

Patenting Drugs in Italy

Review of newborn patentability of pharmaceutical products, processes in light of recent Constitutional Court decision

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A recent decision of the Italian Constitutional Court whereby, after more than a century, pharmaceutical products and processes have abruptly ceased to be unpatentable in my country, has originated a number of problems and given rise to a debate which, I hope, might prove of some interest to non-Italian lawyers and those otherwise concerned with patents and licensing alike.

I will, therefore, try to summarize the main features and aspects of this subject in a general manner.

Italy has, in some way or another, had to live with a statutory bar on the patenting of pharmaceutical products and processes since Piedmontese legislation of 1855. The fundamental reasoning behind this, which has stood unaffected in principle throughout subsequent changes in legislation down to the 1939 Patent Act, still in force, may be gathered from Parliamentary reports and minutes of debates, to have consisted at one time firstly of a somewhat vague policy aiming at keeping the price of medicines low "for the benefit of the working classes" just by ruling out the cost of research from the very outset, and, secondly but of no lesser importance, of a repeatedly celebrated misconception of the "inventor" as somebody who is not supposed to contaminate his hands with money, and should rather be content with ideal considerations such as "the gratitude of the country and the recognition of the authorities." Whatever the merits of the reasoning in 1855 or thereabouts, it takes little convincing that the picture was bound to wear to some extent in the course of the subsequent 120 years.

Indeed, the unpatentability of pharmaceuticals has greatly assisted the building up of the post-war Italian pharmaceutical industry which was thus able to draw reasonably freely from technology developed by foreign research without having to pay for it and without further increasing its general orientation toward dependence upon other countries in basic research. Such has invariably been the position held by the Italian Confederation of Pharmaceutical Industry in the past, and till very recently indeed. On the other hand, it may

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be submitted that this line of thought ceased to reflect reality in the later 1960s when a relatively large-sized and reasonably-developed Italian pharmaceutical industry witnessed a progressive absence of incentive to make significant investment in research, in the concurrent absence of patentability of the findings and, thus, of prospective returns.

At the same time, pressure for Italy to bring its patent legislation in line with that of other major industrialized countries in the matter of pharmaceuticals continued to grow, especially in EEC context and with the more recent patent treaties due to come into effect in the early 1970s.

Parliamentary Action

Such being the general picture, considerations of a legal nature proper certainly made one wonder as to whether the unpatentability of pharmaceuticals was to be allowed to stand after the 1948 Republican Constitution. After an abortive attempt to have the Constitutional Court rule on the point in 1957 (Decision n° 37/1957), and with times having become riper for a repeal of the principle, Parliamentary action in that direction eventually developed, culminating with the introduction of several bills at various points in time, all aiming at removing to some extent the unpatentability rule. Partly due to lobbying and political counteraction exerted by the Confederation of Pharmaceutical Industry, speaking mainly for the small- and medium-sized manufacturers who could not afford to carry out their own research and were unwilling or unable to pay for research made by others, not one was passed. Only recently was interest shown on the government side, and a new Socialist Bill (*disegno di legge Pittella*) was introduced. Faster developments having occurred from the Constitutional Court side did, however, somewhat supersede its contents and did not permit it to go through as one might have expected.

While this is neither the time nor place to go into detail in the matter of Italian constitutional jurisdiction, I'll outline something of it for those not conversant with the subject. Unlike other legal systems, Italian law does not bestow upon the Ordinary Courts the power to rule on alleged conflicts between the prevailing legislation and constitutional principles, and a special jurisdictional body, the Constitutional Court — indeed, the highest court in the country — is set up just to deal with such matters. Individuals have no right to petition the Constitutional Court in a direct manner and, if they desire to claim conflict with constitutional principles, they are expected to do so before an Ordinary Court (whether civil, criminal or administrative) where proceedings must be pending on a different ac-

count: it is then up to the Ordinary Court before which proceedings are current to make a *prima facie* consideration of the merits of a constitutional plea and, if it finds that it is not obviously unwarranted, to grant a sort of leave to petition the Constitutional Court after stay of the proceedings in hand. The Constitutional Court is thus vested with jurisdiction over a particular plea as a result of an *ad hoc* order of the Ordinary Court concerned, and individuals are eventually given access to constitutional proceedings.

Practice

Actually, notwithstanding the until-recently-prevailing unpatentability of pharmaceuticals under Sect. 14 of the 1939 Patent Act, it had for many years been the practice of several pharmaceutical companies, mainly non-Italian, nonetheless to lodge patent applications for pharmaceutical products and processes, await refusal of registration by the Registrar, appeal against the refusal before the Patent Appeals Commission (an administrative body hearing appeals against the decisions of the Registrar of Patents) and eventually await the commission's negative decision, still in the hope that the unpatentability rule might be repealed in the course of this time-consuming exercise. The merits of this practice will be perhaps better seen if one considers that the effect of a patent backdate, under Italian law, to the time of lodging of the application. Had the unpatentability rule on any account been removed, those having lodged applications before the repeal would be given an advantage of a few years over those who would determine to lodge applications then.

As a result of appeals proceedings instituted in 1975 against refusals by the Registrar of Patents and of constitutional pleas raised thereat, the Patent Appeals Commission stayed proceedings in 15 joined cases of patenting of pharmaceuticals by as many orders issued on April 11, 1975, at the instance of as many non-Italian pharmaceutical companies. Constitutional proceedings started as a result and, by its Decision n° 20/1978 (published March 30, 1978), the Constitutional Court of Italy eventually adjudicated Sect. 14 of the 1939 Patent Act unconstitutional, substantially on the following grounds:

(a) The patentability bar conflicts with the constitutional principle whereby the Republic is to promote research, in that the absence of a prospective return would on the contrary dissuade pharmaceutical concerns from investing resources therein.

(b) The patentability bar further conflicts with the equality principle, in that it places manufacturers who nonetheless invest in pharmaceutical research at a disadvantage *vis-a-vis* manufacturers who simply elect to draw on research made by others.

(c) Alleged general considerations of public interest no longer warrant the survival of the unpatentability rule. For example, it may be ensured that patentability neither results in indiscriminate increases in the price of pharmaceuticals sold to the public through the already existing system of administrated prices, nor bars exploitation of unexploited pharmaceutical inventions as a result of the prevailing system of compulsory licensing.

An adjudication of unconstitutionality by the Constitutional Court constitutes a true repeal of the piece of legislation, or part thereof, concerned, in exactly the same way as if the repeal had been contained in an Act

of Parliament. Thus, as from March 31, 1978, pharmaceutical products and processes have become patentable in Italy as well, much in the same manner as any other invention that is patentable under the rules laid by the 1939 Patent Act.

In Line

This somewhat abrupt change in the picture, with a few consequential problems, has but brought Italian patent legislation in line with that of most industrialized countries, and likewise with the system being introduced by most recent patent treaties, namely:

(a) The 1963 Strasbourg Treaty (on the unification of certain principles in the matter of patent law) does not include pharmaceutical products or processes among those liable to being excluded from patentability (Sect. 2).¹

(b) The 1970 Washington Patent Cooperation Treaty does not deal in a specific manner with pharmaceutical products or processes, which are thus patentable like anything else that is patentable.²

(c) The 1973 Munich Treaty on the European Patent likewise fails to include pharmaceuticals among matters subject to being excluded from patentability.³

(d) The 1975 Luxembourg Treaty on the EEC patent likewise fails to provide on pharmaceuticals products and processes specifically, and merely refers on the subject of patentability to the relevant parts of the 1973 Munich Treaty (Sect. 57).

As far as domestic legislations are concerned, one may recall that:

(e) Within the European Community, pharmaceutical processes are patentable anywhere, and pharmaceutical products are patentable anywhere save Denmark and Luxembourg.⁴

(f) Elsewhere in Western Europe, pharmaceutical processes are likewise patentable anywhere, while pharmaceutical products are in principle not patentable in Austria, Finland,⁵ Greece, Iceland, Monaco, Norway, Portugal, Spain and Sweden.

(g) Elsewhere in the industrialized Western World, pharmaceutical products and processes are patentable in the United States and Canada,⁶ Australia, New Zealand, South Africa,⁷ Japan and Israel.

(h) In Eastern Europe including the Soviet Union, pharmaceutical products are as a rule unpatentable, whereas pharmaceutical processes as a rule are.

One may, thus, safely conclude that the patentability principle (subject as stated further below) indeed reflects a consolidated trend in the industrialized world, where it has been realized that the one way to really encourage research in so sensitive a field as that of pharmaceuticals, where the size of investment parallels the extent of public interest in new health discoveries, is to let research be remunerated like every other item of investment. The obvious route to attain this is to permit patentability, adequate systems of compulsory licensing being in every reasonable likelihood sufficient remedy in order to reconcile the respective requirements of public interest and free enterprise. This, it is believed, is the direction in which Italian legislation is heading.

The newborn patentability of pharmaceuticals has thus originated a number of peculiar problems of

transition from old system on to new system, which are presently in the process of being dealt with by Parliament. I would mention the following two hypotheses, which are presumably of some interest even outside a purely domestic context, i.e.:

(a) What should be the legal position of those who have, prior to Decision n° 20/1978, exploited industrially inventions of others in respect of which applications were lodged likewise prior to Decision n° 20/1978. Thus, at a time where the patenting of pharmaceuticals was indeed statutorily barred — letters patent therefore being granted at any time thereafter.

(b) What should be the legal position of those who have, prior to Decision n° 20/1978, exploited industrially their own inventions without having lodged an application, where a third party becomes applicant and thereafter patentee in respect of the same inventions subsequent to Decision n° 20/1978.

There is indeed consensus to the effect that both cases merit some extent of protection, although the unofficial position of the Italian Government and that of the Confederation of Pharmaceutical Industry differ substantially as to the means to be resorted to and as to how far exceptional legislation should be pushed in order to afford *bona fide* manufacturers a fair treatment which would presumably be ruled out if one merely applied general legal principles under the 1939 Patent Act.

Unfair Advantage

Namely, the position of a manufacturer who has commenced production relying on the unpatentability of pharmaceuticals at the relevant time, and notwithstanding the lodging by another of a patent application which at the time could not but be denied, deserves sympathy, lest one should attribute an unfair advantage to the mere "booking factor" of the lodging. The Confederation of Pharmaceutical Industry, once again speaking for the army of small- and medium-sized, goes a long way in this direction, by proposing (a) a reopening of deadlines for the lodging of applications which failed to be lodged prior to Decision n° 20/1978, subject to a basic showing of good faith by the applicant consisting of the prior lodging of not less than four applications for the same invention in as many EEC countries, (b) a system of nonexclusive royalty-free compulsory licensing automatically open to the exploiters of any invention patented by another as a result of such reopening of deadlines, where the licensee has commenced exploitation prior to Decision n° 20/1978, (c) a system of nonexclusive administrated royalty-bearing compulsory licensing automatically open to exploiters of inventions of others prior to Decision n° 20/1978, where letters patent be granted to the patentee thereafter but in pursuance of prior applications outside case b above, (d) a general system of nonexclusive administrated royalty-bearing compulsory licensing automatically open to everybody in respect of patents granted as a result of the reopening of deadlines regardless of prior exploitation, (e) the putting of actual pre-Decision n° 20/1978 exploiters on an equal footing to proposed exploiters having merely engaged in investments intended to that end. It strikes one indeed that, in the event that such proposition be-

came the law of the country, the resulting legal situation would grow uncertain beyond all expectancies over a number of years, and the Confederation's "package" has presumably little likelihood of going through at all in its present form. More sensibly, a governmental bill to deal with transitional aspects has been introduced, whereby:

—Pre-Decision n° 20/1978 exploiters of inventions patented by others thereafter in pursuance of prior applications will be granted a nonexclusive, administrated royalty-bearing compulsory license, subject to evidence of *bona fide* exploitation for not less than one year before the coming into effect of the Constitutional Court's decision;

—Pre-Decision n° 20/1978 exploiters of own inventions patented by others in pursuance of applications lodged before the decision will be granted an automatic, nonexclusive, royalty-free compulsory license for subsequent exploitation within the same limits of prior exploitation.

Parliamentary debate apart, one may reasonably guess that the government bill has more than fair chances to go along in that form in the not-distant future. Regulatory action by the government will be at any rate needed shortly since pre-Decision n° 20/1978 patent applications pending are around 1,300 and it may be expected that the registrar will soon commence issuing letters patent in respect thereof.

Compulsory Licensing

Another interesting aspect very likely to be dealt with in the legislation expected to emerge from the governmental bill and ensuing Parliamentary debate is an extension of the existing compulsory licensing system specifically intended to deal with the newborn patentability of pharmaceuticals.

Law n° 849 of 1968, amending the 1939 Patent Act, did introduce a system of compulsory licensing in Italy substantially in the following cases:

(a) Failure to exploit a patent in Italy by the patentee or its licensees within three years or grant of four years of lodging of the application, whichever is the later.

(b) Seriously inadequate exploitation of a patent in Italy in relation to national requirements by the patentee or its licensees likewise within three years of grant or four years of lodging.

(c) Reduction or suspension in the exploitation of a patent in Italy for a period of time in excess of three years, where this results in a serious disproportion between national requirements and extent of exploitation.

(d) Requirement to exploit a dependent patent together with main patent belonging to another, where the exploitation of the dependent patent represents a substantial technological progress, and subject to cross-licensing of the dependent patent for the benefit of the exploiter of the main patent.

In all above instances the grant of a compulsory license is subject to prior failure by the proposed licensee in reaching agreement with the patentee. No compulsory licenses are granted in respect of patents belonging to the Ministry of Defense or of patents which are covered by official secrecy. Further, no

compulsory license is granted if the patentee has failed to exploit the patent on account of objective reasons beyond its control, financial difficulties or insufficient domestic demand being designated to constitute no such reason. All compulsory licenses are royalty-bearing, substantially nonassignable and for a term not in excess of the remainder of the life of the patent. Infringers of patents of others are statutorily disqualified from being granted a compulsory license therefor. Further, the grant of a compulsory license does not lift the patentee's obligation to exploit the patent, and the patent is still liable to lapse if exploitation does not occur within two years of the grant of the first compulsory license, or if exploitation throughout such a period of time is found to be in serious disproportion with national requirements. Finally, in the event of subsequent licenses being granted contractually by the patentee to others, the compulsory licensee is entitled to the same terms royalty-wise if more favorable.

Such being the legal picture, it need be said that compulsory licensing is not too widely resorted to in Italy, and that proceedings for grant thereof are as a rule both complex and time-consuming. As a result, consensus substantially subsists to the effect that in so sensitive an area such as public health, faster and

more effective mechanisms should be established to make certain that the patenting of pharmaceutical inventions (whether for product or process) does not generate a mere "blocking" effect, where a long time would lapse and complex requirements would have to be met before other manufacturers are permitted to engage in the exploitation of a patent which is left dormant by the patentee save where others would infringe it.

Governmental Bill

The governmental bill deals with compulsory licensing of pharmaceutical patents in two manners. First, by stating that the Ministry of Health be jointly competent with the Ministry of Industry for the grant of the license and the definition of "substantial technological progress" for the purpose of compulsory licensing of senior patents which need be exploited together with a junior patent shall likewise include "techniques intended to reduce or eliminate impurities." Second, by introducing, on the top of and as an alternative to ordinary compulsory licensing, a special compulsory license for reasons of public health to be likewise jointly granted by Ministries of Health and Industry:

CHART I

Country	Pharmaceuticals not patentable	Pharmaceutical process patentable, product unpatentable	Both pharmaceutical process and product patentable
U.K.			X
France			X
Ireland			X
Denmark		X	
Germany (FR)			X
Luxembourg		X	
The Netherlands			X
Belgium			X
Italy			X
Austria		X	
Switzerland			X
Liechtenstein			X
Iceland		X	
Norway		X	
Sweden			X
Finland		X	
Monaco		X	
Spain		X	
Portugal		X	
U.S.A.			X
Canada		X	
Australia			X
New Zealand			X
South Africa			X
Japan			X
Israel			X
Germany (DR)		X	
Hungary		X	
Czechoslovakia		X	
Bulgaria		X	
Poland		X	
Rumania		X	
Soviet Union		X	

CHART II

Country	No compulsory licensing system in general	General compulsory licensing systems	Ad hoc compulsory licensing systems concerning pharmaceutical patents
U.K.		X	X
France		X	X
Ireland		X	X
Denmark		X	
Germany (FR)		X	
Luxembourg		X	
The Netherlands		X	
Belgium		X	
Italy		X	X ^o
Austria		X	
Switzerland		X	
Liechtenstein		X	
Iceland		X	
Norway		X	
Sweden		X	
Finland		X	
Monaco		X	
Spain		X	
Portugal		X	
U.S.A.	X	X ^{oo}	
Canada		X	X
Germany (DR)		X	
Hungary		X	
Czechoslovakia		X	
Bulgaria		X	
Poland		X	
Rumania		X	
Soviet Union		X	

(^o) — Now being introduced.

(^{oo}) — Only as an antitrust measure.

the peculiar feature of the special license is that a particular patent covering pharmaceutical products or processes would be thereby declared *licensable* in a general way. Any manufacturer giving the Ministry of Health adequate proof of technical capability may then apply to the Registrar of Patents for a grant under the decree. The license would be likewise nonexclusive and royalty-bearing, the amount of royalties being left to private negotiations or, if these were to fail, to compulsory arbitration. Pending arbitration on the amount of royalties, the license may nonetheless be granted. The Confederation of Pharmaceutical Industry is substantially backing the governmental bill in these respects.^{8,9}

The features of compulsory licensing of pharmaceutical patents are, by themselves, not too peculiar as opposed to those of compulsory licensing in general, save that the special license for reasons of public health now about to be introduced in the legislation of my country might eventually further narrow whatever results may have been arrived at in EEC integration in the patent field. The basic historical reasoning behind compulsory licensing being to make the patentee work the patent in the country — rather than prevent thereby exploitation by others and dominate domestic demand through either imports or prices — lest he should see the patent licensed to another, it has for a relatively long time been made clear that such manufacturing requirement was not enforceable by any one EEC country in relation to another EEC country, but vis-a-vis non-EEC countries solely. This reasoning is commonly held to constitute the implied consequence of the ban on quantitative restrictions contained in Article 30 of the EEC Treaty, notwithstanding Article 36 exempting import restrictions justified by the exercise of industrial property rights. Such being the general principles laid down by the Treaty, one cannot but note that there exists no EEC uniform discipline on compulsory licensing either already in force or in a reasonably advanced state of development, and that the 1975 Luxembourg Treaty on the Community patent leaves it instead to the domestic legislation of each Member State to regulate the matter of compulsory licensing even where the compulsory license concerns a Community patent (Sect. 46, Luxembourg Treaty), only making it clear that nonworking of a Community patent in a Member State is no ground for the grant of a compulsory license if the patent is adequately worked in another Member State (Sect. 47, Luxembourg Treaty).

While it is thus clear that compulsory licenses of Community (as well as domestic) patents may be granted by any domestic authority having jurisdiction therefor, in cases of the working of the patent outside the Community, Sect. 47 further exempts from the

rule compulsory licenses granted for reasons of public interest (such as the new proposed Italian special compulsory license for reasons of public health): finally, under Sect. 89 of the Luxembourg Treaty Member States may make a reservation whereby even the main principle laid down by Sect. 47 would not apply to them for a maximum period of up to 10 years, liable to being extended to 15 years. This reservation was reportedly introduced as a result of pressure by Italy at the time of drafting of the Treaty, and the combined result of Sect. 47 and 89 might very well result in the possibility of resorting to compulsory licensing of pharmaceutical patents in my country in a substantially protective manner, where exploitation of the patent in any other EEC Member State would be altogether irrelevant for so long as Community Regulations on the particular subject are enacted, whether licensing is on account of nonworking in Italy or for public health reasons.

NOTES

1. On signature of the 1963 Strasbourg Treaty, the Italian Government made a reservation, to the effect that the patentability of pharmaceuticals might have been excluded.
2. Sect. 27 (1) of the Washington Treaty, leaves it open to each Member State to fix particular patentability requisite (other than in matters of form or procedure).
3. Sect. 167 (2) (a) of the Munich Treaty leaves it open to each Member State to declare that pharmaceutical products (but not pharmaceutical processes) will be unpatentable in its jurisdiction, and that patents therefor shall be invalid therein, if so provided by domestic legislation. The reservation cannot exceed a maximum of fifteen years. Italy has not made such reservation, ratification of the Munich Treaty having occurred after Decision n° 20/1978 of the Constitutional Court.
4. In the United Kingdom and in the Irish Republic substances capable of being used as medicines and consisting of a mere mixture of known ingredients are in principle unpatentable as such.
5. New legislation is being introduced in Finland whereunder pharmaceutical products will become patentable.
6. The patentability of pharmaceutical products may be restricted in Canada if the product is obtained through a known technique.
7. Applicable same remark as in note 4 above.
8. The Confederation also applies for an extension of the nonworking deadlines prior to compulsory licensability of a pharmaceutical patent up to six years of lodging and respectively five years of grant. The Confederation finally suggests simplifications in the matter of evidence of failure to obtain a license by private contract with the patentee.
9. It may be noted that substantially all EEC countries, all Western industrialized countries and all Eastern European countries know compulsory licensing to some extent. Certain countries, like the United Kingdom, France and the Irish Republic have special rules making compulsory licensing of pharmaceutical patents more easily accessible than in general. Other countries know a wide enough concept of compulsory licensing for reasons of public interest, with consequences possibly not too wide apart from those of the proposed Italian special compulsory license (Federal Republic of Germany, The Netherlands). Canada also has a specially easy accessible system of compulsory licensing of pharmaceutical patents, and my information is that it is resorted to remarkably often. Finally, United States patent law does not contain provisions on compulsory licensing as such in a general way, save in the matter of patents covering pollution devices of interest to public health (US Code 42, para. 7608), although the courts there have sometimes used compulsory licensing as a specific tool to enforce antitrust legislation (*Chas. Pfizer vs. Federal Trade Commission* and *American Cyanamid Company vs. Federal Trade Commission* US Ct. of Appeals, 6th Circ., 30 Sept., 1968, 401 FR 2d Series 1968 574).