Question Q202

National Group: [Italy]

Title: **The impact of public health issues on exclusive patent rights**

Contributors: [insert names of contributors]

Date: [insert date]

I) Analysis of current law and case law

The Groups are invited to answer the following questions under their national laws:

1) Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?

1) Yes, according to Italian Industrial Property Code (CPI), art.68, the exclusive right granted by the patent right shall not extend to acts performed in private and for non commercial purposes or for experimental uses even though aimed at obtaining, even in foreign countries, an authorization for the commercialization of a medical product and for the subsequent practical fulfilment, including therein the preparation and the use of the pharmacologically active raw materials strictly necessary for that purpose. Research or experimental use are not permitted for commercial purposes.

2) Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?

2) Yes, according to Art.61.5 CPI, in addition to the provision mentioned above, the companies which intend to produce pharmaceutical products for commercial purposes, may start the registration procedure regarding the

active principle one year before the expiration of the complementary patent protection related to the active principle.

3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?*

3) Yes, it's contrary to Articles 28 and 30 of the European Treaty for a patentee to assert its patent rights in one Member State to prevent parallel imports of patented products placed in the market of another Member State by the patentee or with its consent. According to art.5 CPI, the exclusive rights are exhausted once products have been put on the market in the State or in the European Community or in the EEA by the proprietor or with his consent.

There are not decisions of national courts on this matter.

4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

4) Yes, according to art.68 CPI, the exclusive right granted by the patent right shall not extend to the extemporary preparation of medicine in chemists' shop according to a prescription and to the medicaments thus prepared, and to the units thereof, on condition that active principles industrially obtained are not used.

5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?*

5) No, according to art. 45 CPI, methods for treatment of the human and animal body by surgery or therapy and diagnostic methods practiced on the human and animal body shall not be regarded as inventions.

6) *Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency,*

other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.

6) Yes, according to art. 70 CPI, after three years from the date of granting of the patent or four years from the date of filing of the application, whicheer is later, a compulsory license may be granted for a non exclusive use of such invention, in favour of any interested party upon request, if the owner of the patent, or his successor has not put into practice the patented invention, by producing in the territory of the state or importing objects produced in a Country being a member of the European Union or of the European Economic Area or of the World Trade Organization, or put into practice it in a way as to result seriously out of the proportion having regard to the need of the Country.

Moreover, according to art. 71 CPI, a compulsory license may be granted if the invention protected by the patent cannot be used without infringing a patent granted on the basis of the previous application. In such a case, a license can be granted to the owner of the second patent to the extent that it's necessary to exploit the invention. The owner of the patent covering the main invention shall be entitled, in his turn, to be granted a compulsory license over the patent covering the dependent invention on reasonable conditions.

According to art. 81 CPI, third parties that intend to manufacture for exportation an active principle covered by complementary protection certificates granted according to Act 19 October 1991, n. 349, shall have the right to start, with the owners of the above mentioned certificates, a procedure at the Ministry of Production Activities aimed at obtaining the granting of a non exclusive licenses, against payment. The licenses shall in any case be valid solely for the exportation to Countries in which patent protection and the protection conferred by a complementary protection certificate does not exist, is expired or in which the exportation of the active principle does not represent an infringement of the relevant patent. The

effects of the license shall cease upon the expiration of the relevant complementary protection certificate. As regards the procedure of license on active principles (art. 200 CPI), the applicant shall send a request to UIBM (Italian Patents and Trade Marks Office). UIBM shall promptly communicate the request to the interested parties and to those who have acquired rights in the patent. Within ninety days the parties shall reach an agreement as to the amount of a royalty. If the Office has not given any communication to the parties, the license agreement shall be considered as reached. When the parties communicate to the UIBM that an agreement has not been reached, the Office shall start a conciliation proceeding. When, notwithstanding the above conciliation proceeding, the settlement for the license is not concluded, the Office provides for the transmission of the proceeding acts to the antitrust Authority.

On 23 February 2005, the Authority opened an investigations into alleged abuses of dominant positions by Merck & Co. Inc (Case A364), preventing the development of the market for a certain generic drug. The investigation originated in complaints from producers of generic drugs (DOBFAR S.p.A.), who complianed that they were refused a license under artt.81 and 200 CPI by Merck on an active principle (IMIPENEM CILASTATINA, CCP n.76). The complainants considered that they needed the principles in order to be able to compete with Merck's products. The Authority ordered to Merck to grant a license, because the refusal of Merck was at the same time exclusionary, since it prevents the development of the competing products, and exploitative, since it allows the owner of the active principle to charge higher prices and may amount to an abuse under art. 82 of the European Treaty.

7) *Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.*

7) The European Council Decision of 19 November 2007, on behalf of the European Community, has decided to accept the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005. Therefore the art. 31 bis is in force.

8) Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?

No

9) Is the government allowed to expropriate a patent and, if so, under which conditions?

8-9) According to art. 141 CPI, an industrial property rights may be expropriated by the State in the interest of the military defence of the country or for other reasons of public interest. Expropriation may be limited to the right to use for the needs of the country, without prejudice to the provisions concerning compulsory licenses if applicable.

A decree ordering the expropriation for reasons of public interest shall also determine the compensation to which the owner of the industrial property right shall be entitled, based on the market value of the invention.

10) If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.

10) No other means are provided.

II) Proposals for adoption of uniform rules

The Groups are invited to put forward proposals for adoption of uniform rules regarding health-sensitive limitations of patent rights with a view to protecting public health. More specifically, the Groups are invited to answer the following questions:

1) Should patent law provide for

– *research and experimental use exception*

YES

– *Bolar exception*

YES

– *parallel import of patented medicines*

YES, in omogeneous economic areas e.g. EU and EEA

– *individual prescriptions exception*

YES

– *medical treatment defence*

NO

– *compulsory licensing*

YES

– *expropriation*

YES

– *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*

If so, under what circumstances? If not, why not?

YES e.g according to Art 31bis TRIPs

2) *Dou you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

NO

3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*

YES. Harmonisation should be promoted taking into account the different characteristics of the sanitary systems, hence by homogeneous areas.

National Groups are invited to comment on any additional issue concerning the impact of public health issues on the patentee's exclusive rights which they find relevant.

Q202 Summary

With regards to the experimental use exception the big question is whether during the period of protection of a pharmaceutical patent, pre- clinical and/or clinical test may be conducted.

Generally, tests for market approval of a patented substance during the protection of a pharmaceutical patent are permitted. As a result, immediately upon expiration of such patent, the pharmaceutical in question can be put onto marketplace without risk of patent infringement.

According to Italian Industrial Property Code, the companies which intend to produce pharmaceutical products may start the registration procedure containing the active principle one year before the expiration of the patent protection.

Moreover, the extempore preparation of medecine in chemists' shop are permitted, on condition that active principles industrially obtained are not used

With regards to the subject matter of the patent, methods for treatment of the human and animal body by surgery or therapy and diagnostic methods practiced on the human and animal are excluded from patentability. This provision, however, shall not apply to products, in particular substances or compositions of substances, for use in any of these methods. In other words, an invention comprising the use of a substance or composition in such a method may be patentable.

Concerning the compulsory license, nations currently have the right to issue compulsory licenses on patents. The Paris Convention for the Protection of Industrial Property plainly states that "*each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work*." In Italy is in force art. 70 of Industrial Property Code: a compulsory license can be granted for non exclusive use if the owner of the patent has not put into practice the patented invention.

A particular complusory license can be granted if the invention protected by the patent cannot be used without infringing a patent granted on the basis of the previous application. In such a case, a license can be granted to the owner of the second patent to the extent that it's necessary to exploit the invention.

The procedure of license on active principles is very detailed: the applicant shall send a request to UIBM (Italian Patents and Trade Marks Office) and, if the parties communicate to the UIBM that an agreement has not been reached, the Office shall start a conciliation prooceeding. If the settlement for the license is not concluded, the Office provides for the transmission of the proceeding acts to the antitrust Authority.

With regards to expropiation, an industrial property rights may be expropriated by the State in the interest of the military defence of the country or for other reasons of public interest. The decree ordering the expropiation for reasons of public interest shall also determine the compensation to the owner of the patent.