



## **Divisional Practice Around the Globe**

*Special Feature by AIPF Patent Committee*

June 19, 2019

### **Introduction**

*By: Monica Guevara, OlarteMoure & Asociados, and Chintan Desai, Kim IP*

During the course of our intellectual property practice, clients often ask how divisional patent applications can be used strategically to provide protection for an entire concept, and thus defer the cost of patenting multiple inventions. Clients also look to filing divisional patent applications in order to maintain the pendency of an application. Mature clients with an eye to the global market often have sophisticated patent portfolios, with patent applications in multiple jurisdictions. As such, it is particularly important to develop a global strategy that incorporates perspectives regarding divisional applications in various jurisdictions.

The decision to file a divisional application is often triggered by a lack of unity objection, or when an application is nearing the final deadline for acceptance. Although unity of invention is a requirement for most of the patent offices in the world, as we will discuss below, in some jurisdictions the existence of double patenting provisions prohibit pursuing divisional applications for overlapping subject matter, whilst in other countries the subject matter recited in a divisional application is not assessed against the parent case. Similarly, in some jurisdictions a divisional application cannot be used to maintain the pendency of the application, whilst in others it is allowable.

In this article we describe the provisions for filing a divisional patent application in several jurisdictions. In particular, for each jurisdiction we address key issues:

- Unity of invention – is it a requirement and when is it assessed?
- Double-patenting restrictions
- Timing/deadline for filing divisional applications
- Filing a divisional in order to maintain pendency of a case
- Other requirements peculiar to the jurisdiction.

The synopsis for each jurisdiction concludes with advice to address a hypothetical scenario in order to demonstrate how the provisions apply in the particular region.

### **Scenario**

In the hypothetical scenario, a patent application is directed to a product, which is a compound with activity against cancer, defined using a Markush formula (I). The application also discloses a process for manufacturing this compound, and its use in the treatment of cancer. The Applicant wishes to pursue a particular compound encompassed by the Markush formula (I) in a divisional application - that compound being the lead candidate with promising results in cancer treatment. The Applicant is also considering pursuing the methods for preparing the compounds of the Markush formula in a second divisional application. Based on the above description, our

colleagues from the United States, Europe, Australia, Canada, Mexico and Colombia provide their opinion on the best strategy for their jurisdiction.

Although the scenario relates to a pharmaceutical invention, it could equally be translated into a patent directed to a product, a process for manufacturing said product and the use of the product, where there is a particular interest in pursuing a picture claim for the most preferred embodiment (which in the hypothetical case is the lead compound).

## **United States**

*By: Chintan Desai, Kim IP*

### *Unity of invention*

A restriction requirement under U.S. patent law is similar to a unity of invention rejection in other jurisdictions. A restriction requirement will occur when two or more inventions are claimed, and the inventions are not distinct from each other. If the patent application includes claims to (i) a product, (ii) a process of making the product, and (iii) a process for using the product, a three-way restriction may be required when the process of making the product is distinct from the product itself. A product and a process for making the product are considered distinct if: (i) the process as claimed is not an obvious process for making the product and can be used to make another materially different product, or (ii) the product as claimed can be made by another materially different process. However, even if the process of making and the product made are not considered patentably distinct, an applicant may still be required to elect either (1) the product and process of making it, or (2) the process of using it.

### *Timing for assessment of unity of invention*

Generally, the restriction requirement is assessed before the search is performed and prior to the issuance of any office action on the merits. However, it can be issued at any time before the close of prosecution such as, for example, in response to the addition of new claims or claim amendments during prosecution.

### *Double-patenting restrictions*

In certain situations, the U.S. provides a “safe harbor” provision that protects divisional applications from receiving a double-patenting rejection. Specifically, if a divisional application is directed to non-elected inventions of an original parent application as a result of a restriction requirement, the divisional application cannot receive a double-patenting rejection in view of the original parent application. However, if non-distinct inventions are filed in separate applications, a double-patenting rejection may be issued. That is, a divisional application may not be directed to claims that have already been granted. Generally, a divisional application must claim subject matter that is patentably distinct from the subject matter claimed in the parent application. As such, a divisional application must claim subject matter that is not anticipated or rendered obvious by the claims of the parent application. It is important to note that although divisional applications are similar to continuation applications, a continuation application is not immune from receiving a double-patenting rejection.

### *Timing/deadline for filing divisional applications*

A divisional application can be filed at any time before the parent application is either abandoned or a patent is issued (i.e., during the pendency of the parent application). The applicant may choose to file a divisional application directed to the non-elected inventions at the time of restriction or wait to see how the parent application proceeds through examination. It is important to note that if the divisional application contains claims to two or more patentably distinct inventions, a further restriction requirement may be issued in relation to the divisional application as well. Although a divisional application can be filed up until the parent application is issued, it is recommended that any divisional applications be filed well before the issue date of the parent application.

#### *Filing a divisional in order to maintain pendency of a case*

The strategy of filing a divisional application for maintaining the pendency of a case works, to an extent. Provided that the divisional application is filed during the pendency of the parent application, an applicant may be able to continue the prosecution of the subject matter in the parent application. However, an applicant must be careful as a divisional application may not be directed to claims that have already been granted in the parent application. It is important to note that this strategy will not extend the term of a patent with respect to the subject matter in the original application because the term of the patent will run from the filing date of the first application in a series of divisional applications.

#### *Other requirements peculiar to the jurisdiction*

Notably, national phase applications are not subject to restriction rules. Rather, they follow the unity of invention standard for international PCT applications. However, any subsequent continuation and divisional applications claiming priority to a U.S. national phase application are subject to restriction requirements under U.S. patent law.

#### *Application of U.S. law to scenario*

Under U.S. patent law, a restriction requirement may be issued if the claims include a Markush grouping that reads on two or more patentably distinct inventions. In the hypothetical case described above, in the United States, it would be advisable to include all of the claims in a single patent application. Specifically, the patent application should at least include claims directed to: (1) the compound, defined using a Markush formula (I); (2) the process of manufacturing the compound; (3) the process for using the compound in the treatment of cancer; and (4) the particular lead compound encompassed in the Markush formula (I).

As discussed in the unity of invention section above, the Examiner may issue a three-way restriction if the process of manufacturing the compound is distinct from the compound itself. Even if they are not considered patentably distinct, the Examiner may require the applicant to elect either (1) the compound and the process of manufacturing it, or (2) the process for using the compound. Accordingly, if the Examiner issues a restriction or rejection for lack of unity of invention, the applicant can file divisional application(s) to pursue the different claims. If the Examiner does not issue a restriction or rejection for lack of unity of invention, the claims can be prosecuted together and granted in a single patent.

The applicant may choose to file the divisional application(s) at the time of restriction or wait to see how the parent application proceeds through examination. However, in any case, the divisional application(s) must be filed during the pendency of the parent application.

## **Europe**

*By: Dirk Schulz, PhD., Michalski Hüttermann & Partner*

### *Unity of invention*

There is a unity of invention requirement before the EPO (Article 82 and Rule 44 EPC). A European patent application may only relate to a single invention or to a group of inventions which must be linked in such a way as to form a single general inventive concept. The basic principle behind this requirement is that a patent is granted for each invention separately, i.e. in order to proceed to grant, a European patent application is required to contain claims which are only directed to one single invention. The requirement of unity of invention needs only to be assessed if the claims comprise a group of inventions, i.e. if the claims comprise a plurality of independent claims in the same or in different categories, or a plurality of alternative embodiments defined within a single independent claim. If a group of inventions is claimed, the requirement that the inventions in this group are so linked as to form a single general concept is only fulfilled if there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features (Rule 44 EPC). The term “special technical features” in Rule 44 EPC relates to those features which define a contribution which each of the claimed inventions considered as a whole makes over the prior art. Hence, a test for unity of invention requires determining the subject matter that is common to the claims directed to the different claimed inventions, i.e. the technical features of these claims that are the same or corresponding, and then examining whether any of this common matter is special within the meaning.

### *Timing for assessment of unity of invention*

Unity of invention may occur during the search stage and during the examination stage. There might be an invitation to pay additional search fees if the claims are directed to more than one invention. Further, a lack of unity a posteriori objection may be raised if the search shows that the subject matter of an independent claim is not new and the sub claims are directed to alternatives which do not form a single general concept. In that case the applicant would be invited to pay additional search fees for all the different inventions in the sub claims. The final responsibility for establishing whether the application meets the requirement of unity of invention ultimately rests with the examining division. Therefore, the examining division is always obliged to consider the question of unity of invention, even if no such objection has been raised during the search stage. In particular, the previous assessment may change when the claims are amended or further prior art becomes available. When unity is found to be lacking, the applicant is required to limit the claims in such a way as to overcome the objection, i.e. by restricting them to a single searched invention. Further, one or more divisional applications, covering subject matter removed to meet this objection, may be filed.

### *Double-patenting restrictions*

There are double-patenting issues in Europe that need to be assessed when considering filing a divisional. In particular, a divisional application may not be directed to subject matter that has already been granted or for which protection is sought by the same applicant.

### *Timing/deadline for filing divisional applications*

Divisional patent applications may be filed as long as the parent application is pending. An application is pending up to (but not including) the date on which the European Patent Bulletin mentions the grant of the European patent or the date on which the application is finally refused, withdrawn or deemed to be withdrawn. After an application has been refused, a divisional application may be validly filed until the expiry of the appeal period, regardless of whether an appeal has been filed or not. In fact, a divisional may also be filed as long as appeal proceedings are pending.

#### *Filing a divisional in order to maintain pendency of a case*

Filing a divisional application for maintaining the pendency of the case is a strategy that works to a certain degree. Each divisional application might give the applicant another 12 to 18 months, sometimes even more. However, this is a very costly way to keep an invention pending since for a divisional application all the fees are due which have been due to the parent application. It is a lot less expensive to object to Rule 71(3) communications again and again for formal reasons (in the case the patent can be granted) or to start appeal proceedings if the application is refused. In view of currently expected delays at the EPO, an oral hearing in an appeal may not be expected for 3 to 4 years after filing the appeal.

#### *Other requirements peculiar to the jurisdiction*

Divisional patent applications must be filed in the language of the proceedings of the earlier (parent) application. Fees have to be paid as if it was a 'normal' application. *Inter alia*, this means that if the divisional application is filed more than two years after the date of filing of the parent application, the applicant must pay outstanding renewal fees no more than four months after filing the divisional application. If these are not paid in due time, they may still be validly paid within six months of the due date, provided that an additional fee is paid within the time limit. After filing, each divisional application is treated as an independent patent application.

#### *Application of European law to scenario*

For the present scenario there would be no requirement to file divisional applications for unity of invention reasons. If all compounds encompassed by the Markush formula may be achieved by the same process all independent claims would be considered to be linked as to form a single general concept. Regardless, the applicant would be allowed to file divisional applications which are directed to a particular compound encompassed by the Markush formula and the method for preparing the compounds of the Markush formula, respectively. However, respective claims would have to be cancelled in the parent application.

### **Australia**

*By: Jeremy Moller, MichaelBuck IP*

#### *Unity of invention*

Section 40(4) of the Australian Patents Act 1990 (Cth) requires that "the claim or claims [of an application] must relate to one invention only" where an invention is defined in the Act as "any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention."

Unity of invention is assessed in the same way that unity is assessed for a PCT under Rule 13 of the PCT Regulations and is typically defined by the question: “are there are special technical features that provide an advance of the prior art?” In Australia, it is typically sufficient to show that the claims have a shared, novel feature to show unity between the claims.

#### *Timing for assessment of unity of invention*

In practice, the requirement for unity of invention is assessed during substantive examination.

#### *Double-patenting restrictions*

Double patenting, i.e. the grant of two or more patents to the same inventor(s) having claims to the ‘same invention’, is prohibited by section 64(2) of the Patents Act 1990 (Cth). Under Australian law, the accepted test for whether the claims define the same invention is ‘if the claims of the two specifications were located in the same specification, would there be redundancy of claiming?’ (SmithKline Beecham p.l.c. [2000] APO 54). That is, whether there are claims of identical scope. However, the requirement for ‘identical scope’ does not necessarily impose a requirement for identical wording; it is the overall scope of each of the claims that is considered and it has been stated that ‘if the differences in wording of the claims are inconsequential, the two sets of claims may nevertheless relate to the same invention’ (Arbitron v Telecontrol Aktiengesellschaft [2010] FCA 302). In SmithKline Beecham p.l.c. supra, it was also held that ‘any situation giving rise to an objection under section 64(2) must be so plainly evident that it is beyond reasonable argument’. Thus, unless the claims are of identical scope the applicant should not face any double-patenting issues.

#### *Timing/deadline for filing divisional applications*

A divisional application can be filed in Australia at any time up to three months from the date of Advertisement of Acceptance (also commonly referred to as a date of Publication of a Notice of Acceptance) of the parent application and only if the parent application has not lapsed for any reason. In consideration of the 12-month acceptance window, which begins from the date of issuance of the first Examination Report, a divisional application can be used to maintain pendency of the rights to an invention in the event that all and any objections raised during examination are not overcome within the 12 month period.

#### *Filing a divisional in order to maintain pendency of a case*

A divisional application may be filed for an invention disclosed in the specification of the parent application (see s 79B(1) of the Patents Acts 1990). In practice, it is required that at least one claim of the divisional application must be clearly disclosed in the parent. With this in mind, applicants are not prohibited from adding subject matter to the specification of the divisional application. Indeed, following the recent decision in Domestic Australia Pty Ltd v Houghton Leisure Products Pty Ltd [2018] FCA 1573 in the Australian Federal Court, applicants may be required to introduce subject matter in order to ensure that the best method known to the applicant at the time of filing the divisional application is disclosed.

#### *Application of Australian law to scenario*

With regard to the scenario, assuming that the original application is either still pending or is within three months from the date of Advertisement of Acceptance, the applicant may pursue divisional applications one directed to each of the lead compound, the process for manufacturing

the compound and the method of use in the treatment of cancer without invoking the double patenting laws of Australia.

## **Canada**

*By: Nadim Noujeim, Robic*

### *Unity of invention*

Under Canadian patent law, divisional applications and unity of invention are governed by section 36 of the *Patent Act*, which states that a patent shall be granted for only one invention. In Canada, there is a statutory distinction between divisional applications that are voluntarily filed by the Applicant (paragraph 36(2) of the *Patent Act*) and divisional applications that are filed following a rejection for lack of unity of invention (paragraph 36(2.1) of the *Patent Act*).

In practice, this statutory distinction translates into one key difference between “voluntary” divisional applications and divisional applications filed following a lack of unity rejection: “voluntary” divisional applications are vulnerable to double patenting, whereas divisional applications filed following a unity rejection are immune to any double patenting issue that may arise during prosecution or after patents are granted. This difference was confirmed many times over the years by Canadian Courts.

### *Timing for assessment of unity of invention*

While unity of invention is initially assessed by the Examiner after a first search, additional independent claims can be added by the Applicant at any time during prosecution. Unity of invention would then be reassessed by the Examiner as many times as necessary.

### *Double patenting restrictions*

While double patenting is not mentioned in the *Patent Act*, the doctrine of double patenting was introduced by Canadian Courts to prevent the issuance of two or more patents with claims directed to the same inventive concept. Typically, when a double patenting rejection is raised between two co-pending Canadian patent applications, it can only be solved by removing the overlapping subject matter from one of the rejected patent applications. It is also noteworthy that several Canadian patents have been invalidated over the past decades because of double patenting issues.

### *Timing/deadline for filing divisional applications*

A divisional application can be filed in Canada at any time before the issue of a patent on the parent application. Subsequent divisional applications can be filed if at least one application in a given chain of divisional applications is pending.

### *Filing a divisional in order to maintain pendency of a case*

It is quite common in many jurisdictions to voluntarily cancel claims in a patent application to gain allowance of a first patent and then file a divisional application to pursue the previously cancelled claims. This strategy is not recommended in Canada because of the potential double patenting issues outlined above. Instead, a strategy that can be recommended to avoid this issue is to consolidate all the claims that an Applicant wishes to pursue in a single patent application, to force one of the following two outcomes:

- (1) the Examiner issues a rejection for lack of unity of invention and a divisional application that is immune to double patenting can be filed at any time prior to the issuance of the parent application; or
- (2) the Examiner does not issue a rejection for lack of unity of invention and all the claims can be granted in a single patent.

#### *Other requirements peculiar to the jurisdiction*

Since there are no excess claim fees in Canada, the Applicant may introduce as many independent claims (with as many different inventive concepts) as needed. This can be used to incorporate all the desired claims in a single application, trigger a rejection for lack of unity of invention and then safely file divisional applications that are *a priori* immune from double patenting issues.

#### *Application of Canadian law to scenario*

Now turning to the hypothetical case outlined in the “Introduction” section of this article: in Canada, it would be recommended to include all the following claims into the same patent application:

- claim directed to the compound with activity against cancer, defined using Markush formula (I);
- process for manufacturing the compound of Markush formula (I);
- use of the compound of Markush formula (I) in the treatment of cancer;
- claim directed to the particular compound (lead candidate) encompassed in the Markush formula (I); and
- any other claim that can be reasonably inferred by the specification as originally filed and that the Applicant wishes to pursue.

The Examiner can then examine the claims and determine whether a rejection for lack of unity of invention is warranted. Depending on the Examiner’s assessment, either one of outcome (1) and (2) outlined above can then be followed.

## **Mexico**

*By: Victor Garrido, Dumont*

#### *Unity of invention*

Under Mexican law, only inventions sharing the same inventive concept can be accepted in a single patent application. The inventive concept requirement is not defined in the legal framework; however, in practice this requirement is met when independent claims are technically linked by one or more features upon which patentability relies. Hence, compounds, their use, and process for production can be claimed in a single application provided they share a common inventive concept. For example, a group of novel compounds, produced by the same method of manufacture and for the same use will have a common inventive concept.

#### *Timing for assessment of unity of invention*

The inventive concept requirement is assessed at the substantive examination stage.

#### *Double-patenting restrictions*



Double patenting is not permitted under Mexican practice. It is not acceptable that the divisional application claims subject matter overlapping with matter allowed in the parent application. Claims in divisional applications, especially, those derived from voluntary divisions, do not need to come from subject matter previously or originally claimed in the parent application but can be drafted from the contents of the specification.

#### *Timing/deadline for filing divisional applications*

The applicant can voluntarily file a divisional application at any time during prosecution, up to either the payment of grant fees of the parent application or the receipt of the final rejection thereof. It is allowable to voluntarily divide a divisional application whilst the original application is pending. However, once the prosecution of the original application ends via grant or refusal, a divisional application can only be filed in response to a unity of invention objection.

#### *Filing a divisional in order to maintain pendency of a case*

A voluntary divisional application can be filed for any reason, including to maintain pendency of a case.

#### *Application of Mexican law to scenario*

In the hypothetical scenario, there would be no issue in relation to unity of invention. Assuming that (i) all compounds encompassed by the Markush formula (I) are produced by the same process and (ii) that the compounds are novel and inventive, the compounds, the process for manufacturing the compounds and the use of the compounds to treat cancer would be deemed to share the same inventive concept. Nonetheless, the applicant would be entitled to divide the application to claim the lead candidate compound in a first divisional application and the processes for preparing the compounds of the Markush formula in a second divisional application. However, the matter going into the divisional application must be cancelled from the claims of the parent application.

Given the hypothetical scenario, the applicant would be advised to divide the application as soon as the need for a divisional is identified. Otherwise, the application might be allowed without an office action issued during examination. If this were to happen the applicant would have no opportunity to divide the application as desired. Noting the applicant's intention to divide out the method for preparing the compounds, if there is more than one process for obtaining the compounds defined by the Markush formula (I) a lack of unity may arise in the divisional application. This would occur if, in the absence of the compounds, there is nothing to link the inventive concepts of the independent process claims.

### **Colombia**

*By: Monica Guevara, OlarteMoure & Asociados*

#### *Unity of invention*

Article 25 of Decision 486 (Andean IP Law) establishes a unity of invention requirement according to which a patent application can only be directed to a single invention or a group of inventions that are closely related and share a single inventive concept. Various embodiments, such as product and process, and process and apparatus, recited in the claims must coalesce in a single inventive concept. If it is determined that there is a lack of unity, the examiner will

identify different groups of inventions. The applicant is allowed to file divisional applications based on the inventive concepts suggested by the examiner, or other groupings (provided these groupings are explained in the response to the office action).

*Timing for assessment of unity of invention*

Unity of invention is assessed during the examination stage.

*Double-patenting restrictions*

Although Decision 486 does not expressly prohibit the granting of two patents covering identical subject matter, in 2016, the Colombian Patent Office (CPO) prohibited this situation in the CPO's Directives via Resolution 3719/2016. This resolution establishes that claimed subject matter in a divisional application must be different from the subject matter claimed in the parent application, i.e., subject matter in the set of claims of the parent and divisional applications must not overlap.

*Timing/deadline for filing divisional applications*

Applicants are allowed to file divisional applications at any time during prosecution (Art. 36 of Decision 486), even after a non-final rejection is issued (provided administrative remedies are filed to reopen prosecution). However, once a decision to grant is issued, the prosecution stage ends, and divisional applications cannot be filed.

As a caveat, there is no statutory requirement for the CPO to inform that an application will be granted. Therefore, a decision to grant may be made without the issuance of a substantive examination (direct granting). Hence, it is important to consider divisional strategy in early prosecution stages.

*Filing a divisional in order to maintain pendency of a case*

The filing of divisional patent applications to maintain pendency is discouraged. Although applicants are allowed to file voluntary divisional applications, since 2016 the CPO has closely monitored the use of divisional applications as a strategy to extend the pendency of a patent application, issuing a rigorous set of requirements that applicants must comply with when filing voluntary divisional applications (introduced in the CPO's Directives via Resolution 3719/2016).

*Other requirements peculiar to the jurisdiction*

According to Resolution 3719/2016, the splitting out of a divisional application from another divisional application is not allowed. Divisional applications can only be split out from the initial parent application.

Additionally, the claims of the divisional application must be expressly carved out from the claims of the parent application. Claims of the divisional must have been previously included in the claims of the parent case (even to the point of taking into account the consecutive numbering of the claims). This may present difficulties in pursuing a divisional application directed to an example of the specification, if the example was not previously recited in the original claims.

The specification of the divisional should be adapted to match the scope of the claims at filing.

### *Application of Colombian law to scenario*

Both the compounds and the method for producing the compounds would be considered part of the same inventive concept, provided the compounds are novel and inventive. Nonetheless, the applicant would be entitled to divide the application to claim the lead candidate compound in a first divisional application and the processes for preparing the compounds in a second divisional application.

In the hypothetical case, the applicant would not have any issue when filing a voluntary divisional directed to the method for producing the compound, provided it is structurally defined by the steps rendering it novel and inventive. Although some of the requirements for filing a divisional application established in 3719/2016 are currently under review by the CPO, and subject to modification in the near future, double patenting matter will most probably be maintained. The issue of double patenting is usually traversed by differentiating the claimed scope in the parent and divisional. However, if the Applicant's interest is pursuing a particular embodiment encompassed in the claims of the parent (i.e., the lead candidate with promising results in cancer treatment) in a divisional, the CPO will most probably raise double patenting objections. In such a case, our recommendation would be maintaining the compound of interest in an independent claim of the parent application.

### **Conclusion**

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As it is evident from the different perspectives laid out above, it is important to identify and recognize the nuances of divisional practice in various jurisdictions in the early stages of prosecution of a global patent family in order to advise our clients of an effective global patent filing strategy. In particular, elements such as the timing of a divisional, or if double patenting is prohibited in a particular set of jurisdictions are key points that could define whether or not our clients actually obtain protection for the subject matter of their interest.

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