Pharmaceutical Patent Law in Italy

Recent developments in introduction of special law, with added comments by author

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The Italian Constitutional Court's decision of March 20, 1978, deleted the first paragraph of Article 14 of R.D., June 29, 1939 No. 1127 (hereinafter the Italian Patent Law) prohibiting patentability of pharmaceutical inventions.

The Court, in the final part of its decision, expressed some concern about the various transitional problems created by suddenly passing from the old non-patentability system to the new one and practically suggested to the government and the Parliament to take prompt action and enact a new bill solving said problems.

A number of draft bills, of different sources (prepared by members of the Parliament, by the associations of the pharmaceutical industries, by the Ministry of Industry), were published shortly after the publication of the above decision.

Conferences were held on this subject and different opinions were expressed in many occasions by experts and managers as to the opportunity of introducing in Italy a special law regulating pharmaceutical patents. Arguments were brought in favor and against such a special law. The Council of Ministers, in the meeting of October 20, 1978, approved a bill draft (hereinafter the Governmental bill draft), which was not discussed by the Parliament due to its early dissolution for new elections.

For a while, practically during 1979, the enactment of a special bill relating to pharmaceutical patents seemed to be put aside, notwithstanding the fact that certain infringement litigation was started on the basis of pharmaceutical patents filed before March 20, 1978, and forming part of the bunch of patent applications whose granting was refused by the Italian Patent Office and which gave raise to the trial in front of the Constitutional Court.

Recently, a new bill draft has attracted the attention of the interested circles: its text seems to be approved by the Confederation of the Pharmaceutical Industry and acceptable to the Government. The bill draft consists of the following 10 articles:

Article 1

Subject matter of a patent can be any new inventions relating to medicaments of any kind, substances and compositions, to processes for their production including new methods for the manufacture of substances existing in nature and new substances which may be obtained through such methods, and to new therapeutical uses of substances or compositions already known to the status of the art.

COMMENTS

This article corresponds, substantially, to Article 1 of the governmental bill draft. Note that besides drug and methods for their production also new methods for the production of substances already existing in nature and new therapeutical uses of substances or compositions already known are patentable.

Article 2

In connection with medicament patents, the invention must refer to a substance or to a homogeneous series of well defined substances or to one or more compositions of substances, for which the main medical and physico-chemical properties, the method or the production methods, as well as the pharmacological activities that justify their therapeutical interest are adequately described in the patent application.

COMMENTS

Also, this article substantially corresponds to Article 2 of the governmental bill draft. It seems to limit the scope of Italian pharmaceutical patents vis-a-vis pharmaceutical patents which can be obtained, effective also in Italy, through the European Patent Office. If this article is finally approved, problems may arise not only in the sense that Italian inventors in the pharmaceutical field may prefer to file their future patent applications at the European Patent Office in order to obtain broader coverage, but also vis-a-vis Italian pharmaceutical patents granted from patent applications filed after the publication date of the Constitutional Court decision mentioned above and prior to the entering into force of the new bill. In fact, the present Italian Patent Law, applicable also to pharmaceutical patents filed after said decision, does not provide for any limitation of the kind indicated in said Article 2.

Article 3

Second paragraph of Article 52 of R.D. dated June 29, 1939, No. 1127 does not apply to inventions relating to medicaments and methods for their production.

COMMENTS

Article 52, second paragraph, of the Italian Patent Law, referred to in Article 3, deals with the possibility to work an invention through exposition at a trade fair. Article 3 of the governmental bill draft provided also that the second paragraph of Article 14 and Article 32 of the Italian Patent Law were not applicable to

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inventions in the pharmaceutical field, but both said articles have been recently abrogated by Presidential Decree No. 338 dated June 22, 1979. Particularly, Article 14, second paragraph, dealt with the right of the Italian Patent Office to ask the advice of the Superior Council of Health to establish if a given product could be considered a drug, while Article 32 provided for the obligation of the Italian Patent Office to ask the advice of the Superior Council of Health if there was a doubt that a certain invention could be unsafe.

Article 4

The compulsory license of Article 54, second paragraph, No. 2, of R.D. June 29, 1939, No. 1127 as amended by Presidential Decree of February 26, 1968, No. 849, is granted, as to patents mentioned in Article 1 hereof, to the extent necessary to exploit the invention, through a decree of the Ministry of Industry, upon advise of the Health Ministry, according to the procedure provided for in Articles 54-quater, quinquies and sexies of the above mentioned R.D. No. 1127, every time it is obtained a proven pharmacological result, having a real therapeutical interest.

COMMENTS

This article corresponds to Article 6 of the Governmental bill draft. Article 54, second paragraph, No. 2, of the Italian Patent Law provides for the right of the owner of a dependent patent to obtain a compulsory license from the owner of the dominant patent in case the invention covered by the dependent patent constitutes a substantial technological progress. Article 4, applicable only to pharmaceutical dependent patents, seems to limit the broad concept of "substantial technological progress" to include only "a proven pharmacological result, having a real therapeutical interest". This wording seems also to restrict this kind of compulsory licensing only to pharmaceutical product patents, so excluding process patents which may very well constitute a substantial technological progress with respect to prior process patents but which can not show any therepeutical interest since, I feel, only substances or compositions are capable, as such, to show therapeutical interest.

Articles 54 — quater, quinquies and sexies of the Italian Patent Law, deal with the procedure for obtaining compulsory licenses (application to the Patent Office, oppositions, decree of the Ministry of Industry).

Article 5

After Article 54 — sexies of R.D. June 29, 1939, No. 1127 the following article is added:

"Article 54 — septies — In case of serious and ascertained needs of public health safeguard, which the owner of the invention is unable to face, patents concerning medicaments or methods for their production may be subject to a system of special compulsory license for the duration and at the conditions indicated in the decree of the Ministry of Industry, issued upon request of the Health Ministry, after consultation with the Superior Council of Health. The decree of the Ministry of Industry is notified, care of the Central Patent Office, to the owner of the patent and is published in the Official Gazette.

After the publication of said decree, any entrepreneur having proper technical ability may ask the Central Patent Office a special compulsory license for the patents indicated in such decree.

The technical ability of the applicant is ascertained by the Health Ministry, who, to this purpose, orders inspections in the factories.

The granting decree is issued by the Ministry of Industry, in agreement with the Health Ministry, and shall indicate its duration as well as the conditions of the grant among which, particularly, the provisional determination of the compensation.

The final determination of the compensation is left to the agreement of the parties or, in case an agreement is not reached and without prejudice of the right of the parties to go to Court, to a panel of three friendly arbitrators, appointed one by each of the parties and the third one by the first two arbitrators and, in case of disagreement, by the President of the Court identified in accordance with Article 75 of R.D. June 29, 1939 No. 1127.

The disagreement on the compensation does not suspend the effectiveness of the decree of grant of the license and in particular of the provisional determination of the compensation.

COMMENTS

This article corresponds to Article 7 of the governmental bill draft which also provided for a special compulsory license for pharmaceutical patents, if this was necessary to safeguard the public health. However, there are two main differences: first, the compulsory license, according to the new bill draft, will be granted only if the owner of the patent is unable to face such public health needs, and, second, the Ministry's decree granting the compulsory license will fix a provisional compensation to be paid to the patentee. If the parties do not agree with the amount of the compensation fixed by the Ministry, they have to agree between themselves or through arbitration the final compensation, but, in the meantime, the licensee has to pay to the patentee the provisional compensation indicated in the Ministry's decree.

Article 6

The owners of those patents which will be granted upon patent applications filed before March 30, 1978, are obliged to grant nonexclusive compulsory licenses to those who have used the invention covered by the patent in question, or have made investments in order to use same before March 30, 1978; investments meaning the production, commercialization, importation of active ingredients covered by patents, granted in accordance with the present article and/or their use in medicinal specialties already registered or for which, within March 30, 1978, a registration application has been filed together with the complete pharmacological, toxicological and clinical documentation, as required by the existing regulations.

The owner of the patent under the preceding paragraph has the right to obtain a compensation, to be fixed according to Article 9 hereinafter, for the period subsequent to March 30, 1978.

The disagreement on the compensation does not suspend the effectiveness of the compulsory license.

COMMENTS

This article corresponds to Article 8 of the governmental bill draft. Please note the definition of investments given in this article, including also the filing of a complete health registration application.

It is not clear if this compulsory license has to be granted by the patentee or by the Ministry of Industry as the compulsory license under the proceding article. Furthermore, it is not foreseen any technical ability of the company asking for the compulsory license, while the compensation has to be agreed by the parties and, in case of disagreement, by three friendly arbitrators, without prejudice of the right of the parties to go to court.

Article 7

Those who have not filed in Italy, when the first paragraph of Article 14 of R.D. June 29, 1939, No. 1127 was in effect, patent applications for inventions concerning medicament or methods for their production or whose patent applications were finally rejected before March 30, 1978, will be entitled to file or re-file within 180 days from the publication of the present bill, patent applications for said inventions, provided that it is shown that the same application was filed, before March 30, 1978, at least in four member States of EEC.

The duration of the patent starts from the filing date of the application in the first foreign country. The effects of the patent start from the filing date of the application in Italy.

COMMENTS

Also Article 9 of the governmental bill draft contained substantially the same provision, i.e. the possibility of filing in Italy a sort of "importation" patent, provided the same application was filed, of course, before March 30, 1978, in at least four Member States of the EEC.

Article 8

All those who can prove to have used, before March 30, 1978, the invention covered by a patent granted in accordance with Article 7 of the present law, shall have the right to obtain a nonexclusive, royalty-free compulsory license.

The same right shall have those who can prove to have made, within the above date, investments for the use of the inventions described in the preceding paragraph, investments meaning those defined in Article 6.

COMMENTS

This article provides exactly with the same wording contained in Article 10 of the governmental bill draft, a further type of special compulsory license. It is a royalty-free, nonexclusive license to which is entitled anybody who has used, before March 30, 1978, the invention covered by what we have called "importation patent" or has made investments, as this term is defined in Article 6 above, to use such invention.

Article 9

Subject to the provision of Article 8, the owners of the patents granted in accordance with Article 7 are obliged to grant nonexclusive licenses to any requesting party.

The determination of the compensation is left to the agreement of the parties or, if the agreement is not reached and without prejudice of the right of the paries to go to court, to a panel of three friendly arbitrators appointed one by each of the parties and the third one in agreement between the parties or, in case of disagreement, by the President of the Court as identified in accordance with Article 75 of R.D. June 29, 1939, No. 1127.

The disagreement on the compensation does not suspend the effectiveness of the decree granting the license. During the trial of appeal against the arbitration award, the licensee's obligation to pay the compensation fixed by the arbitration panel cannot be suspended.

COMMENTS

Also, this article reflects the content of Article 11 of the governmental bill draft and gives the possibility to any interested party to obtain a compulsory nonexclusive license under a patent filed and granted in accordance with Article 7 of the new bill draft. Of course, there is a substantial difference between the license provided for in Article 8 and this license which is not royalty-free and therefore a compensation shall be agreed upon between the parties and, in case of disagreement, according to a procedure which is the same as the one provided for in Article 5 above.

Article 10

The license provided for in Articles 6, 8 and 9 can be assigned only together with the undertaking or with the particular branch thereof in which the invention is used.

COMMENTS

This provision is obviously dictated with the aim to discourage possible abuses on the part of "compulsory licensee," wishing to assign the compulsory license obtained by the patentee to a third party. It has to be noted that such nonassignability is not provided for the compulsory license under Article 5, which is the only special compulsory license requiring the technical ability of the licensee, to be ascertained case-by-case by the Health Ministry. This seems to be a nonsense, because if the license under Article 5 is freely assignable, even without the undertaking or the particular branch thereof where the invention is used, it may happen that such a license is assigned to a company without the technical ability requested for the first "compulsory licensee."

TRANSLATION OF THE BILL DRAFT NO. 526 PASSED TO THE PRESIDENT OF THE SENATE ON NOVEMBER 29, 1979

Article 1

In the case of patents concerning medicaments, substances and compositions, methods for their production and new therapeutical uses of substances or compositions already known to the status of the art, anyone that can prove to have used, before March 30, 1978, the invention covered by a patent granted upon an application filed prior to said date, shall have the right to obtain a nonexclusive royalty-free compulsory license, granted through a decree of the Ministry of Industry.

Everyone that can prove to have made within the above date, serious and documented investments for the use of the inventions under the preceding paragraph, shall have the right to obtain a nonexclusive compulsory license, granted through decree of the Ministry of Industry.

For the period subsequent to the date in which the present law comes into effect, the owner of the patent shall have the right to a compensation the determination of which is left to the agreement of the parties. If the agreement is not reached and without prejudice for the right of the parties to go to Court, the determination of the compensation shall be decided by a panel of three friendly arbitrators, appointed by each of the parties and the third one by mutual agreement or, in case of disagreement, by the President of the Court competent according to Article 75, R.D. June 29, 1939, No. 1127.

The disagreement on the compensation does not suspend the effectiveness of the decree granting the license.

During the trial of appeal of the arbitration award, licensee's obligation to pay the compensation indicated by the arbitrators does not cease.

Article 2

The compulsory licenses provided for in the preceding article, will be assigned only together with the undertaking or the particular branch thereof in which the invention is used.