

## Standing Committee on the Law of Patents

**Eighteenth Session**  
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### OVERVIEW OF THE RESPONSES TO THE QUESTIONNAIRE ON EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

*Document prepared by the Secretariat*

#### INTRODUCTION

1. At its seventeenth session, held from December 5 to 9, 2011, in Geneva, the SCP requested the Secretariat to prepare, for its eighteenth session, a new document which would present the answers to the Questionnaire on Exceptions and Limitations to Patent Rights (hereinafter referred to as the "Questionnaire") in a revised format, allowing an easier understanding of the material, presenting statistics and reorganizing the information provided in clusters, based on, for example, the sections of the Questionnaire and to post the answers received on the SCP electronic forum (see paragraph 25(a) of document SCP/17/12).

2. The present document provides statistics on the replies and reorganizes the information contained in the responses to the Questionnaire, based on the sections of the Questionnaire as follows:

- Section I: General
- Section II: Private and/or non-commercial use;
- Section III: Experimental use and/or scientific research;
- Section IV: Preparation of medicines;
- Section V: Prior use;
- Section VI: Use of articles on foreign vessels, aircrafts and land vehicles;
- Section VII: Acts for obtaining regulatory approval from authorities;
- Section VIII: Exhaustion of patent rights;
- Section IX: Compulsory licensing and/or government use;
- Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions
- Section XI: Other

3. The document reflects the 72 replies received by March 28, 2012, from the following Member States and patent Offices: Albania, Algeria, Armenia, Austria, Australia, Azerbaijan, Bhutan, Bosnia and Herzegovina, Brazil, Canada, Chile, China, Congo, Costa Rica, Croatia, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Djibouti, Dominican Republic, El Salvador, Finland, France, Gambia, Georgia, Germany, Greece, Honduras, Hong Kong (China), Hungary, Indonesia, Israel, Italy, Jamaica, Japan, Kyrgyzstan, Latvia, Lithuania, Madagascar, Mauritius, Mexico, Monaco, Morocco, Netherlands, New Zealand, Norway, Oman, Pakistan, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Russian Federation, Sao Tome and Principe, Serbia, Slovakia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, United Republic of Tanzania, United States of America, Zambia, Zimbabwe and the Eurasian Patent Office (EAPO).

4. This document does not attempt to summarize the responses, but rather provides statistical information, reorganizes the answers and presents an overview that reflects the information contained in the voluminous original responses. Therefore, in order to comprehend the complete picture of the exceptions and limitations to patent rights, reference is made to the original responses submitted by the above Member States and the regional patent office. The Questionnaire as well as the responses received from Member States are available in full on the website of the SCP electronic forum at: <http://www.wipo.int/scp/en/exceptions/>. With a view to assisting easier access to the information contained in the responses, the said website presents all responses in a matrix format with hyperlinks to each section in each response.

## **SECTION I: GENERAL**

5. Section I of the Questionnaire contained questions regarding: (i) the legal standard used to determine whether an invention was patentable (ex. novelty, inventive step, industrial applicability etc.); (ii) exclusions from patentability; and (iii) the exclusive rights granted with a patent, under the applicable laws. Those questions aimed at obtaining background information on legislative frameworks under the applicable laws in which the exceptions and limitations were applied. The responses to the questions contained in Section I provide information on the underlying patent laws that set forth the conditions upon which a patent is granted and the rights that are associated with it. Therefore, those responses should be considered in conjunction with the responses in other sections on a country-by-country basis. For the purpose of understanding exceptions and limitations to patent rights, they cannot be considered in isolation from the applicable national/regional legal framework.

6. In general, the responses to the questionnaire state that the exclusive rights conferred by a patent intend to prevent third parties from the acts of making, using, offering for sale, selling or importing for those purposes the patented product, without having the consent of the patent owner, and where the subject matter of a patent is a process, to prevent third parties not having the patent owner's consent from the act of using the process and from the acts of using, offering for sale, selling or importing for these purposes the product obtained directly by that process. In some countries, the exclusive rights, by definition, do not cover, for example, the right to prevent private or non-commercial use, or experimental use, of patented inventions by unauthorized third parties (see Sections II and III below). In such cases, there would be no need to have a separate provision concerning a private and/or non-commercial exception or an experimental use exception under the applicable laws. As regards the patentability requirements, in general, novelty, inventive step and industrial applicability (utility) as well as sufficiency of disclosure are required under the applicable laws.

7. Many Member States exclude from patentable subject matter or from patentability some or all of the following:

- discoveries and scientific theories;
- mathematical methods;
- aesthetic creations;
- schemes, rules and methods for performing mental acts, playing games or doing business;
- computer programs;
- presentations of information;
- inventions the commercial exploitation of which would be contrary to ordre public or morality;
- plants and/or animals other than microorganisms
- essentially biological processes for the production of plants or animals other than non-biological and microbiological processes;
- plant and/or animal varieties;
- diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

Where a particular subject matter is excluded from patentable subject matter, there would be no need to provide an exception addressing the same excluded subject. For example, in some countries, since plants and animals are excluded from patentable subject matter, those countries do not provide exceptions and limitations related to farmers' and breeders' use of patented plants and animals. Similarly, in one country in which diagnostic, therapeutic and surgical methods for the treatment of humans or animals are not excluded from patentability, the law of that country provides exceptions and limitations to the activity of medical practitioners related to the treatment of humans and animals (see Section XI below).

## **SECTION II: PRIVATE AND/OR NON-COMMERCIAL USE**

Replies overview:	Total replies	72
	Statutory exception	51
	Exception by case law	1
	No exception or no answer	17
	Unclear or similar exception	3

8. Out of 72 responses, 51 responses indicated that they provided exceptions and/or limitations related to private and/or non-commercial use. Seventeen responses indicated that they did not include such an exception in their national legislation or provided no answer. One Member State does not provide for such a statutory exception, but excludes non-commercial activities from enforcement of patent protection by common law. Three other Member States referred to different mechanisms, such as the scientific and research exception, and/or compulsory licensing for non-commercial purposes in this context.

9. Member States provide for statutory exceptions and limitations for private and/or non-commercial use exceptions in different ways. In some Member States, the right conferred by a patent is primarily defined as the right to prevent others from using the patented invention for specific purposes, for example, for "commercial purpose", for "industrial or commercial purposes", for "production or business purposes", "for profit or for professional purposes", for exploiting "the invention commercially or operationally", for activities "in or for his business" or for working "the patented invention as a business". Consequently, by definition, private use and non-commercial use are excluded from the scope of the right.

10. Most of the Member States, however, provide for a patent right which is encompassing all kinds of activities, but provides for an explicit exception from patent protection, for example, for "private use", "private and non-commercial use", "personal needs with no purpose to make profits" or "use for private non-profit-making purposes". Some of those Member States do not

distinguish between private use and academic research, and provide for exceptions for activities in the “private sphere and for non-commercial purposes, for experimentation, scientific research or teaching purposes”, “use of the invention for personal, family, domestic or other non-business needs” or “use in the private or academic sphere and for non-commercial purposes, carried out purely experimental scientific or technological research, testing or teaching activities”. Two Member States distinguish between the scale and purpose of the activity, but both Member States provide exceptions alternatively for both types of activities, such as done “privately and on a non-commercial scale or for a non-commercial purpose” or pursued “not on a commercial scale and [...] commercial in character”. Another Member State extends the private use exception to the submission of information required by law, for example excluding activities “on a non-commercial scale and solely for purposes reasonably related to the obtaining, development and submission of information required under any law”.

11. Some of the Member States provide for such an exception for private and non-commercial use only under the condition that such a use does not constitute a prejudice to the right of patent holders, such as “unjustifiable harm”, “undue harm to the legitimate interests of the patent holder”, “prejudice the economic interests of the patent holder”, “significantly prejudice the economic interests of the owner of the patent”, or “unreasonably conflict with a normal use of the patented invention and does not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”. Further, one Member State noted that the private and non-commercial use had to be understood in a broad sense. In one Member State, the exception for private and non-commercial use applies only with respect to “patents granted for plants and plant varieties”. One Member State informed that the exception was not included in statutes, but provided by common law as a “non-commercial use defense”. Most of the Member States, however, did not refer to case law.

12. Very few Member States provided information about the definition of the expression “non-commercial activities” in their jurisdiction. Some of those Members States are interpreting commercial activity in a general manner, by the ordinary meaning and mostly in a wide sense, in the light of intellectual property laws. Some others are using the conceptual definitions provided by other laws, such as civil law and tax law. Those Members States which provide for a definition use concepts relating to commercial activities, mostly referring to activities for making profit, for example, as “an economical activity of certain duration, following a unitary concept and suited for repetition, which - without necessarily being acquisitive - does not only serve the satisfaction of personal needs”, “business activity shall be an independent activity conducted at one’s own risk, aimed at systematically deriving profit from the use of property, sale of goods, performance of work or rendering of services by persons registered in this capacity in the prescribed legal process”, “any activity related to a patent as a subject-matter of right or in relation to an invention as the subject-matter of a patent, performed by the owner or any other authorized person with the purpose of making profit”, or “performance of an activity in a professional manner either permanently or on a regular basis, if it aims at, or results in, achieving any value, and it is delivered in an independent way”. In one Member State, the term is not defined, but widely understood as activities for the “purposes of industrial or agricultural production, or for commercial purposes” independently from “being profitable or not”, nor being a “profitable or non-profitable entity”. In two Member States, case law excludes “experiments done for legal proceedings” and “work done in laboratories”, while in another Member State, “universities and governmental/ administrative activities” are included in the concept of commercial activity. One Member State considered that, in the absence of a definition, “in ruling such a case, a court would conduct itself by provisions of the TRIPS Agreement and the Paris Convention for the Protection of Industrial Property.”

13. Other Member States provide for a definition of the concept of non-commercial use, for example, as “unprofitable private use, such as exploitation of the invention for a home purpose”. One Member State noted that “if the material will be distributed for free (not to mention, if offered for sale) to potential clients of the patent holder, then such activity will be considered as

a business activity.” Private use is defined in another Member State as “use of an invention for private, family, domestic, or other needs unrelated to business activity, where the purpose of such use is not to derive profit or revenue.”

14. Referring to other criteria that determine the scope of the exception, further to the criteria already enumerated, one Member State stated that the scope of the exception is limited to activities which do “not significantly prejudice the economic interests of the proprietor of the patent”. It points out that the “actions stated in this Article shall be subject to the condition that those actions do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties”. In one Member State, the patent law clarifies that “the requirement for non-commercial and private use must be cumulatively met.”

15. The majority of policy objectives pursued by the private and non-commercial use exception are related to balancing legitimate interests. Many Member States emphasized the need to establish a balance between private use and commercial use by, for example, establishing a “balance of interest between private use and commercial use” or “reasonable balance of interests between right holders and the society at large”. Other Member States noted that the economic interests of the patent holder were not affected by this exception. It was considered that private use, for example, did “not prejudice the normal exploitation” or “did not harm the right owner”. Similarly, one Member State considered that, while the objective of patent protection was to “develop industries, to provide the exception of private or theoretical working of a patented invention is legitimate.” One Member State considered that extending enforcement of patents to the individual use of patented inventions at home, which went beyond business use, was excessive with regard to the actual social conditions.

16. Other Member States highlighted different aspects of that balance in their policy objectives, in particular, promoting private and academic activity and creativity, not hindering personal and family use and fostering research and teaching as well as dissemination of knowledge. Further, it was noted that the exception was aiming at “eliminating barriers to trade, protecting the strictly personal or family individual right of use and stimulating scientific research and teaching” and “encouraging private initiative, principally learning, in colleges and universities”, and stated that activities in the private or academic sphere and for non-commercial purposes promoted and fostered inventive industrially applicable activity. One Member State considered as an objective of the private and non-commercial use exception that “patents are not intended for intervention in the private sphere.” The “dissemination of technological knowledge within the productive and academic sectors” was quoted by another Member State. It was considered by one Member State that “members of the public have an interest in unfettered access to the protected results of intellectual activity.” For another Member State, it “should be possible to carry out minor activities without hindrance by the threat of patent infringement.”

17. Some other Member States stated that the objectives for providing this exception were to conform with current or future international or regional law, such as Article 30 of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement), Article 27 of the Agreement on Community Patents 1989 (not entered into force), or other EU law. Further, one Member State stated that extending patents to private and non-commercial use would not correspond with the objective of patent protection as an award for the “contribution to the state of the art”. Another Member State stated that it sought *inter alia* to “promote research and avoid abuse of rights in cases of non-commercial (private) use”.

18. Most Member States stated that the applicable legal framework of the exception was considered adequate to meet the objectives sought or provided no answer to this question. Those countries currently do not foresee any amendments to their legislation. One Member State noted that it was carrying out an evaluation on the implementation of the private and non-

commercial use exception “with a view to assessing its usefulness in light of the objective of ensuring a balanced patent system”. Another Member State noted that the statutory legal frameworks “may be subject to revision” in the future, but considered it adequate at that moment. One Member State stated that since there were “no definitions which indicate clearly the scope and content of the exception, it would be advisable to amend the current legal framework”. In another Member State, no study had been undertaken, but it was estimated that, “probably due to the existing level of R&D activities in the country, the exception had not been practically tested”.

19. Many countries stated that no challenges had been encountered in relation to the practical implementation of the exception. With reference to challenges, one Member State referred to case law and the difficulties in distinguishing private or commercial use in cases of activities with “dual purpose”. In those cases, the private use defense would not apply if one of the purposes of those activities was “commercial in nature”.

### **SECTION III: EXPERIMENTAL USE AND/OR SCIENTIFIC RESEARCH**

Replies overview:	Total replies	72
	Statutory exception	61
	Exception by case law	2
	No exception or no answer	9

20. Out of 72 responses, 61 responses indicated that the applicable laws provided for exceptions and limitations related to experimental use and/or scientific research. Nine responses indicated that the applicable laws did not include such an exception in their national legislation or provided no answer. Two Member States do not provide for such a statutory exception, but exclude experimental use and/or scientific research activities from enforcement of patent protection by common law.

21. In most Member States, the right conferred by a patent exempts the enforcement against, for example, activities for “experimental or research purposes”, acts “performed merely for experimental purposes relating to the subject matter of the invention”, activities “only for experimental purposes”, acts “carried out for experimental purposes in the course of scientific and technical research”, or activities for “making or using for purely experimental purposes or for scientific research”. Two Member States already exclude experimental use and scientific research from the scope of the right conferred by a patent, for example, by providing that the “exploitation by experiment relating to the subject matter of the invention for experimental purposes shall remain outside the scope of rights conferred by the patent”.

22. Member States provide for such statutory exceptions and limitations on experimental use and/or scientific research in different ways. Some Member States clearly relate the research exemption to the invention itself by providing, for example, the exemption of the “use in experiments relating to the invention as such”, or “conducting scientific research or experiments on the patented tool (in order to test it, and assess its effectiveness for scientific purposes, etc.)”. Another Member State further emphasized the aspect of development in research by exempting “research and development activities”. Similar to the exemption for non-commercial use, one Member State provided that “protected rights extend only to acts done for industrial or commercial purposes and in particular do not extend to acts done only for the purpose of scientific research.”

23. Other Member States include the validation of studies or trials and the use in administrative processes, for example, through exempting acts with “purposes of a scientific research, experimental study and its validation”, activities “done for experimental purposes including experiments and tests required under a special regulation before the drug is put on the

market”, or “acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorization.” Another criterion for the research exemption in many Member States is that the activities are only exempted if their purpose is exclusively experimental, by providing, for example, “exclusively for trial or experimental purposes”, “solely serving for research on the patented subject matter, including the product obtained directly as a result of using the patented process” or “done only for research and experimental purposes relating to a patented invention.”

24. Some Member States include academic teaching in the research exemption, for example, “experimentation, scientific research or teaching purposes”, “education, research, experiment, or analysis”, “search and experimental purposes, for the evaluation thereof, analysis or teaching”, or “purely experimental scientific or technological research, testing or teaching activities”. One Member States highlighted the aspect of improvement of inventions, by exempting the “experimental act in connection with the invention, the objective of which is to improve the invention or to develop another invention”.

25. Some Member States require that the research exemption does not violate the legitimate interests of the patent holder, for example, not “unjustifiably harm the normal working of the patent, or cause undue harm to the legitimate interests of its owner or its licensee, as long as it does not harm the normal interest of the patent holder” or limiting the exemption “as long as it does not harm the normal interest of the patent holder”.

26. One Member State stated that case law demonstrated that “there is a judicially recognized research exception but no case to date has clearly set out the scope of this exception.” However, it should be for the “ultimate objective of the research which determines whether or not the use of a patented invention for research or experimental purposes infringes a patent.” According to the response, while “non-commercial research would not infringe” patents, it was not clear where the boundary between “commercial” and “non-commercial” research” was by considering the case law. Another Member States provides for such an exception in case law but restricts it further by providing that “any use which has the slightest commercial implication or is in keeping with the legitimate business of the alleged infringer cannot qualify for the experimental use defense.”

27. As regards the nature of the organization conducting research, most of the Member States stated that they did not distinguish “the nature of the organization conducting the experimentation or research”. Two Member States further clarified that “it is the activity which is distinguished” and that the exemption “applies to all experiments relating to the subject matter of the patented invention, irrespective of the aim of the experiment, and of the person or organization conducting the experiment”. Another Member State added that, “if what an organization engaged in production and business does is just to carry out research and experiment on the patented technology itself, one could apply this exception, and consider such acts as not infringing the patent. But if such organization uses a patented technology for other projects of scientific research, it would not fall within the scope of this exception, and would constitute patent infringement.” One Member State specified that the only explicit reference in the provision to the nature of the organization was “academic research”. However, despite the lack of such a distinction, one Member State emphasized that “the government will actually check and control the organization”. In two Member States, the research exemption only applies “in the ‘private or academic’ sphere and for ‘non-commercial purposes’”. The “nature of the use (whether ‘non-commercial’ or ‘commercial’)” determines “whether a particular use is experimental” but it was stated that “the boundary between ‘commercial’ and ‘non-commercial’ use is unclear”. One Member State stated that, while its law did not specify the nature of the organizations which may enjoy the exception, as a matter of fact, acts done for teaching purposes were mostly carried out in educational and research institutes in the public sector and in a few other not-for-profit institutions. In one Member State, “activities infringing a patent only fall under the exception if it can be proven that this research is indeed scientific or that this

research parallels the objectives of the [national patent legislation]”. In another Member State, it follows from case law that “the exception may apply to commercial organizations”.

28. In the vast majority of Member States, the concepts of experimental use and/or scientific research are not defined by the law. One Member State stated that “in the accompanying parliamentary papers, research was explained to include scientific research, also in or for the business”. Another Member State highlighted that “a court would conduct itself by provisions of the TRIPS Agreement and the Paris Convention for the Protection of Industrial Property”. The applicable law of one Member State defines “experimental and development works” as an “activity based on knowledge acquired as a result of conducting scientific research or derived from practical experience, and aimed at preserving life and human health, creating new materials, products, processes, devices, services, systems or methods, and developing them further”. While that law does not provide a legal definition of the concept “scientific experiment”, that Member State explained that a scientific experiment meant a “method of learning which can help in investigating real phenomena under controlled and managed conditions”. It further stated that “the distinction between scientific research and experimentation is that with research, study is undertaken of the subject matter in its pure form (without any additional influence thereon), whereas with experimentation, the subject being studied is placed under certain conditions, i.e., under a certain influence from external forces.” In one Member State, it is clarified that “the studies and the tests carried out to obtain authorization for generic medicines, either in the Member State or abroad,” and the acts to comply with “subsequent practical requirements, including preparation, obtaining and use of the active element for such purposes” were part of the exception.

29. One Member State noted that according to the “case law providing guidance”, “trials carried out in order to discover something unknown, or to test a hypothesis, or in order to find out whether something which is known to work in specific conditions will work in different conditions can fairly be regarded as experiments”. However, trials carried out in order to demonstrate to a third party that a product works or in order to amass information to satisfy a third party are not to be regarded as acts done “for experimental purposes”. Where “a patented pharmaceutically active substance is used in clinical trials with the aim of finding whether and, where appropriate, in what form the active substance is suitable for curing or alleviating certain other human diseases”, it is considered as a legitimate act for experimental purposes. However, in another case, the court “considered that there must be an outward limit to that principle”, and held that the application of the principle should involve the consideration of whether the immediate purpose of the transaction was to generate revenue. The clinical trials in question were not considered to be exempted [...] since one of the purposes of the trials was to ‘generate immediate revenue of a substantial character’. It follows that commercial factors must be considered in determining whether the exception applies”. In another case, it was held that “experiments for the purposes of litigation are exempted [...] if they relate to the subject matter of the invention found in the claims of the patent alleged to be infringed, in the sense of having a real and direct connection with it.” In another Member State, according to its case law, as long as “the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative”.

30. As regards the determination of the scope of the exception, in some Member States, all of the purposes enumerated in the questionnaire, such as the purpose to determine how the patented invention works, determine the scope of the patented invention, determine the validity of the claims, seek an improvement to the patented invention, invent around the patented invention, are relevant. Many Member States referred only to some of those purposes. Some Member States referred to other purposes, such as “academic or teaching” purposes or “improvement of the patented invention or developing a new one”. In another Member State, the “exception includes any experimental purposes, in particular, tests necessary for the



marketing authorization of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention". One Member State noted that neither of the criteria was relevant. Finally, one Member State aimed to cover "non-commercial experimental purposes" with a "very broad definition without any restriction".

31. With regard to the question as to whether the experimentation must be conducted on the patented invention or conducted with the patented invention, some Member States apply both criteria, i.e., "research on" and "research with" the patented invention. For example, one Member State noted that the "patent owner's exclusive right of exploitation of the invention shall not apply to acts done for the purposes of research and development and for experiments relating to<sup>1</sup> the subject-matter of the protected invention". Some other Member States, which count roughly the same number of Member States that applied both criteria, only applied the research exemption to "research on" the patented invention. For example, one Member State, referring to its Statute, stated that "conducting experimentation on a product in which an invention is incorporated involves two situations: (i) where experimentation is conducted on such a product in which an invention is incorporated [...]; (ii) where experimentation is conducted directly on the invention itself, since it also falls under the definition of a product in which every feature of the patented invention is incorporated [...]. Accordingly, the first criterion, 'research and/or experimentation must be conducted on the patented invention', is relevant to the determination of the scope of the exception". No Member State used the criterion of "research with" as a single criterion. None of those criteria was determinative in many Member States, since, for example, the law "contains no requirement to consider the above criteria in determining the scope of the exception".

32. With respect to the relevance of the commercial or non-commercial intention of the experimentation and/or research to the determination of the scope of the exception, most Member States provided no answer. Among those Member States that provided information, most stated that the commercial intention of the experimentation and/or research was not relevant. Some Member States only cover activities relating to non-commercial purposes. One Member State stated that it only covered activities with commercial purposes. One Member State referred to case law which covered "experimental work having a commercial purpose, but not all trials for a commercial purpose". Thereby, the exception is excluded if experiments were to "generate immediate revenue of a substantial character". One of those Member States which only covered activities for non-commercial purposes, however, allowed "research on a patented invention for licensing purposes".

33. Among those Member States that cover non-commercial activities only, most of the Member States do not provide for definitions that distinguish commercial and non-commercial purposes. One Member State stated that there was no distinction or definitions in conceptual terms, but it was interpreted "according to the economic sphere" and a "perception of a gain". Accordingly, "when economic remuneration is not received," the activity is considered to be in the "non-commercial sphere". Some Member States referred to case law noting that, for example, this "is likely to be considered on a case-by-case basis". Another Member State noted that, "according to case law, research on a patented invention for licensing purposes was allowed. Furthermore, also commercial organizations may benefit from the research exception". In another Member State, the concept is defined by case law as "any use which has the slightest commercial implication or is in keeping with the legitimate business of the alleged infringer cannot qualify for the experimental use defense." One Member State noted that the exception "shall be assessed strictly and may apply only to the experimental acts, the aim of which is to

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<sup>1</sup> In this country, the expression "related to the [patented] invention" found in its law covers both research on and with the patented invention. However, it is not clear from the responses to the Questionnaire whether that expression found in national laws of other countries is interpreted in the same manner or not.

participate in the verification of the technical interest of the invention or its development in order to advance knowledge, and not to commercially-oriented acts.”

34. In most Member States, the public policy reasons for the research exemption are the promotion of research and science. Emphasis was put, for example, on the “promotion of scientific research and economic development”, “promotion of R&D”, “freedom of scientific research” and “to encourage inventiveness, educational promotion and scientific research in order to benefit mankind”. One Member State mentioned “generating research from patented inventions and allowing experimentation on the subject matter of the patented invention”. Some Member States highlighted the necessary balance by limiting “rights granted by a patent in order to allow the development of scientific or technological research, thereby striking the right balance between them”. It is considered that a patent is granted for disclosure of the invention, and as part of the balance, “an experimental use exception permits other individuals to investigate that invention, making use of that disclosure.” Another Member State explained that, with reference to that balance, “scientific and technological innovations are always carried out on the basis of prior art” and therefore, “if use of relevant patents for scientific research and experimental purposes would be only possible with prior consent by the patent right holders, it may hinder the research and development process, and would thus not be conducive to scientific and technological progress, and contrary to the legislative purpose of patent laws.” Further, it was noted that the research exemption contributed to the “dissemination of information”.

35. Other Member States mentioned at the “alignment with Article 27b of the Agreement relating to Community Patents, 1989”, the “harmonization of national patent law with the laws of member states of the European Union” or they referred to the “TRIPS Agreement” or the conformity with their constitutional law. Some Member States stated that the research exemption aimed at verifying the “technical interest of the invention, to measure the scope thereof or to improve it and not to seek the commercial impact of the product or process”. Another Member State noted that the “provision was intended to prevent patent protection from hindering research and technological development” which would be contrary to its initial objective. Another Member State noted that “as long as a product developed based on the results of the working of the invention is not put on the market, the patentee does not suffer a direct loss”. One Member State referred to a wide understanding of the research exemption and noted the policy interest in enabling “the generic entry into the market in due time, since this can provide patients with quality medicines at reasonable price, and decrease the costs related to the financing of medicines covered by the health scheme of the state”. Another Member State extends the principle of balance of “the interests of generic industries and the interest of innovative industries”. One Member State highlighted that the policy reason for granting the research privilege would apply to basic and applied research. One Member State stated that compliance with the TRIPS Agreement was one historical reason for this legislation. Another Member State highlighted that the purposes of its patent law were “the promotion of national creativity, attraction of investment, promotion of trade, protection of consumer interests and integration of the national economy into the knowledge driven global economic environment”.

36. For most Member States, the applicable legal frame work is adequate. Some Member States further highlighted that this exception was not part of any ongoing discussion or had never been an issue. One Member State referred to a recent major reform of its patent law, which made any further amendment in this respect quite improbable. In one Member State, the experimental use exception was the subject of a recent consultation. It stated that “the purpose of this consultation was to seek evidence on the effect of the patent research exception and to identify the extent of stakeholder concerns on this aspect as a number of reports had concluded that clarification or restructuring of the research exception was needed”. In particular, it was noted that the lack of case law might lead to uncertainty over the scope of the experimental use exception. However, no conclusive evidence was provided in the consultation responses to indicate that the existing experimental use exception was restricting research, and “the absence

of clear evidence did not support a change in legislation”. However, following the consultation, two areas which do not strictly concern the experimental use exception, namely, the risk of patent infringement during clinical trials and the use of patented plant material by plant variety breeders, are the subject of further investigation and monitoring.

37. In relation to the experimental and/or research exception, two Member States have been reforming their law. One Member State noted that the current legal framework relating to experimental use of patented inventions was not considered adequate, as there was considerable uncertainty as to what did or did not constitute experimental use. A new Bill containing an explicit experimental use exception, namely, “determining how an invention works, determining the scope of an invention, determining the validity of the claims and seeking to make an improvement to the invention (for example determining new properties, or new uses of the invention)”, is currently before the parliament. The amendments are designed to clarify that research and experimental activities relating to patented inventions are exempt from infringement, whereas commercial activities are not. The Bill defines that “experimental purposes relating to the subject matter of the invention include, but are not limited to, the following: (a) determining the properties of the invention; (b) determining the scope of a claim relating to the invention; (c) improving or modifying the invention; (d) determining the validity of the patent or of a claim relating to the invention; (e) determining whether the patent for the invention would be, or has been, infringed by the doing of an act”. In another Member State in which the current patent legislation does not contain a statutory experimental use exception, a new Bill before the parliament contains such an experimental use exception. One Member State intends “to revise the current Law in the medium term”.

38. Most Member States have encountered no challenges in relation to the practical implementation of this exception. Referring to challenges, one Member State noted that an amendment of the applicable law “introduced a specific exception for the bioequivalence tests in the field of medicines with a view to promoting the generic medicines” providing that “the rights conferred by patents shall not extend to: the studies and tests required with a view to obtaining marketing of a medicine, and also for the acts necessary for their production and obtaining the authorization”. In another Member State, while “commentators have expressed concerns that the lack of case law may lead to uncertainty in this area and have called for legislative change”, no problems with the practical implementation of the exception had been found.

#### **SECTION IV: PREPARATION OF MEDICINES**

Replies overview:	Total replies	72
	Statutory exception	34
	No exception or no answer	37
	Unclear or similar exception	1

39. Out of 72 responses, 34 indicated that the applicable law provided for exceptions and/or limitations related to a preparation of medicines through statutory means. Thirty-seven responses indicated that the applicable law did not include such an exception in their national legislation or provided no answer. One Member State, while responding that its applicable law did not provide for such an exception, referred to the government use for public health reasons.

40. Member States provide for such statutory exceptions and limitations relating to the preparation of medicines in different ways. Many Member States exclude “the extemporaneous” preparation of a medicine in a pharmacy according to a medical prescription from the scope of the rights conferred by a patent. Other Member States refer to “individual”, “single”, “occasional”, “direct” or “once only” preparation of such medicines. One Member State’s law stipulates that preparations of medicines in pharmacies “involving no mass production” and carried out “solely” in making up a prescription remained outside of the scope of

the rights conferred by the patent. In addition, most Member States also exclude “acts”, “treatment” or “procedures” relating to the medicine so prepared. In one Member State, the rights of the patentee shall also not apply “to the placement of such drug on the market”. In another Member State, the preparation of a medicine “for subsequent storage and sale” may not be considered a single use, and therefore, be regarded as an infringement of the patent holder’s exclusive rights. Similarly, the law of another country states that such use of the patented invention is covered by the exception, provided “they do not use active ingredients made in industrial mode”.

41. The question of the entitlement to use the exception was responded differently by Member States. In one Member State, the exception covers “anyone entitled to prepare this kind of medicinal products”, while in another country, it covers “authorized” personnel in the pharmacy. In some countries, “pharmacists” or “chemists” who prepare the medicine at the pharmacy are entitled to use the exception. Others mention only “doctors” or “physicians”. Other countries entitle both doctors and pharmacists to use the exception. One Member State, in addition to the above two categories of professionals, mentioned the “persons for whom the medicine is prepared”. Two Member States’ national laws expressly included dentists in addition to physicians. In many Member States, the entitlement was not expressly stated in the law.

42. In many countries, the applicable law does not provide for any limitations on the amount of medicines that can be prepared under the exception. However, some countries emphasized that the exception covers “one-off”, “individual”, or “extemporaneous” preparation in pharmacies. One Member State noted that the “physician is not restricted by the number of prescriptions that he may write for the same medicine to many patients”.

43. Many Member States did not respond to the question on public policy objectives of the exception. However, those who answered highlighted the importance of the balance between the interest of the right holders and the users of those rights and protection of public interests. In particular, for one Member State, the exception was considered to “contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and conducive to social and economic welfare”. It was stated by many Member States that pharmacists should be free to make individual medical preparations as prescribed by a doctor without being exposed to the risk of infringing a patent. That would allow, for example, “to facilitate the exercise of medical activities”, “to meet the social mission of the medicine”, “the protection of human health and assurance of access to medicines”. In addition, one Member State noted that the provision was to supplement the prohibition of patent protection of methods for treatment of the human or animal body by surgery or therapy. Another Member State considered that the policy objective was “to provide patients with low cost, quality medicines” and to “decrease the spending of the state health scheme”. Some Member States emphasized that the exception concerned minimal quantities and was exercised “in extreme situations when it is necessary to administer urgent medical help” so that “it is not prejudicial to the normal exploitation of the patent”. Similarly, while considering it inappropriate for the effect of the patent right to extend to an act of preparing a medicine, two Member States stated that the “medicine itself was generally deemed to be prepared by a medicine manufacturer with a patent license granted, and legally sold by a physician or a dentist”. Among other policy objectives, two Member States mentioned the harmonization of national laws with the law of other countries.

44. All Member States who responded to the question as to whether the legal framework of the exception was adequate to meet the objectives sought replied positively. In this regard, two Member States noted that the exception was not in use, since preparation of medicines in pharmacies was no longer common in their countries. Nearly all countries responded that no challenges were encountered in relation to the practical implementation of the exception.

## SECTION V: PRIOR USE

Replies overview:	Total replies	72
	Statutory exception	61
	No exception or no answer	10
	Unclear or similar exception	1

45. Out of 72 responses, 61 indicated that the applicable law provided for exceptions and/or limitations related to the continued use of patented inventions by prior users (prior use exception). Ten responses indicated that such an exception was not contained in their law or provided no answer. In one Member State, the situation highlighted in the questionnaire was unclear.

46. Many countries allow a third party to continue using a patented invention if he had used the invention for the purpose of his business in good faith before the filing date (or the priority date) or had made effective or serious preparations for that purpose. However, Member States provide for such statutory exceptions and limitations on prior use in different ways.

47. In most Member States, the legal effect of patent protection is *a priori* “limited” or it is impossible to enforce a patent in case of prior use, for example, by providing that a “patent shall have no effect on persons” which have used the invention prior to the filing date (or priority date) or may not “be enforced against” such persons“ or “are not opposable” in the territory of that Member State. In some other Member States, the prior use exception is formulated as a right, providing, for example, “the right, in a personal capacity, to work the invention, despite the existence of the patent”, “the right to perform the acts referred to [...]” or that a prior user is “entitled to utilize” the patented invention. One of those Member States clarified expressly that the prior user was only “personally entitled”. In two other Member States, the continued use of the patented invention by prior users is not an exception to the patent rights *stricto sensu*. Their laws provide that such prior users “shall have a non-exclusive license on the patent right” without any remuneration to be paid to the patentee.

48. As to the scope of the activities covered by the prior use exception, for most Member States, it is sufficient that the person “was using the invention or was making effective and serious preparations for such use”. The preparatory works for the use of an invention are included in the prior use in the majority of Member States which provide the prior use exception, for example, by including the “necessary preparatory works” or “effective and serious preparations”. Some Member States require that the “person was exploiting the product, method or process in the patent area; or had taken definite steps (contractually or otherwise) to exploit the product, method or process in the patent area.” For another Member State, the decisive criterion is the “possession of the invention”. In many Member States, the prior use exception is limited to prior use activities on its own territory. In another Member State, the prior user is not liable to the patentee if he “has purchased, constructed or acquired the subject matter defined by the claim”. In some Member States, it is clarified that prior use has to be for “business purposes”, “in his enterprise or business” or “in or for his business”. One Member State expressly provides the prior use of products and methods, covering “any other person [who] has already manufactured identical products, used identical method or has made necessary preparations for the manufacture or use”.

49. Most Member States require that, as one of the additional conditions, the activity of prior use has been carried out “independently of the inventor and has used it *bona fide*”, or “took measures necessary for such use in good faith”. In one Member State, good faith is defined as “without knowledge of the content of an invention claimed in a patent application”. In some Member States, it is further necessary that prior use is exploited “independently” or “regardless from the author”. One Member State noted that “independence is demonstrated through the

independent nature of the prior user's creativity: meaning that the solution had not been developed on the basis of descriptions and drawings of the person who obtained the patent". One Member State's law stipulates that "a person may not assert a defense under this section if the subject matter on which the defense is based was derived from the patentee or persons in privity with the patentee". In another Member State, the prior use exception exists "provided that the general nature of such previous exploitation is maintained and that the exploitation does not constitute an evident abuse". One Member State explicitly specified that the prior use exception "does not apply if the knowledge is the result of unlawful or immoral acts against the patentee" and it explained that "the burden of proof lies with the person invoking" the prior use. Similarly, in one Member State, the prior user "shall have the burden of establishing the defense by clear and convincing evidence". However, in another Member State, the burden of proof is alleviated as "in case of doubts, action of a prior user shall be considered acting in good faith unless proved otherwise".

50. With regard to the date for establishing the prior use exception, most Member States refer to the date of filing, while some Member States refer to the priority date. In one Member State, the date of prior "commercial use occurred at least one year before" the filing date or date of disclosure of the invention. It further explained that "subject matter for which commercial marketing or use is subject to a premarketing regulatory review period during which the safety or efficacy of the subject matter is established [...] shall be deemed to be commercially used". Another Member State distinguishes between national and regional patent applications, and for regional patent applications, prior use shall be carried out "before the date on which a notification of the corrected translation has been entered in the patent register".

51. In some Member States, the prior user's right does not allow for an extension of the business beyond its scope on the relevant date. For example, the prior user shall not "extend the volume of production existent or planned at the day of filing or of the priority" or "the scope thereof is not extended". In one Member State, it is specified that "the defense asserted by a person under this section is not a general license under all claims of the patent at issue, but extends only to the specific subject matter for which it has been established that a commercial use that qualifies under this section occurred, except that the defense shall also extend to variations in the quantity or volume of use of the claimed subject matter, and to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent". One Member State specifically clarified that the prior use exception ceases with abandonment of use by providing that "a person who has abandoned commercial use (that qualifies under this section) of subject matter may not rely on activities performed before the date of such abandonment in establishing a defense under this section with respect to actions taken on or after the date of such abandonment."

52. As regards the scope of this exception, many Member States noted that the scope of use is "not defined by the applicable law." Despite the above-mentioned statutory criteria defining the scope of use, most of those Member States which provide for an explicit definition of the scope of use refer to the commercial exploitation of the invention, such as "the right to use and sell to others", the "making, using or any preparation" or the "working or preparing working of the invention". One Member State defined the scope of use as "manufacturing a product with the use of a patented invention (utility model), the use of this product, an offer of a product for the market, including an offer via the Internet, selling, import (coming-in) and other its introduction into the commercial circuit as well as storing a product for defined purposes". Another Member State defines the use as to "make, hire, sell or otherwise dispose of the product" and "in relation to a method or process" to "use the method or process" or to do an act as described before "with a product resulting from the use of the method or process". Such use is limited in most Member States, for example, a limitation of the use to "only to the extent of the invention and the purpose of such business worked or prepared" or "exclusively for purposes and in volume corresponding to its purposes and volume of its past use or preparatory works, up to the date of

filing or establishment of priority.” One Member State stated that the use “has to be carried out like a ‘trade-secret’” under the condition that “such use is not extended.”

53. One Member State noted that, in relation to the scope of the prior use defense, “the act in question must constitute infringement of the patent, such person, acting in good faith, commercially used the subject matter [in the territory], either in connection with an internal commercial use or an actual arm’s length sale or other arm’s length commercial transfer of a useful end result of such commercial use; and [...] such commercial use occurred at least one year before the earlier of either [...] the effective filing date of the claimed invention; or [...] the date on which the claimed invention was disclosed to the public.” In another Member State, the term “use” means the “use of the invention in good faith (good faith of the user comes from either his developing of the same invention independently of the holder of the patent, or the user’s believe that he can freely use a given technical solution).” One regional patent office noted that the term “use” was defined under “national laws of Contracting States”.

54. With respect to quantitative or qualitative limitations of the use, most Member States do not provide for such limitations or did not provide any answer. Some Member States provide for such limitations, for example, by stating that “if the actual output is below that expected for manufacture, the quantity produced with the existing equipment is considered as within the original scope”. Continued manufacture or use must be kept within this original scope. Further, in one Member State, the prior use is “territorially limited” and “it can be concluded that use of medicines by the manufacturer in clinical trials in hospitals does not fall within the scope of the exception”. In a few Member States, the prior user right is limited by the concept of “evident abuse”.

55. The vast majority of Member States does not require any remuneration, stating, for example that the user “retains the right to further non-compensated use”, that the “exception to infringement is absolute”. Some Member States, however, clarified that the principle of non-remuneration applied only “within the existing scale” or without “enlarging the scope” of prior use. In one Member State, there is an exception with respect to regional applications where the claimed invention was used “after the filing or priority date, but before grant of the patent”, in which case “the patentee may demand a reasonable compensation”.

56. With reference to assignment or licensing of prior user rights, in nearly two thirds of the Member States and in one regional patent office, the right could be assigned and/or licensed. In some of those Member States, the right could only be assigned, but not licensed. In the rest of the Member States, the right could be neither assigned nor licensed. In the vast majority of those Member States which allow for assignment and licensing of the prior user right, the condition is that the right has to be transferred together with the business, for example, providing for the transfer together with “that part of the business”, “the entire enterprise or business to which the defense relates”, “the production unit”, “the enterprise or business practice”, “business where it originated or where the exploitation was intended to take place”, “assignment or transfer of ownership of a company or its part”, “business establishment in which use is made”, “enterprise or its activities or with that part of the enterprise or its activities”, “working process and production plant” or “firm or establishment in which such production or use was being carried out or had been planned”. In one Member State, the transfer shall take place together with the “enterprise that manufactures identical products or uses identical manufacturing method, or together with the part that involves the manufacturing of identical products or the use of identical manufacturing method, or together with the enterprise or a part of it that is supposed to engage in such production or use”. In one Member State, the transfer is further restricted to a transfer “during the user’s lifetime or by hereditary or testamentary succession together with his enterprise or business, or with that part of his enterprise or business”. In addition, in some other Member States, the conditions are either the “consent of the patentee” or the “transfer together with the underlying business” or through “inheritance or other general succession”. In one Member State, a distinction is made between the prior user

right of an individual, which can be assigned or transmitted on death, and the right of a corporate body which can only be transmitted upon the body's dissolution.

57. Concerning situations where a third party had been using the patented invention or had made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent, some Member States responded that they provide for such an exception. However, many Member States do not provide for such an exception. In a few Member States, the law is silent or the situation is unclear. In one Member State, the right to "subsequent use" requires that "unlike the right of prior use, it may not be transferred to another person together with the enterprise". Further, the subsequent use has to be "undertaken during the period when the relevant subject matter was in the public domain", and "must not be extended by the subsequent user".

58. With regard to the conditions for the use of the exception, the majority of the responses did not mention further criteria beyond those already mentioned in the preceding paragraphs. One Member State noted that the prior use was "subject to the condition that those actions do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties". Further, according to one Member State, the activities should be "used in the territory of the country and within the framework of the continued user's economic activities".

59. As regards the policy objectives for providing for the exception, many Member States mentioned balance, fairness or limitation and reconciliation of rights, for example, the "balance between the rights of the patentee and those of the third party" as "the grant of a patent should not deprive a party from continuing to do what they were doing before the patent was granted" and that "an inventor should not be deprived of patent protection by the secret acts of third parties, of which they can have no knowledge." The exception intends to "help avoid unfairness that exists in real life, arising from the fact that the entities or individuals who have invested human and material resources in the creation of the invention are not able to exploit their own intellectual achievements just because they have not filed any patent applications beforehand. It is to be noted, however, that the party who enjoys such a right of prior use can only continue his production and exploitation within the original scope, and any production or exploitation beyond that scope would constitute patent infringement." It is also considered by one Member State that "whatever the reasons were for the prior user [...] to keep the invention secret (e.g. no interest in a patent, business strategy, etc.), it is considered unfair if the patent holder could maintain his rights against the prior user." In its view, without a 'prior use' provision, applying for a patent would be a necessity instead of a free choice.

60. Some Member States refer to the establishment of rights, for example, referring to the "principle of acquired rights". In one Member State, that principle is part of its constitutional provisions establishing "fundamental rights". Further, some Member States considered that the exception was aimed "to protect the economic status of possession of the prior user" and "avoiding unnecessary burden on good faith users" They rather emphasized the economic aspects, for example, the "investments that were performed in *bona fide*", the "economic status of possession" or "economic security necessary for investment and exploitation of the invention that was made before the filing of the application", in order to avoid the situation where "the legitimately created values are ruined." It is considered "unfair if a patent holder could prevent products already manufactured in a business prior to the grant of his patent, but not put on the market prior to the grant of the patent". One Member State further noted that it should be possible for the prior user "to continue its use in the same amount without paying royalties." Since "the right of prior use is intended to protect the interests of third parties that have already invested capital in production", it is considered as providing "economic benefits to the society as a whole".



61. Some Member States explained that that principle was a consequence of the first-to-file system, stating, for example, that “if the first-to-file system is strictly applied, it is not necessarily fair that a party which had been working the same invention prior to the filing of a patent application by another party should be precluded from working the same invention of the patent right, just because the party was slightly behind in filing an application. Therefore, even if such a policy is applied, there remains a need to adjust the interests of the patent owner and any party already working the invention in question prior to the patent application.” It is further noted that “it is intended to prevent the destruction of legitimately created values. Investments in existing facilities are not to be devalued by another person’s later patent application.” In the context of acquired rights, however, one Member State clarified that “the right provided would serve as a personal defense to an allegation of infringement and cannot be licensed to others”. The policy objective of conformity with the EPC and harmonization with EU law was mentioned by two Member States. Two other Member States mentioned the objective of fostering creativity, research and technological development. Some Member States stated that the policy objectives of this exception were not defined. One Member State informed that it was in the “process of devising such public policy”. Another Member State stated that, in the absence of such a policy, the principle of acquired rights might be referred to. In addition, one Member State stated that the prior user right was a balancing provision for the “grace period for prior public disclosure of the invention” such that “a person who relies on an unfettered disclosure remains free to exploit the invention despite the grant of a patent.”

62. As regards the legislative history, parliamentary debates and judicial decisions, one Member State noted that “an invention which has been used secretly by one person may be patented by another.” Thus, without the exemption for prior use, “the person who had used the invention secretly would have to stop using it, because the use would be in conflict with the patent right. The prior user’s investments would be lost, and this is unfavorable in the light of community economy.” Another Member State referred to the “accession to the EU and subsequent ratification of International Treaties and Conventions, such as the Munich Convention.” One Member State noted that, since secret prior use was no longer one of the grounds for invalidating patents under the current law, without a prior use exception, a secret prior user would not be able to defend himself against the enforcement of the patent rights on the same invention.

63. The vast majority of Member States considered the applicable legal framework of exception adequate to meet the objectives sought. No amendments are foreseen. Another Member State noted that it was “planned to revise the Law in the medium term.” The vast majority of Member States has not encountered any challenges in relation to the practical implementation of this exception in their countries or “no significant” challenges. One Member State highlighted the challenges a right holder might face through the public disclosure of his invention before the filing date, but during the grace period. It explained that if a third party had started to use the same invention before the filing date, on the basis of the information disclosed during the grace period, the right holder might have practical difficulties in proving that the said third party was not a legitimate “prior user”. Further, a patent applicant who challenges the right of prior use might be affected by any evidence capable of destroying the novelty of his invention.

## **SECTION VI: USE OF ARTICLES ON FOREIGN VESSELS, AIRCRAFTS AND LAND VEHICLES**

Replies overview:	Total replies	72
	Statutory exception	60
	No exception or no answer	10
	Unclear or similar exception	2

64. Out of 72 responses, 60 indicated that the applicable law provided for exceptions and/or limitations related to the use of articles on foreign vessels, aircrafts and land vehicles. Ten Member States replied that they did not include such an exception in their national legislation or provided no answer. Two Member States, while noting that their applicable laws did not provide for such an exception through statutory means, stated that Article 5*ter* of the Paris Convention applied in their jurisdiction.

65. The wording of the provision used by many countries was largely similar and reflected Article 5*ter* of the Paris Convention. In general, most Member States stated that the effect of the patent did not extend to the use of patented inventions on the body of foreign vessels, and to the use of patented inventions in the construction or operation of aircrafts and land vehicles entering their territories temporarily or accidentally. One Member State had a specific provision related to the use of a patented invention in a spacecraft: “the rights conferred by the patent shall not extend to the objects intended to be launched in the extra-atmospheric space” introduced onto its territory. Many countries responded that the use of the invention shall be “exclusively” for or “limited” to the needs of the ship, vessel, aircraft or land vehicle. In addition, some countries provided for other conditions to be respected by the foreign means of transportation, for example, that the patented invention is used “in accordance with the agreement concluded between the country it belongs to” and the country in question, “or in accordance with any international treaty to which both countries have acceded, or on the principle of mutual benefit”. Further, some other countries stated other conditions, such as: the patented invention “is not used for entrepreneurial purposes”, or “is not used for the manufacture of any goods to be sold within or exported” from the country in question. Similarly, in another country, the exception does not cover “the manufacture, offering to sell, or importation of patented products”.

66. In some countries, the foreign means of transportation was allowed from “any country”. In other countries, the reference was made to any of the Member States of the Paris Union or the Members of the WTO. Some Member States’ law provided that the exception applied on a reciprocal basis, i.e., the foreign means of transportation should belong to a country according the same rights to the means of transportation registered in their country. In addition, a few Member States’ national laws allowed the importation of spare parts and accessories for aircrafts without being subject to infringement claims to meet the obligations under Article 27 of the Convention on International Civil Aviation of December 7, 1944 (Chicago Convention). In particular, in those countries, notwithstanding the existence of a patent, spare parts and accessories could be imported into their countries, stored and used for the repair of an aircraft from a foreign country.

67. In most countries, the exception applies in relation to vessels, aircrafts and land vehicles. In some other countries, it also applies to a spacecraft.

68. Many responses did not provide a definition of the terms “temporarily” and/or “accidentally” in relation to the entry of foreign transportation means into their national territory. Two Member States responded that, according to the legal principles, the ordinary meaning of the words should be used. In another country, “temporary passes” implied the fact that such a means of transportation was not operating in that country on a permanent basis. They included provisional entries, i.e., entries on a regular basis, and accidental passes, i.e., passes through its territory due to special circumstances. The court of another Member State has ruled on the meaning of the word “temporarily” according to which the “primary purpose of the word was to distinguish between vessels which were engaged in essentially internal operations, and those which travelled between countries”. Since “the intention for the vessel was to enter and then leave its territorial waters, and the fact that each crossing was repeated frequently did not alter the fact that each entry into its waters was designed to be short-lived”. In addition, the court of another country interpreted the phrase “entering temporarily” as meaning “entering for a period of time of finite duration with the sole purpose of engaging in international commerce.” Thus, it

was stated that a vessel, aircraft or vehicle entering to unload foreign goods and/or to load domestic goods destined for foreign markets was considered as entering "temporarily".

69. The policy objectives pursued by the exception included: "to respect the sovereign rights of nations over their own intellectual property laws", "to ensure that movement of foreign means of transportation is not impeded by threat of patent infringement", "to protect international traffic", and "to respect international obligations under the TRIPS Agreement and the Paris Convention", "to foster creativity and research" and "being in public interest".

70. In nearly all Member States providing for such exception, the applicable legal framework of the exception was considered adequate to meet the objectives sought. In two countries, a revision of the law was envisaged.

## SECTION VII: ACTS FOR OBTAINING REGULATORY APPROVAL FROM AUTHORITIES

Replies overview:	Total replies	72
	Statutory exception	43
	No exception or no answer	27
	Uncertain or similar exception	2

71. Out of 72 responses, 43 indicated that the applicable law provided for exceptions and/or limitations related to acts for obtaining regulatory approval from authorities. 29 responses indicated that such an exception was not included in their laws or provided no answer. The responses from one Member State made a reference to a provision concerning the "mandatory license", and another Member State referred to a general provision on "limitation of the effect of the patent".

72. The Member States provide for such statutory exceptions and limitations relating to acts for obtaining regulatory approval from authorities in different ways. Most of Member States' laws provide a specific statutory provision on this exception. However, in one country, there is no specific provision on a regulatory review exception, but the response referred to experimental/scientific research exception where such exception was understood to be covered. In eleven countries, the regulatory review exception and experimental/scientific research exception is expressly provided in a specific provision. In another country, the exception was not included in the law on industrial property, but in the Regulations on Materials for Health.

73. With regard to the question on the entitlement to use this exception, the vast majority of Member States responded that there were no restrictions as to who might use the exception, as the terms such as "any person", "any party", "any third party" or "any legal person" were found in the applicable laws. Some responses referred to the "marketing approval applicant", "person requesting the marketing authorization", "enterprise that wants to register a new medicine", "companies producing generic medicines", "the third importer, exporter, manufacturer or producer of the subject matter protected by a patent" or "non-authorized third parties". The law of one Member State provide that the exception applies to "those carrying out studies, tests and trials on generic medicinal products [...]" including "manufacturers and suppliers of materials for such studies, tests and trials". Another Member State responded that "those whose actions are "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products" were entitled to use the exception. In a few countries, the applicable law did not specify who was entitled to use this exception.

74. Twelve Member States indicated that the exception covered regulatory approval of "any products". However, in a majority of countries, the coverage of the exception is limited to certain products, such as "pharmaceutical products", "patented drugs or patented medical

apparatus and instruments”, “certain medicinal products”, “pharmaceutical and agricultural chemicals”, “medicaments”, “medicinal products”, “certain medicines and agricultural products”, “certain medicinal and plant protection products”, “allopathic medicines”, “medicinal products for human use or medicinal products for veterinary use”, and “generic medicines”. The law of one Member State provides that the exception covers the regulatory approval of “pharmaceutical patents” relating to goods that “(i) are intended for therapeutic use; and (ii) are not medical devices, or therapeutic devices” as defined in its applicable law.

75. Member States’ replies to the question on permitted acts in relation to a patented invention under the exception were as follows. Many Member States stated that acts, such as “studies”, “trials”, “tests” and/or “experiments”, as well as “consequential practical requirements”, “related practical needs” or “related procedures” necessary for obtaining a marketing “authorization”, “permission”, or “registration” for a product, as defined in the applicable law, are permitted under the exception. In one Member State, the exception applies, *inter alia*, to “experiments and clinical trials” in which a pharmaceutical product containing a protected active ingredient is tested to obtain the data required for marketing approval. In many Member States, “making”, using” as well as “selling” and “offering for sale” the patented invention are permitted under the exception. Moreover, in a few other countries, reference was also made to “constructing” and “loan and transfer”. In a few Member States, the applicable law did not specify the acts authorized, stating generally “uses necessary to obtain the marketing approval”.

76. In many Member States, the regulatory approval had to be requested in the country where the relevant acts occurred in order to enjoy the exception, while in eleven Member States, activities made with the purpose of obtaining regulatory approval in other countries were covered by the exception. In one Member State, the relevant acts carried out for the purpose of obtaining a marketing authorization in any State that is a Contracting Party to the Agreement on the Establishment of the World Trade Organization of April 15, 1994 are permitted. Among countries allowing exportation, some countries provide other conditions to be met. For example, one Member State stated that such foreign countries shall be “with comparable regulation for pharmaceutical products”. Another Member State provided that the provision which allowed the exploitation for purposes connected with obtaining a similar regulatory approval under the law of a foreign country “[...] does not apply unless the term of the patent has been extended [...] and the goods consist of or contain [...]” certain products. One Member State, while allowing the exportation of the product outside the national territory, stated that such exportation shall be permitted only to satisfy the requirements for marketing approval in its country. In addition, a few countries’ responses referred to the possibility of importation of goods for the purpose of obtaining the marketing approval in their countries.

77. Referring to other criteria that determine the scope of the exception, a few Member States noted the direct relation between studies, trials and consequential practical requirements, on the one hand, and the permission, authorization or registration on the other. Similarly, some other countries stated that the relevant acts were to be made “solely” or “exclusively” for the purpose of obtaining regulatory approval. Another Member State noted that “the actions stated in this Article shall be subject to the condition that those actions do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties”.

78. Many Member States which provide this exception stated that the policy objectives pursued by this exception were to prevent patentees having a *de facto* extension of the patent term and to achieve an appropriate balance of rights. It was explained by one Member State that “without the exception, alternative manufacturers could not gain regulatory approval until the term has expired. These processes would take some time and amount to an extended period of exclusivity for the original patentee.” In addition, another Member State, referring to

the World Trade Organization panel "Canada - Patent Protection of Pharmaceutical Products",<sup>2</sup> noted that the exception established "[...] a reasonable balance of interests between rightholders and users of intellectual property rights, as well as protecting public interests." According to another Member State's view, the exception is necessary "to ensure that regulatory requirements are not stifling competition." Similarly, other Member States responded that such an exception was provided in order to "facilitate the marketing of generic medicines" in internal and external markets, "incorporate flexibilities in the patent regime [...]" "encourage development and licensing of competing products", "foster creativity and to provide quality and less expensive products through the local manufacturing units, aiming at helping the masses in general, and industrial development in particular" and to "enable the public at large to obtain drugs or medical apparatus and instruments at a cheaper price after the expiration of the term of patent protection". Additionally, one Member State stated: "the public interest in the activities of generic companies combines the significant contributions in promotion of exports [...] and providing an employment for large number of workers, mostly academics, with the public benefits derived from a competition at the pharmaceutical market and the price reduction as a result of the competition." A few countries responded that the exception was provided in order to comply with Directives 2004/27/EC and 2004/28/EC.

79. Most Member States stated that the applicable legal framework of the exception was considered adequate to meet the objectives sought or provided no answer on this question. In a few Member States, amendments of the related provision(s) were envisaged. In one Member State, such an amendment "expands the existing exemption for pharmaceutical inventions to all technologies." Another Member State noted that it was "carrying out an evaluation on the implementation of the exception with a view to assessing its usefulness in light of the objective of ensuring a balanced patent system."

80. Most Member States stated that no challenges had been encountered in relation to the practical implementation of the exception. With reference to challenges, one Member State noted that patentees were not content about the exception; therefore, they "try to prevent the obtaining of regulatory approvals by setting up interim relief in the appropriate court". It further noted that "court decisions are not unanimous regarding this issue." Another Member State noting that the "precise scope of the exception is yet unclear", referred to Article 10(6) of Directive 2004/27/EC and stated that "[...] it is unclear which "trials and studies" are exempted and which activities constitute "consequential practical requirements". In that regard, it further questioned whether that included, for instance, "stock-piling or taking pre-orders". In addition, referring to the recent decision of the court of appeal which ruled that publication of a generic medicine in the G standard constituted an act of infringement, that Member State stated that it appeared that the court "did not take the provision of Directive 2004/27/EC into account, despite the fact that the provision was already implemented into national legislation." Another Member State, referring to the amendment of the relevant provision of its national law implementing Directive 2004/27/CE, questioned whether it had retroactive effect or not in light of the decision of the Supreme Court of that country which stated that "prior to the entry into force of Law No. 29/2006, the provision of samples to public health authorities was not covered by the "experimental use exemption". Another Member State, with reference to challenges, stated that the "exception was never invoked".

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<sup>2</sup> Report of the Panel on Canada-Patent Protection of Pharmaceutical Products (DS 114).

## SECTION VIII: EXHAUSTION OF PATENT RIGHTS

Replies overview:	Total replies	72
	National	25
	Regional	12
	International	7
	Mixed (e.g. national/international)	9
	Uncertain, no answer or no exhaustion	19

81. Out of 72 responses, a national exhaustion rule is found in 25 responses, a regional exhaustion rule in 12 responses and an international exhaustion rule in seven responses. 12 responses indicated that they provided for a mixed system of either (i) national and regional exhaustion; (ii) national and international exhaustion; or (iii) national, regional and international exhaustion. Five responses stated that the situation was uncertain. Thirteen responses provided no answer, and one response indicated that no exhaustion was provided. One regional patent office stated that the exhaustion rules were established by its Contracting States.

82. In case of national exhaustion, Member States' laws stipulate, for example, that the patent protection "shall not extend to acts [...] with regard to a product protected by the patent after the said product has been put on the market" of the territory, "has no right to prevent to put into civil circulation". One Member State clarified that the patent right was only exhausted if it was put on the market "by the owner of the patent or with his consent." Another Member State stated that it "has a doctrine of implied license which indicates that when a patent holder sells the patented item (or an item obtained by a patented process) the buyer acquires a license to use and sell the item and all subsequent buyers receive the same license."

83. In case of regional exhaustion, some Member States provide for regional exhaustion in a unified market, for example, stating that the patentee could not forbid acts related to the products which were put "on the market in the territory [...] by the patentee or with his express consent, except where the patentee has legitimate interests in opposing the further marketing of the product". However, most Member States provide for a limitation of such exhaustion, for example, "when rightful motives subsist so as holder himself opposes to further marketing of products, namely when their condition is modified or altered after their putting on the market" or in case of a "legal basis to object to the further economic circulation of the product." One Member State providing for an exhaustion of a regional type has a "doctrine of implied license, which functions as an exhaustion doctrine". Thus, technically speaking, "on selling a patented product, the patentee transfers with the goods a license for the purchaser to sell or use the article." In another Member State it is established by case law that the party invoking exhaustion has, in principle, the burden of proof as to the preconditions.

84. In the cases of international exhaustion, Member States' laws contain provisions, such as the "import of a patented product including an industrial property subject matter or developed by a patented process into the territory [...] shall not be deemed as infringement of exclusive rights of the patent owner if it has been legally put on the market in a foreign country by the patent owner or with his consent. "Parties have acquired lawfully after that product has been lawfully introduced into the market of any country by the right owner or by a third party with the owner's consent." Some of those Member States require further conditions for international exhaustion, such as no "unjustifiably harm the normal working of the patent, or cause undue harm to the legitimate interests of its owner or its licensee". One Member State added that this exception was based originally on the rulings of the anti-trust commission and now on the rulings of competition courts.

85. Some Member States provide for a combination of different exhaustion rules depending on where the patented product was first put on the market. For example, regional exhaustion

applies if the product was first put on the market in the European Economic Area (EEA), and national exhaustion applies if the product was first put on the market outside the regional market.

86. Some other Member States provide for different exhaustion rules depending on the nature of the goods. Some Member States noted that they provide for “a specific exhaustion provision applying to the propagation of biological material”. In one of those Member States, it is further provided in the rules of exhaustion that “the sale or other form of commercialization of breeding stock or other animal reproductive material to a farmer by the owner of the patent or with his consent implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm” and “to use the protected livestock for an agricultural purpose, with the exception of breeding holdings; this includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity.” According to that Member State, “from case law, it has become clear that for the exhaustion it is decisive whether or not a product has been put on the market lawfully”, and “products put on the market under a compulsory license or prior use are deemed to be lawfully put on the market.” Further, in one Member State, anyone importing a patented medicinal product in accordance with the limited regional exhaustion rule “shall notify the patent holder or his successor in title hereof not later than one month before the application for a marketing license is filed”. In another Member State which applies, in principle, national exhaustion, “the Minister of Health is empowered [...] to prescribe the conditions on which any patented medicine may be parallel imported into [the territory].”

87. One Member State has different exhaustion rules depending on the place where the patented product was first put on the market and on the nature of the goods. According to its applicable law, (i) in principle, the regional exhaustion rule applies; (ii) however, if patent protection is of secondary importance due to the functional characteristics of the patented goods, the international exhaustion applies; and (iii) notwithstanding (i) and (ii), where “the price of the patented goods are set” by that Member State or the country of commercialization, notably medicines, the goods may be imported for professional purposes.

88. In some Member States, the existence of the type of exhaustion is uncertain, as, for example, the law “has not specified the place of exhaustion”. One Member State noted in this respect that exhaustion is determined by case law: “Whether the rights are exhausted or not is likely to depend on any conditions attached to the initial sale by the patentee.”

89. The majority of Member States does not permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice that can override the exhaustion doctrine adopted in the country. While a few others allow for such restrictions, some others stated that the situation was uncertain. In one Member State, restrictions are possible at the national level, as it provides for an implied license which could be replaced by contractual terms, but not at the regional level, because of the unique regional market. Another Member State noted that it is the “right holder’s right to prevent a third party from, without his consent, importing a product that is object of the patent, or a process or a product directly obtained by a patented process.” A provision under a Free Trade Agreement was referred to by one Member State as follows: “Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.” Another Member State allowed for sector-specific restriction as “patented products relating to medicine supplied to Government agencies have been allowed to contain express notice of restriction”.

90. For many Member States, the policy objectives sought relate to the “adequate balance between the interests of patentees and consumers” or to the “balancing patent holders’ rights

with freedom of trade” and the principle that the patentee “has received compensation for the sale”. The exhaustion principle is serving “the purpose of maintaining the normal economic order by avoiding restrictions on the circulation and use of the patented products in the marketplace.” In addition, “the exclusive right to dispose of the protected object lies with the lawful acquirer”. It is noted that the unrestricted right “can compromise certainty of trade” and “obstruct further marketing of the protected product”. Further, it is considered by one Member State that the objective was to “safeguard consumer interests”. In addition, exhaustion should strike a balance “between the protection of the invention and public benefit, as well as to coordinate between product distribution in international trade and the right of the patentee”. Thus, in some Member States, exhaustion intends to “ensure the free trade between member states” of a certain region and to “balance in the system and promoting competition”. One Member State expressed concern that, otherwise “the patent owner’s control of later sales may lead to artificial market sharing in the inner market.” One Member State stated that “the essence of the rule on exhaustion of patent rights is that a patent holder, or other person acting with the permission of the patent holder, foregoes the legal monopoly on the use of the protected subject matter in an economic sense following its initial legitimate introduction into civil circulation. Subsequent movement of material bearers incorporating the technical solutions will be beyond the scope of the patent monopoly”. One Member State referred to the TRIPS Agreement, and one Member State is “devising such public policy”. Relating to sector-specific exhaustion, one Member State noted that it should “ensure that a person purchasing propagation material [...] may in fact grow it since the material was bought for this purpose” and ensure “the supply of medicine.”

91. Some Member States reported on the legislative history, for example, that “this right was described as a ‘license’.” In one Member State, parliamentary debates noted that parallel imports “provide a balance between the industrial property right holders” and “the rights of citizens, which are safeguarded before industrial property rights by the parallel imports mechanism, thus avoiding possible rights abuse”. One Member State noted that this provision was “making use of the freedom of choice which the TRIPS Agreement provides in this respect”.

92. Concerning the appropriateness of the applicable legal framework, the majority of Member States considered their systems appropriate and did not foresee any amendments. One Member State with an uncertain system of exhaustion noted that it had been considering a revision of “the law with a view to clarifying the exhaustion of the right (international).” One Member State noted that its law was “considered to meet the objective”, but all IP legislation would be “revised with a view to possible reform”. One Member State applying the national exhaustion rule stated that “currently the subject is being discussed by different national authorities and sectors.” Another Member State noted in this respect that “bearing in mind that international exhaustion can lead to impairment of the patent, the legislator has decided to prescribe provisions of national exhaustion.” Similarly, one Member State noted that its legal framework on exhaustion was not adequate and therefore, the government had “put in place other complementary exceptions, for example, compulsory licensing regime.”

93. With regard to challenges, the majority of Member States reported no challenges or no significant challenges. One Member State noted that, due to lack of its implementation of the patent registration system, the law on exhaustion had not been implemented yet. One Member State applying the national exhaustion rule reported some challenges “mainly in the area of health and restriction on parallel imports”. One Member State stated that challenges had been “encountered with regard to counterfeit pharmaceutical products that are being imported into the country”.



## SECTION IX: COMPULSORY LICENSING AND GOVERNMENT USE

### A COMPULSORY LICENSING

Replies overview:	Total replies	72
	Statutory exception	70
	No exception or no answer	2
	Different grounds for compulsory licensing	
	Non-working	54
	Refusal to grant licenses	45
	Anti-competitive practices	38
	Public health	43
	National security	42
	National emergency	37
	Dependent patents	46
	Other	21

94. Out of 72 responses, 70 indicated that the applicable law provided for exceptions and/or limitations related to compulsory licenses. Two responses indicated that they did not include such an exception in their laws or provided no answer. One regional patent office stated that compulsory licenses were regulated by its Contracting States. Some Member States made an extensive reference to their case law.

95. In general, a number of common elements or requirements are found in the compulsory license provisions under national law. They include: (i) beneficiaries and the competent body (bodies) which grants compulsory licenses; (ii) the grounds on which compulsory licenses may be granted; (iii) prior efforts to be made by the requester of a compulsory license to obtain a voluntary license (with certain exceptions); (iv) limitation of the scope and duration of a compulsory license to meet the purpose of the authorization; (v) non-exclusive license; (vi) non-transferability, except with the business; (vii) authorization predominantly for the supply of the domestic market (with certain exceptions); (viii) remuneration to be paid to the patentee; and (ix) the possibility of review.

96. The vast majority of responses indicated several grounds on which compulsory licenses might be requested under the respective applicable law. The grounds which were referred to by many responses are “non-working or insufficient working of the patented invention” found in 58 responses; “dependent patents” found in 46 responses; “refusal to grant licenses on reasonable terms” found in 45 responses; “public health” found in 43 responses; “national security” found in 42 responses; “anti-competitive practices and/or unfair competition” found in 38 responses; “national emergency and/or extreme urgency” found in 37 responses; and “other grounds” in 21 responses.

97. Some Member States provide for other grounds for compulsory licenses, such as, “needs of national economy”, “overlapping rights of biotechnological patent owner and a plant variety owner”, “compulsory license for plant breeder”, “compulsory license as a result of the Euratom Treaty”, “where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology”, “environmental protection”, “insufficient supply of appropriate goods, works or services on the market as a result of the specified non-use (insufficient use)”, “the willingness of any person to use the patented subject matter specified”, “serious public interest menace”, “impeding the establishment or development of industrial and commercial activities”, or the “specific provisions under the Clean Air Act, and under the rules of the Nuclear Regulatory Commission”.

98. With regard to the ground of “non-working”, the main elements referred to by Member States were that the patent was not worked within a certain timeframe in the territory or

insufficiently worked to satisfy the demand of the market of the territory, without legitimate reason. Some Member States specifically define the beneficiary as “any legal entity or natural person”. In one Member State, the applicable law explicitly specifies that a “WTO proprietor” (a patent owner who is a national of, or is domiciled in, a country which is a member of the WTO, or who has a real and effective industrial or commercial establishment in such a country) may not obtain a compulsory license on the ground of “non-working or insufficient-working” of the patented invention, although a non-WTO proprietor may request a compulsory license on such ground.

99. For the purposes of determining what constitutes “non-working or insufficient working” most of the Member States define the term “working”. Some Member States further specify that working could/must be done directly or through one or more licensees, by the conclusion of a license agreement, by assignment of the right to the economic exploitation, by granting a license or operating an industrial establishment or by working it “sufficiently and continuously”. Lack of preparations to work is one of the grounds for compulsory licenses in some Member States, for example, a compulsory may be granted where a patentee has “not started to work or to make effective and serious preparations to work”.

100. In most Member States, the time period during which compulsory licenses may not be granted on the grounds of non-working (or insufficient working) is three years from the date of the grant of the patent or four years from the filing date of the application. The applicable laws of many countries further specify that the said time period lasts three years from the date of grant or four years from the filing date, whichever period expires later. Some variations found in the applicable laws of some Member States are, for example, “3 years time from the date a patent is granted” and “three years as from the date of publication”. In one Member State, the time period is “to be determined by the Court”.

101. Insufficient working is defined in some Member States with reference to the market, for example, as “insufficient to cover local demand”, “able to satisfy the demand of the national market” or as compared to an “analysis of the needs of the domestic market”. Some Member States use more general criteria, such as “inadequately used”, “not being met on reasonable terms” or “applied in good faith and on a sufficient scale” or qualitative and quantitative criteria, such as “not available in sufficient quantities or quality or at predetermined reasonable prices in [the territory]”, “insufficient quantity or of inadequate quality, or at excessively high prices” or with reference to “license cost determined under comparable circumstances”. In a few Member States, the condition is that the patent is “not being so worked to the fullest extent that is reasonably practicable”. The “fullest extent” is considered as “the highest rate of production which is practicable and necessary substantially to meet the demand”.

102. In the majority of Member States, it is possible to justify the non-working or insufficient working by legitimate reasons, such as “legitimate grounds for failing to work the invention may be shown”, “regard to given circumstances”, “satisfactory reason”, “the patentee justifies the lack of exploitation”, “acceptable reason for the non-use of the invention” or “valid reasons [that] are shown to exist for the absence of such an establishment”. Those reasons are, in most of those Member States, of a technical, economic or legal nature and further specified as, for example, “arguments of a lawful nature (including legal, technical and economic), confirmed by competent authorities.” As stated by one Member State: “Technical or economic or legal reasons of an objective nature shall be deemed to constitute legitimate excuses for the inability to put the patent to use. The reasons accepted to be in the nature to constitute obstacles for using/working the patented invention are those which are beyond the control and will of the patentee.” Similarly, “objective difficulties of a legal and technical nature, independent of the will and circumstances of the owner of the patent, which make working of the invention impossible or prevent its working from being more extensive than it is”. Another Member State clarified that “for example, if the production, importing or marketing is prohibited by the Government, no compulsory license should be issued on the grounds of non-working or insufficient working.”

Moreover, in another Member State, “force majeure, or circumstances independent of the will or beyond the control of the patent owner”, can “justify the non-working or insufficient working”, but not “lack of economic resources or the lack of economic viability of the working”. One Member State stated that even the “difficulties in providing raw material or has been struggling with lack of resources, this cannot be considered as legitimate reasons”. Further, some Member States clarified that the reasons were not described in the law and would be determined on a case-by-case basis. One Member State noted that the legislation left “any evaluation to the discretion of the judge”. The patentee has to provide, at least in one Member State, “evidence that the circumstances made it impossible to remedy the lack or insufficiency of exploitation of his patent”. In another Member State, there is a specific test which takes into account the following matters; the nature of the invention; the time elapsed and the measures already taken by the proprietor of the patent or any licensee to make full use of the invention; the ability of any person to whom a license would be granted under the order concerned to work the invention to the public advantage; and the risks to be undertaken by that person in providing capital and working the invention if the application for an order is granted.

103. Some Member States only consider non-working or insufficient working in the territory. Two Member States allow for some specific conditions, such as “subject to reciprocity, the Government may decree that [...] the working of an invention in a foreign State shall be deemed equivalent to working in this country”, “or in another State to be designated by the Implementing Regulations”.

104. Some Member States do not consider importation as working of the patent or do not specify such issue in the legal provisions. In the majority of Member States, importation is considered as working of the patent. However, restrictions are applied in some Member States, which provide, for example, that importation is only considered as working “as far as it is not involving excessive pricing”. One Member State provides that importation is considered as working if it is sufficient for “the supply of the internal market in terms of reasonable quantity, quality and price, through production in the country and import”. Further, one country expressly specified that importation of patented products into at least one Member State of the European Union or of the European Economic Area was considered “working” of the patented invention. Two countries expressly indicated that if patented products were imported into at least one member of the WTO, it was considered as “working” of the patented invention under the applicable law. In one Member State, “the importation *per se* does not constitute ‘working’ of the patent; however, a legitimate import can mean that the patented invention is exploited in the territory of the country in order to satisfy the domestic demand.” Similarly, in another Member State, the “import of the patented product from another country will consequently not necessarily prevent the grant of a compulsory license. However, in the case of import, the patentee may have legitimate reasons for the failure to work the invention”.

105. With reference to the ground of refusal by the patentee to grant licenses and the definition of the terms “reasonable terms and conditions” and “reasonable period of time”, most Member States did not provide any further explanations. Some Member States stated that the expression “reasonable terms and conditions” and “period of time” will be decided, for example “based on the facts and circumstances of each case”, on “a case-by-case basis” or “on the conditions pursuant to the common practice”. Some Member States noted that the reasonableness will be “determined by the specific circumstances”, such as “fields of technologies, marketing prospects, royalties of similar technologies, the funds invested” or “the economic value of the authorization [...] bearing in mind the rate of average royalties for the sector in question, in relation to commercial license contracts between independent parties” or the “reasonableness of compensation”. Another Member State clarified that the terms did “not take account of the public interest and arise essentially out of the existence of the patent”. In one Member State, the reasonableness “requires consideration of the patentee’s cost of production and marketing the article, the terms and conditions on which it negotiates with customers, and whether the trade can carry that price”. It was explained that what constitutes

reasonable terms depends on “the nature of the invention, the terms of any licenses under the patent, the expenditure and liabilities of the patentee in respect of the patent, and the requirements of the purchasing public. The price charged by the patentee should be a *bona fide* one and not one adopted to suppress or depress demand”. A test applied by courts in another Member State is “how much are manufacturers who are anxious to make and deal with the patented article on commercial lines ready and willing to pay?”

106. One Member State stated that it was the government which decided what was “reasonable”. Some Member States noted that the requestor had to provide “evidence” or “irrefutable proof”, and one Member State further noted that “the evidence that the patentee’s prices were not reasonable” had to be provided. With reference to the reasonable time period to obtain a voluntary license, some Member States refer to time periods of three or six months. They stated that, for example, “a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time” or that a period of “three months from the request for the license” was a reasonable period. One Member State noted that what would constitute a reasonable period of time should be determined by taking into consideration the time needed by the right holder to make a decision after evaluating both the economic and technological aspects of the inventions.

107. As regards the ground of anti-competitive practices, many Member States did not provide further explanations. One Member State, referring to the case law of a regional patent court, stated that the “use of IP-rights can constitute unfair competition”. Some Member States referred to an enumerative list of anti-competitive practices. Those included, for examples, excessive pricing, such as “fixing, for patented pharmaceutical products, of excessive or discriminatory prices in relation to average market prices”, “the fixing of excessive or discriminatory prices for patented products” or “engaging in excessive prices”, “in particular, where offers of market supply exist at prices significantly lower than those offered by the owner of the patent for the same product”. Further, anti-competitive practices might be related to the denial of access to “essential facilities”, for example, “denying a competitor access to essential facility” or similarly “the lack of market supply on reasonable commercial conditions”. Another type of anti-competitive practices identified by some Member States related to the exclusion of competitors, for example, by “the obstruction of commercial or production activities” or “engaging in an exclusionary act”. One Member State identified the case where a “proposed merger is substantially likely to lessen competition”. Some Member States provide for a more general wording for the determination of anti-competitive practices, such as “any other act which national legislation characterizes as anti-competitive, limiting or restrictive of competition”, “anti-competitive practice which operated or may be expected to operate against the public interest” or “restraint of trade and contrary to public policy”. In most Member States, the determination of anti-competitive practices is made “on the circumstances”, or they do not define the term “anticompetitive practices [...] *per se* but rather indicate specific behavior which is unacceptable”.

108. With regard to case law, one Member State stated that “compulsory licenses may also arise from cartel law”. In that case, it may be possible to raise the “defense that the [patentee] is abusing a market-dominant position by refusing to conclude a patent license contract with the defendant on non-discriminatory and non-obstructive conditions”. “A patent holder, however, only acts abusively if the defendant has made him an unconditional offer to conclude a license contract to which he remains bound and that the patent holder cannot refuse without infringing the prohibition on discrimination or obstruction, and if the defendant, if and as long as he is already using the subject matter of the patent, complies with those obligations that the license contract to be concluded imposes on the use of the licensed object. If the defendant regards the patent holder’s license requirements as abusively excessive or if the patent holder refuses to quantify the license fee, the requirement of an unconditional offer is satisfied by an offer to

conclude a license contract under which the licensor shall specify the amount of the license fee at this fair discretion". Another Member State referred generally to the consumer protection law.

109. Some Member States indicated that the determination or declaration of anti-competitive practices was deferred to specific bodies, such as a "judicial or administrative body", "any anti-monopoly agency or the judicial judgment by any court", "administrative or court proceedings", the "Federal Government and [a] judicial body", the "Competition Commission, the Secretary of State or a Government Minister", or the "Free Competition Court". Some Member States limited the grant of compulsory licenses on the ground of anti-competitive practices to the area of public health and semiconductor technology. In another Member State, the grounds for compulsory licenses also include "the case of an invention relating to a human diagnostic product or process, [in which] a non-exclusive license shall be granted to remedy a practice held to be anti-competitive in judicial or administrative proceedings". One Member State noted that "the anti-trust authorities are not empowered to take decisions on the grant of compulsory licenses based on the results of reviewing cases on the infringement of legislation on the protection of competition."

110. Concerning the grant of compulsory licenses on the grounds of dependent patents, important criteria noted by many Member States are the "technical progress" and "significant economic interest". Most of the Member States that allow such a ground provide for three different requirements such as (i) the invention cannot be worked without infringing another patent, (ii) the invention protected by the later patent constitutes an important technical advance and (iii) substantial economic significance relative to the invention protected by the earlier patent. Similarly, in some Member States, the applicable laws use expressions such as that the later patent is "dependent" or "necessary for the working of the patent". The term "dependent" is defined, for example, that "the applicant for a license is unable to exploit his later patented invention without infringing the earlier patent" or that "without it, exploitation of the patent would be technically and economically unfeasible". In two Member States, it is further required that the party was not able to obtain the patent owner's consent to exploit the invention under reasonable conditions usual in trade within a reasonable period of time or consultations on the grant of a non-exclusive shall be held.

111. Most Member States provide that where such license is granted, the owner of the earlier patent shall also have a claim to a non-exclusive license in the later patent. Such cross-license must be on reasonable terms. In two Member States, it is required that both patents under a cross-license shall "serve the same purpose". Further, "the use authorized in respect of the first patent shall be transferred by the person having the compulsory license only with the simultaneous transfer of the company's part" or "the later patent". In some of those Member States, additionally, the compulsory license may not be exclusive. Some Member States specified that a compulsory license should be limited in the scope and volume that are necessary to exploit the invention by the owner of the later patent. The amount of payment must be not less than the price for a license, which is determined in compliance with common practice. One Member State clarified that with respect to an invention concerning a "process for preparing a chemical, pharmaceutical or food product", both the holder of the process patent and the holder of the product patent are entitled to request a compulsory license. Further, compulsory non-exclusive cross-licenses are provided by the law for biotechnological inventions based on plant variety protection in some Member States (see also Section X).

112. Most of those Member States which provide for compulsory licenses on the grounds of "national emergency" or "circumstance of extreme urgency" do not provide for a definition of such circumstances. In some Member States, national emergencies are defined by listing examples, such as "national security", "state security", "military attack", "war", "disasters, catastrophes or big accidents", "protection of public interest in the field of health and nutrition", "public health", "epidemic or similar situation" "non-commercial public use", "protection and improvement of human environment", "environmental protection and improvement, specific

commercial interest” and the “special interest in a particular branch of economy or where it is necessary to correct practices determined in a judicial or administrative process to be uncompetitive”. In one Member State, it is defined generally as “interruption of normal life and activity of the population at an objective or in a region as a result of accidents, disasters, natural or socio-biological calamities which resulted or could result within human and economic losses”, or in another as “endangers the survival of the state or its citizens”. Another Member State noted that, according to the preparatory remarks of the Act, important public interests concerning, for example, national security, the population’s access to medical products and food, power supply, communication lines etc. were relevant.

113. Even if no definition was provided, one Member State stated that “wars or any emergency that endangers the country or any natural disasters or pandemic diseases would constitute cases of ‘national emergency’ or ‘circumstances of extreme urgency’ were understood to be national emergency”. Another Member State noted that “a case of national emergency or security shall exist where a serious disease is declared to be a priority by the General Health Council” for example “the A(H1N1) influenza epidemic in April 2009. [...] However, it was not necessary to take the step of granting public utility licenses provided that the pharmaceutical companies responsible for the production of the antiviral [...] guaranteed the supply of those medicines.” Another Member State noted that the examples of national emergency might include public health problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

114. In the cases of national emergency, some Member States indicated that “any person who wishes to exploit” a patented invention may obtain a compulsory license. In another Member State, it could be determined *ex officio* that the patent may be worked “by any person” or “by a State entity or by one or more public or private law persons designated for the purpose”.

115. As regards a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee, some Member States noted that they do not provide for such a general policy. Many Member States referred to general guidelines or general policy, determining the amount “with regard to the circumstances of each case and taking into account the economic significance of such an authorization”, also “having regard to the nature of the invention”, or the “licensing conditions in the technical field of the invention”. In most Member States, the economic value of the license is to be taken into consideration. For example, one Member State specified that the competent body should bear “in mind the average rate of royalties for the sector in question, in commercial license contracts between independent parties.” According to another Member State, the remuneration should be “not less than the price for a license, which is determined in compliance with the common practice”. Further, one Member State intends to ensure a “maximum advantage for the patent while permitting the licensee a reasonable profit.” Other additional factors mentioned by some Member States are the need for correcting uncompetitive practices and “the extent of utilization” of the license. As regards the mode of payment, one Member State noted that the competent body “shall fix the amount of the remuneration to be paid periodically by the licensee to the patent owner”. In another Member State, the necessary proceedings provide that the remuneration “shall be subject to consultation between the two parties. In the event of failure to reach an agreement between the two parties, the patent administration department under the State Council shall make a ruling.” In addition, in many Member States, in the event of a substantial change in the circumstances, the competent authority may, upon request by one of the parties, revoke the license or lay down new licensing conditions.

116. One Member State provides specific provisions for the remuneration for compulsory licenses relating to import/export of patented pharmaceuticals. The Courts will take into account “the economic value” and the “humanitarian or non-commercial factors relevant to the grant of the license”. In one Member State the remuneration is defined as “three percent remuneration by the licensee, on the basis of total sales of that chemical product taking into consideration its

trade price". In another Member State, different provisions apply for WTO and non-WTO proprietors, i.e., for patent owners from WTO members, the "remuneration adequate in the circumstances of the case, taking into account the economic value of the license" and for non-patent owners from non-WTO members, "reasonable remuneration having regard to the nature of the invention". With respect to semiconductor technology, some Member States stated that only non-commercial public use may be applied in order to rectify a practice declared anti-competitive following court or administrative proceedings.

117. With reference to the number of times and the technological areas in which compulsory licenses have been issued, most of the Member States stated that they were not aware of such court decisions, had no data available or that no compulsory licenses have been granted in their territory. Some Member States reported that compulsory licenses had been used very seldom and in very few cases related to pharmaceuticals. One Member State reported that its patent office had issued one compulsory license in the period from 1961 to 2004 and that this compulsory license had been revoked by a court. In one Member State, "there were some cases where arbitration decisions were requested" but there had "been no cases where a non-exclusive license was granted by arbitration decision". One compulsory license had been granted in the mining industry in one country, and one compulsory license concerning plant protection products and two others related to pharmaceutical products had been granted in another country. A non-exclusive license related to a method of manufacturing Bis-thio benzene had been granted in another country, since it had not been commercially worked for the previous three years without justifiable grounds. One Member State reported two cases where courts had granted compulsory licenses on dependent inventions with respect to a school desk that allowed the user to work while standing or sitting and could be adapted to any height and on a convertor which could transform alternating current into direct current. In one Member State, a compulsory license was granted in the field of mechanical engineering (IPC Class: F16B13) on the grounds of failure to work. Another Member State stated that no compulsory licenses had been issued during the last 10 years, and that very few requests for compulsory licenses, estimated to be less than one per year on average, had been received.

118. With respect to the public policy objectives for providing compulsory licenses, many Member States identified the following objectives: to prevent abuse of the exclusive right; to create a balance; and to promote the public interest and access to affordable products. Some Member States aim at striking a balance between the interest of patentees and of third parties. For example, they referred to the "balance between the granted monopoly and the public interest" and "balance, by providing tools that limit the right where committed higher interests exist". Another public policy objective pursued by some Member States is to prevent abuses of the exclusive right, such as "to protect the public from any abuse of the exclusive right" or to restrict the monopoly "by economic or social imperatives of general interest, which are considered more important" or "to protect the public from any abuse of the exclusive right to which the patent owner is entitled".

119. Further, some Member States focus on the interest of the State or the public at large, which are described as "public interest considerations", "development of the economy and the well-being of the society", "vital interest to the economy of the country, public health or national defense, or where non-working or insufficient working of such patents seriously compromises the country's needs" or the "public benefit". One Member State highlighted the importance of using patents "in order to encourage innovation and the further advancement of science and technology by other interested persons". Another objective referred to by one Member State was to "promote trade and to boost the economy of our country by using patents as a source of potential income not only to the patentees but also to the whole of [the] country". In its view, compulsory licenses should aim at, among others, "transfer and dissemination of technology". In addition, one Member State noted that "innovation would be hampered if a patent holder could prevent, by not providing licenses [for dependent patents], the use and further improvements of an invention". One Member State pursued multiple policy objectives, such as

“to prevent right holders from abusing their rights, to promote application of inventions and creations, to guarantee the normal operation of the patent system, and to safeguard the interests of the State and the public.” Another Member State highlighted that the policy objectives for compulsory licenses included access to products and “consumer protection” so that the “businesses and consumers have reasonable access to patented products at reasonable prices” and products were “available to potential users”. Through the compulsory licensing mechanism, one Member State intends to create “an incentive for parties to negotiate and agree voluntary licensing agreements rather than go through what is essentially *inter partes* litigation in order to attempt to obtain a compulsory license”. Another Member State stated that one of the objectives was “to prevent or repress anti-competitive behavior.”

120. Some Member States pursue specific public policy objectives on public health. One Member State referred to the specific policy objectives which were “to make use of the system under the Protocol amending the TRIPS Agreement (adopted by the General Council of the WTO on December 6, 2005) to import medicine” and to “export pharmaceutical products to other WTO members”. In another Member State, one specific public policy objective is access to public health, for example referring to “access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics”. One Member State noted that it was in the “process of devising such public policy”.

121. As regards the history of legislation, parliamentary debates and judicial decisions, most of the Member States did not provide any further information. One Member State referred extensively to its common law legislation on that issue. Another Member State noted that the provisions in the Patents Act had been amended for the purpose of applying the provisions of the TRIPS Agreement regarding compulsory licenses to its national law. Another Member State emphasized that “its provisions have undergone various revisions and improvements over the years.” Referring to compulsory cross-licensing related to patents on plants and plant variety protection, one Member State stated that the exception was inserted “after joining the European Union. One Member State stated that the documents on the parliamentary debates showed that the purpose of the compulsory licensing provisions was “to safeguard consumer interests.” One Member State stated that the power to order the grant of compulsory licenses had been initially with the Board of Trade, from which it had been passed to the Judicial Committee of the Privy Council, and then to courts by the subsequent amendment to the Patents Act in the early 20th century. Further, at the regional level, it was decided by the European Court of Justice that one country might “not grant compulsory licenses where demand for a patented product is satisfied by imports from other European member states.”

122. Concerning the appropriateness of the applicable legal framework, most of the Member States either consider it appropriate or do not provide any answer. In one Member State, there is a Bill to reform the system. Three Member States expressed the need to amend their laws in order to implement the Protocol to amend the TRIPS Agreement Implementing the Doha Declaration on the TRIPS Agreement and Public Health. One Member State noted that the system was adequate as “a non-exclusive license by the request made by a person who intends to work a patented invention after undertaking certain procedures, [is considered ] to serve the purpose of the Patent Act”. One Member State considered that, in view of the recent passage of a major patent reform bill, it was very unlikely to have further amendments on this issue soon.

123. Most of the Member States noted that they did not encounter any challenges. Some Member States stated that the system was little used or that in the absence of cases, no challenges had been experienced. One Member State noted the “considerable burden of proof on the applicant for compulsory licensing” as a challenge. Another Member State referred to insufficiency or no capacity on the part of local industries to produce generic pharmaceutical products, even if a compulsory license were issued.



## B GOVERNMENT USE

Replies overview:	Total replies	72
	Statutory exception	49
	No exception or no answer	23
	Different grounds for compulsory licensing	
	Non-working	14
	Refusal to grant licenses	13
	Anti-competitive practices	13
	Public health	29
	National security	37
	National emergency	29
	Dependent patents	5
	Other	20

124. Out of 72 responses, 49 indicated that the applicable law provided for a government use exception. Twenty-two responses indicated that the applicable law did not include such an exception or provided no answer.

125. Many Member States' laws stipulate that, in general, under certain circumstances, a competent body may grant a license without the consent of the patentee, authorizing a government entity or a third party authorized by the government. Member States however provide such a mechanism in different ways.

126. With reference to the legitimate grounds for obtaining government use, the vast majority of responses mention several grounds. The most common grounds referred to are: "national security" in 37 responses; "national emergency and/or extreme urgency" in 29 responses; "public health" in 29 responses; "other grounds" in 20 responses; "non-working or insufficient working of the patented invention" in 14 responses; "refusal to grant licenses on reasonable terms" in 13 responses; "anti-competitive practices and/or unfair competition" in 13 responses; and "dependent patents" in 5 responses.

127. Some other specific reasons for government use indicated by Member States include: "national defense in time of war, uprising, or other similar emergency or for the public interest", "natural disaster, catastrophe, epidemic or other emergency situations", "public interest", "public health protection", "ecological safety", "protection and improvement of human environment", "development of economically important sectors", "special interest in a particular branch of economy or where it is necessary to correct practices determined in a judicial or administrative process to be uncompetitive", "specific commercial interests", "fostering and directing exports and reducing imports or imports of any classes, from all or any countries and for redressing the balance of trade" and/or "national economic needs".

128. As regards the definition of "national emergency" or "circumstances of extreme urgency", most Member States do not provide further definitions, beyond the different grounds already listed. Those Member States which define those concepts refer to the exceptional nature of the circumstances and the threat to the "maintenance of supplies and services essential to the life of the community" or the like. The applicable law of one Member State stipulates that an example of such extreme urgency may include a massive health crisis. In another Member State, the law stipulates: "Emergency is a situation that developed in a certain area as a result of a dangerous natural or man-made phenomena, accidents, disasters, natural or other disasters that may cause or have caused casualties, damage to human health or the environment, significant financial loss and deterioration of conditions of life people". In one Member State, national security refers to the "maintenance of essential supplies and services" and national emergency to "drugs and medicines" only. The applicable laws of some Member States refer to war or similar situations. For example, one Member State noted that the law did

not define the concept, but it could include a military attack or war, epidemic or similar situations.

129. As regards the body authorizing government use, the applicable law of some of the Member States state “courts”, the “competent authority”, the “King”, or the “Crown”. Some Member States’ laws stipulate that government use is “at the request of any interested person or competent authority, or ex officio” or similar formulations.

130. Most of those Member States which provide for a government use exception stated that the owner of the patent shall be notified where reasonably possible and must be informed about the grant of the government use and its scope. Some Member States require that the notifications shall be in writing. They further require that the scope and duration of the use shall be limited to the purpose for which the use was authorized, and that the use authorized shall be non-exclusive. Some Member States expressly stated that “any use shall be authorized predominantly to supply the domestic market”. Moreover, some Member States indicated that the authorization could not be transferred, or could be transferred only “when the enterprise (or a part thereof) in which a patented invention is used.” The applicable law of one Member State provides that the government shall “not deprive the patent owner of the right to grant permissions”. Some Member States specifically indicated that it was necessary for the requestor to make efforts to obtain from the patentee a voluntary license on reasonable commercial terms and conditions within a reasonable period. In another Member State, government use could be granted “at any time” even at the pre-grant stage of a patent application, including the stage during which a patent application has been kept confidential.

131. Some Member States expressly stated that licenses for government use must be non-exclusive licenses. A few Member States provided provisions to “expropriate the patent right”.

132. As regards the beneficiary, most Member States have designated government agencies and third parties as beneficiaries of government use, for example, “government agency or a third person designated by the Minister”, “government departments or [...] an enterprise or agency of the State” or “state or municipal institution, natural or legal persons to market”. Some Member States specified that the competent body may declare the decision null and void, if the circumstances which led to the authorization to use the patented invention cease to exist.

133. Most Member States provide that the government use should only be made with an adequate remuneration in the circumstances, taking into account the economic value of the authorization. They stated that the royalties shall be determined by an agreement between the State and the patent owner (or the patent applicant). In the absence of an amicable agreement, the royalties shall be fixed by the competent body, such as a court. In one Member State, the patentee whose invention had been used or manufactured by or for the government may sue the government “for the recovery of his reasonable and entire compensation for such use and manufacture. “Reasonable and entire” compensation shall include the owner’s reasonable costs, including reasonable fees for expert witnesses and attorneys, in pursuing the action”. Further, one Member State stated that if the proprietor of an invention had suffered loss or damage by reason of that invention not having been kept secret, the government should pay him a reasonable compensation.

134. On the number of times and the technological areas government use has been applied, most Member States stated that it had never been used, that no data were available or that no record existed. Some Member States noted that since none of the administrative bodies were involved in government use, it was difficult to assess its frequency. One Member State clarified that patent offices did not generally get involved in “Crown use matters”, and that the relevant government department negotiated directly with the patent owner. However, according to its understanding, the Crown use provisions were invoked very rarely because the government

preferred to negotiate a license like any other party would. In its view, it seems likely that the need to determine and pay compensation for Crown use was a factor in deciding to conclude a conventional license. Another Member State noted that the frequency of government use could be easily determined since governmental use was not “issued” as such, but rather involved the government being sued for alleged patent infringement and found liable for infringement. One Member State referred to one case in 2004 concerning an invention related to pharmaceutical products.

135. With regard to the policy objectives providing the government use exception, some Member State noted the “vital” and “public interests” of the government. They noted that the government use exception provided “sufficient rights to the government in case of extreme urgency or public emergency”, allowed the government to “procure devices or services that it needs for its own governmental purposes”, provided the possibility to safeguard “the vital interest [in cases which would] seriously compromises the country’s needs” or were supportive to the “well-being of the population”. Two Member States noted that the public interest should be safeguarded in order to “meet the urgent needs of the community during a period of extreme urgency” or in “epidemic complicated emergency situations”. One Member State noted that the primary policy reason was “that the public has access to patented products”. Two Member States pointed out that the government should not be impeded by its own grant of patents in discharge of their functions from acting in favor of the public interest. It was stated that “unlike private traders, the Crown, through its departments and authorities, is ordinarily engaged in public services, rather than commercial activities, and therefore should be in a special position with regard to the use of patented inventions”. One Member State highlighted that, otherwise, the working of the patent would be “contrary to the interest of public health” and “contrary to the interest of the national economy”. As to other public policy objectives, one Member State referred to “consumer protection” and some Member States referred to the TRIPS Agreement.

136. As regards the legislative history, parliamentary debates and judicial decisions, some Member States referred to a long history of the provision and relevant case law. One Member State noted that the legislative intent was to “have the invention available to them for the benefit of the services of the respective governments at once, rather than at the end of the term of the letters patents”. One Member State reported that government use had been in the initial version of the patent law but had been subject to some adjustments in the later three reforms. One Member State noted that the legislative history made reference to the laws of other jurisdictions. Two Member State stated that the rules on government use had a long history, while they had been essentially the same for decades (in one country, they went back to 1883). One court decision noted that government use “was done for the purpose of performing a duty or exercising a power which was imposed upon or invested in the executive government by statute or by prerogative, including providing services to the general public”. One Member State explained that the “Act was passed to secure the government the right to full disposal of an invention, which has significance for the defense of the Kingdom, in order for the invention to provide maximum benefit for the defense of the Kingdom”.

137. The vast majority of Member States considered the applicable legal framework adequate and foresees no amendments. One Member State reported that its legal framework would be amended shortly as follows: ‘Where public health so requires, patents issued for medicinal products, for processes for obtaining medicinal products, for products necessary to obtain such medicinal products or for processes for making such products, may, where such products are not available to the public in sufficient quantity or quality or at unusually high prices, automatically be worked. *Ex officio* working is enacted by an administrative act on the request of the public health administration. The above provisions also apply to medicinal products for exportation to a country which does not have any manufacturing capacity or with insufficient manufacturing capacity in accordance with relevant international agreements in force’’. One Member State considered the current legal framework inadequate, because the legislation did not provide for government use for research purposes.

138. The vast majority of Member States did not encounter any challenges in relation to the use of the government use mechanisms. One Member State noted that the main difficulty that had been tested by the courts was in defining which bodies could be considered to fall within the scope of the Crown.

## **SECTION X: EXCEPTIONS AND LIMITATIONS RELATED TO FARMERS' AND/OR BREEDERS' USE OF PATENTED INVENTIONS**

Replies overview:	Total replies	72
	Statutory exception	26
	No exception or no answer	41
	Unclear or similar exceptions	5

139. Out of 72 responses, 26 indicated that the applicable law provided for exceptions and/or limitations related to farmers' and/or breeders' use of patented inventions. Among those, one Member State provides only an exception relating to the breeders' use of patented inventions, and another Member State only an exception relating to the farmers' use of patented inventions. Forty-one responses indicated that the applicable law did not include such an exception or provided no answer. Five Member States referred to exceptions available under their plant variety protection system.

140. A number of Member States stated that, as a general rule, the protection conferred by a patent on biological material possessing specific characteristics as a result of the invention included any biological material derived from that biological material through multiplication or propagation in an identical or divergent form and possessing those same characteristics. Similarly, where a patent is granted for a process that enables biological material possessing specific characteristics to be produced as a result of the invention, the scope of such process patent covers any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing the same characteristics.

141. However, the law of those Member States derogates from the rights of patentees, which covers the propagated and multiplied materials, if the propagating material incorporating the patented invention is sold to a farmer for farming purposes by the patentee or with his consent. More specifically, their law provides that the sale or any other form of commercialization of plant propagating material to a farmer by the patentee or with his consent for agricultural use implied "authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm". The extent to and conditions under which such use can be made in those countries is analogous to those contained in their plant variety protection laws. The law of a few Member States specifically provides that such use shall not include the "commercial exploitation" of plant propagating material. Another Member State reported that the exception applies only to certain specified varieties of plant species and groups, and the conditions include "(i) the requirement that a farmer (other than a 'small farmer') must pay equitable remuneration to the proprietor (which must, however, be less than the farmer would have paid for buying more plant propagating material from the proprietor); and (ii) certain specified information must be supplied by the farmer and by the proprietor, on request from the other". Another Member State stated that "the King may, by regulation, determine the conditions and the extent of the farmer's rights". In another Member State, while the farmers who have acquired plant propagated material placed on the market by the patentee or with his consent can propagate the product harvested from such material on their own farms, they must obtain the consent of the patentee in order to transfer to a third party, for the purposes of reproduction, *inter alia*, the product of crops. However, this Member State noted that "all agreements restricting or invalidating the farmers' privilege with regard to food and animal feed shall be void".

142. In addition, some Member States stated that the protection conferred by a patent shall not extend to biological material obtained by means of an act of propagation or multiplication of biological material placed on the market, “where the propagation or multiplication necessarily results from the application of the biological material for which it was marketed”. One Member State noted that such act shall be “a single act of propagation or multiplication”. In another Member State, the rights of patentee are not extended to such biological material “provided that the material obtained is not subsequently used for other generative or vegetative multiplication”. In another Member State, the exception was provided to a “third party who, in the case of patents relating to products consisting of living material, uses, places in circulation or markets the patented products for purposes that are not multiplication or propagation, after these have been lawfully marketed by the patent owner or the person who has a license granted.”

143. In addition, the law of some Member States provide a derogation from the rights of the patentee when the patented plant material was used to develop other plant varieties. In particular, one Member State provided that “the rights conferred [...] shall not extend to the acts performed with a view to creating or discovering and developing other plant varieties”. Similarly, another Member State stated that the “non-commercial use of the subject matter of a patent related to living material by third parties was allowed as an initial source of variation or propagation to obtain other products”. Another Member State noted that “a third party who [...] uses the patented product as an initial source of variation or propagation in order to obtain other products, apart from where said use is repeated” did not constitute an infringement to patentee’s rights. In addition, the law of another Member State provides that the rights of the patentee should not apply to biological material whose production in agriculture was “adventitious or technically unavoidable.”

144. In addition, a few Member States reported that compulsory license procedures existed in their countries regarding breeder’s use of a patented invention. For example, the relevant provision of one Member State reads: “Where a breeder may not obtain or work a plant breeder’s right without infringing an earlier patent, he may request the grant of a license for this patent to the extent that this license is required for working the plant variety to be protected and insofar as the variety constitutes, in relation to the invention claimed in this patent, significant technical progress and is of considerable economic interest.” It was further noted that where such a license was granted, the patent owner shall obtain the grant of a reciprocal license for using the protected variety, as provided in the applicable law. In another country, such license was “subject to payment of an appropriate royalty” to the patentee. With reference to the objectives of such compulsory licensing procedure, one Member State stated that the procedure had been introduced “with a view to encouraging patent owners to grant license voluntarily”.

145. In relation to patented inventions concerning animal reproductive material, a number of Member States have specific provisions which provide that the sale or any other form of commercialization of breeding stock or other animal reproductive material to a farmer by the patentee or with his consent imply authorization for the farmer to use the protected livestock for an agricultural purpose. That includes “making the livestock or other animal reproductive material” available for the purposes of pursuing his agricultural activity, but “not the sale” or “except the commercial exploitation” within the framework or for the purpose of a commercial reproduction activity. In addition, in another country, “farmers must obtain the consent of the patentee in order to transfer to a third party, for the purposes of reproduction [...], animals or the reproductive animal material concerned”. One Member State noted that the exception applied “to all varieties of animals”.

146. With regard to the policy objectives of the exception, many Member States noted that the objective was to allow farmers “to use” or “re-use” a “product of his harvest” or a “part of his harvest product”, as provided under the applicable law, for planting “even if the propagating material is patented, since the seeds are intended for agricultural use and were sold for this purpose”. Another Member State stated that “the conventional activity of farmers to use live

material as a source of variation (to obtain new varieties) shall not be considered a sanction". Similarly, in another country, the objective was to develop and protect agricultural and livestock production. In addition, another Member State noted that that was "an exhaustion rule [...]. The farmer should not have to pay remuneration to the patentee for the harvest of protected varieties". Similarly, in another Member State, the policy objective was not to "restrict the use of inventions by farmers". Some countries responded that the exception was provided in order to comply with Directive 98/44/EC on the Legal Protection of Biotechnological Inventions. In another country, the policy objectives were "to avoid abuse of the monopoly that is granted with a patent and to protect the farmers' rights".

147. Most of the Member States stated that the applicable legal framework of the exception was considered adequate to meet the objectives sought or provided no answer on this question. One Member State stated that a public debate on the desirability of the introduction of a breeder's exemption, initiated by the breeders association, was ongoing in its country. According to the association of plant breeders existing in its country, "the pool of plant varieties available for further breeding activities has declined rapidly over the last decade, due to increasing existing patent rights." It further stated that "the introduction of a limited breeders exception [...] which will apply to the use of patented biological material for breeding purposes, i.e., to discover and develop new plant varieties" was in preparation.

148. Most of the Member States stated that no challenges had been encountered in relation to the practical implementation of the exception. However, one Member State expressed its concern regarding the interpretation of the exception, which allowed third parties the use of the patented product as an initial source of variation or propagation to obtain other products, as it related to "the traditional practice of its farmers, and above all as regards transgenic plants, and possible contamination by pollen of traditional crops". It further noted that that was "due to the imminent approval of commercial transgenic crops".

## SECTION XI: OTHER EXCEPTIONS AND LIMITATIONS

Replies overview:	Total replies	72
	Other exceptions and limitations	18
	No exception or no answer	54

149. Out of 72 responses, 18 indicated that the applicable law provided for exceptions and limitations other than those in Sections II to X, or provided additional information. Fifty-four Member States provided no answer.

150. As regards other exceptions and limitations, some Member States referred to other forms or specific forms of compulsory licenses, such as "ex officio license", "non-commercial public use' compulsory license", "the compulsory license for the manufacture of medicine destined for a developing country" and "compulsory license for users acting in good faith once the courts have ordered the transfer of the patent", other restrictions relating to the government use, such as, "powers of the State" in the field of defense and nuclear energy, or "secret patents".

151. Regarding the specific compulsory license for the manufacture of medicine destined for a developing country, one Member State stated that "anyone may apply to the courts to be granted a non-exclusive license for the manufacture of pharmaceutical products protected by patents and for their export to a country that has insufficient or no production capacity of its own in the pharmaceutical sector, and which requires these products to combat public health problems, in particular those related to HIV/AIDS, tuberculosis, malaria and other epidemics (beneficiary country)". The policy objectives of that law is to "improve public health in least developed countries and countries that have little or no manufacturing capacity in the pharmaceutical sector", based on the decision of the General Council of the WTO in 2003. One

Member State's law stipulated that "where for reasons of public health, national security, non-commercial public use, or national emergency or others of extreme urgency, declared by the competent authority, the grant of said licenses shall be justified".

152. Another Member State stated that "the *ex officio* license" would be granted at the request of the Minister of Defense by Presidential Decree fixing the conditions for granting the license. The more general concept of expropriation of property in the "Expropriation Code" was referred to by one Member State. Its law stipulates that "any patent may be expropriated in the public interest on payment of fair compensation, if the need for dissemination of the invention or use by public bodies so requires". With reference to the power of the State, in one Member State, the Ministry of Defense could intervene in the patent examination process of certain categories of patents by restricting "the right to submitting patent applications abroad" and "activities that relate to nuclear energy". Further, concerning secret patents, the applicable law of one Member State provides that the "Ministry of Defense may order [...] the secret processing of a patent application, in which case the applicant or the owner must abstain from any act which might disclose the invention to unauthorized persons. Nonetheless, the Ministry of Defense, at the owner's request, may authorize acts leading to full or partial working of the subject matter of the application or the patent, indicating the conditions by which such acts are bound".

153. Two Member States referred to specific exceptions related to the use of a patent in good faith. In one Member State, where a "patent application has been filed by a person who had no entitlement to the grant of the patent" if the court has ordered a transfer, in respect of licenses or other rights granted in the interim to third parties, a non-exclusive license should be granted if the third parties have already, in good faith, used the invention for professional purposes.

154. Some Member States referred to specific exceptions related to biotechnological inventions such as "patents related to living matter" which had been lawfully introduced in the market or "biological material obtained by multiplication or propagation". One Member State stated that patent protection did "not extend to biological material obtained from the propagation or multiplication of biological material placed on the markets [...] where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication". The policy objectives of the law are to "define the scope of the exhaustion" referred to in EC Directive 98/44.

155. One Member State referred to exceptions and limitations to the activity of a medical practitioner related to the treatment of human and animals, such as "medical practitioner's performance of a medical activity". The law stipulates that patent protection should "not apply against the medical practitioner or against a related health care entity with respect to such medical activity". It is further stipulated that "medical activity means the performance of a medical or surgical procedure on a body, but shall not include [...] the use of a patented machine, manufacture, or composition of matter in violation of such patent, the practice of a patented use of a composition of matter in violation of such patent, or [...] the practice of a process in violation of a biotechnology patent". In those provisions, "medical practitioner means any natural person who is licensed by a State to provide a medical activity and "related health care entity shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic".

156. One Member State referred to "limitations of exclusive rights while performing duties and contracted work". Its law contains several exceptions for "service inventions", "inventions created in performance of work under a contract" and "inventions created in performance of work under a State or municipal contract", including the grant of a simple (non-exclusive) license to the initial inventor. Those exceptions or rights are introduced with the policy objectives to

secure the initial rights of the inventor whose exclusive rights have been transferred to the employer.

157. The law of one Member State provides: (i) a “procedural limitation”; (ii) the “lawfulness of working” limiting the patentees rights to lawful use; and (iii) limitations with regard to a “legal monopoly”.

158. In another Member State, an exception is provided for the “contributory infringement” for the supply and offer of a “staple commercial product”. According to a court decision, the term “staple commercial product” may be construed as a product of the “kind needed every day and generally obtainable”.

159. As an exception to patent rights other than those listed in Sections II to X of the Questionnaire, one Member State referred to the patentability of “second or further medical uses of a known substance or composition” in its territory. It noted a court decision which held that a “second medical use in Swiss-type claims must be for an end-purpose distinctively different from the first even though it was also for medical purposes.” That Member State stated that courts would “continue to acknowledge the validity of patents for second or further medical uses using Swiss-type claims” and that there were no “plans for legislative amendments” or practical problems so far.

160. As a mechanism for the limitation of patent rights external to the patent system, some Member States referred to competition law, such as exceptions under the “cartel law”. One Member State referred to “reasonable and necessary remedies sufficient to address violations of [...] antitrust laws”. Referring to intellectual property rights, the competent authorities “use a flexible, effects-based approach to antitrust analysis, known as the ‘rule of reason’”. While the different anti-trust agencies would follow different procedures, in general, they include either an attempt to obtain “voluntary compliance by entering into a consent order”, an “administrative complaint” which may result in an “injunctive relief in federal court” in case of violation of the law or an “action in federal court seeking a court order forbidding future violations of the law”. In another Member State, the competition law relating to intellectual property refers to two broad categories: one involving an anti-competitive behavior that goes beyond the mere exercise of intellectual property rights, and one involving the mere exercise of intellectual property rights and nothing else. It was stated that “under the very rare circumstances set out in the section [on special remedies] the mere exercise of an IP right might raise a competition issue“. As an example, it was noted that “if an IP owner licenses, transfers or sells the IP to a firm or a group of firms that would have been actual or potential competitors without the arrangement, and if this arrangement creates, enhances or maintains market power, the Bureau may seek to challenge the arrangement under the appropriate section of the Competition Act.” Further, the competition law of another Member State “provides for the possibility of recommending the compulsory license of a patent to the competent authorities as a penalty for the infraction against the economic order.” One Member State referred to Articles 101 and 102 of the EU Treaty prohibiting anti-competitive practices.

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