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# **Standing Committee on the Law of Patents**

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STUDY ON UNITY OF INVENTION

Document prepared by the Secretariat

#### INTRODUCTION

- 1. At its thirty-fifth session, held in Geneva from October 16 to 20, 2023, the Standing Committee on the Law of Patents (SCP) decided that a study on unity of invention would be prepared by the Secretariat, based on the information provided by Member States and regional patent offices, and be submitted to the thirty-sixth session of the SCP. The Committee agreed that the study will touch upon various aspects of the unity of invention including: (i) divisional applications; and (ii) unique aspects of the unity requirement as it pertains to different fields of technology.
- 2. Pursuant to the above decision, Member States and regional patent offices were invited through Note C.9199, dated December 7, 2023, to submit information to the International Bureau on the above elements under the applicable law. In total, 16 Member States and one regional patent office provided their applicable laws and practices in relation to the requirement of unity of invention.<sup>1</sup> Taking into account the submitted information, the Secretariat prepared a study on unity of invention, which is contained in this document.<sup>2</sup>
- 3. While the study addresses the aspect of divisional applications in relation to rectifying non-compliance with the requirement on unity of invention, it does not discuss substantive and

<sup>1</sup> The information received from Member States and the regional patent offices is available on the website of the SCP electronic forum at: https://www.wipo.int/scp/en/meetings.

<sup>&</sup>lt;sup>2</sup> The information received included national and regional legislation, court decisions, patent examination manuals and guidelines. They were generally referred to as "applicable law" where the precision of the type of the legal source was not necessary. As regards the patent examination manuals and guidelines, while they are used intensively through the document, they do not constitute substantive rulemaking and hence do not have the force and effect of law. In general, such manuals and guidelines are simply designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law.

procedural requirements regarding voluntary division of patent applications by applicants, including prohibition of double patenting.

[Annex follows]

# Study on Unity of Invention

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#### UNITY OF INVENTION: GENERAL CONCEPTS AND PRINCIPLES

#### INTRODUCTION TO UNITY OF INVENTION AND DIVISIONAL APPLICATIONS

#### Unity of Invention

- 1. The principle of "unity of invention" is a fundamental principle in patent law, requiring that a patent application encompasses only a single invention or a group of inventions related in a certain manner. In many jurisdictions and under the Patent Cooperation Treaty (PCT), that concept is expressed as a group of inventions so interconnected that they form a single general inventive concept. The goal underlying the principle is the maintenance of an efficient and balanced patent system fair to both applicants and patent offices.
- 2. The principle of unity of invention gained international recognition in patent law through its inclusion in international treaties such as the Paris Convention for the Protection of Industrial Property (Paris Convention) and the PCT.<sup>1</sup> The PCT explicitly requires that an international application under the PCT shall relate to one invention only or to a group of invention so linked as to form a single general inventive concept. Most countries and regional patent offices have adopted the PCT definition and practices of unity of invention, or its close analogue, to their national/regional legislations and practices for national/regional patent applications.

# <u>Divisional Applications Relating to Unity of Invention</u>

- 3. Divisional applications represent a feature of patent law, designed to address the complexities arising when a single patent application is found to encompass multiple inventions. At its core, a divisional application is a derivative process, allowing an applicant to split an original patent application into two or more applications, each covering a distinct invention.
- 4. When a patent examiner identifies non-compliance with the unity of invention requirement, the applicant may split the application into more than one applications, each focusing on a distinct invention. Since the applicant possessed the inventive concepts for all the inventions at the time of the original application's priority date, the divisional applications are entitled to share the same priority date as the original application. Divisional applications thus serve as a mechanism enabling applicants to pursue comprehensive protection for all their inventions even when the patent application as filed was deemed not to meet the requirement of unity of invention.

#### PURPOSE AND RATIONALE BEHIND THE UNITY OF INVENTION PRINCIPLE

5. There are a number of objectives underlying the unity of invention principle. Included amongst these are the objectives of: (1) streamlining the examination process; (2) ensuring the sustainability of patent office operations; and (3) enhancing legal clarity.

# Streamlining the Examination Process

6. One of the main objectives of the unity of invention principle is to simplify and expedite the patent examination process. By mandating that all claims in an application be connected by a single general inventive concept, it becomes simpler for patent offices to assign the application to one examiner with expertise in the relevant technical field. This approach eliminates the need for multiple examiners or for an examiner with cross-disciplinary training, thereby enhancing the efficiency of the patent examination process.

<sup>&</sup>lt;sup>1</sup> Article 4G of the Paris Convention for the Protection of Industrial Property; Article 3(4)(iii) of the PCT and Rule 13 of the Regulations under the PCT.

#### **Ensuring Sustainability of Patent Office Operations**

7. Focusing the examination on a single inventive concept or a group of closely related concepts, the unity of invention principle enhances the sustainability of patent office operations. The fees charged by patent offices in Member States for processing patent applications are generally aligned with the aggregate costs of examination. However, such costs differ for individual applications. Lengthy, complicated, or overly broad applications may incur examination costs that significantly exceed the fees collected for that application. By limiting each application to a single overarching inventive concept, a more direct relationship is established between the fees collected and the effort expended by the patent office. Without this principle, applicants might circumvent fees by bundling multiple, potentially disparate inventions into a single application. Such applications would likely be lengthy, disjointed, and lack coherence, complicating the examination process and straining patent office resources.<sup>2</sup>

#### **Enhancing Legal Clarity**

8. The unity of invention requirement strengthens legal transparency for patent offices, patent holders, and third parties. By delineating the scope of a patent application to a single inventive concept or a cluster of related concepts, it simplifies the process of establishing the extent of protection granted. This clarity facilitates easier classification and searchability of the patent. Moreover, narrowing the invention's scope aids patent offices in referencing the application during the examination of subsequent filings. It also enables third parties to more readily assess their freedom to operate within the field by increasing the navigability and searchability of published patent documents.<sup>3</sup>

#### OPTIONS AVAILABLE AFTER A FINDING OF NON-UNITY

- 9. When confronted with a finding of non-unity, applicants have several courses of action. The choice among these options depends on various factors, including the nature of the inventions, strategic patenting goals, and the specific regulations of the patent office involved. These choices primarily include:
  - i. **Amending Claims**: Applicants may choose to amend the claims to focus on a single invention or modify them to clarify the inventive concept linking the claimed inventions, thereby addressing the examiner's concerns regarding unity.
  - ii. Challenging the Finding: In some cases, applicants may present arguments to the examiner, contesting the non-unity finding. This can involve providing a rationale or evidence demonstrating that the inventions are indeed linked by a single general inventive concept.
  - iii. **Filing Divisional Applications**: As a common recourse, applicants may file divisional applications for the additional inventions identified in the non-unity finding. This involves separating the application into multiple applications, each focusing on a different invention. While this increases the overall patenting costs due to multiple filing and examination fees, it enables applicants to pursue protection for all their inventions.
  - iv. **Abandoning the Application**: After a finding of non-unity, applicants may decide that continuing is not strategically or economically viable. For example, claim restrictions might weaken the invention's scope, reducing its commercial value. Reevaluation of the invention's potential may show that expected returns do not

<sup>&</sup>lt;sup>2</sup> See comments received from Germany in response to C.9199.

<sup>3</sup> Ibio

justify further investment. Additionally, the time and resources needed to address a non-unity rejection can divert focus from other critical activities. In such cases, applicants might choose to abandon the application and allocate resources to more promising projects.

#### LEGAL FRAMEWORKS FOR UNITY OF INVENTION

#### THE INTERNATIONAL LEGAL FRAMEWORK

10. The principle of unity of invention embedded in the legal frameworks of the Paris Convention, PCT, national, and regional patent legislation, regulations, and guidelines ensures that a patent contains a single invention. While each jurisdiction may articulate the principle slightly differently, at their core, these frameworks share a broad similarity: they all mandate that a patent application should either pertain to a single invention or to a group of inventions so interconnected that they form a single general inventive concept. Under the Patent Law Treaty (PLT), its Contracting Parties may declare a reservation in relation to unity of invention.

# The Paris Convention

- 11. The right of applicants to avail themselves of divisional applications in case of non-unity is explicitly recognized by Article 4G of the Paris Convention which provides:
  - (1) If the examination reveals that an application for a patent contains more than one invention, the applicant may divide the application into a certain number of divisional applications and preserve as the date of each the date of the initial application and the benefit of the right of priority, if any.
  - (2) The applicant may also, on his own initiative, divide a patent application and preserve as the date of each divisional application the date of the initial application and the benefit of the right of priority, if any. Each country of the Union shall have the right to determine the conditions under which such division shall be authorized.
- 12. Article 4G(1) grants applicants the flexibility to address unity objections by dividing the application into multiple divisional applications if, during examination, there is a finding of non-unity. Each divisional application retains the priority date of the original application, ensuring that the applicant does not lose the right of priority based on the filing date of the initial application.<sup>4</sup>
- 13. It is important to note that each member country of the Paris Convention has the authority to determine the specific conditions and requirements for filing divisional applications. This means that the rules governing divisional applications can vary significantly between different jurisdictions. Some countries might have more stringent requirements, while others may offer more flexibility, impacting how applicants approach the filing of divisional applications.

#### The Patent Cooperation Treaty (PCT)

14. Article 4(iii) of the PCT requires an application to comply with the prescribed requirement of unity of invention, which is covered in Rule 13 of the Regulations under the PCT. Further

<sup>&</sup>lt;sup>4</sup> Additionally, Article 4G(2) of the Paris Convention supports the concept of voluntary divisional applications. Applicants can proactively divide their patent applications at any stage and claim the priority date of the initial application. This is particularly useful for isolating distinct inventions within a single application to meet patentability requirements or optimize the scope of protection sought.

details on unity of invention are set out in Annex B of the PCT Administrative Instructions. In particular, the requirement of unity of invention is prescribed in Rule 13.1, as follows:

"The international application shall relate to <u>one invention only</u> or to <u>a group of</u> <u>inventions so linked as to form a single general inventive concept</u> ("requirement of unity of invention")." [emphasis added]

- 15. Where there is a group of inventions sharing a single general inventive concept that is claimed in the same international application, Rule 13.2 indicates that:
  - "[...] the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or **corresponding special technical features**. The expression **'special technical features**' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." [emphasis added]
- 16. Rule 13.3 further clarifies that unity of invention is maintained regardless of whether these inventions are contained within a single claim or spread across multiple claims, as follows:
  - "The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim."
- 17. Rule 13.4 allows that an independent claim may have a reasonable number of dependent claims claiming specific forms of the invention claimed in the independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention.
- 18. Rule 13 is interpreted as allowing the inclusion of any one of the following combinations of claims of different categories within the same international application:<sup>5</sup>
  - in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or
  - in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or
  - in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process.
- 19. Here, a process is considered to be specially adapted for the manufacture of a product, if the claimed process inherently results in the product with a technical relationship being present between the claimed product and claimed process. However, the words "specially adapted" are not intended to imply that the product could not also be manufactured by a different process.<sup>6</sup>
- 20. Similarly, an apparatus or means is regarded as specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. It would not be sufficient that the apparatus or means is merely capable of being used in carrying out the claimed process. However, the

<sup>&</sup>lt;sup>5</sup> PCT International Search and Preliminary Examination Guidelines, Part III, Chapter 10 Unity of Invention, paragraphs 10.11 to 10.14.

<sup>&</sup>lt;sup>6</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraphs 10.12 and 10.13

expression "specifically designed" does not imply that the apparatus or means could not be used for carrying out another process, nor that the process could not be carried out using an alternative apparatus or means.<sup>7</sup>

#### Handling Lack of Unity during the PCT International Phase

21. The following paragraphs describe practice during the international phase of the PCT where an international application is considered not to comply with the requirements of unity of invention. It is important to note that there is no possibility for dividing an international application in the international phase; it is for the designated or elected Office to invite the filing of divisional applications in the national phase where it considers that unity of invention is not complied with. All international applications that proceed through the international phase will have an international search unless the application relates to excluded subject matter or a meaningful search cannot be carried out. International preliminary examination and supplementary international search are optional.

#### (i) International search

- 22. Article 17(a) of the PCT requires an International Searching Authority (ISA) to consider whether the international application complies with the requirement of unity of invention and invite the applicant to pay additional fees if the ISA considers that the international application does not comply with the requirement. The ISA shall establish the international search report on those parts of the international application which relate to the invention first mentioned in the claims ("the main invention") and, provided the required additional fees have been paid within the prescribed time limit, on those parts of the international application which relate to inventions in respect of which the said fees were paid.
- 23. Upon deciding that lack of unity of invention exists, the ISA usually issues a communication to inform the applicant of lack of unity, inviting the applicant to pay additional fees<sup>8</sup>. This invitation: (i) specifies the reasons for which the international application is not considered as complying with the requirement of unity of invention; (ii) identifies the separate inventions and indicates the number of additional search fees and the amount to be paid; and (iii) invites the applicant to pay, where applicable, the protest fee if the applicant wishes to challenge the decision on lack of unity. The ISA cannot consider the applicant withdrawn for lack of unity of invention, nor invite the applicant to amend the claims.<sup>9</sup> When an invitation is issued, the other invention(s) or groups of invention(s) will only be searched if the applicant pays the corresponding additional fees or if a protest submitted by the applicant is found to be justified by the ISA.<sup>10</sup>
- 24. The examiner may, optionally, draw up a partial international search report covering the "main invention", which will be sent together with the invitation to pay additional fees. This provides further information for the applicant in deciding whether to pay additional fees for the other inventions in the international application.
- 25. Following the one month period for paying the additional fee(s), the ISA finally draws up the international search report and written opinion on those parts of the international application which relate to inventions in respect of which the search fee and any additional search fee have

<sup>&</sup>lt;sup>7</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraphs 10.12 and 10.14.

<sup>&</sup>lt;sup>8</sup> If little or no additional search effort is required, reasons of economy *may* make it advisable for the examiner, while making the search for the main invention, to search at the same time one or more additional inventions in the classification units consulted for the main invention (paragraphs 10.64 and 10.65 of the PCT International Search and Preliminary Examination Guidelines.

PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.60.
PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.61.

been paid.<sup>11</sup> In the national phase, for parts of the international application that have not been searched, the national law of any designated State may provide that, where the national Office of the designated State finds the invitation of the ISA to be justified, those parts shall be considered withdrawn unless a special fee is paid by the applicant to the national Office of that State.<sup>12</sup>

- 26. The applicant may protest the allegation of lack of unity, or that the number of required additional fees is excessive, and request a refund of the additional fees paid. If, and to the extent that, the International Searching Authority finds the protest justified, the fees are refunded<sup>13</sup>. The protest involves submitting a reasoned statement accompanying payment of the additional fees and possibly a protest fee. The reasoned statement should explain why the applicant believes that requirements of unity of invention requirements are fulfilled<sup>14</sup>.
- 27. The protest is examined by a review body constituted within the framework of the ISA, and a decision is taken on it. The procedure is determined by each International Searching Authority, although the review body must not be limited to the person who made the decision which is the subject of the protest. Some Authorities may review the protest in two stages, with a review body being convened only if a preliminary review of the protest reveals that the protest is not entirely justified. To the extent that the protest is found to be justified, the additional fees are totally or partly reimbursed. However, the protest fee is refunded only where the review body finds that the protest was entirely justified. Where the applicant has paid additional search fees under protest, the applicant is informed promptly of any decision about compliance with the requirement of unity of invention. If the protest is found to be justified to the extent that a partial reimbursement of the fees is made, or the protest is found unjustified, the applicant is informed of the reasons for the decision. At the same time, the ISA transmits to the International Bureau a copy of the protest and of the decision thereon. At the request of the applicant, the texts of the protest and the decision thereon can also be forwarded by the International Bureau to the designated Offices. 17
  - (ii) International preliminary examination
- 28. Under Article 34(3)(a) of the PCT, if the International Preliminary Examining Authority (IPEA) considers that the international application does not comply with the requirement of unity of invention as set forth in the Regulations, it may invite the application to restrict the claims so as to comply with the requirement or to pay additional fees. It should be noted that in most instances lack of unity of invention will have been noted and reported upon by the ISA. However, whether or not the question of unity of invention has been raised by the ISA, it may be considered by the examiner during international preliminary examination, taking into consideration all the documents cited in the international search report and any additional documents considered to be relevant.
- 29. Where the examiner finds a lack of unity of invention, the examiner may issue a communication outlining their findings and inviting the applicant either to restrict the claims, or to pay an additional fee for each additional invention claimed. Where such a communication is sent, at least one possible restriction, which would avoid the objection of lack of unity of invention, is indicated by the examiner. In the invitation to pay additional fees, the examiner sets out a logically presented, technical reasoning containing the basic considerations behind

<sup>&</sup>lt;sup>11</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.62.

<sup>&</sup>lt;sup>12</sup> Article 17(3)(b) of the PCT.

<sup>&</sup>lt;sup>13</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.66.

<sup>&</sup>lt;sup>14</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.67.

<sup>&</sup>lt;sup>15</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.68.

<sup>&</sup>lt;sup>16</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.69.

<sup>&</sup>lt;sup>17</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.70.

<sup>&</sup>lt;sup>18</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.71.

<sup>&</sup>lt;sup>19</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.73

the finding of lack of unity in accordance with the International Search and Preliminary Examination Guidelines.<sup>20</sup> The applicant may protest the allegation of lack of unity of invention or that the number of required additional fees is excessive and request a refund of the additional fees paid<sup>21</sup>. In this case, a protest procedure similar to that at international search takes place.<sup>22</sup>

30. If the applicant fails to comply with the invitation to restrict the claims or pay additional fees, the International Preliminary Report on Patentability (IPRP) is established on those parts of the international application which relate to what appears to be the "main invention". If the applicant timely complies with the invitation to pay additional fees or to restrict the claims, the examiner carries out international preliminary examination on those claimed inventions for which additional fees have been paid or to which the claims have been restricted. In the national phase, for parts of the international application that have not been the subject of international preliminary examination, whether following a restriction of the claims or the applicant not complying with the invitation and the national Office of the elected State finds the invitation of the IPEA to be justified, the national law of any elected State may provide that those parts shall be considered withdrawn unless a special fee is paid by the applicant to that Office.

# (iii) Supplementary international search

- 31. The Authority specified for supplementary search may make its own assessment as to unity of invention, but it should take into account the opinion of the ISA included in the international search report as well as any protest by the applicant or decision by the ISA in relation to such a protest if it is received prior to the start of the supplementary international search.<sup>26</sup> Under Rule 45*bis*.6, if the Authority specified for supplementary search finds that the international application does not comply with requirement of unity of invention, it shall: (i) establish the supplementary international search report on those parts of the international application which relate to the invention first mentioned in the claims ("main invention"); (ii) notify the applicant of its opinion that the international application does not comply with the requirement of unity of invention and specify the reasons for that option; and (iii) inform the applicant of the possibility of requesting, within one month from the date of notification, a review of the opinion. The examiner may, however, exercise appropriate discretion in selecting the invention to be searched.<sup>27</sup> Contrary to the case for the main international search, there is no opportunity to pay additional fees for additional searches of further inventions at the supplementary international search stage.<sup>28</sup>
- 32. The normal protest procedure at international search does not apply to requests for supplementary international search. However, the applicant may, within one month of the date of notification of the supplementary international search report, request the Authority to review the examiner's opinion on unity of invention. This request may be subject to a review fee. The

<sup>&</sup>lt;sup>20</sup> There are cases of lack of unity of invention where, compared with procedure of inviting the applicant to restrict the claims or pay additional fees, nor or little additional effort is involved in establishing the international preliminary examination report for the entire international application. Then, reasons of economy may make it advisable for the examiner for follow the option referred to in PCT Rule 68.1 by choosing not to invite the applicant to restrict the claims or pay additional fees. In this situation, when establishing the international preliminary examination report on the entire international application, the examiner indicates the opinion that the requirement of unity of invention is not fulfilled and the reasons therefore (see paragraph 10.76 of the International Search and Preliminary Examination Guidelines).

PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.78.
PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraphs 10.78 to 10.82.

<sup>&</sup>lt;sup>23</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.75.

<sup>&</sup>lt;sup>24</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.74.

<sup>&</sup>lt;sup>25</sup> Articles 34(3)(b) and (c) of the PCT

<sup>&</sup>lt;sup>26</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.84.

<sup>&</sup>lt;sup>27</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.86.

<sup>&</sup>lt;sup>28</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.83.

results of the review are promptly notified to the applicant.<sup>29</sup> If the examiner's opinion is found to be at least partly unjustified, the Authority should issue a revised supplementary international search report, stating the revised view on unity of invention and, where appropriate, including the search results for all claims which should have been included. If the opinion was entirely unjustified, the applicant should have any review fee refunded.<sup>30</sup>

# The Patent Law Treaty (PLT)

33. The PLT also includes provisions which touch upon the issue of unity of invention. Article 23(1) states:

"Any State or intergovernmental organization may declare through a reservation that the provisions of Article 6(1) shall not apply to any requirement relating to unity of invention applicable under the Patent Cooperation Treaty to an international application."

# 34. Article 6(1) states:

Except where otherwise provided for by this Treaty, no Contracting Party shall require compliance with any requirement relating to the form or contents of an application different from or additional to:

- (i) the requirements relating to form or contents which are provided for in respect of international applications under the Patent Cooperation Treaty;
- (ii) the requirements relating to form or contents compliance with which, under the Patent Cooperation Treaty, may be required by the Office of, or acting for, any State party to that Treaty once the processing or examination of an international application, as referred to in Article 23 or 40 of the said Treaty, has started;
- (iii) any further requirements prescribed in the Regulations.
- 35. It is notable that in accordance with PLT Article 23(4), the reservation relating to unity of invention is the only reservation that is permitted under the Treaty. When the PLT was being negotiated, there were different views amongst Member States as to whether the requirement for unity of invention was a formal or substantive requirement.<sup>31</sup> Furthermore, should the PCT requirement on unity of invention be incorporated by reference to the PLT pursuant to PLT Article 6(1), some jurisdictions did not wish to apply such requirement to their national applications.<sup>32</sup> The Contracting Parties that have made such a reservation to the PLT are Kazakhstan, the Russian Federation, and the United States of America.<sup>33</sup>

#### GENERAL PROCESS OF ASSESSING UNITY

36. This section outlines the general procedure for the assessment of unity of invention, which is primarily based on the PCT administrative instructions, guidelines and case law related to PCT international applications. However, given the substantial similarity between PCT practice and national/regional practices, similar guidance is found in many patent offices for national/regional patent applications filed with those offices.

<sup>&</sup>lt;sup>29</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.87.

<sup>&</sup>lt;sup>30</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.88.

<sup>&</sup>lt;sup>31</sup> Records of the Diplomatic Conference for the Adoption of the Patent Law Treaty, Geneva 2000, at paragraphs 2522 -2530.

<sup>32</sup> Ibid.

<sup>&</sup>lt;sup>33</sup> List of Contracting Parties to the Patent Law Treaty, available at: https://www.wipo.int/wipolex/en/treaties/ShowResults?search\_what=C&treaty\_id=4.

- 37. At a high level, in determining if the requirement of unity of invention is met, the following process is used:
  - i. **Preliminary Analysis of Independent Claims:** The assessment process begins with a thorough review of the application's independent claims. This initial step is crucial for defining the technical scope and characteristics of the proposed invention(s), aiming to identify the number of inventions and a shared inventive concept or special technical features that bind the application into a coherent narrative. Each independent claim generally embodies a single invention unless an atypical claim structure such as claiming in the alternative is used. Therefore, when there is just one independent claim, or when the independent claims cover analogous features (for example, an apparatus and its method of use), the criterion of unity of invention is typically satisfied.<sup>34</sup>
  - ii. Detailed Analysis of Independent Claims: When there are multiple independent claims which lack analogous features, a thorough review is necessary. Unity of invention is considered satisfied if there is a technical relationship among the claimed inventions, characterized by one or more identical or corresponding special technical features. The aim is to pinpoint these shared technical features across the independent claims.

In assessing whether special technical features exist between independent claims, factors to consider include both shared structural features, shared function, or address the same technical challenge.<sup>35</sup> Such correspondence could manifest in various forms, such as alternative mechanisms that provide similar outcomes, or interconnected components that interact in a specific way, like a plug and a socket or a transmitter and a receiver. As another example, a metal spring and a rubber block, although differing significantly in terms of material composition and structural design, may be considered to possess corresponding technical features based on their shared technical effect - that of providing elasticity.

Unity can also manifest itself in a cause-and-effect relationship, where a particular step in a manufacturing process results in a distinct structural attribute of a product. If there exists an absence of such commonalities or shared technical features amongst the independent claims, this may warrant a unity of invention objection at this stage, prior to examining the prior art (for example, a solar panel and a windmill).

If the subject matter of two independent claims is classified in different international patent classification units, this may be an indicator of lack of unity.<sup>36</sup> A preemptive objection, made prior to reviewing the prior art, is known as an *a priori* unity of invention objection.<sup>37</sup>

iii. **Review of and Comparison with the Prior Art:** The process involves identifying the closest prior art and comparing it with the technical features shared among the

<sup>&</sup>lt;sup>34</sup> However, if the scope of the sole independent claim is overly broad, it may encompass features that lack novelty or an inventive step. In such cases, the assessment of unity of invention may need to extend beyond the independent claim and consider the dependent claims to determine whether they introduce separate inventions. This problem will become apparent in the *a posteriori* analysis described in step (iii).

<sup>&</sup>lt;sup>35</sup> See Applicant v. European Patent Office, 22 March 1991, European Patent Office (EPO), retrieved from WIPO PCT Case Law Database at: https://www.wipo.int/pctcaselawdb/en/.

<sup>&</sup>lt;sup>36</sup> See Applicant v. European Patent Office, 9 April 1992, European Patent Office (EPO), retrieved from WIPO PCT Case Law Database at: https://www.wipo.int/pctcaselawdb/en/. However, the mere fact that the claimed inventions are classified in separate classification groups should not give rise to lack of unity objection (see PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, paragraph 10.05).

<sup>&</sup>lt;sup>37</sup> See Applicant v. European Patent Office, 30 September 2003, European Patent Office (EPO) and Applicant v. European Patent Office, 9 November 1990, European Patent Office (EPO), retrieved from WIPO PCT Case Law Database at: https://www.wipo.int/pctcaselawdb/en/.

different inventions. For a plurality of inventions to be considered as sharing a "special technical feature" and thus satisfy the unity of invention requirement, the common elements must make a "contribution" over the prior art.<sup>38</sup> This "contribution" is considered with respect to both novelty and inventive step.<sup>39</sup> Should the common elements of the claimed inventions be deemed known or obvious based on the relevant prior art, and if the remainder of each claim diverges without a cohesive inventive concept, then unity is considered absent.<sup>40</sup> A determination of non-unity made on this basis, or after taking the prior art into consideration, is referred to as **a posteriori** unity of invention objection.<sup>41</sup>

For instance, consider Claim 1 comprising elements A, B, and C, and Claim 2 including elements C, D, and E. Here, element C serves as the shared technical feature between the two claims. However, if element C is already known or deemed obvious in light of existing prior art, it cannot be regarded as a "special technical feature" that establishes a "single general inventive concept" linking the inventions described in Claims 1 and 2 for unity of invention purposes.

- 38. The determination of unity is grounded in the contents of the claims, interpreted in light of the description and accompanying drawings.<sup>42</sup> This holistic approach ensures that the inventive concept is clearly understood and properly assessed against the requirement for unity of invention.
- 39. Even if the claim(s) do not meet the requirement of unity of invention *strict sensu*, in exceptional circumstances, an examiner may be able to complete search and examination of all claimed inventions with negligible additional work. Considering the efficiency of examination and the additional workload that may be imposed on examiners, the examiners may have the discretion in completing the search and examination for the additional invention(s), on a case-by-case basis, without raising non-unity objection. In considering the amount of work involved, the examiner should take into account the time taken to create the written opinion as well as that needed to perform the search, since even when the analysis involved as regards the search is negligible, the opposite may be the case for the written opinion.<sup>43</sup>

#### **Examples and Commentary**

Example 1 – A Priori Evaluation

40. Suppose we had a patent application with the following claimset:

<sup>&</sup>lt;sup>38</sup> See Applicant v. European Patent Office, 2 May 2002, European Patent Office (EPO) and Applicant v. European Patent Office, 21 September 2009, European Patent Office (EPO), retrieved from WIPO PCT Case Law Database at: https://www.wipo.int/pctcaselawdb/en/; PCT International Search and Preliminary Examination Guidelines, Part III Examiner Considerations Common to both the International Searching Authority and the International Preliminary Examining Authority, Chapter 10 Unity of Invention, Process at the International Search Stage. For example, a document discovered in the international search may show that there is a lack of novelty or inventive step in a main claim, so that there may be no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept.

<sup>&</sup>lt;sup>39</sup> *Ibid.* 

<sup>40</sup> Ibid.

<sup>&</sup>lt;sup>41</sup> See Applicant v. European Patent Office, 30 September 2003, European Patent Office (EPO) and Applicant v. European Patent Office, 9 November 1990, European Patent Office (EPO), retrieved from WIPO PCT Case Law Database at: https://www.wipo.int/pctcaselawdb/en/.

<sup>&</sup>lt;sup>42</sup> Administrative Instructions under the Patent Cooperation Treaty, Annex B Unity of Invention.

<sup>&</sup>lt;sup>43</sup> PCT International Search and Preliminary Examination Guidelines, Part III Examiner Considerations Common to both the International Searching Authority and the International Preliminary Examining Authority, Chapter 10 Unity of Invention, paragraphs 10.64-10.65.

- Claim 1: A chair (A) with wheels (B).
- Claim 2: A chair (A) made of plastic (C).
- Claim 3: Wheels (B) made of plastic (C).
- 41. In this case, there is no common subject matter to all claims and there is thus no unity between all 3 claims.

Example 2 – A Priori Evaluation

- 42. Suppose we had a patent application with the following claimset:
  - Claim 1: A compound for the following formula:

• Claim 2: A compound for the following formula:

43. Here, there is no common significant structural element. There is thus lack of unity "a priori".<sup>44</sup>

Example 3 – A Posteriori Evaluation

- 44. Suppose we had a patent application with the following claimset:
  - Claim 1: A multi-function pocket knife (A) with a ball-point pen (B) + a USB Stick (D)
  - Claim 2: A multi-function pocket knife (A) with a pencil (C) + a laser pointer (E)

A multi-function pocket knife (A) with a fountain pen (F) is found as a relevant piece of prior art.

- 45. Here, element A of claims 1 and 2 is the same, and elements B and C are corresponding as they are both a means of writing. However, elements D and E are not corresponding as element D is a means adapted to save data electronically and element E is a means adapted to point to an object.
- 46. As the common feature (A) is known from the prior art, it cannot be considered "special technical features". Element F from the prior art is a writing means and thus the corresponding technical feature of claims 1 and 2 are not special. The common matter has neither the same, nor corresponding special technical features. In this case D and E do make a technical

<sup>&</sup>lt;sup>44</sup> The Israeli Patent Office, "Unity of Invention (Section 8, Israeli Patent Law)," https://www.gov.il/BlobFolder/guide/collaborations/he/collaborations\_unity-of-invention-2016.pdf, Apr. 2016.

contribution over the prior art. However they have different technical properties and thus the inventions in claims 1 and 2 are not linked by a single general inventive concept.<sup>45</sup>

#### NATIONAL AND REGIONAL LAWS AND PRACTICES

#### <u>Brazil</u>

# Legal Framework

- 47. Article 22 of the Brazilian Industrial Property Law provides:
  - "An application for a patent of invention must refer to a single invention or to a group of inventions so interrelated as to comprise a single inventive concept."
- 48. The term "single inventive concept", or unity of invention, is understood that the various claimed inventions present a technical relationship between them, represented by one or more identical or corresponding special technical features for all the claimed inventions.<sup>46</sup>

# Interpretive Guidance and Procedural Approach

- 49. The Brazilian legislation and regulations pertaining to unity of invention mirror those contained in the PCT. The approach taken by examiners at *Instituto Nacional da Propriedade Industrial* (INPI) Brazil towards assessing unity of invention follows similar guidelines to those established by the PCT, emphasizing the importance of "special technical features" in the evaluation process.
- 50. The expression "special technical features" refers to the technical characteristics that represent a contribution the claimed invention makes in relation to the state of the art. These features are interpreted based on the specification and drawings and must be common or correlated across all claimed inventions within the application. It is crucial to determine whether there is a technical relationship between the inventions conferred by these special technical features, even if the features themselves are not identical but instead corresponding. For instance, one claim might include a metal spring to provide resilience, while another might use a rubber block for the same purpose; both claims would be considered to share a special technical feature if they contribute to a unified inventive concept.
- 51. Interrelated elements must be specially adapted to each other so that the patent application meets the condition of unity of invention. If such elements have several other applications and the aforementioned relationship constitutes just one among several possible ones, it is understood that there is no unity of invention. As an example, consider a patent application containing a claim that refers to an anti-slip artificial grass and another that refers to a soccer ball manufactured with material especially suitable for this grass, which can be used on other grasses. In this case, it is understood that there is no unity of invention, even though the ball has a better performance on the aforementioned pitch.
- 52. The unity of invention is primarily assessed based on the independent claims within the patent application. In cases where an independent claim lacks novelty or inventive step, dependent claims must be evaluated for both their individual merit and the existence of a common inventive concept that ties them together. According to INPI Guidelines, a patent application may contain multiple independent claims of the same category only if the claimed subject matter relates to a plurality of interrelated products, different uses of a product or

 <sup>45 &</sup>quot;Unity of invention – outcome of the IP5 work", Presentation by the European Patent Office during the Meeting of International Authorities under the PCT, Quality Subgroup, Cairo, February 2019, available at: <a href="https://www.wipo.int/edocs/mdocs/pct/en/pct\_mia\_26/pct\_mia\_26\_presentation\_epo\_unity\_of\_invention.pdf">https://www.wipo.int/edocs/mdocs/pct/en/pct\_mia\_26/pct\_mia\_26\_presentation\_epo\_unity\_of\_invention.pdf</a>.
46 See comments received from Brazil in response to C.9199.

equipment, or different sets of alternative and essential characteristics for carrying out the invention, linked by the same inventive concept.

- 53. Moreover, independent claims from different categories can also constitute a group of inventions interrelated to each other to form a single inventive concept if they share a common special technical feature. For example, a product, its manufacturing process, and its use might be claimed in different independent claims, but if they all share a common special technical feature, they are considered to form a single inventive concept.
- 54. The lack of unity of invention can be identified either directly, before any prior art search is conducted (*a priori*), or after considering the prior art (*a posteriori*). In an *a posteriori* analysis, if relevant prior art reveals that the special technical feature is already known, the examiner must check for another common special technical feature that links the independent claims. If the lack of unity is identified *a priori*, the patent examiner informs the applicant about the different units of invention or interconnected and unified groups of inventions claimed in the patent application. The applicant is then invited to modify the claims, excluding those not related to the first unit of invention. The excluded subject matter can be submitted as one or more divisional applications.
- 55. If the applicant provides convincing arguments for the fulfillment of the condition of unity of invention, or restricts the claims to a single inventive concept, the initial objection will be withdrawn, and the examination will proceed. Otherwise, the application may be rejected for lack of unity of invention.
- 56. Brazilian law also allows a patent application to be divided into two or more applications until the end of examination, provided the divisional application refers to the original and does not exceed the matter disclosed in the original application.<sup>47</sup> These divisional applications retain the filing date of the original application and the benefit of the priority of the latter, if any.<sup>48</sup> Importantly, only the original application can serve as the basis for a divisional, a division request of a divisional application is not allowed.<sup>49</sup> To address double patenting concerns, a patent applicant, when filing for a divisional patent application, must remove the part of the claimed subject matter that appears in the original application.
- 57. To increase transparency and efficiency, INPI has improved its administrative procedures for handling divisional applications.<sup>50</sup> For example, substantive examination of divisional applications is often conducted by the same examiner responsible for the original application, and efforts are made to decide both applications simultaneously or close to each other. If a divisional application claims subject matter that has already been examined and rejected in the original application, it will be rejected for the same legal reasons.

#### Chile

#### Legal Framework

58. Act No. 19.039 on Industrial Property imposes a series of requirements on the granting of the exclusive right conferred by a patent. These include the patentability requirements that all patent applications must meet in order to be registered, which are laid down in Article 32 of the Act. In addition, Article 31 of the Act establishes that a patent is an exclusive right for the protection of an invention. That is complemented by Article 34 of the Regulations Implementing the Industrial Property Act, which provides that a patent application may pertain to only one

<sup>&</sup>lt;sup>47</sup> Articles 26 to 28 of the Industrial Property Law (Law No. 9,279 of May 14, 1996).

<sup>48</sup> Ihid

<sup>&</sup>lt;sup>49</sup> See comments received from Brazil in response to C.9199.

<sup>&</sup>lt;sup>50</sup> *Ibid.* 

invention or a group of inventions that maintain unity of invention, in other words that are related to each other in such a way as to comprise a single general inventive concept.

#### Interpretive Guidance and Procedural Approach

- 59. The National Institute of Industrial Property (INAPI) of Chile evaluates unity of invention based on whether the claimed inventions share a single common inventive concept. This concept typically connects the technical problem addressed by the inventions and the solution proposed. The common inventive concept may involve either a conceptual aspect of the technical solution or a material component within the claims, signifying a technical relationship between the problem and the proposed solution. The unity of invention is met when this relationship is expressed through one or more special technical features that collectively contribute to the invention's novelty and inventive step over prior art. In Chile, unity of invention is analyzed both a priori and a posteriori in light of the prior art.
- 60. In cases where unity of invention is not met, INAPI allows applicants to file divisional applications to separate distinct inventions into different applications. These divisional applications must be filed while the original application is still pending and must not introduce new matter beyond what was disclosed in the original application. Divisional applications can be initiated either voluntarily by the applicant before the appointment of an examiner or as required by INAPI at any stage of the examination process. The divisional application retains the filing date and priority of the original application, provided it meets these procedural requirements. If the divisional application does not qualify under these conditions, it will not benefit from the original filing date, and the original application will be treated as prior art.<sup>51</sup>

#### China

#### Legal Framework

61. Paragraph 1 of Article 31 of the Patent Law of the People's Republic of China specifies that:

"A patent application for an invention or utility model shall be limited to one invention or utility model. Two or more inventions or utility models belonging to a single general inventive concept may be filed as one application."

62. Rule 39 of the Rules for the Implementation of the Patent Law of the People's Republic of China further provides that:

"two or more inventions or utility models belonging to a single general inventive concept that may be filed as one application under Paragraph 1 of Article 31 of the Patent Law shall be technically interrelated and contain one or more identical or corresponding specific technical features, wherein specific technical features mean the technical features of each invention or utility model as a whole that contributes to the prior art."

63. Regarding the timing and requirements for filing a divisional application in case of lack of unity, Rule 48 of the Rules specifies that:

"where a patent application includes more than two inventions, utility models or designs, the applicant may file a divisional application [...] before the expiration of the time limited [...] however, where the patent application has already been refused, withdrawn or deemed to be withdrawn, no divisional application shall be filed."

<sup>&</sup>lt;sup>51</sup> See comments received from Chile in response to C.9199.

64. Additionally, Rule 49 provides that:

"A divisional application filed under Rule 48 may keep the original filing date and where applicable, the priority date, provided that it does not exceed the scope recorded in the original application."

Interpretive Guidance and Procedural Approach

- 65. The Chinese legislation and regulations on unity of invention and divisional applications closely follow those contained in the PCT. The approach taken by examiners of the China National Intellectual Property Administration (CNIPA) towards the assessment of unity of invention is provided in the CNIPA Patent Examination Guidelines. The approach taken by examiners is also broadly similar to the guidelines established by the PCT.<sup>52</sup>
- 66. As under the PCT, the key criterion is whether the inventions share one or more specific technical features that contribute to the prior art. For example, if a patent application includes claims for a machine and a method for operating the machine, both claims must share a common technical feature that represents an advance over the prior art. The unity of invention is primarily assessed through the independent claims, and if an independent claim lacks novelty or inventive step, dependent claims must be scrutinized for both their individual merit and their contribution to a common inventive concept.
- 67. A divisional application must be filed before the original application is granted, rejected, or deemed withdrawn. Notably, once the original application has been granted or rejected, no further divisional applications can be filed. However, if an examiner issues a notification to make a divisional application due to lack of unity, the applicant may file a further divisional application based on the examiner's guidance.
- 68. The CNIPA's guidelines specify that if a divisional application is filed based on a lack of unity in a previous divisional application, the timing for submission of further divisional applications is linked to the status of the previous divisional application. If the previous divisional application is still pending, a further divisional application can be filed. However, if the previous divisional application has been granted, rejected, or deemed withdrawn, a further divisional application cannot be filed.

#### Costa Rica

Legal Framework

69. Article 7 of Law 6867 on patents for inventions, industrial designs, and utility models, indicates:

"Unity of invention. The application may refer only to a single invention, or to a group of inventions related to each other in such a way that they form a single general inventive concept."

70. Furthermore, in relation to divisional applications, Article 8 indicates:

"The applicant may divide an application into two or more divisions, none of which may imply an expansion of the invention or of the disclosure contained in the initial application.

See Section 5.1, Chapter 1 and Sections 9 and 15.2.2, Chapter 2 of Part I, Chapter 6 and Section 4.4, Chapter 8 of Part II, and Section 5.5, Chapter 2 of Part III of the CNIPA Patent Examination Guidelines; also see Unity of Invention IP5 Report, available at: https://link.epo.org/ip5/IP5\_report\_on\_unity\_of\_invention\_protected.pdf.

Each divisional application shall preserve the date on which the initial application was filed."

# Interpretive Guidance and Procedural Approach

- 71. In Costa Rica, the approach to unity of invention is closely aligned with international norms. The requirement stipulates that an application may only cover a single invention or a group of inventions that are so interrelated that they form a single general inventive concept. Unity of invention is analyzed both *a priori*, before examining the prior art, and *a posteriori*, during the substantive examination.
- 72. If a lack of unity is identified, the applicant is required to clarify the scope of the invention or select the part of the invention they wish to pursue, potentially leading to the division of the application. Failure to comply with this requirement will result in the rejection or abandonment of the application for lack of unity. Divisional applications must be filed before a final decision is made on the parent application, as they cannot be used to re-protect subject matter that has already been reviewed, granted, or denied in the parent application or any related divisional applications.<sup>53</sup>

#### Germany

# Legal Framework

- 73. Paragraph 5 of Section 34 of the German Patent Act provides that "the application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept".
- 74. Paragraph 1 of Section 39 of the German Patent Act provides that:

"The applicant may divide the application at any time. The division is to be declared in writing. If the division is declared after the request for examination has been filed (section 44), the separated part is deemed to be the application for which the request for examination has been made. The date of the original application and any priority claimed for it remains applicable to each divisional application."

#### Interpretive Guidance and Procedural Approach

- 75. In Germany, the requirement for unity of invention is guided by Section 34(5) of the German Patent Act, ensuring that a patent application relates to a single invention or a group of inventions that are linked by a single general inventive concept. To determine lack of unity, the examiner must assess whether, in view of the technological context and the clarity of the inventive complex, processing in different procedures seems appropriate. If the examiner identifies a lack of unity, the applicant is typically notified and given the opportunity to correct the deficiency either through a declaration of division or by abandoning the parts of the application that lack unity.
- 76. The declaration of division is an established but unwritten legal institution in German patent law, distinct from the free division initiated by the applicant permitted under Section 39 of the German Patent Act. Unlike the free division, the declaration of division is initiated by the examining section and requires the consent between the examining section and the applicant to be issued. The strict separation between declaration of division on the one hand and free division under Section 39 German Patent Act on the other hand has been analyzed as a difference between German law and the law of the European Patent Convention.

<sup>&</sup>lt;sup>53</sup> See comments received from Costa Rica in response to C.9199.

77. The declaration of division must rectify the deficiency of lack of unity in such a way that it becomes clear what remains in the parent application. The subject matter of the divisional application must not go beyond the disclosed content of the parent application. If the declaration of division is ambiguous, the applicant is to be invited to clarify the matter within a fixed time limit. If no clarification is received, the original application must be refused. Upon division of an application, the divisional application will immediately become independent under procedural law; processing continues at the procedural stage which the original application had reached at the time of the division.<sup>54</sup>

#### Japan

# Legal Framework

78. Article 37 of the Japanese Patent Act provides that:

"Two or more inventions may be the subject of a single patent application in the same application, provided that these intentions are of a group of inventions recognized as fulfilling the requirements of unity of invention based on their technical relationship designated in Ordinance of the Ministry of Economy, Trade and Industry."

79. This "Ordinance of the Ministry of Economy, Trade and Industry" is enacted by Rule 25 of the Regulations under the Patent Act which provides that:

"The technical relationship specified by the Ordinance of the Ministry of Economy, Trade and Industry set forth in Article 37 of the Patent Law is the technical relationship of two or more inventions which have the same or corresponding special technical feature, and hence, are associated with each other to form a single general inventive idea."

80. In relation to divisional applications, Article 44 of the Japanese Patent Act provides that:

"An applicant for a patent may extract one or more new patent applications out of a patent application containing two or more inventions..."

Interpretive Guidance and Procedural Approach

- 81. The Japanese legislation and regulations pertaining to unity of invention essentially mirror those contained in the PCT. Moreover, the approach taken by examiners of the Japan Patent Office (JPO) towards the assessment of unity of invention is also broadly similar to the guidelines established by the PCT.<sup>55</sup>
- 82. Among the inventions claimed in the application, those inventions that fulfill the requirements of unity of invention as well as those that fulfill certain requirements will be subject to examination with respect to the requirements other than the requirements under Article 37. Only in the case where the applicant claims any other inventions, the examiner shall make a determination that the patent application fails to fulfill the requirements of Article 37. <sup>56</sup>
- 83. In Japan, the examiner should assess unity of invention by determining whether two or more claimed inventions have the same or corresponding special technical features. The term "special technical feature" means a technical feature defining a contribution made by an invention over the prior art. The examiner shall make such assessment by determining whether

<sup>&</sup>lt;sup>54</sup> See comments received from Germany in response to C.9199.

<sup>&</sup>lt;sup>55</sup> See comments received from Japan in response to C.9199; Examination Guidelines for Patent and Utility Model in Japan; Examination Handbook for Patent and Utility Model in Japan.

<sup>&</sup>lt;sup>56</sup> Examination Guidelines for Patent and Utility Model in Japan, Part II, Chapter 3 "Unity of Invention".

a special technical feature of one invention is the same as or corresponds to a special technical feature of another invention. In the cases where the special technical features are the same or correspond with each other, the requirement for unity will be deemed to be met.<sup>57</sup>

- 84. The examiner should identify the "special technical feature" of an invention, based on the contents of the description, claims and drawings, along with the general common knowledge available at the time of filing. However, if later analysis shows that these special technical features do not actually offer any improvement over the prior art, they are retroactively deemed not to meet the criteria for special technical features. The situations where the "later analysis shows that these special technical features do not actually offer any improvement over the prior art" should fall under any of the following cases:<sup>58</sup>
  - i. When the feature thought to be a "special technical feature" is found in prior art;
  - ii. When the feature thought to be a "special technical feature" is merely an addition, deletion, or substitution of well-known or commonly used technology to a piece of prior art, which does not produce any new effect;
  - iii. When the feature thought to be a "special technical feature" is a mere design variation of a piece of prior art.
- 85. Furthermore, two or more inventions are said to have "corresponding special technical features" in any of the following cases:<sup>59</sup>
  - i. Where two or more inventions have common or closely related technical significance in comparison with the prior art among them (e.g., the inventions solve the same or overlapping problems with respect to the prior art); and
  - ii. Where special technical features of two or more inventions are related complementarily to each other (e.g., transmitter and receiver).
- 86. In Japan, a determination that a patent application lacks unity of invention is considered a formal rather than a substantive deficiency. When faced with such a deficiency, applicants are afforded the chance to rectify this issue by either filing one or more divisional applications within a prescribed time limit, omitting claims from the initially submitted patent, or contesting the determination of non-unity. Failing to meet the requirements of Article 37 can be a reason for refusal, it does not constitute a reason for invalidation of a granted patent.<sup>60</sup>
- 87. Article 44 of the Japanese Patent Act covers the division of patent applications in Japan. This Article stipulates that the applicant may make part of a patent application containing two or more inventions a new patent application. It further stipulates that, in general, if a patent application is lawfully divided, the new application is deemed to have been filed at the same time as the original application. The applicant must be the same for both the original and divisional applications at the time of division. Division is permitted during several key periods: (i) while amendments to the original application are still allowed; (ii) within 30 days after receiving a decision to grant a patent; or (iii) within three months following the issuance of a non-final decision of refusal.<sup>61</sup>
- 88. To comply with substantive requirements, the divisional application must ensure that the inventions claimed in a divisional application do not constitute the same inventions as stated in the original application. The divisional application must remain within the scope of the subject

<sup>&</sup>lt;sup>57</sup> Ibid.

<sup>58</sup> Ibid.

<sup>&</sup>lt;sup>59</sup> Ibid.

<sup>&</sup>lt;sup>60</sup> Articles 49 and 123 of the Patent Act of Japan.

<sup>&</sup>lt;sup>61</sup> See comments received from Japan in response to C.9199.

matter disclosed in the original application as it stood at the time of filing and just before division.

#### **Portugal**

# Legal Framework

- 89. Article 73 of the Portuguese Industrial Property Code establishes that:
  - "1. No more than one patent, or a single patent for more than one invention, may be applied for in the same application.
  - 2. A plurality of inventions, linked together in such a way as to constitute a single general inventive concept, shall be considered a single invention.
  - 3. Applicants may, on their own initiative or following examination that reveals that the application does not respect unity of invention, divide the application into a number of divisional applications, where each divisional application maintains the date of the initial application and, if applicable, the benefit of the right of priority.
  - 4. A divisional application may only contain elements that do not go beyond the content of the initial application."

#### Interpretive Guidance and Procedural Approach

- 90. In Portugal, the unity of invention requirement is guided by principles outlined in the Implementation Manual of the Industrial Property Code. This requires a technical relationship among claimed inventions, defined by one or more special technical features that distinguish the inventions from prior art. Whether inventions are presented in separate independent claims or as alternatives within a single claim, they must share a common inventive concept.
- 91. The Portuguese Patent Office may assess unity of invention either *a priori* or *a posteriori*. The a posteriori approach involves two main methodologies: the single general inventive concept approach and the special technical features approach. The single general inventive concept approach involves identifying independent claims, formulating a single concept, and determining whether this concept unifies the inventions. The special technical features approach involves identifying the inventions, assessing differences from the prior art, and determining if there are shared or corresponding special technical features.
- 92. If an examiner finds a lack of unity, the search report and written opinion will focus only on the first claimed invention or inventions that form a single inventive concept, resulting in a partial search and examination. The written opinion will detail the lack of unity, identifying separate inventions and suggesting the possibility of filing divisional applications for the other inventions.
- 93. Non-unity objections can be raised during both the search and examination stages. Applicants can either argue against the objection or accept it and file divisional applications. A patent application may give rise to multiple divisional applications, but it cannot be divided into a utility model or a provisional patent application. Divisional applications must not exceed the content of the parent application. This procedural approach ensures that only technically related inventions are examined together, maintaining the integrity of the patent examination process in Portugal.<sup>62</sup>

<sup>&</sup>lt;sup>62</sup> See comments received from Portugal in response to C.9199.

#### Republic of Korea

#### Legal Framework

- 94. Article 45 of the Patent Act of the Republic of Korea provides that:
  - "(1) A patent application shall be filed for each invention: Provided, that a patent application may be filed for a group of inventions linked so as to form a single general inventive concept.
  - (2) The requirements for filing a patent application for a group of inventions under the *provisio* of paragraph (1) shall be prescribed by Presidential Decree."
- 95. This Presidential Decree is implemented through Article 6 of the Enforcement Decree of the Patent Act which further provides that:

A single patent application for a group of inventions as prescribed in the *provisio* of Article 45(1) of the Act shall meet the following requirements:

- (1) The inventions described in the application shall be technologically correlated; and
- (2) The inventions described in the application shall have the same or corresponding technical features. In such case, the technological features shall be those improved than the prior art in light of the invention at large.
- 96. In relation to divisional applications, Article 52 of the Patent Act states:
  - "An applicant who has filed a single patent application for two or more inventions may divide the application into two or more applications within the scope of the features described in the specification or drawings accompanying the initial patent application [...]"

Interpretive Guidance and Procedural Approach

- 97. The legislation and regulations of the Republic of Korea pertaining to unity of invention and divisional applications essentially mirror those contained in the PCT. Moreover, the approach taken by examiners of the Korean Intellectual Property Office (KIPO) towards the assessment of unity of invention is also broadly similar to the guidelines established by the PCT.<sup>63</sup>
- 98. It is important to note that in the Republic of Korea, the special features of the inventions need not be precisely the same. For example, if the special technical feature for providing elasticity in one claim is a spring, the special technical features for providing elasticity in another claim can be a rubber block.<sup>64</sup> The special technical features are the concept specially suggested to determine the unity of inventions and shall involve novelty and inventive step compared to the prior art disclosed before the concerned patent application is filed.<sup>65</sup> In the Republic of Korea, the special technical features are generally determined after considering the prior art, though they can be determined prior in appropriate cases.<sup>66</sup>

<sup>&</sup>lt;sup>63</sup> See comments received from the Republic of Korea in response to C.9199.

<sup>&</sup>lt;sup>64</sup> See comments received from the Republic of Korea in response to C.9199.

<sup>65</sup> Ibid.

<sup>66</sup> Ibid.

- 99. In the Republic of Korea, when there is a group of inventions filed for a single application, unity of invention is assessed in the following sequence:<sup>67</sup>
  - i. <u>Select the Main Invention</u>: Identify the first invention and specify its special technical features (and there may be multiple special technical features) that improve upon the prior art. This step is focused on understanding how the main invention contributes to its technical field.
  - ii. <u>Identify a Second Invention</u>: Choose a second invention and outline its special technical features, similarly highlighting improvements over prior arts.
  - iii. <u>Evaluate Technical Correlation</u>: Compare the special technical features of the first and second inventions to ascertain if they are the same or correspond with each other and improve upon the prior art. If these features are the same or corresponding and improve upon the prior art, it indicates that the inventions have the technical correlation and thus form a single general inventive concept as required by Article 6 of The Enforcement Decree of the Patent Act.
- 100. The examiner is also able to raise a unity of invention rejection where it is clear that there is no congruence between the special technical features of the two or more inventions without looking at the prior art. In instances where a violation of unity is observed, the examiner is required to communicate this explicitly, identifying the absence of shared or corresponding special technical features among the inventions considered. However, an examiner does not need to force an applicant to make amendments or file a divisional application because of a unity violation, if examination can be completed without any additional examination efforts. For example, where novelty and inventive step of the entire claims can be denied based on the already searched prior art, an examiner may not raise unity as a ground of rejection.<sup>68</sup>
- 101. When a patent application in the Republic of Korea is found to encompass multiple inventive concepts that do not meet the unity of invention requirement, the applicant has the opportunity to file one or more divisional applications. This process allows for the separation of distinct inventions into individual applications, each covering a single inventive concept, while maintaining the original filing date of the parent application.
- 102. Generally, and subject to exceptions and special cases, at the KIPO, an applicant may avail themselves of a divisional application within any of the following periods:<sup>69</sup>
  - i. Amendment Period: During the initial examination process, the applicant can file a divisional application while amendments to the original application are still permissible. This is typically before the examination is concluded, allowing the applicant to respond to an examiner's finding of non-unity by filing a divisional application.
  - ii. **Post-Rejection Period**: If the original application faces a rejection, the applicant can file a divisional application within three months from the date of receiving the certified copy of the rejection ruling. This allows the applicant to preserve the filing date of the original application for the newly divided applications.
  - iii. **Post-Grant Decision Period**: A divisional application can also be filed within three months after a decision to grant a patent has been issued, or after a trial decision to

68 Ibid.

<sup>67</sup> Ibid.

<sup>69</sup> Ibid.

revoke a rejection has been served. This period allows for further division of the application, ensuring that all aspects of the invention are adequately covered.

- 103. For a divisional application in the Republic of Korea, the scope must be entirely based on the subject matter disclosed in the original specification or drawings of the parent application. Any invention included in the divisional application must have been present in the original disclosure; otherwise, the application risks being invalidated or rejected. The examiner determines whether the invention is explicitly described or implicitly recognized in the original documents. The original specification or drawings serve as the foundation for the divisional application's validity. Even if certain inventions were deleted from the parent application during amendments, they can still be included in a divisional application, provided they were initially disclosed. However, inventions added through amendments to the parent application are not eligible for division since they were not part of the original disclosure. Divisional applications are typically considered to have the same filing date as the parent application, which is critical for maintaining priority.
- 104. Procedurally, to file a divisional application, the divisional application must clearly state the intent to divide and specify the parent application. Incorrect indication of the parent application at filing can render the divisional application illegitimate, and amendments to change the parent application after filing are generally not allowed, except for obvious errors.

#### Russian Federation

# Legal Framework

105. Paragraph 1 of Article 1375 of the Civil Code provides:

"A patent application for an invention (invention application) shall relate to one invention or a group of inventions interconnected to the extent that they form a united inventive concept (the concept of unity of invention)"

- 106. Further details of the unity of invention are provided in the following rules<sup>70</sup>: (i) Requirements for the Documents of the Application for Granting an Invention Patent (Requirements); and (ii) Regulations for Drafting, Filing and Examination of Documents Forming the Basis for Performing Legally Significant Actions for the State Registration of Inventions (Regulations).
- 107. Paragraph 2 of the Requirements state that the unity of invention requirement regarding a claimed group of inventions is met when there is a technical linkage between the inventions included in the group of inventions expressed by one or more identical or corresponding special technical features of an invention.
- 108. Paragraphs 44 to 50(1) of the Requirements further specifies the term "special technical features". In particular, the special technical features include same or similar characteristics distinguishing each invention from its closest analogue (features that, together with other distinctive characteristics, determine the contribution made to the state of the art by each of the inventions combined in a group). The identical special technical features include those that coincide in terms of the content. Furthermore, the special technical features comprise mutually dependent features (mutually complementary features that together form a functional unity, for

<sup>&</sup>lt;sup>70</sup> These rules are contained in the Regulations approved by the Order No. 107 "On the State Registration of Inventions" of the Ministry of Economic Development of the Russian Federation of February 21, 2023 (with amendments introduced by the Order No. 148 of the Ministry of Economic Development of the Russian Federation dated March 15, 2024, and entered into force on April 25, 2024).

instance flat pins of an electrical plug in one invention of the group and slotted holes of an electrical socket in another invention of the same group).

- 109. In addition, there are rules for grouping inventions that must be followed together with the technical relationship between inventions in the group of inventions. Paragraphs 63 and 64 of the Requirements reads as follows:
  - "63. Taking into account the unity of invention requirement, set forth in paragraph 2 of the Requirements, the independent claims related to the subject of different types of inventions may be included in the claims in one of the following allowed combinations:
    - an independent claim element covering a product, an independent claim element covering a process for making (obtaining) that product, and an independent claim element covering the application/usage of the product;
    - an independent claim element covering a product and independent claims covering application/usage of that product;
    - an independent claim element covering a process and an independent claim element covering a product designed to perform the process or one of its operations;
    - an independent claim element covering a method and an independent claim element covering a product designed to be used in the method;
    - an independent claim element covering a product, an independent claim element covering a method to make (obtain) the product, and an independent claim element covering a product designed to use the method.
  - 64. Subject to the unity of invention requirement, set forth in para. 2 of the Requirements, the claims may include two or more independent claim elements relating to subjects of inventions of the same type, in one of the following combinations:
    - independent claim elements characterizing variants of an invention relating to subjects of the same kind (several devices or substances), for the same purpose, ensuring accomplishment of the same technical result;
    - an independent claim element characterizing the subject of an invention as a whole and an independent claim element covering its part;
    - an independent claim element characterizing the subject of the invention in general and an independent claim element covering a special case of performance or use of the invention;
    - independent claim elements characterizing intermediate and final products;
    - independent claim elements covering subjects of an invention that complement each other and interact with each other in the course of an operation."

#### Interpretive Guidance and Procedural Approach

- 110. In 2023, Russian legislation and associated practice in relation to the assessment of unity of invention was amended to align more closely with the international standards of the PCT, Eurasian Patent Office (EAPO) and the European Patent Office (EPO).<sup>71</sup>
- 111. When assessing unity, Rospatent follows a two-stage examination process: first, before conducting an information search on an application taking into account the closest analogue indicated by the applicant, and secondly after completion of the information search, taking into account the results of the information search and the closest analogue identified.<sup>72</sup> The key is

<sup>&</sup>lt;sup>71</sup> See comments received from the Russian Federation in response to C.9199.

<sup>&</sup>lt;sup>72</sup> Paragraph 45 of the Regulations.

determining whether the inventions share a technical relationship, characterized by at least one common or corresponding special technical feature that differentiates them from the prior art.

- 112. When Rospatent finds that the claimed inventions do not contain at least one common or corresponding special technical feature of the invention that distinguishes each of the inventions from the prior art, the inventions of the claimed group of inventions may not be considered to share a technical relationship. When analyzing whether the inventions specified in the independent claims are variants of one another, Rospatent will analyze whether the purposes of the inventions, and the technical results coincide.<sup>73</sup>
- 113. If Rospatent finds that the inventions do not meet the unity requirement, they notify the applicant and provide the reasons.<sup>74</sup> The applicant can then either amend the application and/or indicate which invention should proceed. In the absence of such amendment and/or indication, the substantive examination will be carried out in respect of the first invention (or the first group of inventions satisfying the unity requirement) described in the claims.<sup>75</sup> If the applicant disagrees with the determination of non-unity, they may request reconsideration, where the examination will be reviewed considering the applicant's arguments.<sup>76</sup>
- 114. If the unity requirement is not met, the applicant has the option to file divisional applications under Article 1384(4) of the Civil Code. The timing for filing a divisional application is critical. The divisional must be filed before either the exhaustion of the possibility for lodging appeals against a rejection decision on the initial application or before the registration of the invention if a notice of allowance has been issued. This provides applicants with a clear timeframe within which they can secure protection for all disclosed inventions. According to a 2024 ruling by the Supreme Court of the Russian Federation, all divisional applications, including second and subsequent generations, inherit the priority date of the original application.<sup>77</sup> The Supreme Court emphasized that as long as the divisional applications are linked to the same initial application, they should all retain the same priority date.

#### Singapore

# Legal Framework

115. Section 25(5)(d) of the Singapore Patent Act requires that the claims in a patent application relate to one invention or to a group of inventions which are so linked as to form a single inventive concept.

<sup>73</sup> Idem.

<sup>&</sup>lt;sup>74</sup> Paragraphs 18 and 45 of the Regulations.

<sup>&</sup>lt;sup>75</sup> Paragraphs 19 and 45 of the Regulations.

<sup>&</sup>lt;sup>76</sup> Paragraph 45 of the Regulations.

<sup>&</sup>lt;sup>77</sup> Supreme Court of the Russian Federation, No. 300-ES23-27880, Moscow 06/04/2024, Case No. SIP-570/2022.

- 116. Rule 25 of the Singapore Patent Rules further sets out that:
  - "(1) Without prejudice to the generality of section 25(5)(d), where 2 or more inventions are claimed (whether in separate claims or as alternatives within a single claim), such inventions shall be treated as being so linked as to form a single inventive concept only where there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.
  - (2) In this role, 'special technical features' mean those technical features which define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

#### Interpretive Guidance and Procedural Approach

- 117. The Singaporean legislation and regulations pertaining to unity of invention essentially mirror those contained in the PCT. Unity of invention is determined based on the claims in the application. An application may describe a number of different inventions having different inventive concepts, but an objection of lack of unity will only arise if the different inventions are claimed. Lack of unity can be present either across different claims or within a single claim that includes distinct embodiments not linked by a single inventive concept. When considering unity, the description and drawings may be taken into account when interpreting the claims to determine the invention.
- 118. Unity of invention can be evaluated both "a priori" (before considering prior art) and "a posteriori" (after considering prior art). Additionally, literal or over-technical approaches are discouraged. The examination of lack of unity in Singapore follows the principles outlined in the IPOS Examination Guidelines, which emphasize practical and context-sensitive analysis over rigid technicalities.<sup>78</sup>
- 119. Singapore allows applicants to file divisional applications for any part of the matter disclosed in the original (parent) application. The filing date of the parent application is treated as the filing date of the divisional application, provided that the divisional application does not introduce any new matter beyond what was originally disclosed.
- 120. A divisional application must be filed after the parent application is submitted but before the parent application is either granted, refused, withdrawn, or deemed abandoned. Notably, a first divisional application can serve as the basis for a further (second) divisional application, provided the first divisional is still pending when the second is filed. However, the original parent application does not need to be pending for the second divisional application to be derived from the first.

#### Spain

Legal Framework

The unity of invention requirement and the filing of divisional applications are addressed in Article 26 of the Patents Act:

(1) The patent application may not include more than a single invention or a group of interrelated inventions that constitute a single general inventive concept.

<sup>&</sup>lt;sup>78</sup> See comments received from Singapore in Response to C.9199.

- (2) Applications that do not comply with the provisions of the preceding paragraph shall be divided in accordance with the regulations.
- (3) Divisional applications shall have the same filing date as the initial application from which they originate, insofar as their subject matter is already contained in that application.

# Interpretive Guidance and Procedural Approach

121. In Spain, the approach to unity of invention closely follows the PCT process. When the Spanish Patent and Trademark Office identifies a lack of unity during the prior art search, it issues a partial report on the first-mentioned invention. The applicant has two months to either pay additional fees for further searches, divide the application, or contest the objection. If the unity is later confirmed, the office completes the search and refunds any additional fees. If the applicant does not respond adequately, the application proceeds only with the claims covered by the initial search. This procedure ensures that the examination aligns with the unity of invention requirements while offering flexibility for the applicant.<sup>79</sup>

# **United States of America**

# Two Approaches at the USPTO

- 122. The United States Patent and Trademark Office (USPTO) adopts a dual approach when assessing unity of invention, reflecting the differences between international applications governed by the PCT and domestic patent applications filed directly under U.S. law. When acting as an ISA or International Preliminary Examining Authority (IPEA) under the PCT, or for PCT applications that enter the national phase, the USPTO evaluates unity of invention based on standards that align with the international framework established by the PCT. However, for national applications filed directly with the USPTO, a distinct standard is applied, focusing on the concepts of "independent" and "distinct" inventions.
- 123. In relation to the difference between the USPTO's unity practice applied to national patent applications and the unity practices of other patent offices, the Japan Intellectual Property Association reviewed non-unity rejection rates of corresponding national applications filed with the USPTO and three other offices, which were originated from the same priority application. It was found that the USPTO's non-unity rejection rate, based on the concept of "independent" and "distinct" inventions, was higher than the other three offices that applied the unity requirement similar to the PCT.<sup>80</sup>
- 124. When applicants seek U.S. patent protection for an invention initially filed under the PCT, they have two options.<sup>81</sup> In the first option, they can file a U.S. national phase entry of the PCT application. In the second option, instead of entering the U.S. national phase, they can file a new U.S. application, which is entitled to the benefit of the filing date (or priority date) of the PCT application. The filing of a continuation, divisional, or continuation-in-part application of a PCT application designating the U.S. is known as a "bypass" application. Should the applicant pursue a U.S. national phase entry, the examiner will apply the unity of invention standard. In

<sup>&</sup>lt;sup>79</sup> See comments received from Spain in Response to C.9199.

<sup>&</sup>lt;sup>80</sup> See Comments from the Japan Intellectual Property Association to the Heads of five IP Offices, dated September 15, 2015, available at

https://web.archive.org/web/20230707162904/https://www.fiveipoffices.org/sites/default/files/attachments/455f311c-81a3-4ae7-84e9-3553e93e8e05/JIPA+Comments+on+consultation+on+IP5+patent+practices+(2).pdf.

<sup>&</sup>lt;sup>81</sup> USPTO MPEP Section 1895, available at: https://www.uspto.gov/web/offices/pac/mpep/s1895.html.

contrast, should the applicant file a new U.S. application claiming priority to the PCT application, the USPTO's restriction practice will be applied.<sup>82</sup>

# PCT International Applications

# (a) Legal framework

125. Unity of invention is assessed by the USPTO when acting as an ISA or IPEA for international applications under the PCT, and when processing these applications in the national phase as a designated or elected office under 35 U.S.C. 371. The legal provisions for the assessment of unity of invention in these applications is provided in 37 CFR 1.475 (Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage) which provides:

- "(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
- (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
  - A product and a process specially adapted for the manufacture of said product; or
  - A product and a process of use of said product; or
  - A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
  - A process and an apparatus or means specifically designed for carrying out the said process; or
  - A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
- (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
- (d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).
- (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim."

<sup>82</sup> Title 35 of the United States Code, Sections 111(a), 120, and 371.

- (b) Interpretive guidance and procedural approach for PCT international applications
- 126. The evaluation of unity of invention for these applications is conducted in accordance with rules that essentially mirror PCT Rule 13.83
- 127. In Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks, the court held that when the USPTO acts as an ISA or for national phase applications, the USPTO is required to use the PCT rules rather than US domestic rules.<sup>84</sup> In coming to this conclusion, the court noted that Article 27(1) of the PCT provides that "No national law shall require compliance with requirements relating to the form or contents of the international application different from those which are provided in this treaty and the Regulations", and then went on to note that the requirements of PCT Rule 13 were mandatory for these applications.
- 128. This case centered around whether there was unity of invention as between a set of claims directed to a process for forging a sprocket and a set of claims drawn to the apparatus for forging a sprocket and involved the interpretation of the expression "specifically designed" as found in former PCT Rule 13.2(ii). The USPTO had originally interpreted the expression "specifically designed" to mean that in order for unity to be found, there must be exclusivity in the use of the process and apparatus with each other such that the apparatus cannot be used in a materially different process and *vice versa*. The court disagreed with this narrow interpretation and held that there is no exclusivity requirement as this goes against the PCT's language and intent.

# National Applications

- (a) Legal framework
- 129. In contrast to the approach taken under the PCT, the USPTO applies a different standard to U.S. national applications filed under 35 U.S.C. 111(a) which provides that:
  - "If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions."
- 130. For these applications, 37 CFR 1,141 further provides that two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form or otherwise include all the limitations of the generic claim.
- 131. In addition, the same provision also regulates the so-called "three-way requirement for restriction", which refers to a situation in patent applications where claims cover three distinct categories: a product, the process of making that product, and the process of using that product. In such a case, a restriction can only be made where the process of making the product is distinct from the product itself. If these two are not distinct, the process of using the product may be joined with the claims directed to the product and the process of making the product, even though the product is distinct from the process of using the product.
- 132. 37 CFR 1.142 further provides that:

<sup>83 37</sup> CFR 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage; CFR 1.476 Determination of unity of invention before the International Searching Authority; CFR 1.477 Protest to lack of unity of invention before the International Searching Authority; 1.488 Determination of unity of invention before the International Preliminary Examining Authority; 1.499 Unity of invention during the national stage.

<sup>84</sup> Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks, 650 F. Supp. 218 (E.D. Va. 1986).

- (a) If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action.
- (b) Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.
- (b) Interpretive guidance and procedural approach for national applications
  - (i) "Independent" and "Distinct" Inventions
- 133. For these applications, if two or more "independent" and "distinct" inventions are claimed in a single application, the USPTO may require the application to be restricted to one of the inventions. Applicants are then permitted to pursue the additional inventions in one or more divisional applications. While the statutory language uses the term "independent and distinct" which may imply that both conditions must be met for a restriction in practice these terms are interpreted as alternative requirements. The terms "independent" (i.e., unrelated) and "distinct" (i.e., related but patentably distinct) have mutually exclusive meanings and thus are interpreted as alternative requirements. Only one of these requirements must be met in order to support a restriction. This practice has long been upheld to ensure that patent applications are appropriately categorized, even if inventions are related but distinct.
- 134. For a proper requirement for restriction between patentably distinct inventions, there are two criteria:87
  - i. Showing the inventions are independent or distinct as claimed; and
  - ii. Showing that there would be a serious search and examination burden on the examiner if restriction is not required.
- 135. The term "independent" (i.e., unrelated) means that there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect. For example, a process and an apparatus incapable of being used in practicing the process are independent inventions. As a further example, an electronic cash register and a motorcycle being totally unconnected in design and operation are independent inventions. As another example, two different inventions, not disclosed as capable of use together, having different modes of operation, different functions, and different effects would be said to be independent. Such examples could include an article of apparel and a locomotive, a process of painting a house and a process of boring a well.
- 136. Where the two inventions are a process and a product, the inventions are said to be independent where the product cannot be used in, or made by the process. An example of this

<sup>85 35.</sup> U.S.C 121 – Divisional applications; USPTO MPEP, Section 802.

<sup>&</sup>lt;sup>86</sup> USPTO MPEP, Section 802.

<sup>&</sup>lt;sup>87</sup> USPTO MPEP, Section 803.

<sup>88</sup> Restriction practice at the USPTO, May 2019, available at: https://www.uspto.gov/video/cbt/restriction-practice-corpswide/

<sup>89</sup> USPTO MPEP, Sections 802 and 806.

<sup>&</sup>lt;sup>90</sup> Restriction practice at the USPTO, May 2019, available at: https://www.uspto.gov/video/cbt/restriction-practice-corpswide/.

would be a specific process of molding and a molding apparatus that cannot be used to practice the specific process.<sup>91</sup>

- 137. Two or more inventions are related (i.e., not independent) if they are disclosed as connected in at least one of design (e.g., structure or method of manufacture), operation (e.g., function or method of use), or effect. Examples of related inventions include combination and part thereof, process and apparatus for its practice, process and product made, etc. In this definition, the term "related" is used as an alternative for dependent in referring to inventions other than independent inventions. <sup>92</sup> For example an electronic cash register and a manual cash register are not considered independent but are considered to be related inventions. <sup>93</sup>
- 138. Related inventions are **distinct** if the inventions as **claimed** are not connected in **at least one of design, operation, or effect** (e.g., can be made by, or used in, a materially different process) <u>and</u> wherein **at least one invention is patentable** (novel and nonobvious) **over the other** (though they may each be unpatentable over the prior art). An illustrative scenario could involve a novel process and a specifically engineered apparatus for said process; while interconnected, if each introduces a significant, non-obvious advancement distinguishable from the other, they may be considered "distinct" inventions. This categorization acknowledges the existence of related inventions that, despite their connection, present independent innovative leaps deserving of separate patent considerations.<sup>94</sup>
- 139. Restriction between related products or related processes is based on a two-way test for distinctiveness, which means that all claim groups in question must meet these criteria: (i) The inventions as claimed do not overlap in scope, AND (ii) The inventions as claimed are not obvious variants, AND (iii) The inventions as claimed are not capable of use together or can have a materially different design, mode of operation, function or effect.<sup>95</sup>
  - (ii) Search and Examination Burden
- 140. In addition to showing inventions are independent and/or distinction, the examiner must provide reasons as to why a serious search and examination burden would exist if restriction was not required. Reasons must be provided as to why a serious search and examination burden would exist if restriction was not required. A serious burden can be shown if the inventions have one or more of the following:<sup>96</sup>
  - **Separate Classification** to show that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search.
  - Separate status in the art when they are classifiable together to show a recognition of separate inventive effort by innovators.
  - A different field of search to show it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) even though the inventions are classified together.

<sup>91</sup> Ihid

<sup>92</sup> USPTO MPEP, Sections 802 and 806.

<sup>&</sup>lt;sup>93</sup> Restriction practice at the USPTO, May 2019, available at: https://www.uspto.gov/video/cbt/restriction-practice-corpswide/.

<sup>94</sup> USPTO MPEP, Sections 802 and 806.

<sup>&</sup>lt;sup>95</sup> USPTO MPEP, Section 806.05(j); Restriction practice at the USPTO, May 2019, available at: https://www.uspto.gov/video/cbt/restriction-practice-corpswide/.

<sup>&</sup>lt;sup>96</sup> USPTO MPEP, Sections 803, 806 and 808.

#### (iii) Examples of Independent and Distinct Inventions

141. There are a variety of types of related inventions. Amongst these include combination-subcombination, subcombinations usable together, process and apparatus for its practice, process of making and product made, apparatus and product made, product and process of using, product, process of making, and process of using, and related products/processes.<sup>97</sup> The following examples will consider whether restriction is appropriate with regard to the independence and distinctness of the claimed inventions. For simplicity, the consideration of whether a serious search and examination burden exists will not be considered.

# [Combination-Subcombination]

- 142. To support a restriction between a combination and a subcombination, a two-way test for distinctness and reasons for insisting on restriction are necessary. The two-way test for distinctness is met when: (i) the combination as claimed does not require the particulars of the subcombination as claimed for patentability (i.e., to show novelty and non-obviousness of the combination), AND (ii) the subcombination has a utility either by itself or in another materially different combination.<sup>98</sup> For example, suppose we had the following claimset:
  - <u>Claim 1</u>: A wound dressing comprising: an adhesive bandage; and an antibiotic ointment of neomycin and a petrolatum base disposed on a surface of the bandage.
  - Claim 2: An antibiotic ointment for a wound dressing comprising: neomycin; and a petrolatum base.
- 143. In this case the combination in claim 1 requires the particulars of the subcombination in claim 2 for patentability, even though the subcombination has utility either by itself or in another materially different combination, so this claim group pair does not meet the first part of the two-way combination-subcombination test. While the ointment may have separate utility in another type of dressing, or utility on its own, a restriction cannot be made because the two-way test requires meeting both elements of the test. Thus, there is no distinctness and restriction would not be proper in this case.

# [Subcombinations usable together]

- 144. Two or more claimed subcombinations, disclosed as usable together in a single combination, are usually restrictable when: (i) at least one subcombination as claimed can be shown to be separately usable or has utility other than in the disclosed combination, AND (ii) the subcombinations as claimed do not overlap in scope, AND (iii) the subcombinations as claimed are not obvious variants of one another.<sup>99</sup> For example, suppose we had the following claimset:
  - <u>Claim 1:</u> A wound dressing comprising: an adhesive bandage formed as a woven strip; a gauze element formed as a circular pad secured to one side of the bandage; and antibiotic ointment disposed on the gauze element.
  - Claim 2: A gauze element formed of a circular pad.

<sup>97</sup> USPTO MPEP, Section 806.

<sup>&</sup>lt;sup>98</sup> USPTO MPEP, Section 806.05(c); Restriction practice at the USPTO, May 2019, available at: https://www.uspto.gov/video/cbt/restriction-practice-corpswide/.

<sup>&</sup>lt;sup>99</sup> USPTO MPEP, Section 806.05(d); Restriction practice at the USPTO, May 2019, available at: https://www.uspto.gov/video/cbt/restriction-practice-corpswide/.

• Claim 3: An adhesive bandage formed as a woven strip.

145. In this case, the two subcombinations (claims 2 and 3) a restriction requirement would be proper. In this case, the subcombination in claim 2 can be used without an adhesive woven bandage strip and the subcombination in claim 3 can be used without a circular gauze pad. Additionally, the subcombinations in claims 2 and 3 do not overlap in scope and are not obvious variants.

[Process and apparatus for its practice]

- 146. Restriction between a process and an apparatus for its practice is based on a **one-way** test for distinctness which is found where: (i) the process as claimed can be practiced by another materially different apparatus or by hand; OR (ii) the apparatus as claimed can be used to practice another materially different process.<sup>100</sup> For example, suppose we had the following claimset:
  - Claim 1: A process of painting a wall comprising: depositing primer on the wall with a tool; and depositing a pigmented latex paint on the wall with the tool.
  - Claim 2: A brush tool comprising: a handle; and a plurality of bristles attached to a first end of the handle.
- 147. Here the apparatus can be used to practice another materially different process such as a sweeping a floor and the process can be practiced with a materially different apparatus such as painting a wall with a roller. Thus, the inventions are distinct, and a restriction would be proper.
- 148. Similarly, restriction between a product and a process of using the product is based on a one-way test for distinctness: (i) The process of using as claimed can be practiced with another materially different product, OR (ii) The product as claimed can be used in a materially different process.<sup>101</sup>
- 149. In this case and using the claimset above, the product can be used to practice another materially different process such as sweeping a floor and the process can be practiced with a materially different product such as painting a wall with a roller. Thus, the inventions are distinct, and restriction would be proper.

[Process of making and product made]

- 150. Restriction between a process of making and a product made is based on a one-way test for distinctness: (i) The process as claimed is not an obvious process of making the product, and the process as claimed can be used to make another materially different product, OR (ii) The product as claimed can be made by another materially different process. For example, suppose we had the following claimset:
  - <u>Claim 1</u>: A process of making strips of material comprising: weaving cotton fibers together to form a fabric sheet; and cutting the fabric sheet into a plurality of strips.
  - Claim 2: A bandage comprising: a strip of material having an adhesive layer.

<sup>&</sup>lt;sup>100</sup> USPTO MPEP, Section 806.05(e); Restriction practice at the USPTO, May 2019, available at: https://www.uspto.gov/video/cbt/restriction-practice-corpswide/.

<sup>&</sup>lt;sup>101</sup> USPTO MPEP, Section 806.05(h); Restriction practice at the USPTO, May 2019, available at: https://www.uspto.gov/video/cbt/restriction-practice-corpswide/.

<sup>&</sup>lt;sup>102</sup> USPTO MPEP, Section 806.05(f); Restriction practice at the USPTO, May 2019, available at: https://www.uspto.gov/video/cbt/restriction-practice-corpswide/.

151. In this case, the product can be made by another materially different process such as cutting a plastic sheet and the process can be used to make a materially different product such as a towel. Thus, the inventions are distinct, and restriction would be proper.

#### [Apparatus and product made]

- 152. Restriction between an apparatus and a product made by the apparatus is based on a one way test for distinctness: (i) The apparatus as claimed is not an obvious apparatus for making the product and the apparatus as claimed can be used to make another materially different product, OR (ii) The product as claimed can be made by another materially different apparatus.<sup>103</sup> For example, suppose we had the following claimset:
  - Claim 1: An apparatus for doping a material comprising: a mixing chamber; a heater; and an ion implanter.
  - Claim 2: An N-type doped semiconductor device comprising: a silicon base; and a phosphorus dopant in the base.
- 153. In this case, the apparatus can make a materially different product, such as a P-type doped semiconductor and the product can be made by a materially different apparatus, such as a diffusion-type doping apparatus. Thus, the inventions are distinct, and restriction would be proper.

[Product, Process of Making, and Process of Using]

- 154. Where claims relating to three categories product, process of making, and process of using are present, a three-way requirement for restriction can only be made when: (i) the process of making the product as claimed is distinct from the product, AND (ii) the process of suing the product as claimed is distinct from the product, AND (iii) the process of making the product as claimed is distinct from the process of using the product. For example, suppose we had the following claimset:
  - Claim 1: A process of making strips of material comprising: weaving cotton fibers together to form a fabric sheet; and cutting the fabric sheet into a plurality of strips.
  - Claim 2: A bandage comprising: a strip of material having an adhesive layer.
  - **Claim 3:** A method of treating a burn, comprising: applying a strip shaped bandage with burn salve to a patient.

155. In this case, the product of claim 2 can be made by a materially different process than claim 1 such as by cutting a plastic sheet. The product of claim 2 can be used in a materially different process than claim 3, such as holding an incision together. The process of making of claim 1 does not overlap in scope with the process of using of claim 3. Thus, the inventions are distinct, and restriction would be proper.

<sup>&</sup>lt;sup>103</sup> USPTO MPEP, Section 806.05(g); Restriction practice at the USPTO, May 2019, available at: https://www.uspto.gov/video/cbt/restriction-practice-corpswide/.

<sup>&</sup>lt;sup>104</sup> USPTO MPEP, Section 806.05(i); Restriction practice at the USPTO, May 2019, available at: https://www.uspto.gov/video/cbt/restriction-practice-corpswide/.

#### Divisional Applications

156. Regardless of whether the PCT procedure or the USPTO's restriction practice was used to assess unity of invention, the procedure of filing subsequent divisional applications is the same. A divisional application must include at least one inventor from the original application and must claim the benefit of the original filing date, preserving the priority of the invention. This is essential for securing protection against prior art. If the original application involved joint inventors, the inventorship in the divisional may need to be adjusted based on the elected invention. Despite any changes, the divisional can still claim the original filing date as long as the inventor overlap existed at the time of the initial filing.

# **Eurasian Patent Office (EAPO)**

# A. Legal Framework

157. Rule 4 of the Regulations under the Eurasian Patent Convention specifies that:

"The Eurasian application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept.

Where one and the same Eurasian application relates to a group of inventions, the requirement of unity of invention shall be deemed to have been complied with only if there exists a technical relationship among those inventions involving one or more of the same or corresponding special technical features; that is, those technical features which define the contribution made over the prior art by each of the claimed inventions.

Where this requirement is not satisfied, the applicant shall be required to limit the Eurasian application to one invention or to a group of inventions that satisfy the requirement of unity of invention as set out in the preceding item, and he may file one or more divisional Eurasian applications for the other inventions or groups of inventions that satisfy the requirement of unity."

# 158. Rule 25 further specifies that:

- "(1) Subject to Rule 4 of the Regulations, a Eurasian application may contain independent claims relating to the subject matter of different categories of inventions, in particular:
  - an independent claim relating to a device, substance or biotechnological product, an independent claim relating to a process specially adapted for making the device, obtaining the substance or biotechnological product, and an independent claim relating to the use of said device, substance or biotechnological product;
  - an independent claim relating to a process and an independent claim relating to a device specially adapted for carrying out said process;
  - an independent claim relating to a device, substance or biotechnological product, an independent claim relating to a process specially adapted for making the device, obtaining the substance or biotechnological product and, an independent claim relating to a device specially adapted for carrying out said process.
- (2) The Eurasian application may contain two or more independent claims relating to the subject matter of inventions of the same category characterizing the variants of the invention, as well as correlated as a part and a whole."

#### Interpretative Guidance and Procedural Approach

- 159. The Eurasian Patent Office (EAPO) adopts a procedural approach to unity of invention that closely aligns with the general international framework established under the PCT. Unity of invention is assessed based on whether a group of inventions is linked by a single general inventive concept, characterized by the presence of one or more "special technical features" that define the invention's contribution over the prior art. The EAPO examines whether the inventions share a technical relationship through special technical features, which may include common or corresponding features that provide the same technical effect. If the only common feature among the claimed inventions is already known from the prior art, it does not constitute a special technical feature, and unity of invention is not met.
- 160. Unity of invention is examined during both the search and substantive examination phases. A lack of unity may be identified *a priori*, before a detailed prior art search, or *a posteriori*, after considering the prior art. If a lack of unity is found, the applicant is notified and given the option to pay additional fees to cover the search for additional inventions or to specify which invention should be the subject of the search.
- 161. When unity of invention is not met, the EAPO allows the applicant to file divisional applications for the separate inventions identified. These divisional applications must be filed while the parent application is still pending or within a specified timeframe after a decision on the parent application. The divisional application enjoys the same filing date and, if applicable, the same priority date as the parent application, provided it does not introduce new matter beyond what was disclosed in the original filing. Importantly, the EAPO does not consider lack of unity as grounds for opposition or revocation of a Eurasian patent. Once granted, a Eurasian patent is not subject to challenges based on unity of invention issues during post-grant proceedings.<sup>105</sup>

#### European Patent Office (EPO)

#### Legal Framework

162. Article 82 of the EPC specifies that:

"The European patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept".

- 163. Rule 44 of the Implementing Regulations to the EPC provides that:
  - "(1) Where a group of inventions is claimed in a European patent application, the requirement of unity of invention under Article 82 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those features which define a contribution which each of the claimed inventions considered as a whole makes over the prior art.
  - (2) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim."
- 164. The main provisions governing unity of invention under the EPC are thus identical to those under the PCT. In particular, Article 82 of the EPC corresponds to Rule 13.1 of the PCT and

<sup>&</sup>lt;sup>105</sup> See comments received from the EAPO in response to C.9199.

Rule 44 of the Implementing Regulations to the PCT corresponds to Rule 13.2 and Rule 13.3 of the PCT.

Interpretative Guidance and Procedural Approach

- 165. The provisions relating to Unity of Invention under the EPC essentially mirror those under the PCT. At the EPO, the process begins with identifying the closest prior art to pinpoint the special technical features those that are both novel and inventive. By comparing the claimed subject matter with this prior art, features that are novel and potentially contribute to an inventive step are distinguished as special technical features. These features are then examined for any technical interrelationship.
- 166. For there to be unity of invention, the special technical features across all claims must be either identical or equivalent. This means they must share novelty or exhibit a technical linkage, thereby revealing a unified inventive concept.
- 167. A lack of unity occurs when the commonalities between claimed inventions are either known or obvious, diverging from the relevant prior art in such a way that the inventions share nothing more among themselves than what they share with this prior art. This indicates an absence of a unifying inventive concept. Conversely, if there is a novel and inventive concept or principle shared among the claims, then an objection of lack of unity is not justified.

# **COMPLEX CLAIM STRUCTURES AND UNITY OF INVENTION**

#### MARKUSH CLAIMS

- 168. Markush claims, a distinctive claim type within patent law, are often utilized to cover a broad range of chemical compounds through a single claim by specifying generic groupings of elements or substituents. These claims are characterized by the use of the term "selected from the group consisting of" to introduce a list of possible variations within the chemical structure of the compound being patented.
- 169. When the PCT unity of invention standard is applied, the situation involving the so-called "Markush practice" wherein a single claim defines alternatives is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled: 106

All alternatives have a common property or activity, and

- (1) a common structure is present (i.e., a "significant structural element is shared by all of the alternatives") **or**
- (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.
- 170. Here, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in the case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in

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<sup>&</sup>lt;sup>106</sup> Administrative Instructions under the Patent Cooperation Treaty, ANNEX B Unity of Invention, (f) "Markush Practice", available at: https://www.wipo.int/pct/en/texts/ai/annex\_b.html.

view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

- 171. Additionally, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.
- 172. The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.
- 173. When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner (see paragraph 37 regarding the general procedure for the assessment of unity of invention). Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

#### National/Regional Practices

- 174. In general, national and regional Intellectual Property Offices have adopted an approach to examining Markush claims for unity of invention which is broadly in line with the international norms outlined above.
- 175. INPI Brazil closely aligns with the PCT guidelines when examining Markush claims, emphasizing the need for unity of invention. Specifically, the INPI requires that all alternatives within a Markush formula must share a common property or activity and either a significant structural element or belong to a recognized class of chemical compounds. This approach ensures that the claimed alternatives are interconnected, forming a single general inventive concept. Furthermore, the INPI stipulates that even when multiple forms of an invention are claimed as alternatives within a single claim, these alternatives must not make the claim difficult to understand and must still meet the unity of invention requirement.<sup>107</sup>
- 176. Like the international standard, CNIPA requires that all alternatives within a Markush claim must share a common property or activity. Additionally, these alternatives must either have a significant structural element in common or belong to a recognized class of chemical compounds known in the relevant art. In cases where the shared structure is minimal, it must be structurally distinctive and essential to the common property or activity to meet the unity requirement.<sup>108</sup>
- 177. With respect to the assessment of unity of invention for Markush-style claims, the approach taken by the JPO generally corresponds to the generic approach outlined above. Notably in Japan, the examination guidelines explicitly state that "when dealing with alternatives in the Markush-Form, if at least one of the inventions based on the alternatives is found in the prior art, an examiner shall reconsider the question of unity of invention." <sup>109</sup>
- 178. In the Republic of Korea, unity of invention is considered met for Markush-style claims if the alternative elements within the claim have corresponding qualities or functions. This applies whether the alternatives are disclosed in a single claim or across multiple independent claims. If any alternative in the Markush group is found to lack novelty based on prior art, the examiner will reassess the unity of invention. This approach aligns with the general international

<sup>&</sup>lt;sup>107</sup> See comments from Brazil in response to C.9199.

<sup>&</sup>lt;sup>108</sup> CNIPA Patent Examination Guidelines.

<sup>&</sup>lt;sup>109</sup> Examination Guidelines for Patent and Utility Model in Japan.

standards for assessing unity of invention in Markush claims, ensuring that all alternatives within the group contribute to a single inventive concept.<sup>110</sup>

- 179. In the Russian Federation the requirement for unity with respect to Markush-style claims may be recognized if the accomplishment of the same result is confirmed by all the alternative options.<sup>111</sup>
- 180. In Singapore, IPOS follows a well-defined approach to examining Markush claims, particularly in the field of chemistry. Unity of invention in Markush claims is achieved when the alternatives, or compounds defined by the claim, are considered to be of a similar nature. To meet this requirement, IPOS specifies that all alternatives must share a common property or activity. Additionally, the alternatives must either possess a significant structural element that is common across all the compounds or, where a common structure is not present, belong to a recognized class of chemical compounds known in the art. In cases where the compounds share only a small portion of their structures, IPOS requires that this shared structure be both structurally distinctive in light of prior art and essential to the common property or activity. IPOS also emphasizes that an objection to unity should not be based solely on the fact that the alternatives belong to different IPC classes. Instead, a broad consideration of the relationship between alternatives is taken, and lack of unity may be considered *a posteriori* if a prior art compound falls within the scope of the Markush claim. In such cases, applicants are typically required to amend the claim to remove the non-novel compound.<sup>112</sup>
- 181. In the United States, the practice for assessing unity of invention when following the PCT standard is similar to that outlined above. However, under the USPTO's restriction practice, the evaluation proceeds under a unique process. In particular, Markush claims may encompass independent or distinct inventions within a single claim. When such a claim includes alternatives that are so unrelated that a prior art reference could anticipate the claim for one member without rendering the entire claim obvious, the examiner may require a provisional election of a single species or a grouping of patentably indistinct species before proceeding with examination on the merits. This election of species requirement, a type of restriction requirement, helps streamline the examination process by focusing on one representative species within the Markush group.
- 182. If the members of a Markush group are closely related or few in number, the examiner may choose to examine the entire claim without requiring an election. However, if the claim is deemed unallowable after examination, the provisional election is enforced, and only the elected species and related Markush claims are examined further. If prior art anticipates or renders obvious the elected species, the Markush claim and related species claims will be rejected, while claims to non-elected species are withdrawn from further consideration. In cases where the elected species is found to be patentable, the examination may extend to the entire Markush claim. However, if prior art later anticipates or renders obvious the claim regarding a non-elected species, the claim will be rejected, and the non-elected species claims remain withdrawn. The search and examination process is generally limited to the elected species, avoiding unnecessary extension to cover all non-elected species. If an applicant amends a Markush claim to overcome a prior art rejection by excluding certain species, the amended claim will be re-examined to determine patentability.<sup>113</sup>

#### **Examples**

Example 1 – Markush-style Claim

<sup>&</sup>lt;sup>110</sup> Patent Examination Guidelines, Korean Intellectual Property Office.

<sup>&</sup>lt;sup>111</sup> Brazil National Institute of Industrial Property, IP-BRICS, Markush Project.

<sup>&</sup>lt;sup>112</sup> See comments from Singapore in response to C.9199.

<sup>&</sup>lt;sup>113</sup> USPTO MPEP, Section 803.02.

Suppose we had a patent application with the following claim:

$$R^3$$
  $R^2$ 

• Claim 1: A compound of the formula:  $R^4$ , wherein  $R^1$  is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alklthio, alkoxy, and methyl;  $R^- - R^4$  are hydroxyl, methyl, benzyl, or phenyl.

183. In this example, the compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen. The indolyl moiety is the significant structural element that is shared by all the alternatives. Since all the claimed compounds are alleged to possess the same utility, unity is present.<sup>114</sup>

# Example 2 – Markush-style Claim

- Suppose we had a patent application with the following claim:
  - Claim 1: A method of detecting bladder cancer in a subject comprising:
    - contacting a sample obtained from the subject with one or more agents that detect expression of at least one of the markers chosen from MAGEA 10, DSCR8, MMP 12, CXCL9, DSCR8, KRT81, LOC729826, PTHLH, MMP1 1, and S100A7; and;
    - contacting a non-cancerous cell, e.g. a non-cancerous cell from bladder tissue or a non-cancerous bladder cell line, with the one or more agents that detect expression of at least one of the markers listed above;

wherein a higher level of expression of one or more of the markers in the sample compared to the non-cancerous cell indicates that the subject has bladder cancer.

184. In this example, while the alternatives share a common property, namely their role as a biomarker for bladder cancer, the alternatives do not have a common structure. Furthermore, they are not considered to be a recognized class of chemical compounds, because each of the biomarkers identified come from diverse gene/protein families. Therefore, each biomarker is considered to be a separate invention.<sup>115</sup>

#### INTERMEDIATE AND FINAL PRODUCTS

185. When the PCT unity of invention standard is applied, unity of invention is considered to be met in the context of intermediate and final products where the following two conditions are fulfilled:<sup>116</sup>

- i. the intermediate and final products have the same essential structural element, in that:
  - a. the basic chemical structures of the intermediate and final products are the same, or
  - b. the chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential element into the final product, and

<sup>114</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, Example 25(A).

<sup>&</sup>lt;sup>115</sup> PCT International Search and Preliminary Examination Guidelines, Chapter 10 Unity of Invention, Example 41.

<sup>&</sup>lt;sup>116</sup> Administrative Instructions under the Patent Cooperation Treaty, ANNEX B Unity of Invention, (g) "Intermediate and Final Products", available at: https://www.wipo.int/pct/en/texts/ai/annex\_b.html; See also comments received from Brazil in response to Circular 9199.

- ii. the intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates, all containing the same essential structural element.
- 186. Unity of invention may also be considered to be present between intermediate and final products of which the structures are not known for example, as between an intermediate having a known structure and a final product the structure of which is not known, or as between an intermediate of unknown structure and a final product of unknown structure. In order to satisfy unity in such cases, there shall be sufficient evidence to lead one to conclude that the intermediate and final products are technically closely interrelated as, for example, when the intermediate contains the same essential element as the final product or incorporates an essential element into the final product.
- 187. It is possible to accept in a single international application different intermediate products used in different processes for the preparation of the final product, provided that they have the same essential structural element.
- 188. To meet the unity requirement, the intermediate and final products shall not be separated, in the process leading from one to the other, by an intermediate which is not new.
- 189. If the same international application claims different intermediates for different structural parts of the final product, unity shall not be regarded as being present between the intermediates.
- 190. If the intermediate and final products are families of compounds, each intermediate compound shall correspond to a compound claimed in the family of the final products. However, some of the final products may have no corresponding compound in the family of the intermediate products so that the two families need not be absolutely congruent.
- 191. As long as unity of invention can be recognized applying the above interpretations, the fact that, besides the ability to be used to produce final products, the intermediates also exhibit other possible effects or activities shall not affect the decision on unity of invention.

#### National/Regional Practices

- 192. In general, national and regional Intellectual Property Offices have adopted an approach to examining intermediate and final products for unity of invention which is broadly in line with the international norms outlined above.
- 193. In Brazil, the approach to unity of invention for intermediate and final products is aligned with international standards. Unity is considered to be met when the intermediate and final products share the same essential structural element, either through identical basic chemical structures or closely related structures where the intermediate contributes a critical element to the final product. Additionally, the intermediate and final products must be technically related, meaning the final product is directly derived from the intermediate, or from a small number of intermediates that share this essential structural element. Unity can also be present even if the structures of the products are unknown, provided there is sufficient evidence of their technical interrelation. Different intermediate products used in distinct processes can be claimed together if they share the same essential structural element, but unity is not recognized if the intermediates pertain to different structural parts of the final product. If the inventive feature of the final product depends on the intermediate, the application meets the unity requirement, and the existence of other potential uses for the intermediates does not negatively impact the assessment of unity.<sup>117</sup>

<sup>&</sup>lt;sup>117</sup> See comments from Brazil in response to C.9199.

194. In China, the approach to determining unity of invention between intermediate and final products generally follows the international standard. Unity is considered to be met when the intermediate and final products share an essential structural element and are technically related, with the final product being directly derived from the intermediate or through a small number of intermediates that share this structural element.<sup>118</sup>

195. In Japan, the approach to determining unity of invention between intermediate and final products aligns closely with international standards. Unity is considered to be met when the intermediate and final products share a new structural element, either by having the same basic skeleton not found in prior art or by being technically closely related in their chemical structures. The final product must be directly derived from the intermediate, or through a small number of other new intermediates that also share this structural element. Even when the structures are unclear, unity can be established if sufficient evidence demonstrates a close technical relationship between the intermediate and final products. Additionally, the JPO allows for unity in cases where individual intermediate products used in different processes share the same structural element that is present in the final product, even if some final products do not correspond to specific intermediate compounds."<sup>119</sup>

196. In the Republic of Korea, the approach to unity of invention for intermediate and final products closely follows the international standard. Unity is generally met when the intermediate and final products share a major structural element and are technically related, with the final product being directly derived from the intermediate. Additionally, Korea allows for a single patent application to cover multiple intermediate materials used in different processes to produce a single final product, as long as the intermediates share the same structural elements. However, if non-novel intermediates separate the intermediate and final products, unity of invention is not recognized, aligning this approach with global norms.<sup>120</sup>

197. In Singapore, the approach to assessing unity of invention between intermediate and final products is similar to the international standard. When considering unity, it is important that the intermediate and final products are not separated in the production process by a known compound, as this could disrupt the unity of invention. Additionally, Singapore allows for flexibility in claims, where a compound used as an intermediate in the preparation of a final product can also be claimed for other uses. In such cases, the claims may be structured to encompass the final products, compositions containing them, their preparation, and the novel intermediates along with their preparation and use. When dealing with families of compounds, each intermediate compound should generally correspond to a compound in the final product family. However, it is not necessary for every final product to have a corresponding intermediate, allowing for some flexibility in the congruence between the two families. Moreover, while the intermediate may have the same use as the final product, it could also have other uses, which might be considered as further inventions. The final product should be manufactured directly from the intermediate or through a small number of intermediates that share a similar structure, reinforcing the technical relationship required for unity.<sup>121</sup>

198. In the United States of America, the practice for assessing unity of invention when following the PCT standard is similar to that outlined above. However, under the restriction practice, the process is somewhat different. At the USPTO, the determination of whether intermediate and final products should be subject to a restriction requirement hinges on the concept of distinctness between the inventions, as inventions related by an intermediate-final product relationship are by their very nature generally dependent. Distinctness is proven if the claims to the intermediate and final products do not overlap in scope (i.e., a claim to the final product does not read on the intermediate, and *vice versa*) and are not obvious variants and it

<sup>&</sup>lt;sup>118</sup> CNIPA Patent Examination Guidelines.

<sup>&</sup>lt;sup>119</sup> Examination Guidelines for Patent and Utility Model in Japan.

<sup>&</sup>lt;sup>120</sup> Patent Examination Guidelines, Korean Intellectual Property Office.

<sup>&</sup>lt;sup>121</sup> See comments from Singapore in response to C.9199.

can be shown that the intermediate product is useful other than to make the final product. Otherwise, the disclosed relationship would preclude their being issued in separate patents. 122

#### **Examples**

Example 1 – Intermediate and Final Product

199. An application discloses two structurally related molecules A and B. Molecule A is a compound with analgesic properties. Molecule B results from selective methylation and acylation of two hydroxy groups on A. Compound B is not an effective analgesic but has significant bioactivity as a sedative. Suppose in this case the application had the following claimset:

- Claim 1: A compound of structure A.
- Claim 2: A compound of structure B.
- <u>Claim 3:</u> A method for converting compound A into compound B through sequential selective methylation and acylation, comprising the steps

200. Here, compound A is an intermediate that is structurally similar to compound B. Claims 1 and 2 share unity of invention and share unity of invention with claim 3.<sup>123</sup>

Example 2 – Intermediate and Final Product

201. Suppose an application discloses and industrially useful triazole compound defined by formula I, and a method for its preparation by ring-closure of a compound of formula II. The critical structure in the triazole product is the combination of the triazole ring (substructure A) with proximal substituted aromatic rings (structures B and D). The necessary stereochemistry of the groups A, B, and D is provided by a central ring structure C. The description teaches that the ring structure C can be formed by ring-closing reaction of functional groups E and F, which are present in the immediate precursor to the final product. The only disclosed utility of the intermediate production is in the production of the final product.

202. In this example, the patent application has the following claimset:

- Claim 1: A compound of formula I comprising sub-structures A-B-C-D.
- Claim 2: A compound of formula II comprising sub-substructures A-B-E-F-D.

203. Here, the core structures of compound I (the final product) and compound II (intermediate product) differ considerably, compound II is an open-ring precursor to compound I. Both compounds share principal structural elements, namely the triazole A and the substituted aromatic rings B and D. The intermediate structure E-F is, from a chemical perspective, a known precursor for rings of type C. The two structures are, overall, technically interrelated and unity of invention exists. 124

[End of Annex and of document]

<sup>122</sup> USPTO MPEP, Section 806.

<sup>&</sup>lt;sup>123</sup> Manual of Patent Office Practice, Canadian Intellectual Property Office, Chapter 21 Unity of Invention.

<sup>&</sup>lt;sup>124</sup> Manual of Patent Office Practice, Canadian Intellectual Property Office, Chapter 21 Unity of Invention.