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Seminar on Exceptions and Limitations to Patent Rights

Standing Committee on the Law of Patents (SCP)
Twenty-first session (November 3 to 7, 2014)

Presentation by the Secretariat

Introduction

Implementation of exceptions and limitations in Member States, without evaluating the effectiveness of those exceptions and limitations

- ❑ Acts for obtaining regulatory approval from authorities (SCP/21/3)
- ❑ Compulsory licensing and/or government use (SCP/21/4 and 5)
- ❑ Exhaustion of patent rights (SCP/21/7)
- ❑ Farmers' and/or breeders' use of patented inventions (SCP/21/6)

- Based on the Questionnaire on exceptions and limitations to patent rights: 88 responses received
- Full information available on the SCP e-forum website
- Structure of the documents: (i) policy objectives; (ii) applicable national/regional laws and the scope of the exception; (iii) implementation challenges

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ACTS FOR OBTAINING REGULATORY APPROVAL FROM AUTHORITIES

Acts for Obtaining Regulatory Approval from Authorities

- Member States that provided for exceptions and/or limitations related to acts for obtaining regulatory approval from authorities:
  - Albania, Argentina, Australia, Austria, Bosnia and Herzegovina, Brazil, Bulgaria, Canada, Chile, China, Costa Rica, Croatia, Czech Republic, Denmark, Dominican Republic, El Salvador, Finland, France, Germany, Greece, Hungary, India, Israel, Italy, Japan, Jordan, Kenya, Latvia, Lithuania, Malaysia, Mexico, Netherlands, New Zealand, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Republic of Korea, Romania, Slovakia, South Africa, Spain, Sweden, Switzerland, Thailand, Turkey, United Kingdom, United States of America and Viet Nam (52 in total)

Acts for Obtaining Regulatory Approval from Authorities

Public Policy Objectives

- To prevent a patentee from having a *de facto* extension of the patent term (e.g., AU, BR, CL, CN, IL and PT) and to facilitate the marketing of generic medicines immediately after expiration of the patent term (e.g., AT, DE, ES, FR, KE, NL, NZ and PL)
- To balance the interests between right holders and the users of those rights (BR, IL and US)
- To promote competition in the pharmaceutical market (CA, CH and IL)
- To enable the public to obtain quality medicines at cheaper/reasonable prices (CN, HU and PK)
- To comply with regional law

Acts for Obtaining Regulatory Approval from Authorities

The Applicable Law and the Scope of the Exception

- In most Member States - statutory exception
- In some Member States, this exception and experimental/scientific research exception are expressly combined into a single provision
- In few Member States, the exception is provided in laws regulating pharmacy or medicinal products

Acts for Obtaining Regulatory Approval from Authorities

Entitlement

- In most Member States, no restrictions as to the entitlement (“any person”, “any party”, “any third party” or “any legal person”)
- Some Member States specifically noted “companies producing generic medicines” (AT, DE and LV)
- Some laws state generally “those” or “non-authorized third parties” whose acts aim at developing information to obtain the regulatory approval (BR and US)
- In United Kingdom, the exception applied specifically to “those carrying out studies, tests and trials on generic medicinal products” *including* “manufacturers and suppliers of materials for such studies, tests and trials”
- Some laws do not expressly specify the entitlement (CR, NO and SK)

Acts for Obtaining Regulatory Approval from Authorities

Products covered

- In 15 Member States, the exception applies to “any products”
- In a majority of Member States, the scope of the exception is limited to certain products, such as “pharmaceutical products”, “human or a veterinary drug or a medical products”, “certain medicines and agrochemical products”, “allopathic medicines” or “drugs or veterinary biological products”
- In Australia and Norway, the exception does not cover “medical devices, or therapeutic devices” or “patented methods, equipment or other tools necessary to the process”, respectively

Acts for Obtaining Regulatory Approval from Authorities

Permissible acts

- In many Member States, “studies”, “trials”, “tests”, “examinations” and/or “experiments”, as well as “consequential practical requirements”, “related practical needs” or “related procedures” necessary for obtaining a marketing authorization for a product
- In some other Member States, all or some of the following acts are permissible: “making”, using”, “selling”, “offering for sale”, “import” and “export” (e.g., GB, ES, JO, LV, NZ, PE, PK, SV, US, VN and ZA)
  - In Canada and India, reference was also made to “constructing” and, in the Republic of Korea to a “loan and transfer”

Acts for Obtaining Regulatory Approval from Authorities

Purpose of the act − regulatory approval in other countries

- In some Member States, activities made for the purpose of obtaining regulatory approval in other countries are also covered under the exception (e.g., BR, CA, ES, IL, IN, IT, LT and PH)
  - Conditions: in Switzerland, foreign countries shall be “with equivalent medicinal product control”. In Oman and Peru, exportation is permitted only to satisfy the requirements for marketing approval in their respective countries

Timeframe for the regulatory review request

- In most Member States - anytime during the term of patent protection. In Mexico - “within three years prior to the expiry of the patent and registration shall be granted only when the validity of the patent ends”

Protection of undisclosed information (MX, PH)

Acts for Obtaining Regulatory Approval from Authorities

Implementation Challenges

- Majority of Member States responded:
  - The applicable legal framework considered adequate and no amendments
  - No challenges had been encountered in relation to the practical implementation
- Amendments taking place (CL); or were envisaged (SV), or proposals to amend were being considered (GB)
- In Brazil, “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” was carried out
- In Portugal, patentees “try to prevent the obtaining of regulatory approvals by setting up interim relief in the appropriate court”; “court decisions are not unanimous regarding this issue”
- In South Africa, “delay in processing applications to register medicines” by regulatory authorities
- In Pakistan, “the exception had never been invoked”
- Many Member States provided no answer to this question

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EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: COMPULSORY LICENSES AND/OR GOVERNMENT USE (PART I)

Compulsory Licenses

- The exception is provided in:
  - Albania, Algeria, Argentina, Armenia, Australia, Austria, Azerbaijan, Bangladesh, Belarus, Bhutan, Bolivia (Plurinational State of), Bosnia and Herzegovina, Brazil, Bulgaria, Burkina Faso, Canada, Chile, China and Hong Kong (China), Congo, Costa Rica, Croatia, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Djibouti, Dominican Republic, El Salvador, Finland, France, Gambia, Germany, Greece, Honduras,, Hungary, India, Indonesia, Israel, Italy, Japan, Jordan, Kenya, Kyrgyzstan, Latvia, Lithuania, Madagascar, Malaysia, Mauritius, Mexico, Monaco, Morocco, Netherlands, New Zealand, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Sao Tome and Principe, Saudi Arabia, Serbia, Slovakia, South Africa, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Tajikistan, Thailand, Turkey, Uganda, Ukraine, the United Kingdom, the United Republic of Tanzania, the United States of America, Viet Nam, Zambia and Zimbabwe (87 in total)

Compulsory Licenses

Public Policy Objectives

- To achieve a balance between the interest of the patentees and of third parties and/or public interest and/or society (e.g., AU, CA, IN, JP, KE, KG, MY, RU, SA and US)
- To prevent abuses which may result from the exercise of the exclusive rights (e.g., AT, CH, DE, HK, IT, PL, PT and RO)
- To promote the public interest at large, e.g., “development of economy and well-being of society”, “urgent needs of the society”, “situations of public interest and emergency”, “public health”, “national defense” and “to encourage innovation” (e.g., BF, BY, CG, GM, HN, HU, PL, RU, VN, ZA and ZM)
- To comply with obligations under the TRIPS Agreement and/or EU directives (IL, LT, LV, NL and TR)

Compulsory Licenses

The Applicable Law and the Scope of the Exception

- In all Member States - statutory exception*
- Common elements or requirements:
  - (i) beneficiaries and the competent body (bodies) which grant 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 regarding the issuance of the compulsory license as well as decisions relating to remuneration.

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* A statutory exception is also in Hong Kong special administrative region of China

Compulsory Licenses

Grounds for the grant of compulsory license:

- "non-working or insufficient working" of the patented invention (71); "refusal to grant licenses on reasonable terms" (60); "dependent patents" (57); "public health" (56); "national security" (52); "anti-competitive practices and/or unfair competition" (47); "national emergency and/or extreme urgency" (46); and "other grounds" (26)
- Other grounds, e.g.,: "failure to meet market demand on reasonable terms", "public non-commercial use; reasonable requirement of the public not satisfied; the patented invention is not available to the public at a reasonably affordable price", "overlapping rights of biotechnological patent owner and a plant variety owner", "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" and "environmental protection"
- To facilitate access to pharmaceutical products in countries with insufficient or no manufacturing capacities in the pharmaceutical sector

Compulsory Licenses

"Non-working" or "insufficient working"

- Most Member States' laws do not define the term
  - "abuse" or "non-working" occurs if the "exploitation", or "working on a commercial scale" or "adequate use" or "sufficient and continuous working" of the patented invention did not take place within a certain period of time without a legitimate reason (e.g., JP, MX, PT, UA, ZA, ZM and ZW)
  - the demand for the patented product was not satisfied in local market on reasonable terms (e.g., BF, CN, ES, GR, IL, KR and PL)
  - the patented invention is "is not being worked to the fullest extent that is reasonably practicable " or not available to the public at a "reasonably affordable prices", and/or "sufficient quantities or quality" (e.g., DO, IN, MA, OM and PL)
- In most Member States, the beneficiary of such license is "a person", "any person" or "any legal entity or natural person" or "any interested party"
  - In few Member States, a person must have a "legitimate interest" and "the technical and economic capacity" to exploit the patented invention (AL, BR, DO, HN and RU)
- Obligation to "exploit" or "manufacture" a patented invention (PT and VN)

Compulsory Licenses

Does importation constitute "working" of the patent?

- Yes - in most of Member States (e.g., CH, FR, GM, HN, IL, JP, MA, MU, MX, MY, NL, PT and RU)
  - Conditions, e.g.,: importation is only considered as working "as far as it is not involving excessive pricing (ZA); "subject to reciprocity" (DK and FI); the unavailability of the invention "in sufficient quantities or quality or at predetermined reasonable prices in [internal market], either through manufacture in Oman or importation", constitutes "non-working"
- No - in few Member States (TZ, UG and ZM)
- The issue is not specified in the laws (BA, GR, HR, PK and SK) or the issue is *sub judice* (IN)

Definition of "legitimate reason"

- In many Member States "legitimate reasons" are of a technical, economic, legal nature, or force majeure which are beyond the control of the patentee (e.g., AR, DO, HN and TR)
  - the lack of financial resources or the lack of financial feasibility of the exploitation do not constitute legitimate reasons

Compulsory Licenses

Refusal by the patentee to grant licenses on “reasonable terms and conditions” and within “reasonable period of time”

- The laws of most Member States do not define the terms
  - In some Member States, the terms decided on “a case-by-case basis”
  - Reasonableness would be “determined by the specific circumstances”, such as “fields of technologies, marketing prospects, royalties of similar technologies, the funds invested in making the invention” (CN)
  - The conditions “are not fair under the circumstances of the case, do not take account of the public interest and arise essentially out of the existence of the patent” (IL)
- In few Member States “reasonable time period” is three months (SK) or six months (OM) or 150 days from the request for the license (AR)

Compulsory Licenses

Compulsory license on the ground of anti-competitive practices

- In some Member States such practices referred, *inter alia*, to: “the fixing of excessive or discriminatory prices for patented products”, “the lack of market supply on reasonable commercial conditions” (AR, CR and DO), “engaging in an exclusionary act” (ZA); “any other act which national legislation characterizes as anti-competitive, limiting or restrictive of competition” (DO) etc.
- In some Member States, the determination of anti-competitive practices was deferred to specific bodies, such as a “judicial or administrative body”, “anti-monopoly agency” “Competition Commission, the Secretary of State or a Government Minister”, or the “Court of Free Competition (e.g., AU, CL, CN, IN, LK, LT, PK and RO)
- In some Member States, the grant of compulsory licenses on this ground is limited to the area of public health and/or semiconductor technology (e.g., CH, DE, FR and UA)

Compulsory Licenses

Grant of compulsory licenses on the ground of dependent patents

- In most Member States, three conditions should apply:
  - (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
  - (ii) the owner of the first patent shall be entitled to obtain a cross-license on reasonable terms to use the invention claimed in the second patent; and
  - (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent (e.g., AR, CL, CR, MA, PE, PH and ZA)

Compulsory Licenses

Grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”

- In most Member States, the terms are not defined
- In some Member States, “national emergencies” were defined as “state security”, “protection of public interest in the field of health and nutrition”, “protection and improvement of human environment”, “war, uprising, or other similar emergency”, “disasters, catastrophes or big accidents”, “national defense, emergency or noncommercial public good”, “food supplying, environmental protection”, public emergency which “endangers the survival of the state or its citizens” etc. (e.g., BA, HR, JO, KG, KR and RS)
- No time period to be respected before the grant of compulsory license on this ground (DJ, KP and ST)

Compulsory Licenses

Policy in relation to remuneration

- Many Member States stated that “reasonable”, “adequate”, or “equitable” “remuneration” shall be paid to the patentee, the amount of which shall be determined taking into account “merits of each individual case”, and “the economic value of the authorization” (e.g., AM, AR, CR, JO, KE, NO, RS and ZA)
- The economic value of the authorization/license - “the average rate of royalties for the sector in question, in commercial license contracts between independent parties” (CR); “it shall be commensurate with the royalty the holder of the compulsory license would have paid on the basis of an exploitation contract concluded with the patentee, taking into account the licensing conditions in the technical field of the invention (HU); or “at a level no lower than the cost of a license determined under comparable circumstances” (RU)
- In some Member States, conditions of remuneration were determined by the court or another competent body (e.g. GR, MC, SE, SV and UG)
- License can be revoked if the circumstances change (DE and SE)
- Decisions on the grant of such licenses as well as remuneration is subject to judicial review (AR and PT)

Compulsory Licenses

Number and technological areas where compulsory licenses have been issued

- In most Member States - no compulsory licenses have been granted in their territories or no data available (e.g., AM, AR, AU, BA, BO, BT, BY, CA, CL, CN, CR, DZ, GM, KE, KG, MU and OM)
  - Number of compulsory licenses in other Member States:
    - Once – Brazil (pharmaceutical products), Germany, India (pharmaceutical products), Poland (mining industry), Portugal (plant protection products), the Republic of Korea (non-exclusive license), Turkey (mechanical engineering), Zambia (pharmaceutical products), Zimbabwe (pharmaceutical products);
    - Twice - Switzerland (dependent inventions)

Compulsory Licenses

Implementation Challenges

- Most Member States responded:
  - The legal framework of the exception was adequate to meet the objectives sought
  - No challenges in relation to the practical implementation of the exception
- The relevant provisions were “not yet practically tested” (LK and MU)
- In some Member States the amendments were planned or were taking place (BF, CA, CL, QA, SV and UG)
- In Zambia and Zimbabwe the legal frameworks were not considered adequate
- Challenges: “considerable burden of proof on the applicant for compulsory licensing” (ZA); “lack of technological capacity” (UG); “insufficient or no capacity on the part of local industries to produce generic pharmaceutical products when the compulsory licenses were issued” (TZ and ZM)

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EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: COMPULSORY LICENSES AND/OR GOVERNMENT USE (PART II)

Government use

- The exception is provided in:

  - Albania, Algeria, Argentina, Australia, Austria, Azerbaijan, Bhutan, Bosnia and Herzegovina, Brazil, Burkina Faso, Canada, China and Hong Kong (China), Congo, Costa Rica, Croatia, Cyprus, Dominican Republic, Finland, France, Gambia, Georgia, Greece, Honduras, India, Indonesia, Israel, Kenya, Kyrgyzstan, Latvia, Lithuania, Madagascar, Malaysia, Mauritius, Morocco, Netherlands, New Zealand, Norway, Oman, Pakistan, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, the Russian Federation, Sao Tome and Principe, Saudi Arabia, South Africa, Sri Lanka, Tajikistan, Thailand, Uganda, Ukraine, United Kingdom, United, Republic of Tanzania, United States of America, Viet Nam, Zambia and Zimbabwe (62 in total)

Government use

Public Policy Objectives

- Public interest: national security, national emergency, nutrition, health or the development of vital sectors of the national economy, matters of paramount importance to the country, remedy the anticompetitive practice (e.g., BF, DJ, DZ, KE, MY, PK and UG)
- To enable the government to use the invention whenever it is required (BT and IN);
- To permit the government “to procure devices or services that it needs for its own governmental purposes” (US)
- To allow “immediate use of these inventions to meet the urgent needs of the community during a period of extreme urgency” or to enable the government “to use the patented invention at epidemic complicated emergency situations” (HK and KG)

Government use

The Applicable Law and the Scope of the Exception

- Most Member States' laws provided a specific statutory provision on this exception.
- Some Member States referred to provisions on compulsory licensing (e.g., HR, MD, QA and RO)
- Few Member States referred to: "expropriation of a patent", "assignment of invention", "acquisition of a patent by the State" and "the Crown's right to sell forfeited articles" (e.g., AU, PT and ZA)
- In the United States of America, 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"

Government use

Grounds

- “national security” (46); “public health” (38); “national emergency and/or extreme urgency” (35); “other grounds” (19); “anti-competitive practices and/or unfair competition” (16); “refusal to grant licenses on reasonable terms” (14); “non-working or insufficient working of the patented invention” (11); and “dependent patents” (5)
- Other grounds: “public needs” and “development of economically important sectors”, “nutrition”, “public interest” such as “national security, nutrition, health, environmental conservation”, “any other public service”, “matters of “vital public interest” […] including national economy, public order and morality”, and “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”
- “No limitation with respect to the use by Government” (IN) “while the applicable law refers to matters of national security or national emergency, it does not specifically exclude the other grounds”(NZ)

Government use

Competent body which grants government use and beneficiaries

- "the Minister", "the National Executive", "the State", "the Crown", "the Commissioner", "the Commercial Court", the "competent authority", or "the King"
- Beneficiaries: the government or government agencies and third parties
  - "the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States"
- Notification of the patentee or applicant
- The scope, duration and other conditions of government use
  - the scope and duration of the use shall be limited to the purpose for which the use was authorized
  - such use shall be non-exclusive
  - any use shall be authorized predominantly to supply the domestic market
  - 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"
- Remuneration

Government use

Number and technological areas where the government use exception has been applied

- Malaysia and Zambia - once in each country (pharmaceutical products)
- Thailand – seven patents (pharmaceutical products)
- In most Member States - the government use exception has never been invoked or no data available (BT, CA, CN, DO, GM, JO, KE, LV, MA, MU, NZ, NO, OM, PK, PL, PT, RU, SA, ST, TJ and UG)

Government use

Implementation Challenges

- Most Member States responded:
  - The legal framework of the exception was adequate to meet the objectives sought
  - No challenges in relation to the practical implementation of the exception
- In Bhutan, Morocco and Qatar the relevant provisions would be amended
- In Zambia and Zimbabwe, the current legal framework was not considered adequate
- In Uganda, the lack of technological capacity was a challenge

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EXHAUSTION OF PATENT RIGHTS

Exhaustion of patent rights

- Member States that responded to questions regarding exhaustion of patent rights (76 in total)

  - Albania, Algeria, Argentina, Armenia, Australia, Austria, Azerbaijan, Bosnia and Herzegovina, Brazil, Bulgaria, Burkina Faso, Canada, Chile, China, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Dominican Republic, El Salvador, Finland, France, Gambia, Georgia, Germany, Greece, Honduras, Hungary, India, Israel, Italy, Japan, Jordan, Kenya, Latvia, Lithuania, Madagascar, Mauritius, Mexico, Morocco, Netherlands, New Zealand, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Sao Tome and Principe, Serbia, Slovakia, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Tajikistan, Thailand, Turkey, Uganda, Ukraine, United Kingdom, United Republic of Tanzania, Unite States of America, Viet Nam and Zimbabwe (76 in total)

Exhaustion of patent rights

Public Policy Objectives

- Achieving an appropriate balance of rights
  - Avoid indefinite and repeated remuneration to a patent holder for the use of the patented invention pertained to the same product
- Facilitating trade and competition

Applicable laws

- Statutory provisions in most Member States
- In some Member States, provided under case law
  - Doctrine of implied license (CA, UK)

Exhaustion of patent rights

Exhaustion regimes

- National exhaustion
- International exhaustion
  - In some Member States, under certain conditions
    - Parallel importation is lawful, complies with the principles of commercial competition and fairly takes into account the economic value of the protected patents (JO)
    - Cost of parallel imported product is less than the cost of purchasing the product from the patentee (ZW)
- Regional exhaustion
  - MSs of the Agreement Revising the Bangui Agreement on the Creation of an African Intellectual Property Organization or the Agreement on the European Economic Area
  - Often regional and national exhaustion rules apply in parallel
- Uncertain

Exhaustion of patent rights

Exhaustion regimes

- Mixed exhaustion regime (depending on the nature of goods or circumstances)
  - In principle, national exhaustion: parallel import of medicines may be allowed under certain conditions (SA)
  - In principle, national exhaustion: Minister of Commerce and Industry may declare the patent rights exhausted under certain conditions (OM)
  - In principle, EEA regional exhaustion: international exhaustion applies if a patent protection is of secondary importance due to the functional characteristics of the goods or to means of agricultural production and agricultural capital equipment; where the price of the goods are set by the State in Switzerland or the country of commercialization, the goods may be only placed in Switzerland with the agreement of the patentee (CH)

Exhaustion of patent rights

Exhaustion – in details

- "Lawfully" put on the market (e.g., AM, AR, CL, DM, MG, NL, TJ and VN)
  - authorization by the owner (AR); without violation of patent rights (UA); products put on the market under CL or prior use exception
- In some Member States, a patent holder may be able to limit the applicable exhaustion of rights through contractual restrictions or under certain conditions (AU, HU, IT and UK (doctrine of implied license))
  - Mere notice on the product by a patentee cannot override the applicable exhaustion doctrine
- Process patents
  - A patented process is exhausted only when the process is performed with a device, the rights in relation to which have already been exhausted (RU)

Exhaustion of patent rights

Implementation Challenges

- Most Member States responded that:
  - The legal framework of the exception was adequate to meet the objectives sought;
  - No challenge had been encountered in relation to the practical implementation of the applicable exhaustion regime
- Two Member States responded that the applicable exhaustion regime was not deemed appropriate or adequate (DZ, ZW)
- Two Member States stated that it had not been tested (BT, LK)
- In some Member States, the issue is under discussion or amendments to the applicable law is envisaged (CL, SV and RU)
- Challenges were reported by some Member States: e.g., availability of parallel import (KE, SV); importation of counterfeit pharmaceutical products (ZW); recycled goods under design patents (CN)

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FARMERS' AND/OR BREEDERS' USE OF PATENTED INVENTIONS

Farmers' and/or Breeders' Use of Patented Inventions

SCP/21/6 addresses:

Exceptions and limitations to patent rights

(farmers' and/or breeders' use of patented inventions)

It does not address:

Exceptions and limitations to plant breeders' rights

(farmers' and/or breeders' use of plants under plant variety protection)

Farmers' and/or Breeders' Use of Patented Inventions

- The exception is provided in:

  Albania, Austria, Bosnia and Herzegovina, Brazil, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Latvia, Lithuania, Mexico, Netherlands, Norway, Poland, Portugal, Republic of Moldova, Saudi Arabia, Serbia, Slovakia, Spain, Sweden, Switzerland, United Kingdom and Viet Nam (28 in total)

- Plants and animals are not patentable subject matter in some Member States
- The extent of patent protection and exhaustion rule applied to biological material which is propagated or multiplicated from the patented biological material and which has the same characteristics as the patented material

Farmers' and/or Breeders' Use of Patented Inventions

Public Policy Objectives

- To balance the interests of a patent owner, farmers and breeders with respect to patented invention involving biological material

Farmers' and/or Breeders' Use of Patented Inventions

- The sale or commercialization of **plant propagating material to a farmer** by the patent holder or with his consent implies authorization to the farmer **to use the product of his harvest for propagation or multiplication by him on his own farm**
- The sale or commercialization of **breeding stock or animal reproductive material to a farmer** by the patent holder or with his consent implies authorization to the farmer **to use the livestock for an agricultural purpose**
  - Not covering commercial exploitation of harvested product or commercial reproduction activities (ES, GR and LV)
  - Farmers, other than small farmers, shall pay remuneration (NL, UK); no remuneration payment (NO)
  - Limited to certain agricultural species (NL)
- Patent rights do not extend to biological material which was obtained **accidentally or technically unavoidable** in the agricultural sector (AT, DE)

Farmers' and/or Breeders' Use of Patented Inventions

- The patent right does not extend to propagated biological material obtained from the biological material put on the market, if the **propagation necessarily results from the application for which the biological material was marketed**
  - The exception applies to a single act of propagation (no subsequent use for further propagation) (AT, PL)
  - A similar provision in conjunction with the exhaustion of rights (PT)

Farmers' and/or Breeders' Use of Patented Inventions

- Acts for **creating or discovering and developing a new plant variety**
- Non-commercial use of patented living material as an **initial source of variation in order to obtain other products**

  - Creating or discovering and developing other plant varieties (FR; similar provision in CH)
  - Non-commercial use of patented subject matter related to living material as an initial source of variation to obtain other products (BR)
  - Non-commercial use of patented subject matter related to living material as an initial source of variation to obtain other products, provided that such use is not repeated (MX)

Farmers' and/or Breeders' Use of Patented Inventions

- Where **a plant breeder cannot exploit his/her plant variety right without infringing a prior patent**, he/she may request a compulsory license to the extent that such a license is necessary for the exploitation of the plant variety
  - The variety constitutes significant technical progress of considerable economic interest compared with the patented invention
  - Non-exclusive; non-assignable except with that part of the enterprise; payment of appropriate remuneration; unable to obtain a voluntary license from the patent holder
- In case where such compulsory license is granted, **a patent holder is entitled to a cross license** on reasonable terms to use the protected variety

Farmers' and/or Breeders' Use of Patented Inventions

Implementation Challenges

- Most Member States responded that:
  - The legal framework of the exception was adequate to meet the objectives sought;
  - No challenge in relation to the practical implementation of the exception
- Preparation of the introduction of an exception in relation to the use of biological material for breeding purposes, i.e., to discover and develop new plant varieties (NL)
- The exception allowing use of the patented product as an initial source of variation to obtain other products raised concerns about the traditional practice of farmers and possible contamination of traditional crops by pollen of transgenic crops (MX)