

Recent Trends And Developments In Italian Patent Law*

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1. It may at times be noted by those who work in the patent field that a perception exists, above all outside Italy, that Italian legislation and jurisprudential praxis in this matter are unsatisfactory or, at any rate, not completely sound. In actual fact, this perception is not (or at least, is no longer) justified. The aim of this article is to demonstrate, first of all by giving an overview of new legislation and then by examining recent case law, that Italy, too, may be considered a competent jurisdiction for patent cases and that present trends are extremely encouraging.

New Legislation

2. Over the last few years a series of new laws have been introduced relating to the IP sector and specifically the patent sector. These laws have the dual purpose of strengthening measures to protect IP rights and ensuring that IP disputes are handled by Courts which are actually competent, in the sense that they have a specialist knowledge of the matter. The first of these laws was Legislative Decree 27 June 2003, no. 168, whereby Specialized Divisions exclusively competent for all IP cases were set up at twelve Courts and twelve Courts of Appeal. Since 2003, therefore, all patent disputes have been brought before these Divisions composed of judges who have, as the law provides, “specific skills” in the area. However, even before the institution of these Divisions, a *de facto* specialization had developed at the Courts of the cities in which IP cases were frequently held (Milan, Rome, Turin, Venice, Bologna and Naples), in the sense that it was common practice to always assign such cases to a certain division, the judges of which had—or, at any rate, had acquired over time through working in that division—a good level of knowledge of the matter. However, this was a situation in which specialization was the result of a common practice and in which, above all, the possibility that the case would be handled by a specialist judge depended on whether or not the case could be brought before a certain Court, according to the normal rules of competence laid

down in the Code of Civil Procedure (CCP). If, on the contrary, for reasons of competence, a case had to be brought before another court, a particularly complex patent dispute involving substantial sums could be decided by judges who had never before in their careers dealt with such an issue. In addition to eliminating this kind of risk, concentrating patent cases before the twelve Courts and Courts of Appeal (the concentration is, in fact, even greater given that the majority of patent cases are held before the Specialized Divisions of the Courts of the six above-mentioned cities), has led to a series of other advantages.

First, under the law specialist judges now decide on cases which, albeit typically of a patent nature, could never in the past, for reasons of exclusive competence, have been assigned to those judges previously described as (already) having a *de facto* specialization. We refer in particular to disputes between employers and employees relating to ownership of a patent on an invention realized by an employee during the course of his work and remuneration to the employee for inventive activity leading to patentable inventions; these kinds of disputes are now listed among those patent cases assigned to the Specialized Divisions, as provided by Art. 134 of the 2005 Code of Industrial Property (CIP). Previously, such cases, and therefore mainly, on the one hand, actions brought by an employer claiming the ownership of patents by rights belonging to the employer but illegally filed by the employee and, on the other hand, actions brought by an employee seeking payment from an employer for inventive activity conducted in favour of the latter, came, according to the general provisions of the CCP, within the exclusive remit of the Labour Divisions. These Divisions, however, normally dealt with matters of quite a different nature, i.e. union problems, dismissals, the duties and work organization of employees, etc.. Inevitably, when the judges of such Divisions were called on to decide purely patent issues; it could, on most occasions, be seen that they were uncomfortable with and did not have sufficient knowledge of the matter. Furthermore, as the decisions of Labour Divisions are normally inclined to favour the employee, the situation was undoubtedly far from

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satisfactory (and was, in fact, often criticized by IP scholars). Decisions were issued which actually seemed to countermand current legislation (for example, awarding remuneration to an employee even in cases in which such remuneration was expressly excluded by law). Transferring this “block” of disputes to divisions specialized in patent matters constitutes, therefore, real legislative progress. The first decisions handed down by these divisions demonstrate a greater knowledge of the questions at issue and the discipline, and a much more measured approach compared to past practices, which also takes into account the interests of companies investing in research (see, for example, Court of Milan, 13 February 2007, in *Giur. ann. dir. ind.*, 2007, 669).

Other cases, in a certain sense bordering on different sectors of the law, although not expressly assigned to the Specialized Divisions (as happens in the case of employee inventions), still tend to be sent to these Divisions to be examined when a decision on the dispute presupposes assessment based on patent discipline: this is so, in particular, with actions concerning nullity or breach of patent transfer or license agreements, which straddle Civil Law and IP Law. The Court of Milan, 13 February 2007 (in *Giur. ann. dir. ind.*, 2007, 669) held that the Specialized Divisions were competent for an action seeking the nullity of a patent transfer agreement on the grounds of absence of cause, in a case in which an employee transferred a patent to an employer which, according to patent law, already belonged to the employer. The court came to this decision on the grounds that assessment of the agreement’s absence of cause depended on the application of patent law regarding ownership of inventions realized by employees and, as such, “involved the application of institutes, criteria and parameters of patent law.”

3. Leaving aside particular cases, having specialized judges has also tended (although not always) to lead to advantages in terms of the duration and management of cases. For what concerns duration, helped also by recent general reforms of the CCP aimed at shortening the length of proceedings, the time required to reach a decision on the merits in some Specialized Divisions at least is more acceptable than in the past. Although it is probably still not yet in line with the timescales of other European jurisdictions, there has been an effort (also publicly declared by some judges) to contain the length of cases, including the Expertise stage, to two/three years: this is a significant step forward compared to the past when it could at times take more than five years for a decision on the merits to be issued, espe-

cially in cases before the peripheral courts. However, the duration of cases before the Specialized Divisions is not uniform and the length of proceedings in some Courts of Appeal and the Supreme Court is still unsatisfactory.

This does not detract from the fact that, generally speaking, the fears which discouraged many foreign companies from bringing actions in Italy essentially no longer have any foundation and that, as shall be examined later, the risk, with torpedo actions, of Italian cases blocking parallel actions in other countries has now been eliminated.

On the other hand, one area of undoubted efficiency in Italian IP disputes is that of interim proceedings. There are two stages to such proceedings, the first before a single judge and the second (appeal) before a panel of three judges. The

overall duration of such proceedings is usually no longer than two/three months. With such proceedings, once the judges have ascertained that the prerequisites of law hold, injunctions accompanied by fines, seizure orders relating to the goods, documents and accounts of the counterfeiter and orders for the *descrizione* (description) of the goods produced and the processes used in violation of a patent are speedily obtained: seizure and *descrizione* measures, conducted by a Court Bailiff normally with the assistance of a technical expert, allow—albeit with the indispensable measures for protecting confidential information—compulsory access to the premises of the counterfeiter and thus the acquisition of data which would *aliunde* be unavailable.

For what concerns the management of cases, the specialization of judges can be appreciated above all in the organization of the stage involving the Expertise and the subsequent assessment of the Technical Expert’s Report. The main problem with non-specialist judges was that everything was placed in the hands of the Court Expert who was given *carte blanche* in his/her conduct of the Expertise. The result was that the judge would often only follow the conclusions of the Court Expert in his/her ruling, not departing from such conclusions even when one of the parties made well-founded criticisms of them. Now, at least at the main Specialized Divisions, judges play a much more active role, on the one hand interacting with the Court Expert during

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the technical stage (it is not uncommon for the Expert to turn to the judge for clarification on how to proceed or for the judge to intervene at the request of the parties) and, on the other hand, critically analyzing the Expert's Report: from this perspective it is becoming less and less common for a judge to merely repeat the conclusions of the Expert and there are more and more cases in which a judge, on his/her own initiative or after having heard the parties, calls on the Expert to submit clarifications, orders new or further Expert investigations or even simply departs, explaining his/her decision to do so, from the Expert's conclusions. There are consequently more guarantees for the parties for whom there is much less risk of a negative outcome arising possibly from an oversight on the part of the Expert and a greater chance that their arguments, even those of a more strictly technical nature, will be adequately considered.

4. Again with the aim of strengthening patent protection in Italy and making it more efficient, changes have been introduced by the CIP (Legislative Decree 10 February 2005, no. 30) and by Legislative Decree 16 March 2006, no. 140 which amended the Code, implementing the so-called Enforcement Directive. Although, from a substantive viewpoint, no major amendments have been made to previous legislation for what concerns the requisites of patentability and the scope of protection, the new laws (in addition to extending the field of competence of the Specialized Divisions as described earlier) have strengthened the system of sanctions in cases of patent infringement, especially for what concerns compensation.

This point had long been a cause of dissatisfaction and had made Italy an "unattractive" jurisdiction when, as normally happens, an infringement action aims at real relief for damage suffered: until not so many years ago, even when the holder of a patent won a case on the merits outright, the sums awarded as compensation were extremely modest, at times little more than symbolic, and even when the infringement was of major proportions the judge often dismissed a compensation claim, holding that no evidence had been given during proceedings of the claimed damage. In actual fact, the trend towards paying greater attention to the question of compensation had already started in the first years of 2000, and it has undoubtedly been confirmed and strengthened by these new provisions.

On the one hand, judges of the Specialized Divisions are now much more inclined to order a counterfeiter to submit documents and accounts (on the

basis of Art. 121 of the CIP). Such documentation is often the only instrument for realistically assessing compensation. The issuing of such orders is no longer conditional, as was the case in the past, upon prior demonstration of the existence of damage, something which is difficult, if not impossible, to do given that, in many cases, evidence of damage is found—and is only to be found—in the internal documentation of the counterfeiter. On the other hand, although assessment of compensation is often based on equity, judges now have to use criteria laid down in Art. 125 of the CIP, which states that a judge must take into account all "the negative financial consequences" suffered by the holder, the "benefits accruing to the infringer" and also moral damage; and also states that the holder's lost profits cannot be assessed at a sum lower than the royalties which the holder would have received if the counterfeiter had been in possession of a regular licence. Therefore, in IP cases a judge will frequently first of all order that the defendant's accounts be submitted in order that the turnover resulting from infringement may be re-constructed and then appoint an accounting expert to calculate the counterfeiter's turnover and profits and finally to estimate damage, using both the royalties method and any other methods which may be considered, according to the individual case, appropriate (of the relevant decisions see in particular Court of Rome, 6 November 2006, in *Giur. ann. dir. ind.*, 2007, 468; Appeal Court of Milan, 17 September 2005, in *Riv. dir. ind.*, 2008, II, 26; Court of Rome, 9 September 2004, in *Giur. ann. dir. ind.*, 2005, 462; Court of Bologna, 8 June 2004, *ibid*, 2005, 355; Appeal Court of Milan, 28 June 2002, *ibid*, 2004, 237; as well as, in relation to the illegal use of non-patented know how which was protected as a trade secret on the basis of unfair competition law, Appeal Court of Milan, 13 June 2007, *ibid*, 2007, 836). The awarding of damages therefore aims to provide real relief to the holder and the awarding of a certain level of damages (amounting to hundreds of thousands and even millions of Euro) is now not so exceptional.

On the other hand, Art. 125 of the CIP states that a judge may also order that all the profits of the counterfeiter be made over to the holder as an alternative to compensation for lost profits or to the extent to which the profits of the counterfeiter exceed this compensation. This measure is not yet common practice but it has already been noted, in relation to it, how the situation has, in a certain sense, been turned on its head. There is now actually the risk of a patent right being excessively protected and a

counterfeiter being ordered to pay sums which are disproportionate to the gravity of the offence, essentially from a perspective of punitive damages which is, however, extraneous to the Italian legal system.

5. While the 2005 CIP does not contain major innovations at the level of substantive law, Law Decree 10 January 2006, no. 3, later turned into Law 22 February 2006, no. 78, has introduced changes in this field. It provides a specific discipline for biotech patents, in implementation of EC Directive 98/44. The Italian law takes a more cautious approach with regard to this sector than the Directive (Italy, in fact, was one of the countries which challenged the legitimacy of the Directive before the ECJ), resulting in greater limitations on patenting and the scope of protection: the compatibility of these limitations with the Directive has been for the most part affirmed by legal scholars but has not yet been the subject of investigation by the courts. In particular, the Italian law contains a longer list of things excluded from patenting, including things not mentioned by the Directive (e.g. human embryonic stem cell lines or genetic screening protocols); if isolated elements of the human body and sequences or partial sequences of genes are patented, under Italian law their function must not only be actually indicated and described, but also “specifically claimed” so as to limit patent protection to the function in question (the Directive, on the contrary, does not require that the function be “specifically claimed” and mentions actual indication of industrial application only in the case of patenting sequences or partial sequences of genes); and, while the Community legislator did not insert provisions in the Directive on the informed consent of the provider of human biological materials (as this is considered to be a question extraneous to patent rules)—the legitimacy of the decision not to do so having been confirmed by the ECJ (ruling 9 October 2001, C-377/98, published in Italy in *Giur. ann. dir. ind.*, 2001, 1216), under Italian law a patent application must be accompanied by the “express free and informed consent” of the person from whom the material has been taken to taking and using human biological materials (in the case of biological material of animal or vegetable origin, the applicant has to indicate its origin, referring both to country of origin and “the biological organism from which it was isolated”).

In any case, with implementation of the Directive, the legitimacy of patent protection in the biotech sector (something which was previously uncertain) has now been sanctioned in Italy, too, and the difficulties linked to the particularities of inventions in

this field, to which the application of general patent rules appeared unwieldy, have been overcome; it must however be noted that court rulings, albeit rather few in number, were already interpreting these general patent rules in such a way that their decisions were in line with what would later be introduced at legislative level (Community and National), especially in terms of the patentability of living organisms; of the novelty and inventive step of the biotech invention even when it relates to biological material already present in nature or, at any rate, already obtained by “traditional” means; and of consideration, in reconstructing the scope of protection, of peculiarities deriving from the fact that the material in question is reproducible or self-reproducible and, moreover, intrinsically subject to mutations and variations: these are questions which were examined in depth in the principal Italian biotech decision, issued by the Court of Milan, in a case concerning the use of genetic sequences of the Hepatitis C virus for the preparation of diagnostic kits (Court of Milan, 11 November 1999, in *Giur. ann. dir. ind.*, 1999, 1361).

6. Not directly linked to the question of the strengthening and efficiency of patent protection, but still indicative of the current trend for a greater consideration of patent problems, are the Decrees issued by the Ministry of Economic Development of 3 October 2007 and 27 June 2008 which, on the basis of an Agreement with the European Patent Organisation, have compensated in part for the lack in Italy of prior examination of the validity of national patents by the Italian Patent and Trade Mark Office. Under the new provisions the European Patent Office (EPO), at the request of the Italian Patent and Trade Mark Office (which, in any case, “can decide not to subject to a prior art search patent applications for which the absence of the requisites of validity is absolutely clear from the declarations and statements of the applicant or is certain on the basis of well-known facts”), conducts a prior art search and draws up a search report as well as drafting “written opinions” according to the PCT rules for Italian patent applications filed starting from 1 July 2008 (and for which there is no priority claim). The search report and the written opinion are then sent by the Italian Patent and Trade Mark Office to the applicant which, within eighteen months of the date on which the application is filed, may submit its arguments, modify the description, claims and drawings and request permission to submit one or more Divisional Applications. After expiry of this term the Italian Patent and Trade Mark Office publishes the

application and decides whether or not to grant the patent, following an examination based on the EPO search report and the arguments and modifications submitted by the applicant. The aim of the new rules is clearly to reduce the number of patents granted which lack the requisites of validity (which a system which does not provide for prior examination cannot do), and to allow and motivate an applicant to advisedly “correct” the text of the application prior to conclusion of the proceedings before the Italian Patent and Trade Mark Office, avoiding a situation whereby it is always the judge who then has to ascertain the validity of the patent and examine the questions of its limitation and re-wording.

7. At legislative level, the examination of developments in the Italian system concludes, for the moment, with the recent law of 23 July 2009 no. 99 which has impacted on patent rules, on the one side expressly providing for the possibility of using the so-called internal priority mechanism (Art. 47.3 *bis*, CIP) in Italy too and, on the other, rewriting and strengthening the criminal protection of patents which the legislator intends should flank civil protection and operate in all cases of patent infringement, with custodial and pecuniary sanctions being administered. This “criminalization” of patent infringement, albeit inspired by the aim of giving greater protection to patents, lends itself to criticism (already raised during the legislative process), not only for the excessive severity of sanctions but also because it contradicts the guidelines of previous reforms, returning the assessment of patent infringement in the criminal ambit to non-specialized public prosecutors and judges, precisely when in the civil ambit the opposite path has successfully begun to be followed. At the same time, it is feared that the “new” criminal protection may lend itself to abuse and blackmailing manoeuvres which would undoubtedly constitute an unacceptable distortion.

The picture painted thus far could change again shortly, given that Law no. 99 delegated the government to issue further provisions correcting the 2005 Code of Industrial Property, and this within a year of the law coming into force, i.e. by the middle of August 2010. It seems, however, that the amendments which the decree might make to patent rules will not impact on the essential elements of the discipline.

8. On the plane of legislative reform, in which, in any case, the situation is still developing, an overall positive balance may be drawn from what has been said, albeit, as has been seen, with some elements which buck the trend. The importance of specializa-

tion and the greater consideration given to effective protection, also of a compensatory nature, are now widely perceived and consolidated, and the present situation allows the Italian system and the management of IP disputes to be defined as efficient.

Jurisprudential Developments

9. The Italian patent landscape has also been characterized by interesting jurisprudential developments in recent years. The section on new legislation has already covered some of these developments, for what concerns identification of the Specialized Divisions’ areas of competence and the greater sensitivity to questions of compensation. We shall now examine the other developments.

First, there have been various rulings on the issue of the jurisdiction of the Italian courts in cases of patent nullity and infringement. The most discussed aspect is the admissibility of actions seeking a negative ascertainment of the infringement not only of Italian patents or the Italian portion of European patents, but also of foreign patents or the non-Italian portions of European patents brought cumulatively in Italy against foreign defendants (holders of the patents) with the aim of slowing down any actions seeking positive ascertainment of infringement in States where the other patents or the other portions are effective (so-called torpedo actions). Even prior to the ECJ rulings in the GAT and Roche cases, clearly prevailing case law stated that the Italian Courts did not have jurisdiction, thus removing the basis for Italian torpedo strategies. This result was arrived at by observing that, since foreign patents (also foreign portions of the same European patent) are, to all intents and purposes, autonomous and independent of the corresponding Italian patents, if the holder summonsed in the negative ascertainment action does not have domicile in Italy, the jurisdiction of the Italian courts cannot be based either on the *forum commissi delicti* criterion of Art. 5.3 of the Brussels Convention (and thus of EC Regulation 44/2001) as, in relation to foreign patents, infringement can only take place in the State of the patent, or on reasons of connection under the same Convention (and EC Regulation 44/2001), because of the reciprocal independence of the various national portions (Appeal Court of Milan, 2 March 2004, in *Giur. ann. dir. ind.*, 2004, 837; Court of Milan, 24 January 2004, *ibid*, 2004, 783). At times, in the case of a foreign defendant, the Italian courts stated that they did not have jurisdiction even for actions seeking a negative ascertainment of the infringement of Italian patents, on the basis of the fact that the criterion of the *forum commissi delicti*

under Art. 5.3 of the Brussels Convention and EC Regulation 44/2001 would apply only to positive ascertainment actions, founded on the affirmation of a harmful event, and not negative ascertainment actions, founded on the negation of damage (Supreme Court, Joint Sitting, 19 December 2003, no. 19550, in *Giur. ann. dir. ind.*, 2004, 61). In this regard, a number of decisions have also stated that the fact that the foreign holder of a patent elects domicile in Italy at the offices of a patent attorney for the issuing of a corresponding Italian patent or for the “nationalization” of a European patent cannot serve for ascribing jurisdiction to the Italian courts on the basis of the *forum rei* criterion (Court of Padova 30 May 2005, in *Giur. ann. dir. ind.*, 2005, 930). There have, however, been decisions which have held that this election of domicile is sufficient, but only in relation to Italian patents and to the Italian portions of European patents, and never in relation to foreign patents or foreign portions of a European patent, to ascribe jurisdiction to the Italian courts: and thus, in any case, the admissibility of a torpedo action was ruled out (Court of Milan 3 February 2006, *Giur. ann. dir. ind.*, 2006, 627; Court of Milan 11 December 2002, *ibid.*, 2004, 325).

The ECJ rulings in the Roche and GAT cases on the one side confirmed and, on the other, provided further arguments against the practice of bringing torpedo actions. In fact, the Roche judgment (ECJ, 13 July 2006, C-539/03, published in Italy in *Giur. ann. dir. ind.*, 2007, 1177) stated that there is no reason to derogate from the criterion of *forum rei* on the grounds of a connection between cases relating to the various national portions of a European patent, as Italian decisions had already stated. For its part, the GAT ruling (ECJ 13 July 2006, C-4/03, published in Italy in *Giur. ann. dir. ind.*, 2006, 1097) stated that the exclusive jurisdiction of the Courts of the State of the patent in patent validity matters (Art. 16.4 of the Convention of Brussels and Art. 22.4 of EC Regulation 44/2001) holds even when the question is raised only by means of an objection, either “at the time the case is brought or at a later stage in the proceedings.” Since actions seeking negative ascertainment of infringement are usually based on a refutation of the patent’s validity, there is a further argument for holding that, when the validity of the patent is discussed in negative ascertainment actions, there is no jurisdiction of the Italian courts with regard to a foreign patent, and it is the courts of the State of the patent which have exclusive jurisdiction. Some rulings have, in fact, stated that the Italian courts do not have jurisdiction in relation to

actions for negative ascertainment of infringement of the foreign portions of a European patent due to reasons of exclusive jurisdiction according to the principle laid down in the GAT judgment (Court of Milan 18 April 2008, shortly to be published in *Giur. ann. dir. ind.*, 2008; Court of Milan, 10 December 2007 in *Giur. ann. dir. ind.*, 2007, 1100; Court of Milan, 8 August 2007, *ibid.*, 2007, 950).

The inadmissibility of torpedo actions is, therefore, also confirmed by the more recent decisions, although said decisions do not base their arguments, as in the past, on the notions of *forum rei* and *forum commissi delicti*, but on the wider notion of exclusive jurisdiction admitted by the GAT ruling. It follows that jurisdiction in actions seeking negative ascertainment of the infringement of Italian patents should no longer, as occurred at times in the past, be denied, at least when the negative ascertainment claim is accompanied by an objection of patent nullity. Conversely, in actions concerning the infringement of foreign patents, the Italian courts could only have jurisdiction if the holder of the foreign patent has its (real) domicile in Italy and if the action concerns pure infringement, without the validity of the patent being discussed, by way of action or objection.

Naturally, the interpretation now admitted of the scope of exclusive jurisdiction also operates in another direction: i.e. not only denying that the Italian courts can hear a case concerning the validity of foreign patents, but also stating that in Italy foreign decisions which rule on the validity of Italian patents cannot be considered legitimately issued. It seems that such rulings cannot be recognized in Italy, and therefore the path to follow, when Italian patents or Italian portions of European patents are at issue, is not to bring an action abroad and to then attempt to have the decision recognized in Italy, but to directly bring an action in Italy.

10. For what concerns the essential requirements for patent validity, there have been no significant changes in recent years in the assessment of the novelty and inventive step of inventions. According to well-consolidated principles, novelty is assessed by examining identity between the invention and each prior disclosure in the State of the Art and inventive step is assessed on the basis of criteria of evidence and non-evidence which serve to establish whether the invention is within the reach of a person skilled in the art. For what specifically concerns chemical-pharmaceutical inventions, the most common issue tackled in Italian rulings is that of the validity of general formula patents and, consequently, of the

scope remaining for the (selection) patenting of specific compounds subsequently identified within the general formula. The present position in Italian case law has been established by three decisions of the Supreme Court (16 November 1990, no. 11094, in *Giur. ann. dir. ind.*, 1990, 115; 6 March 1995, no. 2575, *ibid*, 1995, 113; 1 September 1997, no. 8324, *ibid*, 1997, 59) which, although nominally recognizing the validity of general formula patents, limited protection (not to the formula per se, but only) to individual compounds either already identified in the patent or which may be easily deduced by a person skilled in the art: thus, a general formula patent is essentially reduced to a patent on a certain number of individual compounds and does not cover the “family” considered per se. On the one hand this is an advantage to derived or applied research which is well-protected against possible “blocking” patents, with the recognition of the full validity of selection patents on compounds which, albeit coming within the general formula, could not be deduced from the formula on the basis of the description contained in the relative application: therefore the validity of patents on active principles with therapeutic effects, which could not be foreseen when filing the general formula patent application but are identified and realized only through further research and experimentation, cannot be disputed (and this is the most significant aspect, also from a financial perspective). On the other hand, it may be asked whether the present position of Italian case law adequately protects the results of basic research for which protection limited to individual compounds identified in or which may be deduced from the application does not seem to satisfactorily reward and motivate the identification of a certain type of molecule, which opens up the road to subsequent applicative research.

In any case, in the next few years there will be further developments in Italian case law with regard to chemical-pharmaceutical patents as cases are now pending before a number of Italian courts in which questions relating to the relationship between general formula and selection patents are being re-appraised and in which judges will have to take up a position on more specific issues already examined in other States and by the EPO but still without precedent in Italy, such as the existence of sufficient inventive step in the identification of an active principle constituted by an enantiomer or by a pair of enantiomers within a racemate or the identification of the correct stereoisomer of compounds of which the “rough” or “structural” (two-dimensional) for-

mula is already known.

For what, on the other hand, concerns new biotech patents, as mentioned earlier there have been a number of Italian decisions which have essentially ruled in line with what would later be introduced by EC Directive 98/44 and Law no. 78/2006, the latter implementing said Directive in Italy. It seems that there are for the moment no decisions which have applied the recently introduced legislation.

11. Something which has been particularly discussed in recent years (and the debate has been made more complex by the entry into force of the new text of the European Patent Convention—EPC 2000) is the question of patent limitation and especially of the amendment of claims, for example by rewriting or pooling, to limit them to the part of the patent which possesses the requisites of novelty and inventive step. The aim is to avoid a declaration of nullity and to save that part of the patent which may be protected, striking out the non-patentable part from its subject-matter. Art. 79 of the CIP allows a patent holder to ask the Italian Patent and Trade Mark Office for limitation of the patent but states that the request cannot be admitted if a nullity action concerning the patent is pending: this blocks the initiative of the patent holder which, summonsed in a nullity action, decides only at that moment to submit such a request to protect itself against the claim of nullity. It must, however, be borne in mind that the new text of Art. 138 EPC admits, in proceedings concerning the validity of European patents before national courts, that a patent holder has the right to “limit the patent by amending the claims,” and hence it is the limited text of the patent which “shall form the basis for the proceedings.” There are at the moment no Italian decisions which have already applied the new discipline or examined the relationship between the new discipline and Art. 79 of the CIP.

In any case, the consolidated trend in Italian case law is to restrict, for all patents, both national and European, the bar under Art. 79 CIP on limitation requests submitted administratively to the Italian Patent and Trade Mark Office and to allow the limiting of claims within the ambit of nullity proceedings. Said limitation will then be reflected in the ruling. The Appeal Court of Milan ruling of 25 June 2002, in *Giur. ann. dir. ind.*, 2003, 326 is particularly clear in this respect: “generally speaking the right to submit a more limited wording of patent claims to a Court Expert must be admitted. The Court Expert and the judge can admit this limited wording, obtaining it, for example, from the combination of the

principal claim with one or more secondary claims, so as to create a more limited scope of protection than the original, when it is deemed that the initially claimed scope may not meet the legal requirements of patentability”; ruling in the same way were Court of Milan 8 March 2007, in *Giur. ann. dir. ind.*, 2007, 731; Court of Milan 27 March 2004, *ibid*, 2004, 972; Appeal Court of Milan, 26 July 2002, *ibid*, 2004, 254; Court of Bergamo, 22 March 2002, *ibid*, 2002, 754.

As may be seen, therefore, the Italian courts feel that they can follow a middle path, so as to say, between recognition of the full validity of a patent and a formal declaration of partial nullity, constituted by a ruling which interprets the patent by rewording its claims in the way now indicated so that they correspond to that part of the patent which may effectively be protected. However, the problem remains, unresolved by the cited rulings, that these rulings only have inter partes efficacy. Therefore, on the one hand they are not opposable to third parties and, on the other, they allow the patent to survive, outside the ambit of the decision, in its original wording. At the same time, such amendments and re-writing are always delicate operations, as there is a risk (which judges have shown they are aware of) that the apparent limitation of a patent is, in actual fact, a ruse to broaden a patent’s scope of protection or actually save a patent which is completely null.

12. Moving on now to infringement matters, there have been some interesting developments in the form of rulings which have investigated and laid down the criteria for establishing when there is infringement by equivalence. After a number of, in some cases fairly old, rulings of lower courts (in particular, Court of Milan 4 May 1992, in *Giur. ann. dir. ind.*, 1992, 589), the Supreme Court intervened in 2004 by pegging assessment of equivalence to that of the inventive step of the “realization” of the alleged counterfeiter with respect to the subject-matter of the patent: according to the principle of law expressed by the Supreme Court “in order to assess whether or not the realization which is alleged to be infringing may be considered equivalent to the patented one, it needs to be asked whether, in permitting the same final result to be attained, it is original, offering a response which is not banal and does not repeat the previous response: that which exceeds the ability of a person skilled in the art faced by the same problem is one such” (Supreme Court 13 January 2004, no. 257, in *Giur. ann. dir. ind.*, 2004, 69). In the case submitted to the Court a ruling was overturned which, accord-

ing to the Supreme Court itself, had only found a structural difference between the patented invention and the product of the third party but had not asked whether this difference was within the abilities of a person skilled in the art or whether it was an expression of inventive step.

The principle expressed by the Supreme Court was then taken up in several first instance and appeal rulings, which all assessed equivalence on the basis of whether or not the counterfeiter’s realization was obvious to a person skilled in the art: see Court of Rome, 13 April 2006 (order) in *Giur. ann. dir. ind.*, 2006, 755; Court of Rome, 9 February 2006 (order), *ibid*, 2006, 638; Appeal Court of Bologna, 19 January 2006, *ibid*, 2007, 174; Court of Rome, 9 September 2004, *ibid*, 2005, 462; Court of Milan, 17 June 2004 (order), *ibid*, 2005, 377. Another interesting decision is that of the Court of Milan, 8 August 2007, in *Giur. ann. dir. ind.*, 2007, 950, whereby “the Doctrine of Equivalents requires verification of the identity of function, way and result as well as obviousness of modification made to the subject-matter of the patent”: the ruling thus seems to be attempting to fuse the criterion of obviousness or non-obviousness of the third party’s realization with the U.S. triple test based on identity of function, way and result.

Naturally, assessment of equivalence in terms of whether or not the third party’s solution constitutes inventive step must take into account the fact that even an original solution may constitute infringement when it is dependent on a previous patented invention: this point was precisely grasped by the Court of Rome, 9 September 2004, cited above.

13. Again with regard to infringement, another issue which has been examined in Italian decisions concerns the protection of process patents and, in particular, of patents relating to processes to be implemented by means of industrial plants, for which the problem arises of what evidence the holder has to provide in order to prove infringement. The lower courts have recently pronounced on this question, propounding conflicting principles, in two distinct disputes, relating to a process for sewage depuration and a process for deriving fuel from solid waste. In both cases the patent holder had provided evidence that the alleged counterfeiter had developed a plant which, on the basis of the machinery used and the characteristics of the plant, could exactly implement, possibly after obvious modification and regulation of the plant itself, the patented process; but had not been able to obtain evidence that the plant was actually run utilizing the process in ques-

tion. In this situation, the Appeal Court of Milan, 21 September 2007, in *Giur. ann. dir. ind.*, 2007, 986 (in relation to the sewage depuration process case), dismissed the infringement claim, stating that actual use of the plant in accordance with the protected process had to be proved and that proof of the “abstract possibility of use” according to this process would not suffice (this decision was issued by a non-specialized division—the case was brought prior to the Specialized IP Divisions being set up in 2003—by applying, for reasons of interim legislation, a probative regime which was less favourable for the holder of the process patent than the regime provided by the CIP). On the other hand, in relation to the process for deriving fuel from solid waste, the Specialized Division of the Court of Turin (in a ruling of 10 March 2009, which will be published in *Giur. ann. dir. ind.*, 2009) stated that infringement was already proven on the grounds of the fact that the third party’s plant “could effect the patented process,” regardless of proof being provided as to actual use of the process. The Supreme Court, before which an appeal against the ruling of the Court of Appeal of Milan was brought, still has to issue its decision on the case.

14. It is worth pointing out that a significant number of patent cases currently pending in Italy concern disputes between pharmaceutical companies which are patent holders (so-called originator companies) and generic drug producers whose aim is to reduce as much as possible the time required for their generics to enter the market upon expiry of patent cover, normally extended through Supplementary Protection Certificates (SPC). This conflict, obviously involving the intercrossing submission of patent and SPC nullity claims on the part of generics producers and infringement claims on the part of holders, is characterized by heated discussion on a specific problem connected to generic drugs, i.e. the lawfulness, on the one hand, of experimentation and clinical trials conducted by generics producers during the final period of patent cover and, on the other hand, of early initiation of the procedure to obtain Marketing Authorization (MA). The problem has been resolved by the CIP by means of a rather complex mechanism which allows experimentation aimed at obtaining an MA and “at the consequent practical procedures including the preparation and use of the strictly necessary pharmacologically active raw materials” even be-

fore expiry of a patent (art. 68.1.b); but also provides that the administrative procedure of registration of a generic may be started only a year before expiry of the SPC (art. 61.5).

On the basis of these provisions, in a number of currently ongoing disputes patent holders have complained that generics producers started the registration procedure more than a year prior to expiry, ignoring the limit provided in the above article. In the first decision issued (Court of Milan, 11 June 2009, which will be published in *Giur. ann. dir. ind.*, 2009) the judges interpreted Art. 61.5 in such a way that the limit was nullified, stating that Art. 68.1.b prevailed and that this article would in any case allow the filing of an MA application and starting the relative procedure, even more than a year before expiry: this represents a jurisprudential revision of the balance established by the legislator, with great favour being shown to generics producers which, the year limit having been removed, would be allowed to plan registration procedures in such a way that the required MAs could always be obtained before expiry of an SPC. The same decision also states that early submission of an MA application may not, per se, be considered an act preparatory to patent infringement, as was also maintained in two orders of the Court of Milan, dated 15 April 2009 and 5 May 2009 (which will both be published in *Giur. ann. dir. ind.*, 2009), whereby the simply granting of an MA for the generic of a drug which is still covered by patent does not, per se, constitute sufficient proof of imminent infringement and of damage to the patent holder.

As these are the first decisions on the matter, it is still too early to say whether they are the beginning of an emerging jurisprudential trend which will go on to become consolidated or whether other decisions will be issued which will be more favourable to the holders of pharmaceutical patents.

15. To conclude, it may be said that a good body of case law is now being built up in Italy, with increasingly refined decisions being issued and deeper examination of specific questions being conducted. Furthermore, judges are acquiring ever greater skills and experience. The examined jurisprudential developments also suggest that the present situation of and the future prospects for patent cases in Italy are indeed positive. ■