IP_LAW_GALLI *Newsletter*

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RECENT DEVELOPMENTS IN ITALIAN IP LAW

✓ *The new civil process and revision of the Industrial Property Code: what's changed and what is going to change for IP cases*

As is well-known, at the end of 2004 the Government approved the **Industrial Property Code** (by means of Legislative Decree no. 30/2005). It contains numerous **new provisions**, especially regarding procedural law, aimed at speeding up and streamlining IP proceedings.

Most of these new provisions came into force on 19 March 2005, fifteen days after publication of the Code in the Official Gazette, and the specialized IP Courts began to use them immediately. These courts had been set up in 2003 and their competence was extended by the Code to all cases which had «***reasons of connection, even improper***» to those explicitly attributed to the Specialized Divisions (industrial and intellectual property right disputes including copyright, Antitrust disputes pertaining to these rights and cases of "*interfering*" unfair competition).

In particular, as we shall expound more fully in the third section of this Newsletter , the Court of Milan has issued a number of **seizure and description orders for the protection of confidential**

information, availing itself of those articles of the Code which also permit application of these measures for the protection of Industrial Property rights not based on registration and patent, and therefore also for the protection of geographical indications, de facto trade marks and trade secrets.

On 19 September 2005 that provision of the Code applying **special procedural discipline,** (provided by Legislative Decree 17 January 2003, no.5) to IP cases also came into force. This is better known as the «**company procedure**», since it originally applied only to cases in this branch of the law. Under this procedure the parties, after service of the Writ of Summons and filing of the defendant's Appearance and Reply Brief, containing any counterclaims, may exchange **further briefs**, in order to restate their respective applications, both of inquiry and into the merits, and submit documents; each party may, however, bring this exchange to an end at any moment, by refraining from replying to the opponent's brief and asking the Court (which has not yet examined the papers of the proceedings) to **schedule a hearing**. In this hearing, preceded by an exchange of **final briefs**, the necessary evidence may be acquired or an expertise may be ordered after which the Court will decide in the merits. The biggest problem with this system is that **neither party knows in advance how long it will be allowed to submit documents and formulate inquiry requests for**, since this activity is foreclosed when the other party presents its request for a hearing and is thus decided by that party.

In April 2005, the Italian Parliament approved, in converting the so-called Competition Decree (Legislative Decree 14 March 2005) into law, a full **reform of the ordinary civil process**. It will come into force in **January 2006** and seems particular suitable for IP disputes. In fact, this reform:

a) concentrates all the preliminary activity of the process, from checking that proceedings have been duly initiated to possible additions to the applications, into **one single hearing** (plus a second possible hearing, held only on the agreement of the parties, in order to reach a settlement),

b) provides for **only one exchange of briefs and reply briefs, requesting evidence, between the parties** before the Court decides, in chambers, on admission of these requests (in practice, in patent cases this would allow the technical expertise normally arranged in the proceedings into the merits to begin within six months of the start of the case).

Compared to the company process, which in turn is very rapid, the advantage of this reform is that it **reduces the exchange of briefs** between the parties in the company process (said exchange risks being costly and pointless) and offers **greater certainty** as to how the proceedings will develop (in the company process proceedings are not predetermined from the outset, both because each party may interrupt the exchange of briefs, asking for the single hearing to be scheduled, and because in proceedings in which there are a number of parties this exchange of briefs becomes much more complex).

Furthermore, it **affords greater protection to foreign defendants**, since it gives them more time to file an appearance and reply brief.

The possibility of applying the new ordinary procedure rather than the company procedure to IP cases was immediately placed on the agenda of the **Commission of Experts** set up in July 2005 at the Ministry of Productive Activities, presided over by the Under Secretary delegated to deal with IP matters Mr. Roberto Cota. It was instructed to lay down a plan for a **Legislative Decree for Modification of the Code**. In fact, Art. 2 of the Law of Conversion of Legislative Decree 9 November 2004, no. 266, states that «*within a year of entry into force of the legislative decrees*» issued on the basis of the original delegation «*the government may adopt, subject to the opinion of the competent parliamentary commissions, provisions which modify or add to said legislative decrees*».

In particular, Professor Cesare Galli argued in the Commission that it would be opportune to intervene urgently with a **decree-law**, whereby not the company procedure but the new ordinary procedure would be extended to IP proceedings. This proposal was approved by the Commission and the competent Minister. However, a decree-law was not adopted as it was eventually decided that it would be preferable to intervene in a procedural matter using ordinary legal instruments.

In all likelihood, therefore, application of the new ordinary procedure to IP proceedings will be provided in an article of the **Legislative Decree for Modification of the Code** or in the **Financial Law** which will be passed by the end of the year. If this should be so, the new ordinary procedure will apply to **all cases within the remit of the Specialized IP Divisions brought after this article comes into force**, while the company procedure will continue to be used in proceedings started after 19 September 2005 but before entry into force of this article.

✓ *Protection against infringement has been strengthened: more stringent penalties for infringers and new administrative sanctions for those purchasing counterfeit goods*

As was mentioned in the previous edition of this Newsletter, the Industrial Property Code has also **strengthened criminal law protection of registered trade marks**, and of Industrial Property rights acquired by registration or patenting (which the Code refers to as «*Industrial Property Rights*»).

In fact, Art. 127 (1) of the Code states that «*Save for the application of articles 473, 474 and 517 of the criminal code, whoever manufactures, sells, displays, uses industrially or brings into the country goods which violate an Industrial Property right which is valid according to this code, is punishable, upon the request of the offended party, with a* ***fine of up to a maximum of € 1.032,91***». This article is particularly important in trade mark matters as it should apply in all cases of **non-confusing infringement** which are not covered by the cited articles. In this regard it has been asked whether the wording of the delegation by virtue of which the Code was issued (which allowed the Government to proceed with the «*formal and substantive co-ordination of the articles in force*» for the purposes of «*juridical, logical and system consistency*») makes it opportune to apply **more stringent sanctions** to these cases, and others covered by the new article, similar to those provided by articles 473 and 474 Criminal Code, or at least by Art. 517 Criminal Code. This issue, just as that of anti-piracy measures, was submitted by Professor Galli to the attention of the Commission for Revision of the Code.

The protection of trade marks by **instruments other than civil instruments** was further strengthened on approval of the previously mentioned «Decree on Competition» (Legislative Decree 14 March 2005, no. 35).

This decree introduced a new article whereby «*Unless the act constitutes a crime, the purchase or handling, without first having ascertained lawful origin, of any type of good which, by reason of its quality, the condition of the offeror or the price, causes one to believe that laws pertaining to the origin of goods and to intellectual property have been violated, constitutes an administrative offence punishable by a fine of up to €10.000*». It also states that the same sanction also applies «*to those who act as an intermediary in buying or handling the above goods in any way whatsoever without having first ascertained their lawful origin*» (Art. 1 (7) and (8) of Legislative Decree no. 35/2005).

The reason for the article, which expressly excludes cases constituting a crime, lies in the fact that the **purchase of goods bearing counterfeit marks** may also give rise to the **crime** of **handling stolen goods** (Art. 648 Criminal Code), or at least that of **purchase of property of apparent illegal origin** (Art. 712 Criminal Code). The Court of Cassation has stated, in a recent case, (see Criminal Court of Cassation, 17 March 2004, no. 12926), that Art. 648 Criminal Code also applies in cases of sale of goods bearing counterfeit marks, admitting, in that case, concurrence of the crimes of criminal counterfeiting and handling stolen goods. However, the Italian Courts have always been rather reluctant to apply these articles to consumers, while the new administrative provision had already been **widely applied** in the first months after its entry into force. This also received a lot of coverage in the media, thereby raising public awareness of counterfeiting. An in-depth article with Professor Cesare Galli on this question was published in the popular weekly "DiPiù".

The Decree on Competition was also involved in the modification of Art. 4 (49) of Law 24 December 2003, no. 350 (Financial Law 2004), which expressly stated that the «***import and export for the purposes of sale or the sale of goods bearing false or deceptive indications of origin***»,

was covered by Art. 517 Criminal Code, adding to this case that of goods bearing «***false or deceptive indications of origin***» (Art. 1 (6) Legislative Decree no. 35/2005). The extension was made in order to overcome the restrictive trend adopted by the Court of Cassation, which interpreted this article as relating only to cases in which the marks could mislead the public as to the business from where the goods originated (Criminal Court of Cassation, 2 February 2005, no. 3352).

When the decree became law a binding agenda was approved. This obliges the Government to **further strengthen customs and criminal protection of trade marks**, coinciding in timely fashion with the recent draft EU Directive of the EU Council aimed at obliging Member States to adopt criminal law instruments in this field. In fact, also as regards customs protection, in recent years the Italian customs has become notably more efficient so much so that Dr. Cinzia Bricca, Head of the Customs Anti-Fraud Office received an award from INDICAM at its annual meeting.

✓ *The Court of Cassation clarifies the transitory system for trade marks having a reputation*

An important decision of the Court of Cassation (Court of Cassation, 9 July 2005, no. 14473) has finally clarified, more than twelve years after implementation of EEC Directive 89/104, the limits of the «extended» protection for trade marks having a reputation, introduced into Italy with the reform of the Trade Mark Law by Legislative Decree no. 480/92, for the purposes of implementing this Directive. The decision was issued in a case involving a trade mark with a reputation in the dietary products and baby foods sector and an identical trade mark relating to IT products which had begun to be used in Italy prior to reform even though it had been registered in the country only after reform.

The problem lays in the fact that the transitory system which had regulated passage from the old to the new system of protection provides that «*The right to exclusive use of a trade mark granted prior to this decree's entry into force and which has a reputation does not allow the holder to oppose the further use of an identical or similar trade mark for goods or services which are not related to those for which the trade mark was registered*» (Art. 88 Legislative Decree no. 480/92, which has now become Art. 232 Industrial Property Code).

Therefore, the wording of this article could lend itself to **misleading constructions**:

a) in the sense of **definitely excluding trade marks having a reputation from extended protection if registered prior to 1992 reform**, if «*further use*» is to be understood as each use which takes place after entry into force of the new provision and not only use which is a continuation of previous use, with respect to which it is «further»; or

b) in the sense of providing a **binding interpretation of the previous law**, ruling out the interpretation given by the Courts which already admitted protection for trade marks having a reputation for goods which were not closely related, when there was still a risk of confusion as to origin (both these constructions were suggested by VANZETTI, *La nuova legge marchi*, Milan, 1993, pp. 202-203, who put forward the view that this article, if so construed, was **unconstitutional**).

The problem of interpretation was **worsened** by the fact that when Art. 1 of the Trade Mark Law was reworded with implementation of the TRIPs Agreement (Legislative Decree no. 198/96) no article of law was provided to cover the interim period. Some writers thus argued that the new wording would give rise to the **tacit abrogation** of the transitory article in Legislative Decree no. 480/92 and therefore the possibility that the holders of trade marks having a reputation could brandish their exclusive rights without limit, also against those who had already lawfully used identical or similar trade marks prior to extension of protection (see in particular SENA, *Il nuovo diritto dei marchi*³, Milan, 2001).

However, both these positions were **refuted** in legal theory by GALLI, who contended (in *Il diritto transitorio dei marchi*, Milan, 1994, p. 69 ff) that in reality a systematic reading of the article leads to the interpretation that **the new legislation providing extended protection for trade marks having a**

reputation must also be applied to trade marks registered before 1992 «*making only those limitations which are necessary to ensure respect for rights acquired through use by other parties on trade marks which are identical or similar to those in consideration but which, on the basis of the old law, could lawfully co-exist with them due to the distance between the commercial sectors in which they were respectively used*».

With regard to the 1996 Legislative Decree, GALLI (in *Nuove leggi civ. comm.*, 1998, pp. 83-84) again pointed out that «*questions of interim law can only be raised in relation to articles introduced by the Decree which actually were new, and not to articles which were changed only as regards their positioning*», as is the case for the article on protection of trade marks having a reputation, which was simply moved from letter (b) to letter (c) of Art. 1 (1) Trade Mark Law, but whose content was **the same** as that of the 1992 text, and thus **there was no question of tacit abrogation of the 1992 transitory article**.

The Court of Cassation first tackled the question in 1999 without resolving it since, in its decision no. 14315, it left it to the trial court to decide whether or not the article was unconstitutional in relation to the case in question.

In the case decided by this new decision the Court was directly given the task of resolving the question and expressly tackled it, deciding that «*The transitory article … confirms the old system of protection for trade marks having a reputation and does not extend to them the new and fuller protection which disregards relatedness and forbids unfair advantage even if the product bearing the trade mark is not related, when the conflict involves* ***trade marks predating the new legislations***» and that therefore «***The new and stronger system of protection which waives the limit of relatedness may be invoked against trade marks which have not been used any further, but which have been used only following entry into force of the new legislation***», concluding that, thus correctly interpreted, «*The article, as has been clarified for some time now by the best and most widespread legal theory,* ***runs into no constitutional obstacle***», and therefore «*the relative question is manifestly unfounded*». The Court of Cassation also **rejected the argument of the tacit abrogation** of this transitory article, observing that Legislative Decree no. 198/96, which implemented the *TRIPs Agreement*, had not «*changed the previous articles*» regarding protection of trade marks having a reputation but only repositioned them, and therefore did not give rise to any problem of interim law in their regard.

The decision also opportunely resolved another problem in the case in question (in which, as stated, the disputed trade mark was already in use prior to the 1992 reform, but was registered only following introduction of reform). The problem was which articles were to be applied in deciding on the validity of trade marks registered after they have already had a public pre-use. The decision stated that «***the novelty of the pre-used trade mark must be ascertained with reference to when pre-use began***» and that therefore «*legislation pre-dating the reform must be applied also in this regard*».

Having thus excluded, on the basis of the above statements of principle, the possibility that the conflict which was the subject-matter of the case could be resolved on the basis of trade mark legislation in force prior to implementation of EEC Directive 89/104 the Court of Cassation was unable to tackle the further question submitted to the Court regarding **extension of protection for trade marks having a reputation** which resulted from said implementation. However, the decision made two important references to this question. Firstly, it rejected the argument of lack of grounds which the appellant had leveled against the decision under appeal (Court of Appeal of Milan, 4 May 2001, in *Giur. ann. dir. ind.*, 2002, which had still ruled out the possibility of interference between the two trade marks in the case in question, also on the basis of the new law, in that the use of the latter did not actually cause «***undue advantage in favour of the third party user, or rather detriment to the holder of the trade mark***»), pointing out that the trial court had «*dealt clearly with both the range of articles 1 and 17 of the Trade Mark Law, and therefore that of the transitory article, and of its compliance with the Constitution*». Secondly, the Court of Cassation, as mentioned previously, defined the content of the extended protection for trade marks having a reputation, stating that it «*disregards relatedness and forbids unfair advantage even if the product bearing the trade mark is not related*», thus couching the requirement for

this protection in terms of «*unfair advantage*», or rather of the undue benefit derived by the trade mark of the imitator from the prior imitated trade mark.

THE CASE

✓ *The "extended" protection for trade marks having a reputation may not be invoked against those who lawfully used an identical or similar trade mark prior to extension of protection* (Court of Cassation, 9 July 2005, no. 14473) – The text of the decision

The Court of Cassation has finally stated that the extended protection of trade marks having a reputation introduced into Italy with the reform of the Trade Mark Law by Legislative Decree no. 480/92 also applies in favour of all trade marks which pre-date reform and that the only effect of the, still operative, transitory system introduced by the reform is to exclude the possibility of the extension of protection being invoked to stop the «further» use of trade marks pre-dating the entry into force of Legislative Decree no. 480/92 and then lawful, since they were used in very different commercial sectors and there was no risk of confusion for the public.

Thus the decision admitted the arguments of the defendant, represented by a team which also included Professor Cesare Galli. He discussed the case before the Court of Cassation and had already in 1994 presented the arguments now admitted by the Court of Cassation in one of his books.

A commentary on this decision (which the specialized press has also handled fully: see, in particular, the in-depth article in the financial daily "Italia Oggi") is given in the previous section of this Newsletter.

The text of the ruling now follows.

THE SUPREME COURT

FIRST CIVIL DIVISION

Composed of the judges

Dr. Antonio Saggio, President

Dr. Maria Gabriella Luccioli

Dr Massimo Bonomo

Dr. Giuseppe Maria Berruti, judge-rapporteur

Dr Gianfranco Gilardi

has issued the following

RULING

on the appeal brought by :

Plasmon Dietetici Alimentari s.r.l., (...) -APPELLANT

against

Plasmon Plc, Plasmon Data System Ltd., Reflection System Ltd., electively domiciled at the offices of the attorney-at-law Luigi Biamonti, who represents and defends them together with

the attorneys-at-law Adriano Vanzetti and Cesare Galli – COUNTER APPELLANT

against ruling no. 1168/01 of the Court of Milan, filed on 04.05.01;

having heard the report of the case presented in the public hearing of 26.04.2005 by Giuseppe Maria Berruti;

having heard, on behalf of the appellant, the attorneys-at-law … who requested admission of the appeal;

having heard, on behalf of the appellees, the attorneys-at-law Biamonti and Galli who requested rejection of the appeal;

having heard the Public Prosecutor's Office in the person of deputy public prosecutor Dr Antonio Martone who concluded by requesting rejection of the appeal.

DEVELOPMENT OF THE PROCEEDINGS

Plasmon Plc, Plasmon Data System Ltd., Reflection System Ltd., companies with registered offices in the UK, summonsed Plasmon Dietetici Alimentari (Plada) s.r.l. before the Court of Milan, requesting a ruling of non-infringement with regard to the trade mark "Plasmon" held by the defendant and used to mark baby foods. They stated that they were companies forming part of a group operating in the production and sale of IT products bearing the trade mark Plasmon and that Plada had warned them not to use said trade mark as it infringed its own. They stated that negotiations aimed at settling the dispute had not been concluded and that the distance between the commercial sectors concerned was such that there was no interference with or detriment to Plada. They also sought compensation for damage suffered as a result of the warning.

Plada responded by stressing that its trade mark had a reputation and claiming specific protection for it. It requested that the petitions be rejected and that an injunction be issued against the plaintiffs barring them from further use of the trade mark Plasmon.

The Court admitted the plaintiffs' petitions, giving a ruling of non-infringement and ordering Plada to compensate the plaintiffs for damage suffered as a result of the warning, the amount to be assessed in separate proceedings.

Plada brought an appeal which the Court of Appeal of Milan rejected. The Court in these proceedings, having resolved a number of questions which are not yet relevant as they were not submitted again to this Court, ruled firstly that the legislation regarding trade marks having a reputation introduced by the changes to the Trade Mark Law of 1992 could not be applied to the case in question but that the transitory article 88 of the law itself should be applied. It found in this regard that the appellant's argument was unfounded. The appellant had argued that the transitory system was no longer operative following Legislative Decree no. 198 of 1996 since the changes introduced by this decree resulted in the addition of letter a) to the already in force Art. 1 of the Trade Mark Law and letters f), g) and h) to Art. 17 d), with the simple new sequencing of the letters distinguishing the other retained provisions of the original text. Therefore, according to the Court of Milan, since the provisions introduced in the previous text pertain to events which differ to those covered in the articles regarding trade marks having a reputation, contained in the retained articles, in the 1996 Decree there was no explicit or implicit wish to abrogate the above mentioned transitory system. Therefore, in the light of the retained article 88 of the Trade Mark Law, a transitory article between the old and new systems concerning trade marks having a reputation, the mention it makes of the concept of similarity must be understood as being the same as the notion created during the lifetime of the abrogated system. In conclusion, in the case in question there is no infringement given the great distance between the commercial sectors in which the two products bearing the same trade mark operate.

The trial court then ruled that in any case there would have been no unlawful interference between the trade marks in question, also pursuant to the new and broader protection for famous

trade marks or those having a reputation. These further grounds for the already refuted infringement were supported by the final finding that there was no undue advantage for the subsequent user of the trade mark having a reputation, required by law as a prerequisite for applying the new rule.

Plasmon Dietetici Alimentari s.r.l., now Heinz Italia s.r.l., appeal against this ruling on three grounds. Plasmon Plc, Plasmon Data System Ltd. e Reflection System Ltd. present a counter-appeal. The parties have filed briefs.

GROUNDS FOR THE DECISION

1. The second and third grounds for the appeal must be examined first, even separately, since they regard claims relative to the alleged applicability to the case of Art. 88 of the transitory system of Legislative Decree no.480 of 1992, which, as was stated at the outset, was the basis for the first of the two alternative grounds given by the Court of Milan. These charges, therefore, must be considered prior to those relative to the second ground given by the trial court.

1.a. As regards the second ground for the appeal, the appellant complains that Art. 88 has been violated and applied incorrectly because of its unconstitutionality and implicit abrogation. The appellant contends that the appealed ruling did not apply the new rule concerning trade marks having a reputation on the basis of an erroneous reading of Art. 88, which, although intended for trade marks registered prior to the new legislation, did not abrogate the protection for trade marks having a reputation already admitted in case law, so that the appealed decision was wrong in denying protection for the above situation. The appellant also maintains that unlike the 1992 legislation, Legislative Decree no. 198 of 1996 came into force from issue of the law, without any transitory article and without distinguishing between trade marks registered prior to or following its entry into force, and that it must be deduced that Art. 88 corresponds to an inexact transposition of EC Directive 89/104 or an excess of delegation and it is therefore unconstitutional.

1.b. The Panel observes firstly that the appealed ruling clearly dealt with the above question, handling both the scope of articles 1 and 17 of the Trade Mark Law and therefore that of the transitory system, and its compliance with the Constitution. The generically alleged lack of grounds for the decision must therefore be ruled out.

1.c. As to the merits of the charge, it must be observed that Art. 88 states:

"The right to make exclusive use of a trade mark granted prior to the entry into force of this Decree or which has a reputation does not allow the holder to oppose the further commercial use of a trade mark which is identical or similar to the trade mark for goods or services unrelated to those for which it was registered".

The panel is of the opinion, in accordance with the trial court, that the transitory system (which was not set up by chance and cannot be understood if construed in a different way) confirms the old system of protection of trade marks having a reputation and does not extend to them the new and broader protection which disregards relatedness and forbids unfair advantage even if the product bearing the trade mark is unrelated, when the conflict involves trade marks predating the new legislation. The new and stronger system of protection which waives the limits of relatedness may be invoked against trade marks which are not used further but are used only starting from the entry into force of the new legislation (in this sense see also Court of Cassation 14315 of 1999, mentioned opportunely by the trial court).

The article, as the best and most widespread legal theory has already made clear, does not run into any constitutional obstacles (again Court of Cassation cit.). The relative question is therefore manifestly unfounded.

1.d. Equally unfounded is the argument regarding abrogation of Art. 88 by the 1996 Legislative Decree. The legislative innovation operated by this Decree has not changed the previous rules

already contained in the articles amended by the above Decree, as referred to in summarizing the appealed ruling, apart from the slightly different lettering. It cannot be deduced, therefore, given the complete compatibility between old and new provisions, that there was any implicit partial abrogation of the said articles, as again the Court of Milan clearly wrote.

1.e. This ground for the appeal must therefore be completely rejected.

2. In its third ground for the appeal, the appellant claims that Art. 88 has been violated and incorrectly applied and that there are no grounds for the decision on the relative point. It claims that, even admitting the just indicated interpretation of the transitory article, it must be held in consideration that the trade mark of Plasmon Data System was registered after the entry into force of Legislative Decree no. 480 of 1992. Thus the requirement of priority to the entry into force of the said Decree is lacking, which would make lawful the use (not by chance indicated as further by the law)carried out in compliance with the previous state of affairs and legislation.

2.a. The Panel observes that the trial court with an unchallenged statement ascertained that the Plasmon trade mark held by the counter appellants had been the subject of pre-use since 1991 (sheets 11 ff of the appealed ruling). It is a clear principle, which the Panel endorses, that the novelty of the pre-used trade mark must be ascertained by referring to the moment in which pre-use started. And thus, also in this regard, the legislation predating reform must be applied. The complaint is unfounded.

3. The handling of the first ground for the appeal, which concerns the alleged refutation of interference between the trade marks in question and of undue advantage accruing to the counter appellants, that is a prerequisite for considering unlawful the act in question pursuant to the new legislation on trade marks having a reputation, is absorbed by the rejection of the two above motives, given the alternativeness of the ground adopted by the Court of Milan on this point with respect to that which is based on the applicability in the case in question of Art. 88 of the 1992 legislation.

4. The appeal must be rejected. The appellant is ordered to pay the costs of the proceedings.

FOR THESE REASONS

The Court rejects the appeal. It orders the appellant to pay the costs of the proceedings amounting to € 120,00 plus defence fees amounting to € 16.000,00, plus general and additional expenses as per the law.

Rome 26 April 2005.

THE ARTICLE

✓ *The protection of biotech inventions and GMOs in Italy* – The updated version of an article by Professor Cesare Galli published in the review *Rivista di Diritto Industriale*

At the end of 2002, the review *Rivista di Diritto Industriale*, the oldest Italian legal periodical in the IP sector, published an in-depth essay by Professor Cesare Galli on biotech inventions and GMOs. It focused in particular on problems of the practice and case law of the Italian courts, in which Professor Galli has played a part, having been involved in all the first Italian cases in the field, and having obtained in 2001, in the capacity of co-defender of the patent holder, the first trial Italian decision which recognized the validity and infringement of a biotech patent. The article in question was subsequently republished, in a revised and updated version, first in the volume of collected works *Le nuove frontiere del diritto dei brevetti*, edited by Professor Galli (The New Frontiers of Patent Law, Turin, Giappichelli, 2003), and then, at the beginning of 2005, in the *Occasional Papers* of the Istituto Bruno Leoni.

A further updated version of the article by Professor Galli follows.

CESARE GALLI

THE PROTECTION OF BIOTECH INVENTIONS AND GMOS IN ITALY

SUMMARY: 1. Introduction: the relationship between Italian legislation, EC Directive 98/44 and the EU Patent Convention. – 2. Italian case law concerning biotech inventions. – 3. The relationship between invention and discovery: "actual disclosure" of the industrial application of gene sequences and the scope of protection of the relative patents. – 4. Sufficient description and the limits on exclusive right of patents concerning biological material. The notion of dependence. – 5. Inventive step in biotech inventions. – 6. The patenting of micro-organisms and Genetically Modified Organisms (GMOs) and relations with the protection of new plant varieties. – 7. The public order limit in the patenting of GMOs according to EC Directive 98/44. The importance of Recitals 26, 27 and 56 of the Directive. – 8. The patenting of isolated elements of the human body.

1. Although the Italian courts have been dealing with the validity and infringement of biotech patents since the early '90s there is as yet no specific Italian law covering biotech inventions.

Italy is, in fact, one of the few EU countries not yet to have implemented EC Directive 98/44 of 6 July 1998 on the legal protection of biotech inventions[1]. It is most unlikely that the Draft Bill delegating the Government to implement the Directive, initially approved by the Chamber of Deputies on 26 September 2002 and then amended by the Senate, will complete the procedure necessary for final approval during this legislature, due to end in April 2006. On the contrary, most of the EU member States have implemented the said Directive and the Board of the European Patent Office (EPO) has even made some amendments to the Regulation relating to the European Patent Convention[2].

Cases so far submitted to the Italian courts have, therefore, been decided by applying the general provisions of Patent Law, common to most European countries. These are the result of adapting the original text of Royal Decree 29 June 1939, no. 1127 by Presidential Decree no. 338/79, in order to harmonize Italian legislation on industrial inventions with the European Patent Convention, and now transposed to articles 45-81 of the Industrial Property Code. The Convention (and thus also Italian legislation) does not have an open formula similar to the one provided in corresponding US legislation[3]. It is no coincidence that the US has acted as a pathbreaker in recognising "new inventions", from biotech applications to software and business method inventions. However, the interpretation of the Convention by the EPO Boards of Appeal has shown reasoning which is, on the whole, favourable to the patentability of biotech inventions. The domestic courts of the signatory states (including those of Italy) have, in essence, conformed to this interpretation, which has also been a reference point for the EU legislator.

Despite the polemic created by the Directive, its innovative importance must not be overvalued. Neither must failure to implement the Directive in Italy be overestimated. In fact, many problems

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[1] The Italian government, together with the Norwegian government, supported the judicial initiative for annulment of the Directive undertaken, pursuant to Art. 173 of the EC Treaty, by the Netherlands (C-377/98). The annulment petition was rejected by the Court of Justice in its ruling of 9 October 2001. On this subject see also MOORE, *Challenge to the Biotechnology Directive*, in *EIPR*, 2002, 149 ff.. Regarding the various stages which led to adoption of the Directive it is worthwhile consulting the articles of NOTT, *The Proposed EC Directive on Biotechnological Inventions*, in *EIPR*, 1994, 191 ff; *The Biotech Directive: Does Europe Need a New Draft*, *ibid*, 1995, 563 ff; e *"You Did It!". The European Biotechnology Directive At Last*, *ibid*, 1998, 347 ff.

[2] On this point see FAELLI, *La tutela delle invenzioni biotecnologiche in Europa: prime valutazioni d'insieme*, in *Riv. dir. ind.*, 2001, I, 124 ff., pp. 124-125.

[3] U.S. Code, 35 U.S.C. § 101: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title". For a comparison of US and EU legislation, with specific reference to GMOs, see SHILLITO-SMITH-MORGAN, *Patenting Genetically Engineered Plants*, in *EIPR*, 2002, 333 ff.

tackled by the Directive had already been dealt with in the Italian decisions mentioned at the outset. Thus the Directive seems to integrate rather than eclipse the principles pronounced by the Italian courts in interpreting general patent legislation.

2. If we quickly go through the inventions handled in the first cases in this area in Italy , we see that they essentially concern the use of DNA – or rather:, of its specific parts called "genes", and formed of base units called nucleotides – for the production of active biological substances, through insertion in micro-organisms selected for that purpose (e.g. yeasts and bacteria).

The first Italian case regarding biotech inventions concerned a number of patents relating to the recombinant production of erythropoietin, a key protein in the treatment of illnesses such as haemophilia, but rather scarce in nature[4]. The second – the first to have obtained a trial decision – concerned the identification of the genetic sequence of the hepatitis C virus (or rather, of most of it) and the use of this discovery in the production of immunoassay kits to identify the presence of this illness in the blood[5].

In both cases the invention consisted essentially in identifying the genetic information (i.e. the DNA sequence) relative to the production of the protein and subsequently inserting it in a micro-organism which is thus capable of producing the desired amount of the protein in question. Naturally, in the case of viral proteins, the aim was not to multiply the virus but to produce immunologically active proteins (i.e. which stimulate the immune response of the organism, inducing the production of specific antibodies to fight against the illness), which do not transmit the infection. These proteins may, therefore, be used without risk to check for the presence of the illness in the blood samples of possibly infected people.

Another three patents relate to the production of immunoassay kits and have been involved in as many cases: the first patent claims a method for checking the presence in blood of the nucleic acid of infective agents based on a piece of technology known as PCR (polymerase chain reaction)[6]; the second concerns the identification of the most antigenic sites of the hepatitis C virus, or rather the identification of those parts of the viral protein which are most effective in stimulating the immune response, the use of which gives a quicker and more reliable diagnosis of the illness[7]; and the third concerns the discovery of the genetic code of HIV, the virus responsible for AIDS, applied here too for the recombinant production of viral proteins which can be used in immunoassay kits[8].

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[4] This involved, in particular, European Patents 148.605, 205.564, 209.539 and 411.678. Prior to being decided by settlement, the dispute had given rise to a series of interim decisions, the most important being those of the Court of Milan 22 November 1993, in *Giur. ann. dir. ind.*, 1993, 768 ff; and of the Appeal Court of Milan, 5 May1995, *ibid*, 1995, 970 ff. See also Court of Milan, interim order 28 January 1999, in *Giur. ann. dir. ind.*, 1999, 909 ff. and Court of Milan, interim order 19 May 1999, *ibid*, 1145 ff.

[5] European Patent 318.216. The case was decided in first instance by the Court of Milan, 11 November 1999, in *Giur. ann. dir. ind.*, 1999, 1361 ff. (which ruled that the patent was valid – except for some minor claims – and infringed), preceded by the interim orders of the Court of Milan, interim order 10 February 1997, *ibid*, 1997, 615 ff; and of the Court of Milan, interim order 22 March 1997, *ibidem*, 646 ff. Following lodgement of the decision, the holder of the patent reduced the content of the patent and abandoned some of the claims; in the following appeal proceedings it was decided that there was no longer any matter in issue as regards infringement and nullity of the abandoned claims: Court of Appeal of Milan, 28 May 2002, no. 1357 (in *Giur. ann. dir. ind.*, 2002), which did not even aver on the validity of the remaining claims since the appellant had, in turn, abandoned its claim that they were null.

[6] European Patent 505.012; the case resulted in the Court of Milan issuing a partial decision (published in *Giur. ann. dir. ind.*, 2002; its English translation can be read in *Italian Intellectual Property*, 2002, 97 ff.), which declared that the Italian courts did not have the jurisdiction to decide on applications for a finding of non-infringement with regard to activity carried out in countries other than Italy which possibly infringes parts of the European Patent in suit other than the Italian part.

[7] European Patent 450.931; the case was decided in first instance by the Court of Milan, in an as yet unpublished decision, which ruled out infringement.

[8] European Patent 181.150; the case was held before the Court of Milan and was resolved by settlement, after the Court, in a partial decision of 23 May 2002, no. 6470 (published in *Giur. ann. dir. ind.*, 2002), had declared

Lastly, it is worth mentioning two other cases (one concluded by settlement before a trial ruling[9], the other still pending[10]), regarding, on the other hand, patents relating to so-called acellular vaccines: unlike traditional vaccines, made of natural non-virulent forms of the same pathogen against which the patient is to be immunised, these vaccines are made of artificial proteins, obtained by means of recombinant technology, which contain only the immunizing components of the pathogen and not the infective components, thus eliminating the risks normally involved in vaccination.

3. From this quick (and, of necessity, simplified) perspective it may be understood how, in practice, biotech inventions include a plethora of extremely heterogeneous subjects, which lend themselves neither to arbitrary generalizations nor to indiscriminate demonisation.

Taking our starting point from the above cases, it seems evident that one of the key points of biotech research is identifying the sequence of nucleotides constituting a certain gene and, as we have seen, containing the necessary genetic information for production of a corresponding protein: i.e. the *discovery* of something which already exists in nature but is unknown. However, it is traditional in the patent field to distinguish between discovery and invention – understood as an intellectual *creation,* consisting in the new and original solution to a technical problem – and to reserve patentability only for the latter [11]. Thus, taken to its extremes, this would possibly mean that the greatest results in biotech research whose achievement requires the greatest (also financial) efforts are non-patentable.

However, the Italian courts, and in particular the Court of Milan in its ruling of 11 November 1999 (and the two interim orders previously issued in the same case), have stated that the legislation does not authorize this interpretation since Art. 45 Industrial Property Code (just as with the completely correspondent Art. 52 of the European Patent Convention) excludes from patenting only discoveries "considered per se", which means, on the contrary, that discoveries are also patentable if they are not simply theoretical but may also be open to technical application. Naturally, in this case, the subject-matter of patent protection is limited to the claimed application as the discovery per se must remain at the disposition of the public. If applied to biotech inventions, this principle, already pronounced in a decision of the Italian Supreme Court of Cassation relating to a question of mechanical inventions[12], means that the sequences of nucleotides of a certain gene may also be patented with regard to their technical application (in the case in question, involving a viral protein, this application consisted in the preparation of immunologically active fragments of the virus to be used in assay). This naturally signifies that the sequence may be freely used by others for different non-equivalent uses. Again keeping to the case in question, the ruling excluded use of the protected sequence for the production of vaccines from the scope of patent protection. An extremely important corollary to this principle is naturally that the pre-requisites of validity of the invention, and particularly inventive step, must be assessed in relation to the discovery and not to its application, which may per se be within the range of a skilled practitioner in the field.

The Directive seems to go even further on the distinction between discovery and invention, at least at first sight, since under Art. 3 "*Biological material which is isolated from its natural environment or*

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that it lacked the jurisdiction to decide on applications for a finding of non-infringement regarding activity carried out in countries other than Italy.

9 European Patents 120.551 and 460.716; two interim decisions were rendered in the case: Court of Milan, interim order 27 January 1998, in *Giur. ann. dir. ind.*, 1999, 294 ff; and Court of Milan, interim order 19 March 1998, *ibidem*, 377 ff, which, however, did not enter into the merits of the patent problems raised.

10 European Patent 471.726; the case is still pending before the Court of Milan.

11 On this matter see for all SENA, *I diritti sulle invenzioni e sui modelli industriali*[3], Milan, 1990, p. 95 ff. and more recently GUGLIELMETTI, *La brevettazione delle scoperte-invenzioni*, in *Riv. dir. ind.*, 1999, I, 97 ff.

12 Court of Cassation, 29 December 1988, no. 7083, in *Giur. ann. dir. ind.*, 1988, in reality rendered on the basis of the old Art. 12 of the Patent Law, but which expressly states in the grounds – pp. 159-160 – that its statement also applies to the new text of that article introduced by Presidential Decree 22 June 1979, no. 338 and corresponding to Art. 52 of the European Patent Convention.

produced by means of a technical process may be the subject of an invention even if it previously occurred in nature". This provision seems to indicate that isolated DNA may be protected even *considered per se*, just like a normal product patent. However, Art. 5 seems to have a limiting effect. It expressly states that "*The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application*", and must be read in relation to Recitals 23 and 24 of the Directive, the first of which states that "*a mere DNA sequence without indication of a function does not contain any technical information … (and) is therefore not a patentable invention*", while the second states that "*in order to comply with the industrial application criterion, it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs*".

These articles resolve, in line with the praxis followed by the EPO, another problem that has been much debated, i.e. the patentability of partial DNA sequences. The problem was raised in particular for *Expressed Sequence Tags* – ESTs – and *Single Nucleotide Polimorphisms* – SNPs , whose function is not necessarily that of encoding the production of a protein or part of a protein but, respectively, of facilitating the identification of still unknown gene sequences and of being possibly inserted in other gene sequences thus modifying their properties[13]. These functions also seem to be industrial applications and therefore these partial sequences should be patentable. However, the articles leave open the question of establishing whether or not patents relating to DNA sequences cover all their possible uses, or only the specific functions disclosed in the patent application (and those which are equivalent to them). As we have seen, in fact, this latter limitation arrived at by the Italian courts was based on the general rule provided by the European Patent Convention (and Italian domestic legislation) on the relationship between invention and discovery. For these specific inventions, this rule has now been replaced by the special rule provided in the above articles of the Directive.

This point is not even tackled in the other articles of the Directive specifically concerning the scope of protection for biotech patents, but it is to be found in the broader debate on protection for the product patent[14]. In favour of "limited" protection, seems to be the fact that the rule provided

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[13] On this subject see FAELLI, *La tutela delle invenzioni biotecnologiche in Europa: prime valutazioni d'insieme*, *cit.*, 128-130 and 133-137; and more fully THE BRITISH GROUP OF AIPPI, *Report Q 150: Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and Entire Genomes*, in *EIPR*, 2000, 39 ff; and, with specific reference to ESTs, OSER, *Patenting (Partial) Gene Sequences Taking Particolar Account of the EST Issue*, in *IIC*, 1999, 1 ff; regarding SNPs, NORDSTRÖM, RONAGHI, FORSBERG, DE FAIRE, MORGENSTERN, NYRÉN, *Direct analysis of single-nucleotide polymorphism on double-stranded DNA by pyrosequencing*, in *Biotechnol. Appl. Biochem*, 2000, 107 ff (where SNPs are defined as "a substitution, insertion or deletion at a single base position on a DNA strand").

[14] In general on the scope of protection for product patents see, for opposing views, DI CATALDO, *I brevetti per invenzione e per modello²*, in *Comm. cod. civ.*, edited by Schlesinger, Milan, 1988, pp. 123-126, and ID., *Le invenzioni e i modelli²*, Milan, 1993, p. 123 ff. (whereby the product patent is always limited to the uses described in the application); and SENA, *I brevetti per invenzione e per modello³*, *cit.*, p. 393 ff (in favour of full protection for the product patent). With specific regard to biotech inventions, in the sense of limitation of protection to the industrial applications indicated in the application see again DI CATALDO, *I brevetti per invenzione e per modello²*, *cit.*, pp. 130 –131 and ID., *La brevettabilità delle biotecnologie. Novità, attività inventiva, industrialità*, in *Riv. dir. ind.*, 1999, I, 177 ff, pp. 188 ff; while in favour of full protection see again SENA, *Directive on Biotechnological Inventions: Patentability of Discoveries*, in *IIC*, 1999, 731 ff, especially p. 736. FAELLI argues that the problem is "misleading" since the DNA and its fragments have by definition a single function while the function of the encoded protein cannot have a direct effect, as this protein is outside the scope of protection of biotech patents: see FAELLI, *La tutela delle invenzioni biotecnologiche in Europa: prime valutazioni d'insieme*, *cit.*, 137-140; this importance is however challenged from a technical point of view by MARKL, *Who Owns the Humane Genome? What Can Ownership Mean with Respect to Genes*, in *IIC*, 2002, 1 ff, who observes that "each single gene … may be involved in the production of a ten- or twentyfold number of functional proteins, and many such proteins may be enmeshed in a number of different functions of an organism" and concludes that "Assigning broadly defined patent rights to a specific gene plus its protein, for which only one function has been described, in such a way that all additional functions described in the future are also covered … could be ruinous to an economic landscape of biotech startups". Again in foreign legal theory, in favour of the protection of biotech inventions being limited to "the use of DNA to diagnose, prevent or treate specific disease (use claims) and

by Art. 5 of the Directive is not so much an exception to the general provision forbidding protection for discoveries "*considered per se*", as much as an application of the general provision to the specific area of biotech inventions, as is witnessed by the provisions stating that the industrial application of the isolated or modified DNA which is the subject-matter of the patent must be disclosed. A wider interpretation, on the other hand, would seem to place excessive weight on derived research, considerably limiting the possibility of independently protecting and exploiting its results, in contrast to the general rationale of the patent system which is to stimulate technical progress. In addition, the proposed solution seems more balanced from a standpoint of legislative policy[15], since it would make it evident that we are not speaking of "patenting life", as is at times emphatically claimed by some opponents of patent protection for the results of biotech research, but only of protecting specific technical applications of this research[16]. From this point of view the need to disclose the industrial application of the identified DNA sequence would not just have a bearing on the requisite of the industrial application and sufficient description of the patent but would affect the very existence of a patentable invention.

Following this line of thinking it also seems possible to arrive at a balanced solution for another open question, that of establishing what is meant precisely by "*disclosed*" in the patent application of the industrial application of the claimed genetic sequence. Obviously from this viewpoint, requesting too specific disclosure which describes with precision the final application of the biotech discovery means delaying patenting, making it difficult for the inventor to keep the discovery secret, and at the same time postponing the moment in which this discovery becomes accessible to the public and augments the knowledge of the entire technical and scientific community[17]. On the other hand, granting extended protection to any use of a discovery on the basis of a patent application which simply describes a solely hypothetical use for the discovery in general terms is the same as awarding the inventor an exclusive right out of all proportion to his actual technical contribution. In the US in relation to the, to some extent, corresponding requirement of "*utility*", the Patent and Trade Mark Office recently stated in the Guidelines for Examination of Applications for Compliance with the Utility Requirement that the application must disclose an application which is "*specific, substantial and credible*"[18] and the same criterion was adopted in a decision of the EPO Opposition Division in the *Icos* case[19] which seems to indicate that the inventor may also be awarded a patent for just disclosing a probable, albeit not definite, application. However, this conclusion appears acceptable only if the scope of protection is correlatively limited to the disclosed and equivalent applications.

4. If, as has been said, the fundamental importance of many biotech inventions lies in identifying the sequence of nucleotides which codes for a certain protein to be reproduced, it is evidently crucial to establish, on the one hand, when the invention may be considered sufficiently described and, on the other, to define the scope of protection of the relative patent, i.e. the scope to which the

… the resulting end product" see, for example, also JACOBS-VAN OVERWALLE, *Gene Patents: A Different Approach*, in *EIPR*, 2001, 505-506.

[15] JACOBS-VAN OVERWALLE, *op. loc. cit.*. expressly highlight this aspect

[16] Expressly in this sense see MARKL, *Who Owns the Humane Genome? What Can Ownership Mean with Respect to Genes*, *cit.*, 4, where he emphatically writes "'No patent on life' is a nonsensical phrase since it is not life that can be or should be patented, but only practically useful and creatively applied knowledge or material derived from living matter".

[17] GUGLIELMETTI highlights this aspect in *La brevettazione delle scoperte-invenzioni*, *cit.*, 140-141.

[18] On this matter, also for a comparison of US and EU law, see WEE LOON, *Patenting of Genes – A Closer Look at the Concepts of Utility and Industrial Application*, in *IIC*, 2002, 393 ff, especially pp. 393-396 and 411-413. In the sense that in the EU system a disclosure of the industrial application is also required "in credible terms (in the light of the state of the art)" see FAELLI, *La tutela delle invenzioni biotecnologiche in Europa: prime valutazioni d'insieme*, *cit.*, 135, which also refers to the EPO praxis whereby "the patenting of a gene requires the 'final' use of the invention (which corresponds to the function of the encoded protein) to be disclosed in the patent application only in credible terms (in the light of the state of the art), almost in the form of a prediction".

[19] EPO Opposition Division 20 June 2001, Icos Corp. v. Smith Kline Beecham and Duphar International Research.

exclusive right awarded to the patent holder is extended. This is particularly a problem in relation to the fact that it is often possible to arrive at other sequences which encode the production of variants of the same protein, i.e. essentially individuals of the same species, relatively easily from the first sequence of the identified DNA [20].

Therefore, the Italian courts have admitted the criterion of homology, or rather of partial identicalness. They have ruled that not only proteins whose aminoacid sequence is exactly as disclosed in the patent (and which are therefore encoded by the DNA sequence also disclosed in the patent) but also proteins which share with the former only part of the sequence of amino-acids of which they are composed (and which are therefore encoded by DNA sequences which only partly correspond to those disclosed in the patent) are sufficiently described and included within the scope of protection for a patent relating to the identification of the genetic code of certain proteins (in the case in question, viral proteins)[21]. For the same purpose, *similarity* may also be taken into account. This considers not only the identical amino-acids in the two proteins but also those which, albeit not identical, are interchangeable because they are similar or equivalent to each other. The decision which tackled this problem most directly[22] also stated that the percentage ratio of the shared parts to the total parts of the sequence in question (or rather the percentage of homology) required in order to avoid falling out of the scope of patent protection is to be determined on a case by case basis, in relation to the specific know-how of the sector, i.e. essentially in relation to its ability to define the field which has actually been "ploughed" by the inventor. In the case in question, the percentage was assessed at 40%, with a corresponding similarity of 60-70%. The same criteria were then adopted to determine infringement, which had been ascertained in the use of two immunologically active fragments of the virus, traceable to the sequence covered in the patent, in immunoassay kits, even if they did not correspond exactly.

In this case too, therefore, EC Directive 98/44, rather than eclipsing trends which have emerged in Italian case law, seems to deepen them. In fact, articles 8 and 9 of the Directive state that protection of a biotech invention relating to biological material possessing specific characteristics "*shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing the same characteristics*"; and that protection of a patented product containing or consisting in genetic information "*shall extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function*". Italian legal theory has contended that "*On the basis of these articles, a patent for a DNA sequence extends its protection both to the organism in which the DNA sequence is inserted and to organisms which descend from this organism and which contain said sequence*"[23].

The above decision also handled a further problem, that of establishing whether other polypeptides corresponding to parts of the virus differing from those whose genetic code the inventor discovered come within the scope of protection of a patent relating to the identification of part of the DNA sequence of a virus and to the viral polypeptides encoded by it. The Court ruled that it was not possible as the relative sequences were not described in the patent itself. The Directive does not seem to consider this question directly also because it deals only with the protection of DNA sequences and not the protection of corresponding proteins. It must, however, be pointed out that the notion of dependence may be taken into account in this regard. This notion can be found in Art. 68 of the Industrial Property Code, which states that the patent whose implementation involves that of prior patents may not be implemented without the consent of the holders of these prior patents with whose scope of protection the former would interfere. The question is whether the role of "pathfinder" played by the first sequence identified does not lead to this situation of dependency with respect to the identification of the other sequences, even if it may

[20] In Italian legal theory on this issue see LEONINI, *Tecniche di DNA ricombinante e tutela brevettale*, in *I nuovi brevetti* edited by VANZETTI, Milan, 1995, p. 43 ff, p. 51.

[21] See in particular Court of Milan, 11 November 1999, *cit.* and the two interim orders issued in the same case (Court of Milan, interim order 10 February 1997, *cit.*; and Court of Milan, interim order 22 March 1997, *cit.*).

[22] Court of Milan, 11 November 1999, *cit.*.

[23] FAELLI, *La tutela delle invenzioni biotecnologiche in Europa: prime valutazioni d'insieme*, *cit.*, 138.

be the fruit of further inventive step and therefore, hypothetically speaking, independently patentable.

Authors who give a particularly broad interpretation of the scope of patent protection naturally tend towards full support for the notion of dependence also as regards biotech inventions. They argue that dependency also concerns possible patents relating to subsequent identification of uses for the DNA sequence which are different and not equivalent to that or those disclosed in the patent application[24]. If, however, we accept the premise mentioned above – and expressly admitted by the Directive – whereby the DNA sequence *considered per se* is never independently patentable, but only patentable as a specific industrial application, the conclusion reached by these authors seems inadmissible[25]. Nevertheless, the case of a new sequence, whose identification (albeit inventive) derives from that of the first and which has the same application as the first could be different. In fact, in this case, it seems difficult to deny that implementation of the second invention (or, if we prefer, discovery-invention) involves that of the first and thus that it comes within the legislative definition of dependent patent.

5. It is implicit in what has been stated so far that inventive step – a fundamental requirement for patent validity – is also singularly implicated in the world of biotech research.

In this regard, a number of Italian scholars have put forward the notion that this requirement needs to be disregarded for biotech inventions, and that patenting must essentially be considered a prize for investment made in the relative research [26]. An echo of this notion can be heard in some of the judicial rulings quoted at the outset and, in particular, an interim order which, after pointing out the "*gaps*" in the reports drawn up by experts for the parties "*above all for what concerns the inventive step of the invention*" whose infringement was under discussion, underlined in rather a polemic tone, that this issue had been "*substantially omitted from the technical examination of the parties (completely understandably, as this was a problem common to reciprocal patenting …)*"[27].

In reality, if it is true that the methods used for identifying the DNA sequence encoding for a certain protein are well-known, what leads to research being crowned with success is often the choice of one *combination* of those methods rather than another. This happened, for example, with the identification of the genetic code for the hepatitis C virus, examined in another of the mentioned cases. The research team of the company holding the patent had used methods which were well-known per se but generally considered inadequate in the case in question for obtaining results and thus discarded by the scientific teams of other companies involved in the same research.

Identification of the genetic code for HIV is still more emblematic. This was patented for the realization of immunoassay kits and was the subject of one of the cases mentioned at the outset. The defence team of the patent holder strongly emphasized the technical problems that had arisen at every stage of the process leading to the invention[28].

Italian court decisions in these cases have placed great importance on so-called *circumstantial*

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[24] Expressly in this sense see again SENA, *Directive on Biotechnological Inventions: Patentability of Discoveries*, *cit.*, 736-737.

[25] This also seems to place in doubt the possibility of extending to biotechnological material the "intermediate" criterion proposed for chemical patents by DI CATALDO, *La problematica delle invenzioni chimiche*, in *I nuovi brevetti*, *cit.*, p. 69 ff; and ID., *I brevetti per invenzione e per modello*[2], *cit.*, pp. 127-130, whereby dependency exists when a new (inventive) use is identified for a patented compound whose originality concerned first and foremost the chemical structure of the compound, while the second patent would be considered completely independent "when the compound was, at the date of the first invention, structurally obvious, only its function being original ". The same author (*op. ult. cit.*, pp. 130-131) considers the applicability of this rule to new use biotech patents doubtful.

[26] On this issue see especially VANZETTI, *Presentazione*, in*I nuovi brevetti*, *cit.*, pp. VII-VIII, where it is observed that "it is essentially from this perspective that today the requirement of inventive step must be reconsidered"; and BIANCHETTI-PIFFERI, *Il requisito evanescente dell'attività inventiva delle invenzioni chimiche e biotecnologiche*, in *Il dir. ind.*, 2000, 10 ff.

[27] Court of Milan, interim order 28 January 1999, *cit.*.

[28] See the case mentioned above in note 8.

evidence of inventive step[29], or rather, circumstances considered to reveal the fact that the invention (in the case of biotech inventions relating to the identification of DNA sequences, the discovery) does not result in an evident way from the state of the art and thus involves activity which is such as to justify grant of the patent. In the case of the genetic code of the hepatitis C virus, the decision had considered in particular the recognition of the scientific community and the fruitless research carried out at the same time by other teams. Another circumstance that could also have some bearing in this matter is the *technical prejudice*, which discouraged researchers from taking up the path then followed successfully by the inventor. As has been noted, from this perspective, which is increasingly being adopted by the Italian Courts in the most varied sectors of technology[30], it is not so much a question of identifying a notion of inventive step peculiar to biotech inventions as much as generally reconsidering the idea itself of inventive step, adjusting it to the dynamics of today's research[31]: and remembering that the scope of the granted protection must be in strict proportion to the extent of the invention.

EC Directive 98/44 now expressly states that biotech inventions are also patentable only insofar as they involve inventive step. Art. 3.1 states that "*For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable*"; while Recital 22 states even more explicitly that "*according to this Directive, the granting of a patent for inventions which concern … sequences or partial sequences* (of genes) *should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application*".

6. The Italian courts have also taken up a position on another problem involving biotech inventions. This concerns the possibility that a biotech patent may be considered null as it concerns living matter. The problem arises because Art. 45 of the Industrial Property Code expressly forbids the patenting of new animal varieties. However, the same article, just as with the completely correspondent Art. 53 of the European Patent Convention, states that "*this provision does not apply to microbiological processes or the products thereof*", or rather to micro-organisms.

In this perspective too the Italian Courts have adapted themselves to the interpretation of the article given by the EPO (and foreign legal theory dealing with the issue[32]), equating micro-organisms obtained by genetic engineering with those obtained microbiologically and thus also admitting patenting for the former. In the decisions which have examined this question, assertion of this principle is, however, an *obiter dictum*, since the polynucleotides containing the genetic code of the virus, which in the case in which these decisions were issued were the subject-matter of the patent, considered per se are chemical compounds constituting inanimate material. The relative

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[29] As regards this evidence see, in general, DI CATALDO, *I brevetti per invenzione e per modello*², *cit.*, pp. 109-113, and ID., *Le invenzioni e i modelli*², Milan, 1993, p. 51.

[30] On the importance of circumstantial evidence of inventive step see, in Court of Cassation decisions, Court of Cassation, 10 November 1976, no. 4129, in *Giur. ann. dir. ind.*, 1976, 104; among the decisions of the trial courts, in addition to the decision concerning biotech inventions recounted in the text, see Court of Milan, 28 September 1978, *ibid*, *Rep.* 1979, 1114: "The so-called historical proof of inventive step of an invention comes about with the identification of a technical problem which is still unresolved (or for which the proposed solutions do not seem sufficient and further investigation is felt to be required at invention level) in relation to which an idea for a new solution (or one which is not equivalent to any of those already proposed) may thus only be considered an original idea for a solution"; Court of Milan, 26 June 1975, *ibid*, 1975, 505 ff.: "An invention involves inventive step when it has intervened at a certain stage of the technological development of the pertinent sector to resolve a problem which is considered to be such by operators in the sector, bringing about actual technical progress (the so-called historical proof of inventive step)"; and Court of Verona, 20 June 1974, *ibid*, 1974, 884 ff.: "The originality of the invention must be assessed on the basis of the state of the art, and must be considered to exist when the prior patents did not lead the skilled practioner in the field towards the patented solution but towards different solutions".

[31] Expressly in this sense see DI CATALDO, *La brevettabilità delel biotecnologie. Novità, attività inventiva, industrialità*, *cit.*, 184-188.

[32] In the sense that the European Patent Convention admits the patenting of "micro-organisms ... obtained by means of a microbiological or genetic process" see SINGER-SINGER, *Il brevetto europeo*, Torino, 1993, p. 110.

patents from this standpoint were therefore regarded just like normal chemical patents[33].

In realty this assertion does not take into consideration the peculiarity of polynucleotides – i.e. of DNA –, which, even when isolated from the organism to which they belong, still possess the ability, when inserted in another organism, of reproducing themselves. This peculiarity, which, as was said at the beginning, lies at the basis of genetic engineering technology, is now expressly recognised in Art. 3 of EC Directive 98/44 which admits the patentability of inventions which "*concern a product consisting of, or containing, biological material or a process by means of which biological material is produced, processed or used*"; Art. 2 of the Directive defined biological material as "*any material containing genetic information and capable of reproducing itself or being reproduced in a biological system*".

The patentability of real living matter is not, what is more, an absolute novelty. The patentability of micro-organisms had in fact already been admitted by the European Patent Convention. New plant varieties were excluded from patentability (and still are). However, since 1961 they have been covered by a special right, now regulated in Italy by articles 100-116 of the Industrial Property Code (which incorporated the content of Legislative Decree 3 November 1998, no. 455[34]) and by EC Regulation 94/2100, which provides for a single form of protection at EU level.

Art. 4.3 of the Directive is particularly important as regards micro-organisms. According to this article, the non-patentability of "*essentially biological processes for the production of plants or animals*" (provided by Art. 4.1, *b*, corresponding to the same rule contained in Art. 53 of the European Patent Convention and in Italy by Art. 45 (5) of the Industrial Property Code) "*shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process*". This rule must be read in correlation with that of Art. 2.2 whereby "*A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomenon such as crossing or selection*". This means that all processes which do not *exclusively* consist in natural methods of selection or crossing, and thus all processes which include at least one microbiological or, at any rate, technical stage are patentable (on the basis of the usual requirements of validity for an invention). This considerable broadens the scope of patentability for these processes compared to the praxis adopted in the past by the EPO which, in order to establish whether or not a "mixed" process (i.e. partly biological and partly technical) was to be considered "*essentially biological*", plumped for a judgment of prevalence between the various stages[35].

New plant varieties are a different matter. In fact, at least originally, i.e., prior to the spread of recombinant DNA technology, the subject matter of the special protection for plant varieties was only the varieties obtained by biological methods such as crossing and selection. These methods are not, by definition, based on technology but on nature and in their regard there was (or is) no problem of inventive step. The requirements of validity for plant varieties are novelty, the difference to already known varieties, homogeneity and stability, which essentially mean that "*the characteristics of the new variety are sufficiently similar in one single reproductive cycle and remain such in subsequent cycles*"[36]. With the advent of biotechnology the chances of changing the genetic make up of living organisms have

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[33] See again Court of Milan, 11 November 1999, *cit.* and the two corresponding interim orders (Court of Milan, interim order 10 February 1997, *cit.*; and of the Court of Milan, interim order 22 March1997, *cit.*).

[34] See in this regard the in-depth comment by MORRI, in MARCHETTI-UBERTAZZI, *Commentario breve al diritto della concorrenza – Appendice di aggiornamento*, Padova, 2000, p. 151 ff.

[35] See on this point FAELLI, *La tutela delle invenzioni biotecnologiche in Europa: prime valutazioni d'insieme*, *cit.*, 140-142, which notes that the Regulations of the European Patent Office have also been adapted to the new rule deriving from the Directive.

[36] VANZETTI-DI CATALDO, *Manuale di diritto industriale*[2], *cit.*, p. 440. On the different "philosophies" which lie at the basis of patent protection and the protection accorded by special legislation on new plant varieties see LLEWELYN, *The Patentability of Biological Material: Continuing Contradiction and Confusion*, in *EIPR*, 2000, 191 ff, especially pp. 194-196, where it is stated moreover that "Plant variety rights do not protect something new which has been 'invented' by the applicant. The right does not protect unobvious research results, much conventional breeding relies on doing the obvious, nor is the applicant required to demonstrate that s/he has done anything particularly inventive in order to obtain the right. In contrast, the patent system serves to protect things which are not only new but which result from an inventive step, something unobvious, which must be disclosed in order for an application to succeed".

evidently multiplied. It is these possibilities which are currently at the centre of the debate which is besetting these new technologies.

From the patent point of view, the first problem is evidently that of co-ordinating the different forms of protection offered, respectively, by patent legislation and legislation on rights for the new plant varieties. There is still no case law in Italy on this subject. The issue has, however, been handled on a number of occasions by the EPO, whose Enlarged Board of Appeal, turning round a previous and more restrictive trend of the Technical Board of Appeal, finally reached the conclusion (in the *Novartis-Transgenic Plants* case of 1999) that patentability was admitted when the subject of the claim was not a specific plant variety but a technical process allowing the insertion of an extraneous gene into the genome of certain plants in order to obtain certain required characteristics which do not regard one single variety. In this regard the Board explained that in this case "*the inventor … aims at providing tools whereby a desired property can be bestowed on plants by inserting a gene into the genome of those plants. Providing these tools is a step which precedes the further steps of introducing the gene into a specific plant. Nevertheless, it is the contribution of the inventor in the genetic field which makes it possible to take the second step and insert the gene in the genome of any appropriate plant or plant variety. Choosing a suitable plant for this purpose and arriving at a specific, marketable product, which will mostly be a plant variety, is a matter of routine breeding steps which may be rewarded by a plant breeders' right* "[37]. The same solution was adopted by the EPO Examining Division for an animal GMO in the famous *Onco-mouse* case (a transgenic mouse predisposed to breast cancer and used in the relative experimentation): in this case too it was held that a biotech invention which did not concern a specific breed but a broader taxonomic category could not be included in the bar on patenting animal varieties[38].

7. The Italian courts have not yet had occasion to tackle these issues even though it seems reasonable to suppose that their position would not differ too much from that which has emerged in these decisions.

In fact these decisions appear to be consistent with the rules laid down in EC Directive 98/44 (which, in fact, was issued a few months before the decision of the Enlarged Board of Appeal), Art. 4.1 letter a) of which reiterates the rule of the European Patent Convention (and Art. 45 of the Industrial Property Code) whereby "*plant and animal varieties*" are not patentable. However, the Directive adds in Art. 4.2, that "*Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety*". Recitals 31 and 32 assert even more explicitly that "*a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants*"; while "*if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process*". Art. 6.2 also refers to animals. It excludes patentability, as being contrary to public order, in letter d) for "*processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes*", and letter a) " *processes for cloning human beings*": thus implicitly

[37] Decision of the Enlarged Board of Appeal, December 20, 1999 – Case No. G 1/98 (Novartis AG), in *IIC*, 2000, 430 ff; see also the ruling which referred the decision on these problems to the Enlarged Board of Appeal: Decision of the Technical Board of Appeal 3.3.4, October 13, 1997 – Case No. T 1054/96, *ivi*, 1999, 78 ff. For a brief history of the development of EPO praxis on this matter see SHILLITO-SMITH-MORGAN, *Patenting Genetically Engineered Plants*, *cit.*, 333 ff, where US case law, which is, in turn, also in favour of the patenting of GMOs, is also presented in parallel fashion. For some comments on this decision see however LLEWELYN, *The Patentability of Biological Material: Continuing Contradiction and Confusion*, *cit.*, 196-197.

[38] Harvard/Onco-mouse, Case No. T 19/90 in *E.P.O.O.J.*, 1990, 476. In relation to this case some public order questions were also raised but were rejected on the basis of a sort of weighing up of interests, comparing the benefits that the patented innovation could bring to progress in medical science and the disadvantages that it could cause for the environment. The range of this patent, originally extended to all transgenic mammals, was subsequently limited to transgenic rodents by the EPO Opposition Board in March 2003 and then to transgenic mice with the Technical Board of Appeal ruling of 6 July 2004.

recognising the patentability of processes modifying the genetic identity of an animal and the resulting animals, which leads to "*substantial medical benefit to man or animal*", and the cloning of animals other than humans[39].

Whether or not the choice of the legislator is correct is, however, much discussed. In this regard, in fact, it has been observed that when we are faced by a plant variety (or an animal variety) obtained not by purely biological means (and thus, by definition, not inventive, as pointed out by the EPO in the above mentioned *Novartis* decision), but by inventive genetic engineering (in the sense given above), there is no reason to exclude it from patent protection[40]. This is, in fact, the solution adopted in the US where the Supreme Court stated that the legislative definition of patentable invention does not allow plant varieties to be excluded from its scope when they obviously possess the requirements of validity and, above all, when they involve inventive step[41]. Paradoxically the EU solution, handling similar cases in different ways, seems to favour cleverness in the wording of claims, rather than the real innovative importance of inventions[42].

As is well known, the major opposition to GMOs is founded on considerations as to the hypothetical danger they pose for humans and the environment. Of course, a new food or a new drug being harmful to the health is a standard case of conflict with public order and they are thus unpatentable according to Art. 53 of the European Patent Convention, for lack of the requirement of lawfulness[43]. The alleged danger of GMOs has not yet been proved[44], thus the general allarmism in relation to GMOs seems unjustified and even counterproductive. It has in fact been noted that an excess of regulations and the increase in checks on the use of these organisms – many more than those provided for other areas of biotech research – leads to an escalation in costs which only large companies can afford, leading to many smaller companies being pushed out of the market and the sector becoming ever more concentrated, risking ever decreasing competition in the field[45].

On the contrary, it seems impossible to deny the contribution that GMOs can make to agricultural development, even in hostile environments and climates, and thus to the possibility of ensuring that a large part of mankind has access to reasonably priced food, leading to the continuation of that "green revolution", which from 1960 to 1990 considerably increased the planet's agricultural resources, but which no longer seems ecologically sustainable, as it was based on

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[39] A patent of this kind (the so-called Edinburgh patent) was awarded by the EPO: on this matter see PIGANTA, *Il contrastato brevetto rilasciato dall'U.E.B. inerente alle cellule staminali animali*, in *Il dir. ind.*, 2000, 313 ff.

[40] On this point again see LLEWELYN, *op. ult. cit.*, 195, which examines the wording of Art. 92 of EC Regulation 94/2100 and argues that this, by expressly excluding the possibility of accumulating patent protection and the special protection for new plant varieties, implicitly admits that recourse can be made to one or the other.

[41] J.E.M. AG Supply, Inc. dba Farm Advantage, Inc. v Pioneer Hi-Bred International, Inc., Supreme Court of the United States, December 10, 2001, No. 99/1996 (fully commented on in SHILLITO-SMITH-MORGAN, *Patenting Genetically Engineered Plants*, *cit.*, 333-334), which largely repeats the arguments contained in the previous decision of the Supreme Court in Diamond v Chakrabarty of 1980 (447 U.S. 303), which was considered a landmark case in the US in relation to the patentability of biotech inventions.

[42] See in this regard BLAKENEY, *Protection of Plant Varieties and Farmers' Rights*, in *EIPR*, 2002, 9 ff, pp. 13-14, where, commenting on the *Novartis* decision, it is observed that "through creative claims drafting, a patent may be broad enough to cover innovations in the production of new plant varieties or specific genes and their corresponding traits".

[43] On this point see, for all, DI CATALDO, *I brevetti per invenzione e per modello*², *cit.*, pp. 113-114.

[44] A book published by ASSOBIOTEC, the Italian Association for the Development of Biotechnology (*Biotecnologie in agricoltura. Realtà, sicurezza e futuro*, edited by DELLEDONNE e BORZI, MILAN, 2001), highlights (at page 12) the fact that "The economic and social department of the Food and Agriculture Organization … has confirmed that all experimentation carried out has not shown any degree of toxicity for the plant GMOs on the market " and that "In the US, where they entered the food chain some years ago, there has been no increase in the rate of illness among consumers compared to Europe where plant GMOs are not yet grown".

[45] On this point see MILLER, *The Biotechnology Industry's Frankensteinian Creation*, in *Trends in Biotechnology*, n. 101, April 2001, where responsibility for this increase in checks is also attributed to anti-competition lobbying by some of the largest US companies working in the GMO sector.

the heavy use of fertilizers and pesticides, which can be avoided with the adoption of GMOs[46]. Nevertheless, it is actually from this perspective that GMOs have been the butt of further accusations, in that it has been argued that their spread would constitute an "attack on biodiversity", as concentrating on the most profitable and resistent plants created by means of recombinant DNA technology would threaten "traditional" varieties with extinction, impoverishing the planet's genetic heritage and increasing the dependence of poor countries on more developed countries which would become the suppliers of sowing materials[47].

It is easy to say that, in reality, this accusation could also be leveled against traditional crossing techniques, whose aim has always been to obtain the highest yielding plant (or animal) varieties, which have then progressively supplanted the less profitable varieties. However, the problem exists and it has a legal bearing. The last Recital of EC Directive 98/44, Recital 56, expressly refers to the Biodiversity Convention[48] and to Decision III/17 adopted in the third conference of Signatory States of the Convention, held in November 1996, which stated that work is required to help "*develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPs Agreement and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity*".

It is, however, extremely doubtful whether consideration of these aspects may be directly integrated into the patent system, rather than forming the subject-matter of distinct and independent regulations. In fact, the preservation of biodiversity does not, per se, run contrary to the creation of new organisms by means of genetic engineering techniques but rather requires the creation (and the, evidently costly, storing) of a system of "genetic banks". In fact, these have been set up[49] and are important for biotech research itself as, at times, it uses the genetic material they conserve[50]. Awarding financial renumeration to the community which has conserved these plant varieties is, in turn, also unusual in the patent system, which came into being to create and encourage innovation rather than to give a sort of "*retrospective reward*"[51] for something lying behind this innovation. It has been suggested that these differing needs could possibly be conciliated by having recourse to contracts, whereby the party which intends to avail itself of "genetic material" for its research must negotiate the relative right with the party which lawfully owns the right; alternatively by obliging the

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[46] For its emphasis on these points see again BLAKENEY, *Protection of Plant Varieties and Farmers' Rights*, *cit.*, 9, which, after observing that "A reliance on the chemically nurtured, high yielding crop varieties of the past is no longer economically or environmentally acceptable", concludes that "A second Green Revolution is required which combines traditional agronomic wisdom with modern agricultural science". Also see Recitals 10 and 11 of EC Directive 98/44, which assert respectively that "regard should be had to the potential of the development of biotechnology for the environment and in particular the utility of this technology for the development of methods of cultivation which are less polluting and more economical in their use of ground"; and that "the development of biotechnology is important to developing countries, both in the field of health and combating major epidemics and endemic diseases and in that of combating hunger in the world (…)".

[47] For an example of this radical critique see SHIVA, *Campi di battaglia. Biodiversità e agricoltura industriale*, Italian translation, Milan, 2001.

[48] Convention of Rio de Janeiro of 5 June 1992, ratified by Italy on 15 April 1994 (there have been 186 ratifications so far). The subsequent Protocol of Cartagena on Biosecurity of 24 May 2000 (defined as "disastrous" by MILLER, *The Biotechnology Industry's Frankensteinian Creation*, *cit.*, in that "Under this unscientific and Draconian regulatory regime, no biologist, plant breeder, or farmer will be allowed to grow crop or garden plant, no matter how small the test-plot, without prior approval from the UN-sanctioned bio-police") has not been ratified by Italy.

[49] See on this point BLAKENEY, *Protection of Plant Varieties and Farmers' Rights*, *cit.*, 10-12; there are 16 centres currently operating under the auspices of the Consultative Group on International Agricultural Research (CGIAR).

[50] Again BLAKENEY, *op. ult. cit.*, 13 asserts that "It is estimated that about 6,5 per cent of all genetic research undertaken in agriculture is focused on germplasm derived from wild species and landraces".

[51] Again BLAKENEY, *op. ult. cit.*, 15.

patent applicant to disclose the geographical origin of this material, thus imposing an all-in share in the profits on him [52]. The subject is still being fully debated both in the W.T.O.[53], and in W.I.P.O., where an *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (GRTKF)* has actually been set up. Again in W.I.P.O., an attempt to conciliate the varying positions taken up in this regard by industrialized and developing countries, the latter led by Brazil, has greatly slowed down the progress of the *Substantial Patent Law Treaty*[54], although some headway, at least at procedural level, seems to have been made at the General Assembly held from 26 September to 5 October 2005. On this occasion, it was proposed that the two problems should continue to be examined in parallel fashion, waiving the possibility of using one as an obstacle to the progress of the other.

Recital 26 of EC Directive 98/44 also seems to be inspired by the idea of negotiated consent. It states "*if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law*"[55].

Although these provisions seem to be more in the nature of a programme rather than a real rule, they reflect the effort which has been put into looking for a middle way between the various clashing needs in such a delicate sector as that of biotechnology[56].

8. Evidently we still have to speak of human beings. In this regard paragraphs 1 and 2 of Art. 5 of EC Directive 98/44 are first of all taken into consideration. The first states that "*The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions*"; while the second states that "*An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention even if the structure of that element is identical to that of a natural element*". Evidently , these rules are not substantially different from the general rules given in Art. 3 for any biological material (except for the obvious bar on patenting the human body as a whole), and they are justified, first of all, because of the huge importance which inventions (or discoveries-inventions) regarding human genetics have in the treatment of numerous illnesses[57]; Art. 5.3 also applies to genetic sequences and other elements isolated from the human body and thus their industrial application must be disclosed in the patent application.

More substantial differences in treatment are to be found in Art. 6.2 of the Directive, regarding specific cases on inventions considered contrary to public order and thus non-patentable. In fact,

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[52] BLAKENEY, *op. ult. cit.*, especially 17 (where it is noted that the first approach corresponds substantially to the US point of view) and 11.

[53] See in particular the *Ministerial Declaration* adopted at the Doha Conference of 2001.

[54] On this point see BECKER, *WIPO GRTFK – Recent Developments*, in *AIPPI Newsletter*, August 2005, p. 10 and the paper presented by Becker at the AIPPI ExCo Meeting held in Berlin in September 2005. See also VAN OVERWALLE, *Belgium Goes its Own Way on Biodiversity and Patents*, in *EIPR*, 2002, 233 ff; e ID., *The Legal Protection of Biological Material in Belgium*, in *IIC*, 2000, 259 ff, especially pp. 281-283, which refers to the proposals developed in Belgium to enhance the reference to the geographical origin of the genetic material used placing it in relation to Art. 15.5 of the Convention on Biological Diversity whereby "*Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party* ".

[55] BEYLEVELD examines this in *Why Recital 26 of the E.C. Directive on the Legal Protection of Biotechnological Inventions Should Be Implemented in National Law*, in *I.P.Q.*, 2000, 1 ff, especially 15-16 and NOTT, *"You Dit It!". The European Biotechnology Directive At Last*, *cit.*, 348, which underlines the ambiguity of the wording used, as it does not specify whether consent refers only to harvesting or also to subsequent use of the biological material in genetic engineering.

[56] The same need can be found in two further provisions contained in EC Directive 98/44 again relative to GMOs, i.e. Art. 11 on the so-called "plant breeder's right" and Art. 12 on possible interference between GMO patents and new plant variety rights.

[57] SPRANGER highlights this aspect in *Ethical Aspects of Patenting Human Genotypes According to EC Biotechnology Directive*, in *IIC*, 2000, 373 ff.

three of the four cases concern human beings: therefore, "*processes for cloning human beings*" (letter *a*); "*processes for modifying the germ line genetic identity of human beings*" (letter *b*); and "*uses of human embryos for industrial or commercial purposes*" (letter *c*) are non-patentable.

The intention of the EU legislator in setting these limits, which correspond to themes much discussed on an ethical level, is extremely clear. Some reservations have been expressed only with regard to the bar on the patenting of processes for modifying the germ lines of human cells, or rather those capable of transmitting themselves to subsequent generations. In fact, one of the most important applications of biotechnology on human beings are the so-called gene therapies, i.e. therapies which modify or replace defective genes. The question is whether it is not too limiting, in this regard, only to permit intervention on somatic cells (or rather non-reproductive cells). Actually, applying gene therapy to germ cells could stop genetic illnesses being passed on to subsequent generations[58].

However, it is probably too soon to weigh up the experiences which have so far matured in this matter. The political, economic and moral problems involved in biotech patenting are so complex that the results so far attained, also at legislative level, must of necessity be temporary and liable to change. If the Directive and its implementation serves to raise awareness of the fact that the real problem is not the patentability of biotechnology but possible limits on this patentability and the way to arrive at a real balance between the different needs to be conciliated, a major step will still have been taken.

CESARE GALLI

ABOUT US

✓ *Professor Cesare Galli has been appointed a member of the Commission of Experts set up at the Ministry of Productive Activities for the purposes of revising the new Industrial Property Code*

Professor Cesare Galli has been **appointed Member of the Commission of Experts set up at the Ministry of Productive Activities** for the purposes of revising the new Industrial Property Code. In this capacity Prof. Galli has made a series of **proposals for correcting** the text of the Code, aimed at clarifying a number of its problem areas and further strengthening the protection of Industrial Property rights against infringement.

In particular, Professor Galli has tackled the procedural provisions, promoting application of the **new ordinary civil process** to **IP cases**, considering it more able to meet the needs of operators in this field, and revision of the provisions relating to interim measures and other typical sanctions of IP law to thus fully implement EC Directive 2004/48 (the so-called « **Enforcement Directive**»), also as regards **compensation** for infringement.

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✓ *Recent IP decisions obtained by our firm*

Trade secrets – Seizure and description of stolen documents and their analysis

Under the Industrial Property Code trade secrets are included among Industrial Property rights. Thus, trade secrets can be protected by the typical sanctions and interim orders previously used only for trade marks, patents and copyright. Following this inclusion, our firm obtained two important ex parte interim orders from the Court of Milan. These concerned two cases of **secrets stolen** by former Directors and employees and respectively ordered the **seizure** and **description** of the

[58] On this point see, in particular, NOTT, *"You Dit It!". The European Biotechnology Directive At Last*, *cit.*, 349.

documents stolen and the documents obtained from analysis of the former. In both cases the order was expressly extended **not only to hard copy documentation but also the computer files** recovered from the premises of the alleged infringer.

The first order, of 30 April 2005, led, moreover, to the **recovery of the original designs** for a series of machines which had been stolen and **cancellation** of the relative files from the infringer's computer system, thus preventing the infringer from using them. The second order, of 1 July 2005, authorized the acquisition of copies of secret chemical formulas which the infringer had prepared by making small changes to the originals.

The 30 April order was the first to apply the new legislation (which had come into force only a few weeks earlier) and received good coverage in the specialized press.

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Patents – Relationship between nullity and infringement actions

A key decision on the relationship between nullity and infringement actions was issued on 8 April 2005 by the Court of Brescia. A party sued for patent infringement often attempts to bring the action to a standstill by requesting another Court to ascertain that same patent is null and asking for the infringement proceedings to be suspended until a decision is reached in the nullity proceedings. However, the Court of Brescia admitted the argument of the patent holder, who was represented by our firm. According to this argument these cases come within the procedural notion of **lis alibi pendens**, and the two cases must consequently **proceed together before the Court which is competent to decide on both applications**. Should both courts be competent the first applied to shall decide. It is, therefore, evidently advantageous in terms of **procedural economy**.

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Patents – multiple independent infringers

In ruling 15095 of 16 July 2005 the Court of Cassation upheld a finding that the patent for a particular plastic bottle for carbonated drinks had been infringed. The finding had been issued by the Appeal Court of Venezia in two joined cases against two **independent infringers**. The Court of Cassation tackled, in particular, the consequences of **interrupting** the joined cases. The cases were interrupted after one of the sued companies had been incorporated with another. The Court of Cassation ruled that in this case service of the Writ of Summons in reinstatement within the six month period provided by Art. 305 Code of Civil Procedure on only one of the parties «*must of necessity lead to* ***reinstatement of the entire proceedings****, given that the inseparability – as to the effects of interruption – deriving from joinder, must also reciprocally apply with regard to reinstatement*».

Professor Cesare Galli was a member of the defence team for the winning party. He also discussed the case before the Court of Cassation..

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Patents – Validity and counterfeiting of utility models

The Court of Milan **rejected** preventive remedy requests brought against a leading Italian producer of motorcycling footwear. The producer, represented by our firm, had been accused of infringing a utility model. In particular, in its order of 19 July 2005, later upheld at the appeal stage, the Court ruled that the prior art submitted in the proceedings, mostly consisting in patents and products of our client, demonstrated that the allegedly infringed model "***lacked the – albeit modest – degree of originality also required for utility models***»; and that the differences between the allegedly infringing and infringed products would rule out infringement even if the model in question were recognized as having a degree of originality. The Court reached this second conclusion by applying the principle, asserted by our team, whereby «***the scope of protection of a model relates to the margin of validity which it, in turn, presents with respect to priorities***».

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Trade Marks –Transitory system of extended protection for trade marks having a

reputation

In ruling 14473 of 9 July 2005 the Court of Cassation specified the scope of application for the **extended protection given to trade marks having a reputation** following the 1992 reform, thus precisely clarifying the limits of applicability for the new legislation relating to trade marks predating reform. The decision has been widely dealt with in the first section of this Newsletter and has appeared in full in the second section. In this case Professor Cesare Galli was again part of the defence team of the winning party. He also discussed the case before the Court of Cassation.

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Trade Marks – Partial imitation of a trade mark

In its 18 July 2005 ruling issued ex parte, subsequently upheld, the Court of Bologna admitted a petition presented by our firm on behalf of the holder of an important trade mark for sports clothing, originally used in a famous '70s film. The holder had requested a seizure order and injunction with regard to goods imitating some of the **distinctive figurative features which were part of its complex trade mark**, claiming that the actual circumstances of the case –and in particular the fact that the goods «*had the same shape, designs and colour as the originals*» – meant that there was an actual risk of confusion.

The decision is also highlighted because it involved a seizure order not only for the goods and the related advertising material but also for «***accounting documentation,*** *indicated in the petition, relating to the advertisement and sale of the goods in suit*», making it possible to **identify the foreign producer** of the infringing goods and to acquire key evidence for the assessment of damage.

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Unregistered designs and models – requirements for protection

The Court of Bologna, in its 8 September 2005 order upholding the above ruling, also accorded protection to our client's **non-registered EU model**, relating to the shape of a particular type of swimming trunks, since it found that the characteristics giving the trunks their **individual character** had been **copied**.

The Court granted the requested protection, stating that the holder of the model had made mention in its petition of «*the aspects of the product which gave it its individual character*» and had supplied evidence of divulgation within the EU as required by EC Regulation 2002/6 and that a comparison of the samples of the original product and that of the alleged infringer «*demonstrates such a* ***level of similarity*** *in the individual nature of the models as to* ***render creative coincidence improbable***».

This decision is highlighted because **it is one of the first (if not the very first) giving protection in Italy to non-registered models** on the basis of the EU Model Regulation.

*** *** ***

Antitrust Law – Limits on the jurisdiction of the trial courts

The Appeal Court of Bologna, in its decision of 15 July 2005, (rendered at the end of **Antitrust interim proceedings** brought pursuant to Art. 33 Law 287/90), rejected a request for a preliminary order against the defendant (a spa in the Province of Bologna, represented by a team of lawyers which included Professor Cesare Galli, who also discussed the case before the Court) to give spring water to the plaintiff so that it could carry out activities in competition with the former

The Court did not need to enter into the merits of the question since it admitted the defendant's objection of **lack of jurisdiction**, supporting our preliminary objection whereby **issuing an order creating contractual obligations,** such as the one requested by the plaintiff, **comes within the remit not of the trial court but of the Antitrust Authority**.

*** *** ***

✓ *Our latest publications and meetings*

This year the review *AIDA*, in its soon to be published 2005 volume, will once more carry an

essay by Professor Cesare Galli, entitled ***Trade Marks and the Cultural Industry.*** It will examine and succinctly comment on the principal Italian and EU decisions in trade mark matters issued during the year, in relation to their reflections on the cultural industry.

Another essay by Professor Cesare Galli on ***IP Rights and Renumeration of Investment*** will also appear in the 2005 volume of *AIDA*. It further develops the Report presented by Professor Galli during the «IP and Constitutions» meeting held in Pavia on 23 and 24 September 2005.

Various **interviews with Professor Galli**, regarding the new Industrial Property Code and problems in the fight against infringement, have appeared both in specialised publications, such as the financial newspaper *Italia Oggi* and the Business Association press, and in newspapers with a wider circulation, such as the popular weekly *DiPiù*.

*** *** ***

Of the latest meetings in which Professor Cesare Galli has participated as speaker we highlight:

* 16 May 2005 - a course organised in Bologna by the Forensic Foundation, during which Professor Galli gave a paper on ***Protection of the appellations of origin of viticultural products***

* 13 June 2005 - a meeting on **The** Industrial Property **Code** organized in Firenze by Avvocatura Indipendente, during which Professor Galli gave a paper on ***The Substantive and Procedural Innovations of the*** *Industrial Property* ***Code***

* 6 July 2005 - a meeting on **The Fight against the Infringement of Made in Italy and its Protection** organized in Rome by *Business International – The Economist*, during which Professor Galli gave a paper on ***Legislative Framework and Legislative Innovations in the field of Trade Marks, Patents and the Fight against Infringement***

* 23 September 2005 - the previously mentioned meeting on **IP and Constitutions**, organized by the University of Pavia, during which Professor Galli gave a paper on ***IP Rights and Renumeration of Investment***

* 7 October 2005 - a meeting of the Council of **ECTA (European Communities Trademark Association)**, held in Rome, which invited Professor Galli to give a paper on ***The «New» Trademark Infringement***

* 14 October 2005 - Prof. Galli chaired the annual National IP Law Convention in Parma, dedicated this year to **The Value of Trade Marks: Registering, Protecting and Enhancing Trade Marks and Appellations of Origin**, during which he also gave a paper on ***Trade Marks, Shapes and Appellations d'Origin: the «New» Infringement and the Instruments to Defend Businesses***.

* 25 October 2005 - a Round Table on ***The Industrial Property Code: The Latest Developments***, organized in Milan by A.I.C.I.P.I., the Italian Association of Business Consultants in Industrial Property

As Co-ordinator of the Trade Mark Group of the Italian Section of **A.I.P.P.I.** Professor Cesare Galli also took part as Italian Delegate in the work of the A.I.P.P.I. **Executive Committee** held in Berlin from 25 to 28 September 2005. He presented a paper for Italy on **Question Q 188,** dedicated to ***Conflicts between Trademark Protection and Freedom of Expression***.

Finally, within the sphere of **INDICAM**, the Italian Trade Marks Owners Institute for the Fight against Infringement, Professor Galli was appointed member of the **Study Commission** on the new draft **EC Directive on Criminal Protection of IP Rights**.

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If you would like to receive further information on the Convention in Parma or the other Meetings, write to GALLI.PR@IPLAWGALLI.IT.

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