

# WIPO



SCP/9/5

ORIGINAL: English

DATE: March 17, 2003

**WORLD INTELLECTUAL PROPERTY ORGANIZATION**

GENEVA

**E**

## **STANDING COMMITTEE ON THE LAW OF PATENTS**

### **Ninth Session**

**Geneva, May 12 to 16, 2003**

#### **“INDUSTRIAL APPLICABILITY” AND “UTILITY” REQUIREMENTS: COMMONALITIES AND DIFFERENCES**

*Document prepared by the International Bureau*

#### **I. INTRODUCTION**

1. At the eighth session of the Standing Committee on the Law of Patents (SCP), held in Geneva from November 25 to 29, 2002, the International Bureau was mandated to prepare a study regarding commonalities and differences between the “industrial applicability” and the “utility” standards (see paragraphs 307 and 313 of the draft Report (document SCP/8/9 Prov.2)). The present document contains an overview of various national/regional laws and practices concerning the industrial applicability and utility requirements, and attempts to identify certain characteristics of these requirements. Further, it reviews those areas in which there is a substantial overlap of practices as well as those in which the two requirements differ substantially. Finally, it provides some background information on the alternative texts contained in Article 12(4) of the draft Substantive Patent Law Treaty (SPLT) (see document SCP/9/2).

2. It is recalled that, following the decision made at the fourth session of the SCP, which was held in Geneva from November 6 to 10, 2000, the International Bureau invited the SCP Electronic Forum members to provide information regarding the industrial applicability and utility requirements under their national/regional law. All the responses received at that time are available on the SCP Electronic Forum (<http://www.wipo.int/scp>). Based on those responses, the International Bureau prepared an informal paper containing information on the application of the industrial applicability or utility requirement under national/regional

practices. The informal paper, which is also available on the SCP Electronic Forum, was submitted to the SCP at its fifth session, held in Geneva from May 14 to 19, 2001.

3. In order to prepare the present document, after the eighth session of the SCP, the SCP Electronic Forum members were invited to submit further comments which might assist the International Bureau. Those comments are also available on the SCP Electronic Forum.

## II. INDUSTRIAL APPLICABILITY REQUIREMENT

### *National and Regional Laws and Practices*

4. The patent laws of many countries and regions require that an invention be susceptible or capable of industrial application. The responses<sup>1</sup> received from Austria, Belgium, Denmark, France, Germany, Portugal, Serbia and Montenegro, Spain, Sweden, the United Kingdom and the European Patent Office (EPO) showed that, in these jurisdictions, an invention shall be considered to be susceptible (or capable) of industrial application “if it can be made or used in any kind of industry, including agriculture.” The general understanding is that the term “industry” shall be interpreted in the broadest possible sense.

5. The Guidelines for Examination in the EPO,<sup>2</sup> Part C, IV, 4.1 state that the term “industry” should be understood “as including any physical activity of ‘technical character’, i.e., an activity which belongs to the useful or practical arts as distinct from the aesthetic arts; it does not necessarily imply the use of a machine or the manufacture of an article and could cover, e.g., a process for dispersing fog, or a process for converting energy from one form to another.” According to those Guidelines, Part C, IV, 4.4, in general, methods of testing should be regarded as inventions susceptible of industrial application and therefore patentable, if the test is applicable to the improvement or control of a product, apparatus or process which is itself susceptible of industrial application. According to EPO document EUROTAB 2/99 as well as the submission from the EPO, as regards the distinction between the criterion of technical character (see the EPO Guidelines, C-IV 1.2 (ii) and 2.2) and the criterion of industrial applicability, an invention susceptible of industrial application does not necessarily have a technical character. If the claimed subject matter as a whole lacks technical character, an objection to it cannot be raised under Article 57 of the Convention on the Grant of European Patents European Patent Convention (EPC) [industrial application], but should be based on Article 52 EPC [patentable inventions]. As regards methods of surgery, therapy and diagnosis under Article 52(4) EPC 1973, they will be discussed in paragraph 18.

6. The submission from the EPO states that the industrial applicability requirement might play a decisive role in the determination of the patentability in respect of three types of inventions: (1) those which appear to be impossible to carry out because they contravene the laws of physics (for example, a perpetual motion machine); (2) those concerning methods which could be considered to fall entirely within the private or personal sphere; and (3) those involving gene sequences, for which the industrial application must be disclosed (on this point, see paragraphs 20 to 24). In relation to the second point, the EPO Boards of Appeal

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<sup>1</sup> The responses listed or mentioned in this document include both the responses received after the fourth session of the SCP (see paragraph 2) and the responses received after the eighth session of the SCP (see paragraph 3).

<sup>2</sup> See [http://www.european-patent-office.org/legal/gui\\_lines/index.htm](http://www.european-patent-office.org/legal/gui_lines/index.htm).

have held that the requirement for industrial applicability implies a “commercial exploitation,” with the purpose of achieving “financial gain” (see Board of Appeals decisions T204/93; T144/83). On the other hand, it was confirmed in decision T74/93 that, when a method falls entirely within the private or personal sphere of a human being, it cannot be considered to be susceptible of industrial application. This case focused on a contraceptive method for women. The compound, which was new and inventive, was held to be patentable, but the method claim was found to be lacking in industrial applicability, as the use of the compound was a purely personal use which could only be carried out in private by the women themselves.

7. The response from France indicated that the condition of industrial applicability requires that the invention could be exploited (made or used) in the industry at large, including commerce and agriculture. With respect to the quality of the result of the exploitation of the invention, the *Tribunal de grande instance de Paris* has ruled that “the law takes into account neither the result of the usage of the invention nor the quality of such result; an imperfect result or even a regression does not lead to a non-compliance with the requirement of industrial applicability” (PIBD, 1998, No. 659.III.398). According to the response, this refusal of appreciating the merit of the invention distinguishes the notions of industrial applicability and utility. Nevertheless, to be patentable, the invention should produce a real technical result. The *Tribunal de grande instance de Paris* decided, in another case, that “in order for the invention being patentable, it is sufficient if the invention procures a immediate technical result of industrial nature, even if its result is fable and imperfect, and even if engineers consider that the invention did not have any commercial benefits or any utility in its exploitation” (PIBD 1985, No. 375.III.246).

8. The response from Denmark explained that the fundamental meaning of the industrial application requirement was that an “invention is available or existed as a practical reality.” In other words, the inventor should be able to indicate at least one practical application/utility with respect to an invention.

9. The response from Austria noted that, although the Austrian Patent Law did not contain any definition of the term “industrial applicability,” it was understood in a very broad sense that the invention must be able to be made or used in any kind of industry, including agriculture. According to its practice, “the invention must be capable to be carried out within professional activities,” that is, the invention must be “workable and reproducible.” It was explained that the invention should be able to achieve the objective claimed in order to be workable, and that the same result should be obtained each time the invention was carried out in order to be reproducible. According to its practice, a “theoretical” possibility to apply the invention within professional activities was sufficient.

10. The theoretical possibility of manufacture or use in any industry was also mentioned in the response from Germany. In order to comply with the industrial applicability requirement, it is not necessary to demonstrate real manufacture or use in the industry, or to get an approval by the Technischer Überwachungsverein (technical inspection association). It indicated that the industry within the meaning of “industrial applicability” was a continuing, independent, authorized activity geared towards profit, including primary production, such as agriculture, forestry and horticulture. It further noted that, if a process was applied exclusively by so-called free professions, such as practicing doctors, lawyers or pharmacists, it was not industrially applicable.

11. The response from Portugal indicated that, as a result of the definition of industrial applicability, inventions which lacked practical reality or were absurd or clearly going against the laws of physical or chemical sciences were not patentable. Similarly, any kind of artisan made products or techniques lacked industrial applicability, as each artisan product had a *per se* value, which was not the case for mass-produced goods.

12. The response from Sweden explained that industrial applicability should be considered in a broad sense, for example, commerce, forestry, public administration, gardening, hunting, fishery and the defense. It noted, however, that an “invention” within the meaning of the patent law should: (i) exhibit a technical character; (ii) yield a technical effect; and (iii) be reproducible. Therefore, it concluded that the discussion on industrial applicability was closely linked to the interpretation of “invention” under the patent law.

13. The Manual of Patent Practice issued by the Patent Office of the United Kingdom<sup>3</sup> indicates that the term “industry” should be understood in its broadest sense as including any useful and practical, as distinct from intellectual or aesthetic, activity (apart from medical methods which are described in paragraph 16, below). It is restricted neither to tangible material nor to purely commercial or profitable activities. Citing the views of the High Court of Australia in *NRDC’s Application*, [1961] RPC 134, the Manual explains that, to meet the industrial applicability requirement, there must be something in which a new and useful effect, be it creation or alteration, may be observed. According to the response from the United Kingdom, perpetual motion machines are considered to be inherently without utility, and although many are specifically intended for use in industry, they are always considered to fail the “applicability” test.

14. The Brazilian Association of Intellectual Property (ABPI) explained that, according to Article 15 of the Brazilian Industrial Property Law 9279/96, “inventions and utility models are considered to be susceptible of industrial application when they can be made or used in any kind of industry.” It concluded that the possibility of “industrial application” would seem to imply that an invention must: (i) be feasible, i.e., it can be reduced to practice; (ii) have a known utility, otherwise it would not have a practical application; and (iii) be of a technical or technological nature, otherwise it would not relate to industry.

15. In some other countries, the definition of industrial applicability contains explicit examples, in particular, services, clarifying the broad scope of the term “industry.” For example, the response from Argentina stated that, according to Article 4 of Law No. 24,481 (T.O. 1996), industry should be understood as including agriculture, forestry, livestock breeding, fisheries, mining, processing industries in the strict sense and services. Nevertheless, in practice, it explained that the concept of industrial applicability included any physical activities of a technical character. For instance, certain activities that belong to the customs and practices of the aesthetic arts may be included in the concept of industry. Similarly, Article 12, IV of the Law of Industrial Property of Mexico provides that inventions can be made or used in any field of economic activities.

16. According to the response from Japan, the Japanese Patent Law provides for the industrial applicability requirement without a statutory definition. Instead, the Examination Guidelines<sup>4</sup> issued by the Japan Patent Office (JPO) provide an exhaustive list of inventions

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<sup>3</sup> See <http://www.patent.gov.uk/patent/reference/index.htm>.

<sup>4</sup> See [http://www.jpo.go.jp/tetuzuki\\_e/t\\_tokkyo\\_e/1312-002\\_e.htm](http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/1312-002_e.htm).

which are not considered as industrially applicable. They are: (i) methods for the treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body (see paragraph 16, below); (ii) commercially inapplicable inventions (e.g., inventions applied only for personal use, or inventions applied only for academic or experimental purposes); and (iii) practically inapplicable inventions (e.g., “a method for preventing the increase in ultraviolet rays associated with the destruction of the ozone layer by covering the whole surface of the earth with an ultraviolet ray absorbing plastic film”). The response from the Republic of Korea stated that a similar list was provided for in the Examination Guidelines of the Korean Intellectual Property Office (KIPO).

17. The response from the Republic of Moldova stated that, according to Article 7 of the Patent Law of its country, an invention shall be considered as susceptible of industrial application if it could be used in industry, agriculture or any other field of activity. In practice, it noted that an invention should be considered as susceptible of industrial application if the following information resulted cumulatively from the description of the invention: (i) the subject matter of the invention can be used at least in one field; (ii) the problem and its solution; (iii) the invention is disclosed in a way that a person skilled in the art could make the invention without being engaged in an inventive activity; and (iv) the invention can be reproduced with the same characteristics and effects as many times as necessary. A similar practice is also found in the response from Romania. According to Article 4, paragraph 1 of the Patent Law of the Russian Federation, an invention shall be deemed industrially applicable if it can be used in industry, agriculture, public health and other sectors of the economy. The response from the Russian Federation clarified that, when determining whether an invention could be used in a certain sector of the economy, the following points were examined in accordance with the Regulations: (i) whether the application as filed contains the principal objective of the claimed subject matter; (ii) whether the application as filed defines means and ways to achieve this objective as specified in the claims; (iii) whether it is actually possible to achieve the objective as specified by the applicant when carrying out any of the claimed invention.

18. In addition to the above, many countries indicated that methods for the treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body should not be regarded as inventions which are susceptible of industrial application. For the purpose of this document, however, it may not be necessary to discuss this issue in detail, since in some other countries, such methods for the treatment of the human or animal body are excluded from patentability without any reference to industrial applicability. Such an exception is then rooted in grounds of public policy. It should be noted that, according to Article 27.3(a) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), Members of the World Trade Organization (WTO) may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals without any reference to the industrial applicability requirement. Against this backdrop, Article 52(4) of the European Patent Convention was amended by the Act Revising the Convention on the Grant of European Patents of November 29, 2000, so that methods for the treatment of the human or animal body are one of the categories of inventions in respect of which European patents are not granted, without any reference to industrial applicability. In Japan, the issue as to inventions relating to medical methods is now under consideration by the Medical Methods Working Group of the Industrial Structure Council.

19. The responses show that, apart from inventions regarding methods of treatment of the human or animal body, decisions based on the lack of industrial application are, in general,

very rare. Many responses pointed out that this follows from the fact that the concept of industrial applicability was applied very broadly and that other grounds for refusal, such as the enabling disclosure requirement and the requirements concerning patentable subject matter, were more often imposed to refuse an application. As regards the enabling disclosure requirement, if a claimed invention fails to demonstrate its practical application, it is probable that the disclosure of the claimed invention in the application would fail to enable a person skilled in the art to carry out the claimed invention. With respect to patentable subject matter, aesthetic creations, for example, may be considered as not being applicable in industry, while, at the same time, they may not be regarded as creations falling under the definition of “inventions” under the patent law.

### *Industrial Applicability and Biotechnological Inventions*

20. In recent years, the requirement of industrial applicability has gained significant importance for the determination of the patentability of inventions in the field of biotechnology, more specifically, of inventions concerning, for example, a sequence or a partial sequence of a gene. In general, in order to comply with the industrial applicability requirement, an applicant has to indicate the ways by which the claimed invention satisfies the possibility of industrial application in the description unless it is clear to a person skilled in the art from the nature of the claimed invention. In relation to sequences and partial sequences of genes, this general requirement is given a specific form in many countries. According to Article 5.3 of the Directive 98/44 of the European Parliament and of the Council on the legal protection of biotechnological inventions,<sup>5</sup> the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. Recital 23 of the Directive provides that a mere nucleic acid sequence without indication of a function does not contain any technical information and is therefore not a patentable invention. Recital 24 of the Directive specifies that, in order to comply with the industrial applicability requirement, in the cases where a sequence or partial sequence of a gene is used to produce a protein or a part of a protein, it is necessary to specify which protein or part of the protein is produced and what function this protein or part of this protein performs. Rule 23b(1) of the Implementing Regulations to the EPC provides that the above Directive should be used as a supplementary means of interpretation. Further, Rule 23e(3) of those Implementing Regulations and the Guidelines for Examination in the EPO, Part C, IV, 4.6 provide a requirement and explanations similar to the above Directive. The submission from the EPO, however, noted that, arguably, Rule 23e(3) EPC did not really focus on the contents of the concept of industrial applicability, but rather addressed the issue of enabling disclosure. It further noted that this issue could be dealt with under different provisions of the EPC; if the function of a gene sequence is not disclosed, arguably, it is a discovery and not an invention, running afoul of Article 52(2)(a) EPC. Moreover, the absence of such a disclosure could also give rise to an objection under Article 56 EPC, since without such use or function there would be no technical effect which could provide the basis for an inventive step.

21. Specific guidelines for the determination of industrial applicability in the biotechnological field are also found in the Examination Guidelines for Inventions in Specific Fields (Biological Inventions) issued by the JPO and in the Examination Guidelines for Biological Inventions issued by the KIPO. They state that inventions relating to a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein or a

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<sup>5</sup> See <http://www.europa.eu.int/cgi-bin/eur-lex/udl.pl?REQUEST=Seek-Deliver&COLLECTION=lif&SERVICE=all&LANGUAGE=en&DOCID=398L0044>.

monoclonal antibody, whose utility is not described or not inferred based on the specification, do not meet the industrial applicability requirement.

22. The Patent Office of the United Kingdom (UK) issued, in September 2002, Examination Guidelines for Patent Applications relating to Biotechnological Inventions<sup>6</sup> and, in particular, the practice concerning the industrial applicability requirement in respect of sequences or partial sequences of genes. The Guidelines explain that the determination of industrial applicability with respect to sequenced or partially sequenced genes was not easy, because the industrial application of genes or protein sequences was not apparent from the invention itself. On the other hand, the use of short DNA sequences or ESTs as probes is well known. Thus the question arises what needs to be shown to demonstrate industrial applicability. Referring to the Utility Examination Guidelines and the Guidance on the Application of the Utility Guidelines issued by the United States Patent and Trademark Office (USPTO), the said UK Examination Guidelines further state that, although the Guidelines issued by the USPTO did not have direct effect in the UK, the requirement in the United States of America that a “specific, substantial and credible” utility must be disclosed, was arguably the sort of disclosure, relating to industrial applicability, which the UK Office would expect to be contained in a UK application. The Guidelines, however, further noted that, in the absence of a judgement from the UK courts or of a decision from the EPO, there could be no certainty that such an approach would be upheld in the UK if challenged.

23. In this context, reference is made to the Decision of the Opposition Division of the European Patent Office dated June 20, 2001, *ICOS Corporation/Seven transmembrane receptor (EP-B-0630405)*, *OJEPO 2002*, 293.<sup>7</sup> In this case, the Opposition Division decided that, as “potential uses of the invention are disclosed in the specification which however are based on a proposed function of the V28 protein as a receptor which is not sufficiently disclosed in the specification,” “the potential uses disclosed in the application are speculative, i.e., are not specific, substantial and credible and as such are not considered industrial applications.”

24. As described in paragraph 20, in general, in order to comply with the industrial applicability requirement, an applicant has to indicate the ways the claimed invention satisfies the possibility of industrial application unless it is clear to a person skilled in the art from the nature of the claimed invention. The Guidelines for Examination in the EPO, Part C, II, 4.12 regarding EPC Rule 27(1)(f) provide that the description should indicate explicitly the way in which the invention is “capable of exploitation in industry,” if it is not obvious from the description or from the nature of the invention. It further states that the expression “capable of exploitation in industry” means the same as “susceptible of industrial application.”

#### *Main Characteristics of Industrial Applicability*

25. As described above, national and regional laws and practices concerning the industrial applicability requirement vary significantly. At one end of the spectrum, the requirement of industrial applicability is met as long as the claimed invention can be made in industry without taking into account the use of the invention. This view is, for example, found in one of the commentaries to Article 57 of the European Patent Convention, according to which the requirement of industrial applicability is complied with, if the product invention can be either

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<sup>6</sup> See <http://www.patent.gov.uk/patent/reference/index.htm>.

<sup>7</sup> See [http://www.european-patent-office.org/epo/pubs/oj\\_index\\_e.htm](http://www.european-patent-office.org/epo/pubs/oj_index_e.htm).

made in industry or used in industry. Therefore, as long as the invention can be made in industry, the requirement of industrial applicability is met even if it could be used only in a non-industrial environment, such as use in the private sphere (for example, games and sporting goods).<sup>8</sup>

26. At the other end of the spectrum, the “usefulness” of the claimed invention is fully taken into consideration for the determination of industrial applicability. Bearing these differences in mind, it may be possible, however, to extract certain characteristics which form the core concepts of this requirement. Since this requirement is defined as “being susceptible of (or capable of) industrial application,” the following analysis will focus on two aspects of this requirement, namely, “industrial” and “application.”

27. Firstly, an invention shall be applicable in “industry.” All the responses emphasized the broad scope of the term “industry.” From the explanations given in respect of the national/regional practices, the following characteristics may be commonly found in the various practices.

28. The first characteristic is that an invention must be applicable in any non-mental activity that belongs to the useful or practical arts. A similar explanation is also found in the PCT International Preliminary Examination Guidelines, IV-4. 1<sup>9</sup>, according to which “industry includes any physical activity of a technical character, that is, an activity which belongs to the useful or practical arts as distinct from the aesthetic arts.” The invention shall be applicable in the non-mental activity in the sense that the activity is not a mental or spiritual act, but rather an act in the real world. In accordance with the words “useful or practical arts,” activities that belong to aesthetic or intellectual arts are not considered as susceptible of industrial application. In view of the illustrative examples of “industry” which are provided for in national/regional legislation and practice, it could be said that the business setting in which the invention is applied, such as the manufacturing sector, the agricultural sector, the service sector, the trading sector, etc., is not relevant in this context. Rather, it is the nature of the activity in connection with the exploitation of the invention which is at stake.

29. Because of the nature of the word “industry,” certain inventions, however, are not considered as susceptible of industrial application in many countries, even if they are applicable in a non-mental activity that belongs to the useful or practical arts. The first category of these inventions are inventions which could be applied only in the private and personal sphere for one’s own needs. Examples of such inventions include a method for the local application of a contraceptive composition (EPO), a method of smoking (JPO) and a method of fixing a ski shoe to a ski (Intellectual Property Office of Switzerland). The second category of these inventions are inventions which could be applied only in association with a particular person. This concept is connected to the reproducible feature of the word “industry.” For example, although a certain product could be made or used in a non-mental activity that belongs to the useful or practical arts, the essential value of that product may be derived from specific personal skills associated with a person concerned, and therefore, each of these products has its *per se* value. Such a product may not be considered as susceptible of

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<sup>8</sup> Europäisches Patentübereinkommen, Münchner Gemeinschaftskommentar, Article 57, IV.D. It may be argued that, as regards these examples, the games or sporting goods could be sold to others, and therefore, could be used in an industrial environment, bearing in mind the broad scope of the term “industry.”

<sup>9</sup> See [http://www.wipo.int/pct/en/access/legal\\_text.htm](http://www.wipo.int/pct/en/access/legal_text.htm).



industrial application. Although the draft SPLT does not cover matters concerning the rights conferred by patents, it should be noted that, in many countries, exploitation of a patented invention for private purposes is not considered as infringing the exclusive rights conferred by the patent. Therefore, in those countries, if a patent is granted to an invention which could be usable only for private purposes, such a patent would probably not be enforceable anyway.

30. The second aspect of industrial applicability is that the invention shall be capable of “application” in industry. By definition, this means that an invention which has no application in industry is not an invention susceptible of industrial application. One of the typical examples of such inventions is an invention alleged to operate in a manner clearly contrary to the laws of nature, for example, a perpetual motion machine.

31. As described above, since the notion of “industry” in the context of “industrial applicability” can be characterized by the nature of the activity that belongs to the useful or practical arts, it could be said that, if an invention can be made or used in connection with an activity that belongs to the useful or practical arts, such an invention shall be considered as susceptible of industrial application. In this case, industrial applicability means that the claimed invention can be made or used in “any kind of industry” in the sense that it must have a useful or practical application. It is not sufficient that the claimed invention can be simply made or used. Such a view is, in particular, found in a comment by the English Court of Appeal in *Chiron Corp v Murex Diagnostics Ltd and other* [1996] RPC 535.<sup>10</sup>

32. This aspect of practical applicability is found in many of the responses from national/regional Offices that require industrial application. In other words, an invention should have practical or useful purposes and should produce a real result. A speculative use is not sufficient. This aspect is highlighted, in particular, in the field of biotechnological inventions. For example, with respect to an invention concerning a gene sequence that produces a protein, not only which protein is produced, but also the function or utility of the protein should be disclosed in order to meet the requirement of industrial applicability. In this case, a decisive question raised is not whether a gene sequence concerned can be isolated (i.e., “an invention can be made or used” in the field of biotechnology), but whether that gene sequence has a practical or useful application. It may also be noted, however, that this approach does not appear to be applied to the same extent to all categories of inventions.

33. If a claimed invention fails to demonstrate its practical application, in many cases, the disclosure in the application as filed will also fail to enable a person skilled in the art to carry out the claimed invention (enabling disclosure requirement). Although this requirement, according to which the claimed invention shall be disclosed in the application in an enabling manner, is a separate requirement from the industrial applicability requirement in many national/regional laws, in some countries, the industrial applicability requirement also contains aspects of the enabling disclosure requirement. Similarly, many of the inventions which do not fall under the definition of the term “invention” in the context of patent law or which are not considered patentable subject matter would not comply with the requirement of industrial applicability.

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<sup>10</sup> It stated that “industry does not exist to make or use that which is useless for any known purpose” and that “IP rights should be confined to that which has some useful purpose.”

### III. UTILITY REQUIREMENT

#### *National Laws and Practices*

34. The patent laws of another group of countries do not provide an “industrial applicability” requirement, but require “utility.” The law of the United States of America requires that a patentable invention be a new and useful process, machine, manufacture, or composition of matter, or a new and useful improvement thereof.

35. The Guidelines for Examination of Applications for Compliance with the Utility Requirement<sup>11</sup>, issued by the USPTO, provide that an invention has a well-established utility if: (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful, and (ii) the utility is specific, substantial and credible. If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a “specific and substantial utility”) and the assertion would be considered credible by a person of ordinary skill in the art, the utility requirement is met.

36. The definitions of the terms “specific” and “substantial” utility are given as follows:

“‘Specific utility’ — The specific utility contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a “gene probe” would not be considered to be specific in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.”

“‘Substantial utility’ — Utilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities. The examples of situations that do not define “substantial utility” are:

- (i) basic research such as a studying the properties of the claimed product itself or the mechanisms in which the material is involved;
- (ii) a method of treating an unspecified disease or condition;
- (iii) a method of assaying for or identifying a material that itself has no “specific and/or substantial utility”;
- (iv) a method of making a material that itself has no specific, substantial and credible utility;
- (v) a claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.”

So-called “throw away” utilities do not meet the tests for a specific or substantial utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice

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<sup>11</sup> Manual of Patent Examination Procedure (MPEP), 2107  
(see <http://www.uspto.gov/web/offices/pac/mpep/mpep.htm>)

could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a “real world” context of use).”

37. In order to comply with the utility requirement, the assertion of utility should be credible. The assertion of utility is considered credible if the assertion is believable to a person skilled in the art based on the totality of evidence and reasoning provided.<sup>12</sup> The assertion is credible unless the logic underlying the assertion is seriously flawed, or the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. A credible utility is assessed from the standpoint of whether a person skilled in the art would accept that the claimed invention is currently available for such use. For example, nucleic acids could be used as probes, chromosome markers or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the specific and substantial tests. Situations where an invention is found to be inoperative, and therefore lacking utility, seem to be very rare. Examples of such cases include: an invention asserted to change the taste of food using a magnetic field, a flying machine operating on “flapping or flutter function” and a method of controlling the aging process.

38. Case law in the United States of America determining whether an applicant identifies any specific utility for the claimed invention or not has been developed, in particular, in the field of chemistry and pharmacology. For example, indicating that the compound may be useful in treating unspecified disorders, or that the compound has useful biological properties, would not be sufficient to define a specific utility for the compound. Further, although many research tools, such as nucleotide sequencing techniques, have a specific utility, if an invention is useful only in a research setting, it does not address whether the specific invention is in fact “useful” as required under the patent law.

39. MPEP 2107.1, IV. provides detailed explanations about the relationship between 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph. Where a claimed invention does not have utility, in many cases, the specification could not enable a person skilled in the art to use that invention. Consequently, in those cases, the disclosure of the claimed invention does not comply with the requirement under 35 U.S.C. 112, first paragraph. The fact that an applicant has disclosed a specific utility for an invention and provided a credible basis supporting that specific utility does not provide a basis for concluding that the claims comply with all the requirements of 35 U.S.C. 112, first paragraph.

40. Under the law of Canada, the term “invention” means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter. Utility means having industrial or commercial value in a manner that benefits the public.<sup>13</sup> For example, a perpetual motion machine that serves no useful purpose does not comply with the utility requirement. Similarly, a device that only suits the convenience of a specific manufacturer, for example, by impressing a trademark on a product or holes to fit another of the patentee’s products, has no utility.

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<sup>12</sup> Revised Interim Utility Guidelines Training Materials issued by the USPTO (see <http://www.uspto.gov/web/patents/guides.htm>).

<sup>13</sup> Patents: A Canadian Compendium of Law and Practice, George Francis Takach, 1993, page 34.

41. A finding that the alleged invention is not useful may be expressed in a way that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promised it would do (“false promise”).<sup>14</sup> It is sufficient if the specification correctly and fully describes the invention and its operation or use as contemplated by the inventor, so that a person skilled in the art may be able to use the invention as successfully as the inventor himself. Further, if a genus claimed is not proved by a person attacking the patent in suit to include inoperable species, if the claim includes so many species that not all could have been tested and found by the inventor to have the promised utility, the claim is invalid, absent a possible showing by the patentee that the entire claim could be soundly predicted to have the requisite utility (“sound prediction”).

42. “Control” in the sense that a claimed invention results from the control of the inventor or of those practicing the invention, and does not merely result from the application of the laws of nature, may be a factor in the analysis of whether an invention is “useful.”<sup>15</sup> The Patent Act of Canada, however, does not require that all characteristics of the claimed invention be under the inventor’s control in order that the invention be useful and patentable. Similarly, reproducibility of an invention may be considered insofar as it relates to the question of utility, but the reproducibility of all characteristics of an embodiment of the invention is not a prerequisite to a finding that an invention is present.<sup>16</sup>

43. The law of Australia provides that a claimed invention shall be “a manner of manufacture within the meaning of Section 6 of the Statute of Monopolies” and be “useful.” The Australian Office notes that certain aspects of the “manner of manufacture” requirement and “useful” requirement under its law considerably overlap with the “industrial applicability” requirement. What constitutes “a manner of manufacture” is determined by case law and traditional principles, including the exclusion of fine arts and mere ideas or discoveries. The courts have pronounced on a number of occasion that “a process, to fall within the limits of patentability..., must be one that offers some advantage which is material, in the sense that the process belongs to a useful art as distinct from a fine art... — that its value to the country is in the field of economic endeavor.”<sup>17</sup>

44. The following examples relate to inventions which are not considered “*a manner of manufacture*”:

- (i) claims to microorganisms *per se* without any practical application;
- (ii) an improved plan for a subterranean utility distribution scheme (“the issuance of instructions to a gang of workmen to dig evacuations and lay conduits as indicated on a plan of a site cannot of itself constitute any development in a useful art”);
- (iii) a method for operating a jet aircraft to reduce noise over built up area (considered not patentable because it represented operating instructions for a known aircraft and because it was mischievous to the state or generally inconvenient by adding demands on pilots).

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<sup>14</sup> Canadian Patent Act Annotated, Robert H. Barrigar, 1999, 2:160.

<sup>15</sup> Canadian Patent Act Annotated, Robert H. Barrigar, 1999, 2:175.

<sup>16</sup> Canadian Patent Act Annotated, Robert H. Barrigar, 1999, 2:175.

<sup>17</sup> National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 252, IBM v Commissioner of Patents (1991) 22 IPR 417.

45. The concept of “manner of manufacture” also includes a threshold inventiveness requirement that would exclude an invention consisting of merely a new use of an old substance, involved old integers without a working interrelationship producing a new or improved result or was otherwise obvious on the face of the specification. Examples of these principles include a container with its contents with a set of written directions (it does not constitute a manner of manufacture unless the package itself is novel) and rocket projectors of known design manufactured from reinforced synthetic resinous plastic material (it is merely “the use of a known material in the manufacture of known articles for the purpose of which its known properties make that material suitable”).

46. On the other hand, the requirement that an invention be “useful” is closely associated with questions of false suggestion and misrepresentation, and it does not include any judgement as to the social benefit or the value or morality of the invention. The essential principle is that the invention should allow the addressee to achieve the effects or results promised by the patentee. Therefore, it is sufficient if the invention can be used and offers the public a useful choice. Lack of utility is a ground for revocation of the patent, but not a ground for objection during examination or in opposition proceedings. It nevertheless may be addressed to some extent in examination and opposition proceedings when considering sufficiency, fair basis and clarity of the description and claims.

47. The following inventions are considered not to meet the requirement that an invention be “*useful*” under the law of Australia:

(i) An invention related to control circuits for gas discharge lamps. The specification indicated that the invention would reduce heat generation in the ballast. However the evidence was that some circuits falling within the scope of the claims failed to work and caused lamp failure because of excessive heat generation. Consequently the promise of the invention was not fulfilled.

(ii) The promise of a cheese for “permanent keeping” was not fulfilled by the sterilization process claimed.

48. According to the response from New Zealand, Section 41(1)(g) of the New Zealand Patents Act 1953 states that a patent may be revoked on the grounds that the claimed invention is not useful.

#### *Main Characteristics of Utility*

49. As in the case of the industrial applicability requirement, practices in the countries which require utility (or usefulness) vary. As a general rule, however, certain characteristics commonly applicable to the utility requirement can be identified.

50. Firstly, inoperative inventions or, more broadly, inventions which do not work in a way they promised to do, do not comply with the utility requirement. In other words, claimed inventions which are clearly not operative, or which could not be soundly predicted to have the requisite utility, do not meet the utility requirement.

51. The second common concept is that, even if any use of a claimed invention is asserted, the utility requirement would not be met where such use is too general, absurd or non-realistic in view of the gist of the claimed invention. Under the practice of the United States of

America, this concept seems to be covered by the expression “specific and substantial utility.” The same concept expressed in more general terms is also found in the responses from Australia and Canada. In connection with the explanation of the term “manner of manufacture,” the submission from Australia addressed the point that a claimed invention should offer some material advantage in the sense that it belonged to a useful art and that its value to the country was in the field of economic endeavor. The submission from Canada indicated that “utility” meant having industrial or commercial value in a manner that benefited the public and that the control of the inventor and the reproducibility of the claimed invention might be considered in respect of utility. Both submissions suggested that the claimed invention with the asserted utility should offer concrete benefits to the public.

52. As in the case of the industrial applicability requirement, the utility requirement also relates to other patentability requirements, in particular, requirements concerning the disclosure of the claimed invention. Since the required utility could not be a speculative one, it is also related to a principle that the scope of the claims is commensurate with the invention as disclosed. Under national practices, this aspect is found, in particular, in relation to expressions such as “credible utility,” “sound prediction” and “false suggestion.”

#### IV. COMMONALITIES AND DIFFERENCES BETWEEN THE INDUSTRIAL APPLICABILITY AND THE UTILITY REQUIREMENTS

53. The scope of the term “industrial applicability” differs from one country to another, and so does the term “utility.” Considerable overlaps, however, exist between these two requirements.

##### *Commonalities*

54. Focusing on the general common characteristics of the two requirements, an invention that is inoperative, for example, an invention which is clearly non-operable in view of well-established laws of nature, would not comply with both the industrial applicability and utility requirements. This type of invention is considered either having no application in industry or not being useful for any purpose, because it doesn’t work.

55. In respect of an invention that is operable, the same invention may not always meet both the industrial applicability requirement and the utility requirement. However, at least in part, both requirements seem to address a similar issue. Generally speaking, an invention which is not useful in a substantial or concrete way, for example, its asserted use is too general, too absurd, not realistic or speculative, does not comply with the utility requirement. On the other hand, the practice applied to, in particular, biotechnological inventions, and a comment by the English Court of Appeal in *Chiron Corp v Murex Diagnostics Ltd and other* [1996] RPC 535, show that the practical and useful application of the claimed invention is not foreign to the question of industrial applicability. Although it is not possible to draw any general conclusion in view of the differences which exist among the countries that require industrial applicability, at least certain inventions that can be made or used in any kind of industry, but cannot show any practical or useful application, could be refused on the grounds of both the industrial applicability requirement and the utility requirement. However, the extent of “utility” or “usefulness” required may require to be further examined by the SCP members if the need for a general rule in this respect was felt.

### *Differences*

56. One of the differences between the industrial applicability requirement and the utility requirement is that claimed inventions which could apply solely in the private or personal sphere for one's own needs, or which could be applied solely in association with a particular person, would not meet the industrial applicability requirement, even if the term "industry" is interpreted in the broadest sense. Although not many examples of inventions falling under this category were suggested by the SCP members, it may be further explored how the patentability of these inventions is assessed in those countries which apply the utility requirement. At least in the submissions from Australia and Canada, with respect to "a manner of manufacture" and "utility," respectively, a commercial value in connection with benefits to the public was mentioned (see paragraphs 40 and 43). It may be noted that at least some of the countries applying utility, although they grant patents for inventions applicable only for private use, provide some safeguards for limited uses of the invention, such as the "*de minimis*" doctrine.

### *Overlaps with other requirements*

57. First, both requirements are closely related to, in particular, the enabling disclosure requirement, the definition of "invention" in the context of patent law, and the exclusions from patentable subject matter. In practice, many of the inventions which do not comply with the industrial applicability or utility requirements do not comply with these other requirements either. In the context of the draft SPLT, the enabling disclosure requirement is provided for in draft Article 10 and draft Rule 10, the texts of which are, in general, agreed by the SCP. This means that the practices of the Offices could be harmonized to the extent that the enabling disclosure requirement and the industrial applicability/utility requirement overlap. The patentability of those inventions which fall within the scope of the overlapping area would be refused in any Contracting Party, on the grounds of, at least, non-compliance with the enabling disclosure requirement. On the other hand, the definition of "invention" under the patent law and patentable subject matter vary significantly among national and regional laws. As it was suggested at earlier sessions of the SCP, unlike the enabling disclosure requirement, it would be difficult to reach full agreement on these matters in the SCP. One of the key issues relevant to this matter could be the "technical character" of the claimed invention. In view of the fact that the term "industry" is construed in the broadest sense in many of the countries which require industrial applicability, it may be envisaged to separate the technical character of an invention from the industrial applicability/utility requirement, as suggested in paragraph 147 of the Practice Guidelines under the SPLT in document SCP/8/4.

58. As a general conclusion, an invention that is inoperative, for example, an invention which is clearly non-operable in view of well-established laws of nature, is not patentable on the grounds of both the industrial applicability requirement and the utility requirement. Under certain circumstances, an invention not having the requisite utility may be refused on the grounds of non-compliance with the industrial applicability requirement, where the invention could be made or used in any kind of industry, but could not show any practical or useful application. A clear difference exists between the industrial applicability requirement and the utility requirement as to inventions which could be solely used in the private and personal sphere, although the utility requirement applied in certain countries takes into account the public benefit of the invention.

V. ALTERNATIVES IN DRAFT ARTICLE 12(4) OF THE SPLT

59. As regards the industrial applicability and utility requirements, three alternative texts are proposed in draft Article 12(4) of the SPLT (see document SCP/9/2). Although a Contracting Party may use either the term “industrial applicability” or the term “utility” under the applicable law, the provision is intended to provide a single definition that could be expressed in either terms. The texts of the three alternatives are reproduced below:

“[Alternative A]

A claimed invention shall be industrially applicable (useful). It shall be considered industrially applicable (useful) if it can be made or used for exploitation in any field of [commercial][economic]activity.

“[Alternative B]

A claimed invention shall be industrially applicable (useful). It shall be considered industrially applicable (useful) if it can be made or used for exploitation in any kind of industry. “Industry” shall be understood in its broadest sense, as in the Paris Convention.

“[Alternative C]

A claimed invention shall be industrially applicable (useful). It shall be considered industrially applicable (useful) if it has a specific, substantial and credible utility.”

60. According to Alternative A, the words “for exploitation in any field of [commercial][economic] activity” imply that the claimed invention has a practical or useful application, rather than that it could simply be made without any use, or could be simply used in a non-reasonable manner. The general rule as to what constitutes an invention with “practical or useful application” (or alternatively, what constitutes an invention without “practical or useful application”) may be provided in the Practice Guidelines, if the SCP Members agreed that further elaboration is necessary. The expression “[commercial][economic] activity” attempts to capture the broad scope of the term “industry” that appears in many national and regional laws. Further, this expression is intended to exclude inventions that could be applied solely in connection with the personal and private sphere. In practice, according to the broad scope of the term “industry” in Alternative B, the term “any kind of industry” in Alternative B and the expression “any field of [commercial][economic] activity” may not be substantially different. Alternative A, however, aims at using an explicit term that covers the activities which could fall within the scope of “industry” in its broadest sense.

61. Alternative B reflects the standard wording of the industrial applicability requirement that appears in many national and regional laws. In addition to the question concerning the scope of the term “industry,” the provision could be interpreted in a strict sense so that, for example, an invention concerning an isolated partial gene sequence may be considered as complying with the requirement under Alternative B, although no function of, or utility for, such a sequence is disclosed, apart from the general understanding that the sequence could be used as a probe.

62. The wording of Alternative C is modeled after the practice of the utility requirement, in particular, in the United States of America. In addition to the question as to the extent to



which utility of the claimed invention should be required, Alternative C could be interpreted in a way that an invention that could be applied only in connection with personal needs or personal skills would be considered to comply with the industrial applicability/utility requirement as long as that invention has the required utility.

63. One possible way which may be explored by the SCP could be to first identify, based on this document, the commonalities between the two requirements. These elements, together with other requirements which overlap with industrial applicability/utility, may form the basis to attempt to elaborate a common requirement. The next step could be to identify and attempt to solve the existing differences. Finally, it may be noted that any terms chosen in respect of a new requirement would need to be clearly circumscribed, for example, in the Practice Guidelines. In any event, it should be ensured that such wording, if it had already been used in some jurisdictions, would not result in the importation of the case law and practices used in such jurisdiction in relation to that wording.

*64. The SCP is invited to note the contents of this document.*

[End of document]