verify the viability of the product, let alone to carry out any market research in most territories. Thus, it is normal that months after national/regional phase entry, protection is either lacking in some territories, or is considered not to have been necessary in others.

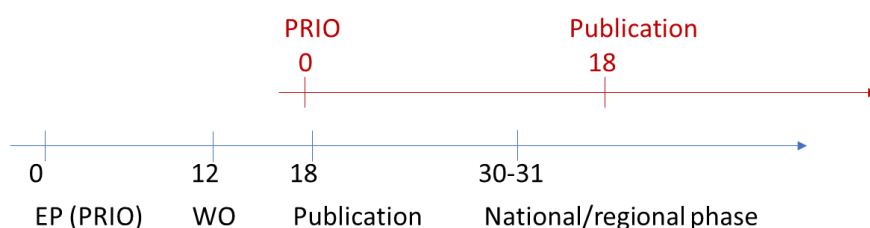
It may therefore be a good strategy to make regular use of Diagram 4. In this way, the territories considered suitable are entered using the priority, and this priority is then withdrawn, leaving the remaining territories where the invention will be protected one more year to take a final decision.

**3. Reaction to unforeseen events**

There is no one applicant who protects in all possible territories, not even in those where they may have commercial activity. Therefore, it is possible that, in the usual situations, an applicant may be clear where to protect at the end of the PCT period. However, there are circumstances which may change their mind.

It is not so unusual for two patent applications for inventions that are very close to each other to be processed simultaneously and independently by two different applicants. Moreover, when this happens, prior to publication of the applications, applicants for both are often unaware of this fact. Moreover, it is possible that the first applicant takes the decision to enter the national/regional phase without knowing that there is a second patent application from a competitor in progress, as shown in Diagram 5.

Diagram 5



As can be seen, if the priority application for the second invention, indicated in red in Diagram 5, is made between the 12<sup>th</sup> and 18<sup>th</sup> month of the schedule of the first invention, the applicant for the first invention will not be aware of the existence of the second invention before the end of the normal period for entry of the PCT into the national/regional phase.

In the above situation, if the first applicant does not enter a territory, the second applicant would be able to obtain a patent valid in that territory, since the patent application of the first applicant would not be published prior to its priority, nor would there be any documents pending from the first applicant in the territory.

In this case, not only would the first applicant have no protection, but they would not even be able to commercialize their invention in that territory. In this new situation, the first applicant could have decided to protect in more territories than usual. Again, the withdrawal of priority according to Diagram 4, after the entry into the national/regional phase, would have allowed them to do so in month 42-43, when the application of the second applicant would certainly be public. Obviously, it would be convenient for the applicant to carry out a search to locate possible applications from competitors before month 42.

In sectors such as pharmaceuticals and biotechnology, where it is possible for two institutions to come up with the same invention independently (e.g., new indications of known active ingredients, biomarkers, polymorphs, etc.), this strategy may be particularly interesting.

### **Conclusion**

Withdrawal of the priority claim during the processing of a PCT application allows the time limit for national/regional phase entry to be postponed from the month 30/31 from the priority date to the month 42/43. With proper precautions, the risk involved is minimal and can be a good solution in many situations. It is also possible to make entry into some territories by claiming priority before withdrawal. This implies great flexibility and the reduction of risk to almost zero, while maintaining a number of advantages. Thus, withdrawal of priority of a PCT application should not only be seen as an emergency solution but could be adopted in some cases on a regular basis (withdrawal of priority after entry into the a priori territories of interest) by certain applicants in order to reduce risks in their patent policy.