

Italian Senate Drafts Patent Bill

An article-by-article analysis of draft bill on pharmaceutical patents; great concern expressed among Italian authors

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The Italian Senate approved on March 18, 1981, a new bill draft on pharmaceutical patents: to become law, said bill has to be confirmed by the other branch of the Parliament. It is hard, not to say impossible, to foresee now if and when said confirmation will come and therefore if and when the new bill will be enacted.

What is sure is that the new bill draft has already created great concern among Italian authors and that more criticisms and discussions will follow. If the House of Representatives finally approves the bill as passed on to it by the Senate and no amendments are made to clarify the main interpretation problems, to obviate the most relevant objections and to reconcile the new bill with the Italian Constitution, the European Patent Convention (duly ratified by the Italian Parliament), the Italian Patent Law (recently amended by Decree No. 338 dated June 22, 1979, to make it consistent with the European Patent Convention) and the Italian general law principles, I am afraid a sort of juridical monster will be introduced in this country's law with consequent increase of litigation among pharmaceutical companies.

I am quite sure that there is enough ground to bring the most important provisions of the new bill to the Constitutional Court's scrutiny for a declaration of constitutional illegitimacy, and consequent cancellation of such provisions.

It is my intention to analyze each article and paragraph of the new bill draft to point out those provisions that, in my opinion, give rise to doubts and criticisms. The reader may probably find useful to know that in the *Les Nouvelles* of June 1980 a translation was published of the old bill draft as approved by the government (i.e. bill draft No. 1113) and of another draft, referred to as bill draft No. 526. Any difference between the above bill drafts and the new one may be easily checked by referring to said translations, keeping in mind that the Senate merged into the new bill draft the above-mentioned bill drafts Nos. 1113 and 526 as well as bill draft No. 1079, proposed by Senators Del Nero, de'Cocci et. al. on August 6, 1980.

A final preliminary remark: I have tried to translate each article as literally as possible, with a view also to have the poor language of the original Italian text reflected in the English translation. The inappropriate

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use of single words and the use of a different terminology to indicate the same legal concepts shows that the merger of the three original bill drafts was made without the necessary care and attention. I have also numbered each paragraph for better reader's reference. Said numbers, however, do not appear in the original text.

Article 1

1.1 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.

1.2 In connection with pharmaceutical product 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 are adequately described in the patent application:

- (a) chemical and chemico-physical characteristics which are sufficient to identification;
- (b) quantitatively expressed pharmacological properties that justify their therapeutical interest;
- (c) the production method or methods which allow, upon verification of any expert of the art, to obtain the compound in reference.

1.3 Patent applications, or patents granted before the entering in force of the present bill, which are nonconforming with the requirements of items (a), (b) and (c) above, must be completed in their descriptions in accordance with the prescriptions provided for in the preceding paragraph, upon request of the Patent Office of the Ministry of Industry, to be made within the term of two years from the entering in force of the present bill, under penalty of forfeiture. Such completion must be made within the term of six months from the abovementioned request, under penalty of forfeiture.

1.4 In case of medicament inventions it is also patentable the invention relating to a new therapeutical use of a substance or of a composition of substances known to the status of the art in connection with one or more previous therapeutical uses.

COMMENTS

Paragraph 1.1 is identical to Article 1 of bill draft No. 1113, except for the last sentence relating to new therapeutical uses of substances or compositions. Said concept was slightly modified and appears now at the end of said Article 1 (the same wording of Article 2 of bill draft No. 1079 is used).

Paragraph 1.2 is the result of a merger of Article 1 of bill draft No. 1079 and Article 2 of bill draft No. 1113, but it states more clearly what has to be adequately described in a pharmaceutical product patent application.

It is evident, in my opinion, the lawmakers' worry that someone may apply for and obtain in Italy very broad pharmaceutical patents which may be used to bar third parties' patents in the same field or industrial activities falling generically under the scope of such very broad patents, with great detriment to small and medium size Italian pharmaceutical companies. This is the reason why this paragraph requests that pharmaceutical patent applications must indicate not only the chemical and chemico-physical characteristics of the substance, but also that such characteristics be sufficient to identify the substance itself, and also that any pharmacological properties must be quantitatively expressed and that any production methods have to be clearly indicated so that they may be understandable to any expert.

In this connection, I must say that the wording in item (c)—“upon verification of any expert of the art” (“a verifica di ogni persona esperta del ramo”)—is rather misleading: this sentence might be interpreted as if the patent granting is subject to a previous verification by an expert of the production method(s) described therein! But I do not feel that this is the real intention. Rather, I note that it seems, if we stick to the literal wording of this paragraph, that no “pure” product patent can exist in the pharmaceutical field, since any product patent has to disclose also any production method(s) through which the product can be obtained. And this is not in line with Paragraph 1.1.

Paragraph 1.3 introduces a provision that never appeared in any previous bill drafts and that causes very serious concern. It says, that any patent application (filed) and patent granted before the entering in force of the new bill, which is not conforming with the prescriptions listed in items (a), (b) and (c), must be modified accordingly, upon request by the Patent Office; such request to be made within two years, under penalty of forfeiture! In other words, the Italian Patent Office will have to examine, one by one, all pharmaceutical patent applications and patents filed before the new bill is enacted in order to ascertain as to whether they conform or not with the prescriptions contained in items (a), (b) and (c) above. Once it has done so, the Patent Office has to request applicants and patentees to modify their patent applications or granted patents to conform them with said prescriptions.

This work has to be performed by the Patent Office in a two-year period! But, what happens if the Patent Office does not succeed in performing such work within the above stated time? Any nonconforming patent and/or patent application has to be considered as forfeited and lost! What can the applicant or the patentee do in order to avoid this? There is no provision in the new bill draft expressly providing that the applicant or the patentee may ask himself the Patent Office to modify his nonconforming patent application or patent! I must say here that Article 59—quater of the Italian Patent Law gives the patent owner the right to ask the Patent Office for a limitation of his patent. But is this provision applicable to a special situation as that one of a

pharmaceutical patent? And, is it really a patent limitation, the modification of a patent application and of a patent to conform it with the provisions contained in items (a), (b) and (c)?

Also note that, according to paragraph three of said Article 59—quater, the limitation cannot be granted by the Patent Office if a litigation is pending before a competent court and the validity of the patent is at stake. Frankly, I do not understand why the patent applicant or the patentee has to wait for the Patent Office's request and only then, within six months, he has to modify his patent, under penalty of forfeiture of the patent, if this term runs off.

And what happens if the Patent Office, after the expiration of the above six-month term, informs the patentee or patent applicant that the modifications to the original patent description, duly submitted by the patentee to the Patent Office, before the expiration of said six-month period, are not enough to conform his patent to the requirements under items (a), (b) and (c)?

But what is really absurd, under a legal point of view, is that forfeiture of the patent is dependant upon something that the Patent Office and not the patentee has to do within a certain period of time, so that the patentee or patent applicant may very well lose his patent or patent application if the Patent Office is unable or even unwilling to perform its work within the above two-year period!

It is an established Italian law principle that forfeiture of a right is a penalty against a right owner if he does not accomplish with certain law requirements or other burdens within a given time. This provision seems therefore in contrast with Italian general law principles.

Under a practical viewpoint I must add that everyone knows that a very great number of patent applications is pending before the Italian Patent Office, which is unable to grant them although there is in Italy no previous examination on the technical merit of the invention, but only a formal examination. How can the Patent Office face with such new, impressive duty if it is unable to perform even its “routine” work? It is true that Paragraph 7.4 of the new bill draft provides that within nine months from the enactment of the new bill, the Patent Office's staff has to be properly strengthened, but it is also true that, even if the above term is complied with, only 15 months will remain to the Patent Office to examine any and all patent applications and granted patents in the pharmaceutical field and to request their owners to possibly modify them according to items (a), (b) and (c): but it is really so easy to distinguish if a given chemical compound, for instance, useful as insecticide, can be used also as a drug or if a chemical process can be used also to manufacture a compound which is also an active ingredient useful in the pharmaceutical field?

A Trick?

I hope this is not a sort of diabolic trick, to render completely unenforceable any and all pharmaceutical patent applications and patents filed before the enactment of the new bill! Otherwise, it would be really a detestable way to make old Article 14 of the Italian Patent Law still survive after its death was decided by the Constitutional Court in March 20, 1978!

If this is not the lawmaker's intention, then the House of Representatives must modify this absurd provision, at least by giving to any patent applicant and patentee the right to file an application at the Patent Office in order to modify his patent application or patent with the view of making it consistent with items (a), (b) and (c).

But this is the least the House of Representatives must absolutely do. There are other serious reasons to be considered and that may convince the House of Representatives that the best solution for everyone would be to drop out completely Paragraphs 1.2 and 1.3 of this Article 1.

A first reason is of Constitutional order: Article 3 of the Italian Constitution states the fundamental principle of equality of every citizen before the law. I have the strong feeling that all restrictions contained in Paragraphs 1.2 and 1.3 put inventors and patent owners in the pharmaceutical field on a different and discriminatory footing vis-a-vis inventors and patent owners of other technological sectors. To obtain a valid patent, the latter do not have to observe all restrictions contained in items (a), (b) and (c) and therefore they may obtain more easily public recognition and legal protection of their inventions than pharmaceutical inventors.

The second reason is that, as mentioned before, Italy has duly ratified the European Patent Convention and has also modified its pre-existing Patent Law in order to put it in line with said Convention (DPR No. 338). Now, Article 52 of said Convention clearly states what is patentable and what is not: no special provision exists as to pharmaceutical inventions. Article 167 allowed a transitory reservation for those countries wanting to exclude in their territories, pharmaceutical products "per se" from patentability, but Italy did not express such reservation either when the Convention was signed or when it was ratified; then, the Italian Parliament cannot approve now a bill which is not in line with the above Convention without contradicting itself and without going against International law and Article 10 of the Constitution.

But also other practical reasons exist: since anyone may obtain a pharmaceutical patent in Italy by filing an European patent application according to the rules of the Munich Convention, we would find ourselves in Italy in a rather awkward situation, as far as pharmaceutical patents are concerned. In fact, different kinds of pharmaceutical patents would co-exist and be valid in Italy, with different kinds of disclosures: patents granted by the European Patent Office and more restrictive patents granted by the Italian Patent Office in accordance with items (a), (b) and (c)! I am afraid this situation would not favor Italian small and medium pharmaceutical companies that Paragraph 1.2 probably wants to protect. Larger domestic and foreign pharmaceutical companies would more easily be in a position to obtain, also in Italy, pharmaceutical patents through the more expensive and difficult route of the European Patent Convention. Furthermore, said larger companies would certainly have more financial resources and research facilities than smaller ones to perform any additional works, studies, analyses and experimentations necessary to file in Italy a patent application in accordance with the requirements of items (a), (b) and (c).

Article 2

It is not infringement of a pharmaceutical patent the extemporary and per unit preparation of medicaments made by a pharmacist upon doctor's prescription, and the use of the invention for the purpose of experimentation, study or research.

COMMENTS

The provision contained in the above Article 2 did not appear in any of the three bill drafts which were, as mentioned before, merged into the new bill draft. I think there is nothing more to say about this Article 2, and particularly about its second part which seems to be a useless repetition of what is a general principle of patent law accepted not only in Italy, but also in any other country.

Article 3

As to inventions in the medicament field the terms within which to work the patented invention as indicated in Article 54, first paragraph, of Royal Decree No. 1127 dated June 29, 1939, as said article was modified by Article 1 of Presidential Decree No. 849 dated February 26, 1968, are raised respectively to 5 years from the date of the patent grant or to 6 years from the date of the application filing, if the latter term expires later.

COMMENTS

This article corresponds to Article 3 of bill draft No. 1079. Article 54, first paragraph, of the Italian Patent Law provides that if the patentee or its licensee does not work in Italy the patented invention (or has worked it insufficiently) within 3 years from the patent grant or 4 years from the filing date, whichever date is later, it will be obliged to grant a compulsory license on a nonexclusive basis to any third party requesting such license.

Due to any necessary pharmaco-toxicological and clinical studies and experimentation as well as health registrations time consuming proceedings, any new drug needs more time to be marketed than other patented products: probably it is in consideration of this fact that Article 3 raises from 3 to 5 years and from 4 to 6 years the time period within which a pharmaceutical patent must be worked.

The above sounds reasonable, but it is not clear if such longer terms apply also to pharmaceutical process patents: the words "inventions in the medicament field", if intended broadly, may be interpreted as including also inventions relating to new methods to produce known substances. But the above time extensions, in my opinion, is unjustified as to process patents, since there is no need to perform pharmaco-toxicological and clinical trials and to file a new health registration if the substance is already known. Therefore, I think it would be wise to clarify the wording of this Article 3 and allow said time extensions for product patents only. Otherwise, Article 3 of the Italian Constitution could be again appealed, this time, by inventors and pa-

tentees of technological sectors other than the pharmaceutical one, who would claim to be discriminated against by said clause creating an unjustified privilege in favor of inventors ad patentees of pharmaceutical process patents!

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, and subsequent modifications, 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 to be issued within one year from the application, in agreement with the Ministry of Health, according to the procedure provided for in Article 54—quater, quinquies and sexies of the above-mentioned R.D. No. 1127, also when it is obtained a new and proven pharmacological result, having a real therapeutical interest, or a technical progress giving an advantage in connection with ecology conditions or a contribution to reduce the dangers of production processes for workers.

COMMENTS

Article 54, second paragraph, No. 2 of the Italian Patent Law, which is presently in effect for any kind of patents (including also pharmaceutical patents until a new bill is not enacted) provides for two different cases of compulsory licenses. The first case is that the owner of a dependent and later patent has the right to obtain a compulsory license under the earlier and dominant patent, if the former constitutes a substantial technological progress. The second case applies when the two inventions have the same industrial aim: in this situation, it is the owner of the earlier and dominant patent having the right to obtain, in its turn, a compulsory license under the later and dependent patent.

Now, Article 4 of the new bill draft considers a particular type of compulsory license for pharmaceutical patents, to be granted by decree of the Ministry of Industry, in agreement with the Ministry of Health, within one year from the application, not only when a substantial technological progress is achieved through the dependant patent, but also when the result mentioned in said article is obtained. This new text of Article 4 has clarified a doubt which could raise from the wording of Article 4 of the bill draft No. 1113: in fact, the use of the words "also when" instead of "every time" now makes clear that Article 54, second paragraph, No.2 of the Italian Patent Law applies *also* to pharmaceutical patents; but it is still unclear if also the second kind of compulsory license considered in said Article 54, applies to pharmaceutical patents. In other words, the doubt remains as to whether the owner of the earlier and dominant patent has the right to obtain a compulsory license from the owner of the later and dependent patent, when the two intentions have the same industrial aim.

Article 5

After Article 54-sexies of R.D. June 29, 1939, No. 1127 as amended by Presidential Decree of February 26, 1968 No. 849 and subsequent modifications, the following article is added:

5.1 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.

5.2 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.

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

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

5.5 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.

5.6 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.

5.7 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

Article 5 of the new bill draft, is practically the same as Article 5 of bill draft No. 1113. The only difference is that it is no more necessary for the Ministry of Health to ask for the previous advice of the Superior Council of Health.

Article 6

6.1 The owners of patents 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.

6.2 The owner of the patent under the preceding paragraph has the right to obtain a compensation, for the period subsequent to March 30, 1978, the determination of which is to be agreed upon by the parties. In case of disagreement, the compensation is determined according to Article 50 of R.D. June 29, 1939, No. 1127, as amended by Article 24 of

Presidential Decree June 22, 1979, No. 338, with a reduction, on the evaluation so made, of 66% for the period from March 30, 1978, to the entering in force of the present bill, and of 33% for the remaining validity period of the patent.

6.3 The disagreement on the compensation does not suspend the effectiveness of the compulsory license decree. Pending the law suit to contest the arbitrators' award, licensee's obligation to pay the compensation as determined by the arbitration panel can not be suspended.

COMMENTS

This article is the result of the merger of Article 6 of bill draft No. 1113 and of Article 5 of bill draft No. 1079 and contains some important new provisions.

Paragraph 6.1 corresponds to first paragraph of Article 6 of bill draft No. 1113, but the interpretation problem caused by the use of the future tense ("patents which *will be* granted upon applications filed before March 30, 1978") at the beginning of Article 6 of bill draft No. 1113, has been now solved with the inclusion of a great number of pharmaceutical patents within the scope of the compulsory license obligation. The old formulation excluded, in my view without any justification, applicability of the above provision to the following patents:

(i) Patents which were already granted before the entering in force of the new bill upon patent applications filed before March 30, 1978.

(ii) Patents which were already granted before the entering in force of the new bill upon patent applications filed after March 30, 1978.

(iii) Patents which were granted before March 30, 1978, upon patent application filed before said date.

Paragraph 6.2 is similar to second paragraph of Article 5 of bill draft No. 1079, but contains a new provision that, in my opinion, has no legal ground at all! In fact, this paragraph provides that the patentee granting a compulsory license must obtain, for the period after March 30, 1978, a compensation to be determined by mutual agreement of the parties. In case of disagreement, said compensation shall be fixed by a panel of three friendly arbitrators pursuant to Article 50 of the Italian Patent Law (who knows why here and in Paragraph 5.6 two different arbitration proceedings are contemplated?). Now, said arbitrators, according to Article 50 above, have to fix a "fair" compensation and I can hardly understand why the licensee shall have the right to a discount on the compensation fixed by the arbitrators if such compensation is "fair" compensation is "fair" and why said discount shall be equal to 66% from March 30, 1978, up to the entering in force of the new bill, and to 33% for the remaining life of the patent! I feel it may be reasonable not to pretend from the good-faith user of the invention any compensation up to March 30, 1978, as he has made investments before the Constitutional Court decision, i.e. when Article 14 of the Italian Patent Law was in force. But I can not find any legal reason justifying the above discounts of 66% and 33%, although it is clear the political intentions of helping the local pharmaceutical companies that are using third parties patents!

Article 7

7.1 The compulsory license under the preceding Article 6 may be granted directly by the patent owner to the party wishing to obtain it. It must be notified to the Central Patent Office by the patent owner, after an agreement has been reached with the licensee, for any possible further carrying out pertaining to the Ministry of Industry.

7.2 In any other case, anyone who wants to obtain the compulsory license provided for in Article 6 of the present bill, must apply to the Central Patent Office pursuant to the procedure of Articles 54-quater, 54-quinquies, 54-sexies of R.D. June 29, 1939, No. 1127 and subsequent modifications thereto.

7.3 The compulsory license application has the effect of the license itself until it has not been denied by decree of the Ministry of Industry.

7.4 The procedure shall come to an end within 180 days from receipt of the justified application at the Central Patent Office which will be given any proper staff and suitable means within nine months from the entering in force of the present bill.

7.5 The compulsory license under the preceding Article 6 is granted effective as of March 30, 1978. It has the life corresponding to the remaining life of the patent and can be assigned only together with the licensee's firm or with the particular branch thereof in which the licensed invention is used.

COMMENTS

Paragraph 7.1 contains something new vis-a-vis the preceding bill drafts and introduces in the Italian law a third license category that creates in the writer substantial doubts and perplexities. As known, there exist now two types of licenses: the voluntary one, granted under an agreement, and the compulsory license, granted by the authority through an administrative deed (i.e. a decree) independently or even against the will of the licensor, provided, however, that all conditions required by the law are satisfied.

Paragraph 7.1 of the new bill seems to introduce a third license category: the compulsory license granted by force by the licensor through a private agreement! According to said Paragraph 7.1, this sort of forced agreement has to be notified to the Patent Office, provided that the licensee agrees! On what the licensee has to agree? What if he does not agree?

Another provision which is, in my opinion, without legal reason is contained in Paragraph 7.3: the compulsory license application has the same effect as a granted license up to the time when the compulsory license is denied by the Ministry of Industry! Here, not only is it given for granted that somebody can apply for a compulsory license even if he has no ground to obtain it, but also an immunity is warranted for the whole period of time of the bureaucratic procedure, i.e. until the Ministry of Industry decides to refuse the grant of the compulsory license to whom has used a patent without any ground! Now, it may sound reasonable that the compulsory license, once it has been granted, has retroactive effects starting from the application date (see Paragraph 7.5), but it has absolutely no justification any retroactive effects of a compulsory license which is never granted! Paragraph 7.3 says that the proceedings to obtain a

compulsory license must come to an end within one year from the application date, but it does not say what happens if the same proceeding does not end within said period.

Paragraph 7.5 was taken by Article 6, second paragraph, of bill draft No. 1079 and needs no more comments. A final consideration on this Article 7 it has taken the place of another rather strange article, i.e. Article 7 of bill draft No.1113 which provided for the possibility to file patent applications in Italy, after the priority year was expired, to those patentees that had filed corresponding patent applications in a least four Member States of the EEC. Also, old Articles 8 and 9 of bill draft No. 1113, providing for compulsory licenses under the above patents have disappeared.

Article 8

The fees provided for in items 90 and 91 of the tariff attached to Presidential Decree dated October 26, 1979, No. 641 and subsequent modifications are due for any compulsory license under Article 5 of the present bill.

COMMENTS

I do not believe it is the case to examine here how much are the fees due under items 90 and 91 mentioned above; I have to note that this article corresponds exactly to Article 7 of bill draft No. 1079 and that the reference to Article 5 is completely wrong! In fact, bill draft No. 1079 contemplated in Article 4 the compulsory license which is contemplated now in Article 5 of the new bill draft and in Article 5 the kind of compulsory license which is now provided for in Article 6! This may be considered as an example of the accuracy with which the new bill draft has been worked out!

A final remark about this new Article 8: it has disappeared in the new bill draft, old Article 8 of bill draft No. 1079, saying that the provisions of the bill has a duration of 10 years from the date the bill entered in force. The fact that this provision has been canceled has to be interpreted in the sense that the new bill will not have transitory nature.

Article 9

Any license agreement or supply agreement concerning patented active ingredients entered into after March 30, 1978, between patent owners and users under Article 6 hereof, which are not conforming to said article, are null and void.

COMMENTS

Also this Article 9 is completely new and has no juridical ground, although it is clear the political aim for which it has been written. It provides for the invalidity of any and all license and supply agreements signed after March 30, 1978, among patent owners and those licensees being in the position to obtain a compulsory license under Article 6 of the bill, if the agreements in question are not in accordance with the provision of said Article 6. But

what does Article 6 provide for? It states, first, that the compensation for the license has to be agreed upon by the parties, and therefore I do not see the reason why any such agreement shall be considered as null and void, if the compensation has been agreed upon by the parties, as it is usual in any agreement. If, on the contrary, what is meant is that are null and void those agreements that do not foresee the 66% and 33% discounts on the compensation fixed by the arbitrators, it would be better to express this concept more clearly. But this would also lead to the absurd consequence that any compensation, even if duly and freely agreed upon by the parties, has to be submitted to the arbitrators and that the revised compensation fixed by them should be thereafter reduced by applying the 66% and 33% discounts!

In my view, this article is against the general principles of Italian law and probably also contrary to the Italian Constitution, and particularly to Article 41 (freedom of any private economic initiative) and Article 42 (recognition and warranty of the private property), as it provides for the retroactive invalidity of agreements dealing with proprietary rights, negotiated in good faith and freely executed by the parties.

CONCLUSION

The above analysis has pointed out the main practical problems that the final approval of the new bill draft by the House of Representatives may create in Italy. It has also shown that many of its provisions are contrary to the Italian Constitution, to the European Patent Convention, and to general law principles. It is sad to notice that when political considerations are predominant in a given situation, any legal principle may be trampled on and forgotten even in a country such as Italy. Italy was proud of this legal system deriving from Roman law, and that for this was called the mother-country of the Right.

But I really wonder whether this political choice is correct and whether in so doing our country will benefit from further progress and scientific development in a field so important and delicate as the one connected with public health. Are we sure that a new bill on pharmaceutical patents along the lines of the draft we have seen is aimed to stimulate in Italy innovation and research in the pharmaceutical field? Are we sure that it will not increase the number of medicinal specialties based on molecules which are the result of researches performed abroad?

Under these circumstances, I can only express my hope that the House of Representatives, taking into account all criticisms made to the bill draft approved by the Senate (including those contained in the letter written by EEC Commissioner Mr. Narjes to the Italian Government on May 7, 1981), will substantially modify the bill draft recently approved by the Senate and will eliminate all provisions which are contrary or inconsistent with our law and, more generally, with equity principles.