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MILAN - NOVEMBER 2009

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RECENT DEVELOPMENTS IN ITALIAN IP LAW

✓ Italian Parliament approves the «anti-infringement package»:

1. Delegation to the Government renewed for revision of the Code of Industrial Property (CIP): one year to introduce new provisions

After a very lengthy parliamentary procedure, starting in the summer of 2008 and involving two readings in the Chamber of Deputies and two in the Senate, the **«anti-infringement package»**, has finally become Law. The package is the result of the activity of the **Working Group** set up by the High Commissioner for the Fight against Infringement a few months prior to the role of Commissioner being abolished (Professor Cesare Galli was also a member of this Group). The IP provisions are to be found in articles 15-19 of Law 99, 23 July 2009, which was published in the Official Gazette of 31 July 2009 and entered into force the following 15 August.

The text which was passed is very different from that which was originally drawn up by the High Commissioner and it cannot be said that it has changed for the better. The **delegation** for **renewal of the CIP** which the Government has **one year** to effect has, however, remained, albeit in a less precise text than that which was initially proposed.

Right from its very introduction it was intended that the Code be revised: Art. 2 of Law no. 306/2004 stated that *«within a year of the legislative decrees* (which had been issued on the basis of the delegation for drafting of the Code) entering into force, the Government may adopt, subject to the opinion of the competent parliamentary commissions, provisions amending or adding to said legislative decrees». The idea, therefore, was that the new Code would be «run in» for a year, to see whether changes or adjustments needed to be made. A Commission of experts - including, in this case too, Professor Cesare Galli – had already been set up in July 2005 and before the end of the year had drawn up a full report which not only corrected the material errors in the Code and recovered a number of provisions which had been «skipped» when the Code was introduced (in particular internal priority and the new discipline relating to university researcher inventions), but also radically re-examined the provisions of the Code, with a view to strengthening the protection of IP rights and making it more effective, considered a key factor in fostering the competitiveness of «Italian business». This would be done, in particular, by means of an increasingly precise definition of infringement as covering all forms of parasitism and the adjustment and coordination of various juridical instruments - civil, criminal and administrative - in order to counter it. However, despite the fact that the Commission's work was concluded in good time, the disposition ran aground in the course of the various competent Ministers coming to office and the deadline for carrying out the delegation, 19 March 2006, expired without being renewed. The only provisions drawn up by the Commission to actually enter into force were, therefore, those which were linked to implementation of EC Directive 48/2004 (the so-called «Enforcement» Directive), introduced by Legislative Decree 16 March 2006, no. 140 which, inter alia, introduced the sanction of the infringer's profits being returned.

The new delegation, albeit less specific than that envisaged in the project of the High Commissioner (which expressly indicated as one of the criteria to follow that of *«strengthening IP rights protection and making it more effective, in particular against parasitism, also at procedural level, also by inserting an express provision relating to the pre-requisites for the protection of non-registered trade marks and the discipline applicable to thems*), states, however, that **not only substantive but also procedural provisions** shall be revised, which should avert the risks of judgments of unconstitutionality such as those which have been made against the Code precisely for this reason. The other criteria worthy of note are those regarding the *«counter-reform»* of the discipline relating to **the inventions of employees of universities and public research institutions**, with the patent right being given to the institution.

Coordination will also be required with regard to the **Regulation for Implementation of the Code**, currently being rewritten after the drafted text was rejected last year by the Council of State. It is, therefore, to be hoped that the legislative committee set up by the new Director General of the Italian Patent and Trademark Office (UIBM) and of the Fight against Infringement, Dr. Loredana Gulino, in the **Meeting Table** with private business and individuals, will be involved in the drafting of the law.

✓ 2. New provisions of the Code which have already come into force: internal priority, the new interim regime for design and the procedural rules. No longer any risk of pending proceedings being adjudged unconstitutional

In addition to renewing the delegation for revision of the Code, Law 23 July 2009, no. 99, has already directly introduced a series of **new provisions**, most again deriving from the project of the High Commissioner. From the perspective of civil law what appears to be of particular significance is the introduction of the so-called **«internal priority»**, i.e. the possibility of claiming the priority of an Italian patent application also in a subsequent patent application likewise filed in Italy. This was already originally provided in Art. 4 of the Code which covers priority. It was, however, removed at the suggestion of the Council of State only for reasons of a systemic nature, it being clear that «internal priority» has nothing to do with the general priority claim institution disciplined by that article, but must instead be considered a special institution applicable only to inventions and utility models i.e. intellectual creations of a technological content. With the new law the internal priority institution is more correctly placed in Art. 47 of the Code (paragraph 4), with the express warning that a subsequent application must concern elements already contained in the application whose priority is being claimed. Thus the Italian patent system has now been given the opportunity, already existing in the principal foreign legal systems, to compete on equal terms at international level from this perspective too.

Equally significant is the abrogation of Art. 3 of Ministerial decree 3 October 2007, i.e. the decree, much criticized (cfr. IP_LAW_GALLI Newsletter, December 2007/January 2008), which stated that *«lapse of an IP right»* should there be a *«delay in the payment of the fifth year tax for invention patents (or) of the second five year period tax for utility model patents and for the registration of designs or models»* and *«non or late presentation of a petition for extension under Art. 238 of Legislative Decree no. 30/2005, relating to the second five year period of designs and models»*, has retrospective effect, i.e. said lapse operates *«from the date on which the relative application is filed»*, while the general principle in matters of lapse of IP rights – and this principle holds for distinguishing lapse from nullity – is that whereby a right lapses when the situation causing the lapse occurs. Therefore, abrogation of the article has reaffirmed this general principle.

Still more important at a practical level are the amendments made to articles 120, 122 and 134 of the Code. The new text of Art. 120 states that a judge has the right to **suspend nullity or infringement proceedings brought on the basis of rights not yet granted** until the UIBM has granted (or refused) the application. Although the article already stated that the UIBM would examine the application involved in the proceedings before applications submitted earlier, a decision could be reached on the case before the UIBM had done so. Art. 122 now states that the **writs of summon and rulings of proceedings relating to the IP rights must be submitted to the UIBM, only if said rights arise from an administrative act of registration or patenting**, i.e. there is no such obligation for the proceedings concerning the remaining rights, like unregistered trademarks and designs, trade secrets and appellations of origin, in relation to which submission would be completely pointless. Finally, the provision of Art. 134 of the Code, i.e. that on the **competence of the Specialized IP Divisions**, has been reworded, in order to take into account Constitutional Court ruling no. 170/2007, which ruled out the application of the so called Company Law Procedure to IP cases was unlawful (incidentally, in last July this procedure has been cancelled also in company matters as it proved to be inefficient).

Even if apparently minor these procedural changes are, in actual fact, of the greatest importance, since they have offered the legislator the chance to provide an **interim regime** which makes the amended provisions applicable to pending proceedings. The **risk has thus been removed of these**

provisions being declared unconstitutional, on the grounds that they were introduced into the Code even though there was no delegation for the adoption of new procedural provisions, as the Constitutional Court already ruled in its judgment no. 112 of 14/24 April 2008, in relation to Art. 235 CIP (cfr. IP_LAW_GALLI Newsletter, September 2008). This would have had very serious consequences, in particular for cases brought before the Specialized Divisions for reasons of connection and for appeal proceedings, the latter with the risk that they would be sent back to the Court of First Instance. Precisely in relation to the above mentioned ruling of the Constitutional Court, again by way of interim regime, the law No. 99/2009 has rewritten the provision declared unconstitutional, stating that «The Specialized Divisions, set up in accordance with Legislative Decree 27 June 2003, no. 168, remain competent for disputes at appeal stage in matters covered by Art. 134 begun after this Code entered into force, even if the First Instance or arbitration proceedings were begun or were conducted according to provisions previously in force, unless a ruling on competence has already been issued within the ambit of these proceedings» (Art. 245. 2 CIP, while under paragraph 3 an analogous rule has been laid down for proceedings following on from interim measures and begun prior to institution of the Specialized Divisions). Thus, in these appeal proceedings the Court applied to cannot be declared noncompetent and the parties shall not be forced to bring again these appeal proceedings before the Courts which would have been competent according to the ordinary rules of competence applicable before the set up of the IP Specialized Divisions. This results in great advantages in terms of lower costs and shorter proceedings.

The rewriting of the interim provisions on copyright of works of industrial design (Art. 239 CIP) is more questionable. The new article amends the previous rule, since it expressly admits to copyright protection works created prior to 19 April 2001 (the date on which the law which first introduced copyright protection for designs possessing artistic value came into force), but grants at the same time the right to continue to copy such works to all imitators who can demonstrate that they began their activity before that date. However the article states that the imitator's activity may continue only «*within the limits of prior use*», i.e. without exceeding the (possibly, also quantitative) levels which it had prior to 19 April 2001. I believe it may be argued that it is the imitator who must prove both prior use, which is the basis of its right to continue to copy, and this prior quantitative level, which constitutes the extent of the right.

The new article, in any case, must also be considered *sub iudice*. As shall be discussed in greater depth later, the Court of Milan submitted a request to the ECJ for a pre-judicial interpretation of EC Directive 98/71, precisely in relation to the interim regime of copyright protection for designs and implicitly, therefore, also on its compatibility with an article such as this.

✓ 3. New criminal and administrative sanctions: light and shadows

Law 99/2009 has also amended the system of criminal and administrative sanctions for infringement, albeit with less propitious results. While the consistent and co-ordinated provisions of the «anti-infringement package» of the High Commissioner were, almost to the letter, taken on board by the initial text of the Bill, they were radically changed during the first reading to the Senate.

What has been preserved, at least in part, is essentially the **increase in sanctions**. These now range from a six month to a three year prison term for the infringement of trade marks and from a one year to a four year prison term for the infringement of patents and models (this disparity is difficult to fathom). A specific aggravating circumstance – infringement committed on large quantities or in a continuous and organized fashion – takes the minimum sentence to two years and the maximum to six (articles 473, 474 and 474-*ter* Criminal Code). A similar sanction has also been introduced (Art. 517-*quater* Criminal Code) for the **infringement of the denominations of origin of agricultural foodstuffs**. However, in a number of the provisions on infringement (but not all, which again raises the problem of disparity in the handling of analogous situations and thus of the potential violation of the constitutional principle of equality) a condition of punishability has been introduced consisting in the circumstance that the perpetrator «*was able to be aware of the existence of the IP right*». This risks limiting application more than a little as it is unclear whether

the words of the provision will be interpreted as meaning a **hypothetical possibility of awareness** (something which exists from the moment in which the right becomes accessible to the public) or a **concrete possibility of awareness**, to be assessed on a case by case basis and almost always open to question. It is likewise unclear whether the «rights» to which the provision refers are **only patents, design and trademark registrations already granted or also those at application stage** (but published: which would explain the reference to the possibility of awareness and would thus strengthen the first of its two interpretations above), as was held in decisions based on the corresponding provisions previously in force and as would seem logical to hold now.

At procedural level although the law provides for the **confiscation** of infringing goods it does not provide for a pre-trial procedure for early destruction of such goods, which would have resulted in a reduction in holding costs and less chance of such goods surreptitiously coming back into circulation. Likewise, at investigative level the possibility of making recourse to delayed seizure and controlled delivery (that had been introduced in the project of the High Commissioner working group) has been struck out. These measures have been shown to be extremely effective in countering other criminal activity such as drug trafficking and this is why the project of the High Commissioner (and the initial text of the Bill) provided for their extension to infringement. In this regard everything has remained essentially as it was before, and in practice it is possible to make recourse to more incisive investigative instruments only in cases in which real criminal organizations are running the counterfeiting business and can thus be accused of crimes under articles 416 Criminal Code. In any case the holder of the violated right can co-operate with the Public Prosecutor during investigations and the best results in the fight against piracy and counterfeiting are attained by using together civil procedures (especially discovery and seizure) and criminal procedures (to strike at the ramifications and possible criminal organization aspects of the phenomenon).

What was extremely deleterious – and in fact immediately rewritten although without any great improvement being made – was the umpteenth amendment to Art. 4.49, of Law 24 December 2003, no. 350 (see IP_LAW_GALLI Newsletter, November 2006) which introduced a provision whereby the affixing of trade marks *«of Italian firms»* on goods made abroad was, in any case, forbidden, unless their real geographical origin were indicated by means of *«evident fonts»* or *«another indication sufficient to avoid any error as to their real foreign origin»*.

Not only did this provision unjustifiably hinder a practice – that of decentralization and production integration at international level – which clearly promotes competition, reduction in costs and, at the end of the day, advantages for consumers, it also introduced an absurd **disparity in the treatment** of goods made abroad by Italian firms and those made by foreign, even EU, firms. This would seem to be unconstitutional, even beyond its more than dubious compatibility with EU law. Furthermore the risk was that, in order to escape this rule, **the most important Italian trade marks would be transferred to foreign related companies**, within the ambit of Group management of IP right portfolios. This would obviously be impracticable for **smaller firms** which would find themselves at a disadvantage with regard to both foreign companies and Italian Companies with a multinational group composition. Actually the new Director General of the Italian Patent and Trademark Office and the Fight against infringement, Ms. Loredana Gulino, commendably tried to mitigate the most pernicious effects of this provision by means of a interpretative circular to the Customs Agency, which **correctly excluded application in all cases in which the affixing of trade marks occurred prior to the provision coming into force**.

The outrage expressed by various entrepreneurial associations and the negative comments of experts led to a hurried «about front» and the provision was abrogated, but not completely by Article 16 of Law Decree 25 September 2009, no. 135, which introduced a new rule which is due to **enter into force on November 9 next**. Although the new rule has eliminated the criminal sanction, it has replaced it with a very high administrative sanction (from 10.000 to 250.000 Euro) and goods are still confiscated. Furthermore a marked disparity in treatment remains: even though the new article no longer speaks of *«Italian trade marks»*, it forbids the *«use of the trade mark by the holder or licensee in such*

a way as to lead the consumer to believe that the product or good is of Italian origin», unless the real origin is indicated. In actual fact sanctions are applied not when there is a difference between any apparent and real geographical provenance of the goods but only when the apparent origin is Italian. Therefore, by way of example, a trade mark used in such a way as to lead the consumer to believe that goods come from France when they are actually produced elsewhere will not be considered unlawful even though, as is obvious, this situation is completely the same as the former. It could reasonably be argued that this disparity in treatment violates:

(a) the constitutional principle of **equality** (Art. 3 Italian Constitution), according to which the law cannot use different measures to regulate cases which are completely the same (if it does so this is a case of unjustified discrimination); and

(b) Art. 28 (30) EC Treaty, which prohibits quantitative restrictions and all measures with equivalent effect.

It cannot even be precisely understood from the law exactly what is sanctioned, i.e. the simple affixing of a trade mark with an «Italian sound» (or which is, in any case, well-known to be Italian) will suffice or further action taken by the trademark owner or licensee to make the consumer believe that not only is the trade mark Italian but that the goods bearing that mark come from Italy. The latter would seem to be the logical assumption if the new provision were interpreted in line with consolidated trends in Italian criminal case law, according to which a trade mark *per se* does not inform the public as to geographical provenance. Likewise, it is not clear how to interpret *«use of the trade mark by the holder or licensee*»: if the provision is interpreted as meaning that simply putting on the Italian market products which do not comply with the rule is sanctioned, even should they be intended for markets other than the Italian market, where the rule obviously does not apply, this would lead Italian companies to relocate their logistics outside Italy, penalizing Italian business also from this perspective. Furthermore, the fact that application of the provision is entrusted to the **administrative authorities**, which do not usually have adequate training in this regard, makes it particularly important that these authorities receive a circular which interprets the article in order to clear up these doubts.

Moreover a further rule was introduced by Law Decree 135/2009, whereby criminal sanctions apply (.i.e. those laid down by Article 517 of the Criminal Code, incongruously increased by a third) for the use of «a sales indication which presents the product as entirely produced in Italy, such as "100% made in Italy", "100% Italia", "tutto italiano", in whichever language expressed, or anything else which may engender in the consumer a conviction that the product was completely produced in Italy, or signs or figures which induce the same fallacious convictions in relation to goods which were not actually «completely produced in Italy», understanding by this those products whose *«design, planning, production and packaging were exclusively* carried out in Italy». In this case too, beyond problems of compatibility with EC Law, the provision seems extremely imprecise and difficult to apply. Given that expressions such as «Made in Italy» may also be used for goods which have only *«undergone the last, substantial working»*, as laid down by the Community Customs Code, it seems logical to think that the «signs» and «figures» which communicate 100% Italian origin cannot be simply the tricolour or an image of Italy, if they are not accompanied by verbal expressions such as «100%» or «all». However, the provision evidently may also lend itself to a different interpretation. It is, moreover, unclear how it may be ascertained that «design» and «planning» actually took place in Italy, especially when these activities involve foreign designers, as frequently happens for Made in Italy companies and symbol-products.

Therefore, there is a risk that this provision on «100% Made in Italy» will also generate **misconceptions** and cause an endless series of disputes rather than attain the hoped-for outcome. The latter could much more easily be achieved by means of recourse to **collective trade marks**, provided, moreover, by both Italian and EC Law.

Instead, something very positive at administrative level and which was, in fact, already provided in the original «anti-infringement package», is the amendment of Art. 1.7 of Legislative Decree 14 March 2005, no. 35 (converted, with amendments, by Law 14 May 2005, no. 80). A **minimum**

sanction of 100 Euro is laid down for a purchaser who was aware that the goods he/she was buying were counterfeit (the maximum sanction has been reduced to 7.000 Euro instead of the current 10.000 Euro). This takes the sanction to a socially acceptable level and thus actually enforceable by local police; the incipit of the provision «*Unless the circumstance constitutes a crime*», has also been struck out so as to make it clear that this administrative sanction substitutes any criminal sanction (for imprudent purchase of counterfeit goods), which should likewise make application by the administrative authorities easier.

Reform of civil proceedings: the Expertise has changed in patent matters too

On 4 July last another reform of civil proceedings came into force, applicable to cases brought since that date but not to those which were already in course. The aim of the new rules, just like almost all the laws introduced in the last decade on procedural law, is to **shorten the duration of proceedings into the merits**, still much longer than the European average. This reform, therefore, only marginally affects the IP sector, which in Italy is mainly based on the use of **interim proceedings**. These are extremely efficient and quick and by making recourse to them the ensuing proceedings into the merits can often be avoided, by means of agreements reached on the basis of the outcome of such proceedings.

One of the new provisions which has direct relevance to IP disputes is Article 195 Code of Civil Procedure (CCP), relating to the **Expert Witness Stage**, which takes place in Italy in almost all patent cases. The new article sanctions by law a common practice already followed in various Courts, i.e. that of asking the Court Expert to prepare a sort of **draft Report**, to submit to the **parties' experts**, registering their comments and replying to them in the final Report. The aim is to avoid the technical discussion extending into a second supplementary stage ordered by the Court to respond to objections raised by the parties to the Expertise. However, in the light of experience gained in relation to this practice, it is reasonable to doubt the real validity of this method, at least in patent matters. The final Report usually confirms the preliminary Report and the reply to the observations made by the parties' experts becomes, rather than an opportunity to deepen examination and reconsider, a sort of **«justification**» of the Court Expert, who inevitably ends up defending his/her own work.

✓ Interpretation of EC Directive 98/71 has been referred to the ECJ in order that the interim regime for design copyright protection may be established

Assoluce, the Italian Association for Domestic Lighting, has won its battle to **bring before the ECJ the absurd Italian interim rule on industrial design**. This rule seems to deny protection to works created prior to 2001 and not registered as models, contrary to what appears to be the letter and spirit of the 2001 EC Directive relating to the matter, which makes no distinction as regards the moment in which the design is conceived. The Court of Milan decided thus tp bring the question before the ECJ, with an order of March/30 April 2009 containing detailed reasoning. It was issued in a case debating the infringement of a cornerstone of Italian design in matters of lighting – the Flos «Arco» lamp, created by the Castiglioni brothers in the 1960s. Assoluce participated in the proceedings, represented by Professor Cesare Galli, with the declared aim of achieving this objective i.e. beyond the case in question, of **obtaining a clear and binding ruling from the ECJ**, which would resolve the uncertainties displayed in this matter in Italian court rulings (see the rulings cited and commented upon in IP_LAW_GALLI Newsletter, September 2008) and, before this, in Italian legislation.

In Italy the interim regime of the copyright protection of works of design has, in fact, already changed three times since its introduction, by means of Legislative Decree no. 95/2001, in implementation of EC Directive 98/71. In 2001, a few days after the new rules came into force, the legislator introduced Art. 25-*bis* into the Legislative Decree. This implicitly recognized protection also for works of industrial design created prior to introduction of copyright, **excepting, for a**

period of ten years, in certain conditions, the rights of whoever had already started production and sale of products which were copies of the original before said introduction. Furthermore under Legislative Decree no. 95/2001 the duration of copyright protection for such works was only twenty-five years from the end of the year of the death of the author. This was in open conflict with the provisions of the EC Directive on copyright which stated that the relevant protection was to last seventy years from the end of the year of the death of the author. In fact, under Italian law, copyright protection for all other categories of works also lasts seventy years. The two provisions gave rise to an infraction procedure brought by the European Commission against Italy, upon the indication of INDICAM.

Following European pressure, the duration of design copyright protection was finally aligned with that of other works by Decree Law 15 February 2007, no. 10, later converted into Law 6 April 2007, no. 46 (cfr. IP_LAW_GALLI Newsletter, June 2007). However the new law also affected Art. 239 CIP, i.e. the interim rule into which Art. 25-*bis* of Legislative Decree no. 95/2001 had been inserted. The new text, introduced in 2007, stated that *«The protection accorded to industrial designs and models under Art. 2, first paragraph, no. 10, of Law 22 April 1941, no. 633, does not apply to products made according to designs or models which, prior to Legislative Decree 2 February 2001, no. 95 coming into force, were in or had entered the public domain».*

As we have seen, this provision has now been replaced by a new rule which expressly admits protection for works prior to 2001, but states that this protection cannot be used against imitators who were already active prior to 2001 (i.e. when these works were not protected under Italian law) and who are allowed to continue this activity *«within the limits of prior use»*. The Italian legislator was, therefore, not able to grasp the opportunity offered by the Court of Milan ruling to directly remedy the situation, replacing the provision which gave rise to referral to the European Court with a provision which fully complied with the Directive. We can therefore only await the judgment of the ECJ in order to finally put this affair «to rest», restoring to Italian design the protection which it is due.

✓ First reports on EPO searches on Italian patent applications: trends of the Italian Patent and Trade Mark Office (UIBM)

The first **reports on EPO searches on Italian patent applications**, in accordance with the Convention entered into by the UIBM and the EPO, in implementation of Art. 1 of Ministerial Decree 3 October 2007 (cfr. IP_LAW_GALLI Newsletter, December 2007/January 2008 and September 2008) have started coming into the UIBM.

The first indications show that the UIBM sends applicants the search reports in due time, thus allowing them to **correct the applications**, if necessary, to take into account the results of said reports. The trend which has so far emerged seems to be that, even without correction, applications are nevertheless granted, save naturally for the different weight that should be attributed to the corresponding patents in relation to the outcome of the search.

✓ The new Director General of the Italian Patent and Trade Mark Office (UIBM) and of the Fight against Infringement re-launches the Meeting Tables with businesses, taking up the work of the High Commissioner. Institution of the National Anti-Infringement Council

Re-organization of the Ministry of Economic Development has led to the institution of a new Head Office, entrusted to Dr. Loredana Gulino, who holds the role of **Director of the UIBM** and the powers previously vested in the High Commissioner for the **Fight against Infringement**, a post which was eliminated in June 2008. Law no. 99/2009 has entrusted coordination between the various government bodies involved in the fight against infringement to a **National Anti-infringement Council**, headed by the Minister or by a delegate and including representatives of the various public institutions involved. Private individuals may also be called to participate in its work.

With this objective in mind, even before institution of the National Council, Dr. Gulino has also convened **Meeting Tables** with **private firms** and **parties involved in the fight against infringement via Internet**, in which Professor Cesare Galli also took part. In particular, within the ambit of the Meeting Tables with private companies, a small legislative committee will be set up with the task of screening new provisions whose adoption may be proposed. In this sense the positive experience of meetings between government and business realized by the High Commissioner has been taken up again and strengthened, demonstrating the consciousness of the government that IP matters are a decisive factor in the competitiveness of the Italian system of production.

THE CASE

 ✓ A patent relating to an alleged second therapeutic use which is analogous to the drug's already known uses is null, in the absence of technical prejudices which would have advised against said second use (Court of Milan, 14 May 2009) – The text of the ruling and of our final brief

With a decision published on 14 May last the Court of Milan ruled on a delicate question in patent matters, which concerned an already known substance, patented in relation to a **particular therapeutic indication**, which the patent holder considered inventive by reason of the existence of a hypothetical technical prejudice which advised against use with the specific indication then patented.

The party which had sought a ruling of nullity with regard to the patent – the Swiss company IBSA S.A., represented by our firm – disputed both the claim that there was a second therapeutic use in the case in question, given the **homogeneity of the «new» therapeutic indication** with those already known and, in any case, its inventive nature, in that the known technique placed at the disposition of a person skilled in the art elements which could guide him towards this indication, against which no **technical prejudice** militated. In this situation it was the **duty of the patent holder to demonstrate technical prejudice**. However, not only did it fail to be proven, it was even refuted by a **protocol** published prior to patenting, which provided for clinical experimentation aimed at checking the efficacy of that new indication. The Court found for the plaintiff, stating first that any entrepreneur in the sector had **legitimatio ad processum with regard to nullity** and then declared the **nullity** of the EP in suit (and the corresponding Italian patent, with a broader content). It based its finding on a **reconstruction of the elements which the inventor took into consideration in tackling the technical problem which was the subject-matter of the patent, following an approach essentially in line with that of the E.P.O.**

The Court also examined in depth, probably for the first time in Italy, the **concept of technical prejudice**. It held that this exists only when there is a **widespread and deep-rooted conviction**, which cannot be demonstrated on the basis of simple individual opinions.

There now follow the text of our final brief (the reply brief which concentrates on the questions under discussion), and that of the ruling which found in favour of the plaintiff.

COURT OF MILAN

Specialized IP Division

Judge: Dr. Rosa – R.G. no. 21484/06

in the case brought

by IBSA Institut Biochimique S.A., represented by the attorneys Professor Cesare Galli and Mariangela Bogni

- plaintiff -

against Pharmacia & Upjohn s.p.a. and Pfizer Italia s.r.l. (incorporating Pharmacia Italia

s.p.a.), both represented by the attorneys (...)

- defendant and third party summonsed -

*** *** ***

Reply brief

on behalf of the plaintiff

IBSA Institut Biochimique S.A.

*** *** ***

1-. Well aware of the weakness of its patents – text book cases of *ever-greening* intended to artificially extend the patent protection of its drug ESAPENT sold by Pfizer (cfr. p. 24 of Pfizer's final brief) –, the third party summonsed devotes its case almost entirely to the singular argument (already expounded in previous briefs) that IBSA lacks legitimatio ad processum.

From this perspective too the opponent's case seems feeble, since it is forced to twist the teaching of case law and legal theory (as we stressed in our final brief in relation to "surgical" cuts to the text of the rulings cited in its previous briefs and again here) and to cite irrelevant rulings in matters of Antitrust Law (!) and even the notion (likewise irrelevant, regarding in turn only Antitrust Law ...) of "relevant market", or to submit "solicitous" studies commissioned on its behalf which allegedly show that "if IBSA were a rational economic subject and did not pursue aims other than profit it would without a doubt decide not to enter the omega 3 hypolipemiant market in Italy" (Pfizer final brief, p. 28).

All this with the aim of **backing up an argument which is clearly** <u>erroneous in law</u>, let alone in fact: i.e. the argument whereby the only parties which have legitimatio ad processum with regard to the nullity of a patent concerning an (alleged) new therapeutic use of a substance are those already currently producing and selling "cardiovascular drugs ... with an indication which is at least similar to that of the active principle protected by the patents in suit" (Pfizer's final brief p. 17), or which seem – in the unquestionable judgment of Pfizer, let it be understood... – about to profitably carry out such activity.

On the contrary, as is manifestly clear and reasonable, legal theory and case law, as cited on p. 54 of our final brief, self-evidently connect legitimatio ad processum to the fact that the party submitting a claim of nullity is a **current** <u>or potential</u> competitor of the holder, i.e. a party which operates <u>in the same sector</u>. This principle lies at the basis even of the very rulings cited by the opponent, despite the opponent's attempt to distort them, since although they refuted the existence of this premise for action in the cases examined they did so only in that said cases related to a patent covering the use of a substance <u>in the veterinary field</u>, challenged by a party which produced the substance as <u>a drug for human use</u>, i.e. a patent concerning the <u>non-medicinal</u> <u>use</u> of a compound, whose nullity was claimed by a party which produced and sold the substance <u>exclusively for pharmaceutical uses</u>: and thus a case in which a claim of nullity is made against the holder by a business operating in a <u>different sector</u>.

Moreover, the reason why the yardstick for assessing the existence of legitimatio ad processum in the field of IP rights (and, more specifically, of the nullity of exclusive rights) must not be excessively selective is because there must be a <u>fair compromise</u> between the needs of justice not to be burdened by cases which are merely (and clearly) "hypothetical" and that of the market <u>not to remain "ossified" on the basis of assessments (i.e. those on the dynamics of competition between parties operating in the sector and their possible development) which are difficult to effect *a priori* and, so as to say, *in vitro*, as the opponent (not impartially...) claims.</u>

Therefore, IBSA entirely meets with the balanced positions expressed in legal theory and case law as to the existence of legitimatio ad processum. It is a company operating <u>in the pharmaceutical</u>

<u>sector</u> with registered offices in <u>Canton Ticino</u>, a few kilometres from the Italian border, and is the <u>parent company</u> of a series of controlled businesses (including the I<u>talian firms</u> IBSA Farmaceutici Italia s.r.l. and Gelfipharma International s.r.l.) <u>holders also in Italy of</u> <u>Marketing Authorizations (MA)</u> (our docs 21, 23 and 24).

It must also be said that the aim of the opponent's brief is clearly to give the (false) impression that the drug covered by the Pfizer patents is **so revolutionary and advanced** that it cannot be the prerogative of companies like IBSA, even if the same lists among its drugs products such as antiinflammatories or preparations for rejuvenating the skin (opponent's final brief). However, this case concerns EPA and DHA ethyl esters (at the end of the day, <u>fish oil</u>), i.e. **substances which are found in numerous food supplements**, one of which <u>is today already sold in Italy by a company belonging to the IBSA Group</u>, Gelfipharma International S.r.l., as stated in our final brief).

2.- Finally, on p. 33 of its brief (a total of 48 sides!), Pfizer enters, "as a subordinate claim", "into the merits of the patent", i.e. the only real question: but does so only by **briefly running through the Expert's Report**, which we fully, and with detailed grounds, criticized, first of all in law, in our final brief.

Therefore, as regards this point (i.e. the merits of the dispute) the opponent's brief only requires a short reply. This reply will mainly aim to highlight how the opponent has concentrated its efforts in trying to avoid the priority landscape in which the alleged invention is collocated, and which the invention suggested (rather, taught) explicitly.

Pfizer attempts to give the impression that, prior to its patents (and the alleged discovery of the therapeutic efficacy of EPA + DHA ethyl esters in the reduction of mortality in post-infarct patients), there was only the GISSI 93 Protocol, which it presents as "a clinical hypothesis which was completely original at the time" which did not "follow in the wake of previous work" (Pfizer's final brief p. 47), and for which there was a technical prejudice so as to <u>substantially make it non-credible</u>.

In actual fact this was in no way the state of affairs.

First of all, as is ascertained in the Expert's Report (which also failed to deal in depth with the legal consequences), and as is incontrovertibly shown by the documents submitted in proceedings, the use of EPA + DHA precisely for the <u>reduction of mortality</u> in post-infarct patients was <u>perfectly well-known</u> in the State of the Art (so it is difficult to understand how, in relation to the opponent's patents, a second medical use can be spoken of, which, as explained by the case law cited on pp. 23-25 and p. 50 of our final brief, exists only with regard to a "new technical application which is <u>different and conceptually separable</u> from the previous"): and this since the DART Study, cited by the GISSI Protocol (p. 28 of the Expert's Report), a study which connected a 29% reduction in deaths in patients treated with MAXEPA, a drug whose content of EPA+ DHA is over 30% of the weight of the product, and which was further confirmed by the subsequent studies of Christensen in 1996 and Singh in 1997 (both prior to filing of the defendant's patents), as well as the US patent US 5 760 081, which the Court Expert, Dr. Capasso, held could deprive Claim 1 of Pfizer's Italian patent of novelty (this patent contained the general teaching of the administration of EPA + DHA in the form of ethyl esters for the specific claimed use).

Furthermore, the use of EPA + DHA in the treatment of post-infarct patients was <u>known also</u> in the form of the ethyl esters of these substances (i.e. in the form claimed by the patent), as taught by patent IT 1 235 879, which highlights the "efficacy of the EPA/DHA mix in modulating some risk factors" in post-infarct patients, such as blood pressure, pulse rate, levels of triglycerides, seric cholesterol, HDL cholesterol and platelet aggregation and blood coagulation factors (Expert's Report, p. 40). The Christensen Study (our doc. 10, p. 677) also cites <u>EPAX 5500</u> as being one of the drugs which may be used for the treatment of post-infarct patients (also by way of preventing sudden death). This drug, as shown by our doc. 18, was available in the form of

both triglycerides and ethyl esters.

Conversely, the studies of Swahn and Smith (the latter **prior to the GISSI 93 Protocol**, having been conducted in **1989**), which allegedly show an increase in bad cholesterol following administration of EPA + DHA in the form of ethyl esters to post-infarct patients, **cannot be a technical prejudice the overcoming of which confers inventive nature on the opponent's discovery** (unlike the *a posteriori* reconstruction which Pfizer tried to confirm) for two reasons both *per se* prevailing, since:

a) as has been clarified by Italian case law and that of the EPO Board of Appeal already cited in IBSA's final brief, technical prejudice only exists when there is a **widespread and deep-rooted conviction contrary to the invention**, which cannot be demonstrated on the basis of <u>two isolated</u> **documents**, but only on the basis of "institutional" medical literature;

b) as stated in the Expert's Report, <u>there is no evidence</u> of the fact that the known use of **EPA + DHA** in the form of triglycerides to prevent death in post-infarct patients would not lead to an increase in cholesterol, thus making this form of administration of the acids in question seemingly preferable to that in the form of esters claimed by the patent.

It must also be said that the drugs containing EPA+ DHA in the form of ethyl esters in a measure exceeding 85% of the weight which the GISSI 93 Protocol provided for administration with the aim of preventing death in post-infarct patients (i.e. **SEACOR**, **ESKIM** and **ESAPENT**, now sold by Pfizer) were sold with a **therapeutic indication relating to the reduction of triglycerides**, i.e. of a **serious risk factor for cardiovascular illnesses**: with the result that these drugs were, **already prior to filing of the Pfizer patents**, **also administered to post-infarct patients**.

4.- As things stand it seems patently clear that the GISSI 93 Protocol was, upon its appearance in the landscape of medical literature, **neither an "original" hypothesis, nor a hypothesis** "**contradicted by the facts**", which, therefore, must not be taken into account in proceedings relating to novelty and the originality of an invention, as the opponent claims. On this point allow us to cite once more the **case law** we referred to in our final brief, which excludes from assessment of the requisites of patentability of an invention only documents of a **speculative nature** which, when the patent application was filed, appeared to be completely improbable.

On the contrary, the GISSI Protocol appears to be the **expression of the knowledge of medical science at the moment in which it was drawn up**; and represents, in any case, further **proof** (even should this be necessary) **of the absence of a technical prejudice** against the "solution" which was then patented, which was evidently considered to be a road <u>which could be</u> <u>taken and which was anything but precluded</u> by a (non-existent and undemonstrated) common conviction to the contrary.

Thus the Protocol was **confidently published in 1993**: as no-one could reasonably have considered that the use of EPA+ DHA in the form of ethyl esters for the reduction of deaths in post-infarct patients was something which could form the subject-matter of a valid patent.

Therefore, what Pfizer is now requesting is an <u>extension of the exclusive right on a drug like</u> <u>ESAPENT, already (also) administered to the same category of patient identified as the</u> <u>recipient of the (alleged and, in actual fact, non-existent) second therapeutic use claimed by</u> <u>the patent</u>, for the simple reason that it had completed, with the simple, completely routine and most certainly non-inventive stage of administration of the drug and data collection, something which the GISSI 93 Protocol had already fully outlined, on the basis of the knowledge of the time, also from the perspective of the oral administration of the treatment and even the **percentage** of EPA+ DHA in the drug, which is <u>exactly copied and claimed</u> by the Pfizer patents, and was also already preceded by other documents.

This appears clearly unacceptable and contrary to legal rules on the requisites of patentability,

as, generally speaking, is the common, unfortunately widespread, practice in the pharmaceutical sector (which precisely because of the range of interests at play should, on the other hand, be particularly transparent!), to **abuse the patent**, changing it from a just prize for innovation into a means of **impeding**, by means of simple *maquillage* operations (such as that in suit), <u>competition on the active principles</u> which – in the interests of the market, but also those of patients (and the National Health Service, which naturally bears the costs arising from the existence of exclusive rights impeding the presence of **generics**) – should fall into the public domain once a patent has expired.

It is in this light that IBSA is confidently awaiting the ruling of this Court which it requires – this is why IBSA has committed itself to bearing the costs of such a burdensome and complex case (and the opponent has strenuously opposed it!) – in order to develop its activity in relation to the drug which Pfizer expects to monopolize until the expiration of **two patents which exist only on paper**.

Milan, 5 May 2009.

ITALIAN REPUBLIC IN THE NAME OF THE ITALIAN PEOPLE COURT OF MILAN

Specialized IP Division

composed thus

Dr. Stefano Rosa - President Rapporteur

Dr. Maria Nardo – Judge

Dr. Claudio Marangoni - Judge

meeting in Chambers has issued the following

RULING

In the civil proceedings R.G. 21484/2006 between

IBSA Institut Biochimique S.A., represented by the attorneys Professor Cesare Galli and Mariangela Bogni

and

Pharmacia & Upjohn s.p.a. and Pfizer Italia s.r.l., represented (...)

(Omissis)

DEVELOPMENT OF PROCEEDINGS

By Writ of Summons of 22 March 2006 IBSA Institut Biochimique SA summonsed SPA Pharmacia & Upjohn before the Court of Milan – Specialized Division P.I.I. seeking a ruling of nullity with regard to Italian patent 1308613 and the Italian part of EP 1152755B1, both held by the defendant. The plaintiff – presenting itself as a «Swiss pharmaceutical company», whose research activities include «the identification of formulas for the realization of drugs for the prevention of myocardial heart attack» – stated that the disputed patents «both concerned the use of acids containing a mix of two specific esters which were perfectly known precisely because of the function claimed in the patents ... just as the form of administration taught by the patents was perfectly known ... ». In this regard patents and (published) scientific studies prior to the defendant's patent filing were cited.

In the case – which followed Company Law Procedure Art. 134 CIP 2005 (in the text prior to the annulment by the Constitutional Court) – Pharmacia & Upjohn in liquidation entered an appearance, whereby it contested its own capacity to be sued (as it had, in 2001, transferred business to Pharmacia Italia Srl) as well as IBSA's legitimatio ad processum, stating that the plaintiff had

absolutely no industrial interest in the sector of cardio-vascular drugs; in the merits, it refuted IBSA's claims of nullity and then requested that the application be dismissed. The entry of appearance was served on 19 May 2006 and the defendant declared that it was not assigning deadlines for a reply, as it intended to serve an "immediate petition for a hearing to be scheduled pursuant to Art. 8.2.c) of ... Legislative Decree 5/03." Pharmacia & Upjohn did so by means of a brief served on 23 May 2006 and the plaintiff filed conclusions (1 June 2006) in which it demurred the inadmissibility of the petition pursuant to Art. 8 Legislative Decree 5/03.

The Court Reporting Judge, once appointed (Decree of the President of the Court 9 June 2006), by an order of 28 July 2006 referred the case to the President of the Division to rule on the demurred inadmissibility (Art. 8.5 Legislative Decree. 5/03). In the meantime – however – the proceedings into the merits proceeded since IBSA had served a brief pursuant to Art. 6 Legislative Decree and a brief suing Pfizer Italia srl as the company incorporating the transferee of the patents, Pharmacia Italia (service at the registered offices 15 June 2006), confirming the application of nullity with regard to the known patents.

Therefore, pending the hearing of the President pursuant to Art. 8.5, Pfizer Italia entered an appearance with a brief served on 20 September 2006, in which the defendant confirmed ownership of the patents in suit, but stated that its own summonsing was inadmissible; repeating its argument that IBSA had no *legitimatio ad processum*, the defendant presented a full defence in the merits.

At this point it was the plaintiff which served a petition for a panel hearing to be scheduled (10 October 2006). However, the defendant and Pfizer on 20.10.2006 lodged a petition seeking a declaration of inadmissibility, given the previous petition (*sub judice*) of 23 May 2006.

At the entry of appearance hearing of 22 November 2006, the delegated President declared inadmissible the petition of Pharmacia & Upjohn for a panel hearing to be scheduled (revoking the first appointment of the Reporting Judge) and, acknowledging the new petition (now admissible due to the fact that the previous petition was no longer pending), gave deadlines for filing conclusions and confirmed the second appointment of the Reporting Judge (Decree 15.12.2006).

The Court, with a decree containing grounds, called the parties to appear before it at a hearing of 28 March 2007 and – on that date (as well as at the adjournment hearing of 5 June 2007) – the defence teams of the parties declared that they would abandon the IBSA/Pharmacia & Upjohn proceedings and (the defence team of) Pfizer that it would definitively accept a discussion in the merits; they left it up to the Court to decide on the method for calculating the specific costs of the proceedings. With an order reserving judgment of 8 June 2007 the Judge (in the meantime confirmed as Investigating Judge by a procedural order of 7 June 2007, adopted according to the Constitutional Court decision No. 170/07 and Art. 16 Legislative Decree 5/03) referred to the Panel (upon the final decision being issued) a declaration that the matter at issue had ceased and a ruling on costs with regard to the position of Pharmacia. In the last part of the proceedings a patent Expertise was conducted and – as the parties did not request further deadlines for critical notes or evidence gathering – the case came to the final statement of claims stage at the hearing of 11 February 2009. Deadlines having been given to file final briefs, at the expiry of said deadlines (4 May 2009) a decision was taken on the case in Chambers on 14 May 2009 (as per the Division calendar).

GROUNDS OF THE DECISION

As shown by the preceding narrative, these proceedings concern only the nullity of the patents 1308613 of 9 January 2002, granted upon application MI99A000313 of 17.2.1999, and EP1152755B1 of 17 April 2002 granted upon application 7 February 2000 (naturally regarding the Italian part). These patents are indisputably held by the third party summonsed Pfizer Italia srl but, as was anticipated, the plaintiff IBSA Institut Biochimique S.A. summonsed Pharmacia & Upjohn, owner of the financial rights (the inventor was Pamparana Franco) according to the UIBM website, on the basis of the «printouts» of 8 March and 1 June 2006 submitted as IBSA docs 15 and 16.

Having entered an appearance, Pharmacia & Upjohn dedicated a great part of its defence to contesting its own capacity to be sued – on the grounds that it had transferred the patents – as well

as the plaintiff's legitimatio ad processum.

On the first point – which had given rise to the petition, then declared inadmissible, for a panel hearing following Company Law procedure to be scheduled and the summonsing of Pfizer Italia by IBSA (see narrative) – the judge (then Reporting Judge) was successful in his request to the parties to abandon the IBSA/Pharmacia proceedings (hearings 28 March and 5 June 2007) and then referred the decision on case costs to the Panel, holding that the case in question was more consistent with the so-called cessation of the matter in suit than Art. 306 Code of Civil Procedure (order reserving judgment 8 June 2007, which noted the change in procedure).

The defense did not raise any objection to this decision, but the (original) defendant concluded by asking that it be awarded the costs of the proceedings.

The Court – repeating that IBSA's withdrawing of the action (and not only abandonment of the claim) seems to justify a ruling on «the merits» rather than a merely procedural ruling – does not believe that there is any reason for ordering the plaintiff to pay costs. It acted on the basis of consultations which are now the norm (i.e. visiting the web-site <u>www.UIBM.gov.it</u>); for its part, Pharmacia & Upjohn, which could extra-judicially have given the data countering the information obtained from the website (transfer of business to Pharmacia Italia srl in 2001, transcription of the transfer at the competent patent offices), chose to submit a weighty statement of defence (also in the merits) with a simultaneous petition for a panel hearing to be scheduled and consequent prosecution of the discussion as outlined above. The defendant's doc. 4 (website printout of information from the UIBM) confirms that the website was updated with the announcement of the transfer to the defendant Pharmacia Italia S.p.a. between March (plaintiff's doc. 15) and April 2006 (defendant's doc. 4), probably after service of the Writ of Summons. On that date the transferee company had no longer existed for some time, having been incorporated by Pfizer Italia, and thus its address was not shown on the title search (doc. 4 *cit.*).

In conclusion – <u>the matter at issue having been declared ceased</u> – there are justified grounds for <u>setting off case costs</u> for what concerns <u>the IBSA / Pharmacia & Upjohn proceedings</u>.

A further preliminary question – insisted upon by the third party summonsed, Pfizer Italia, (which, as stated in the narrative, ended up accepting a discussion within the ambit of the above procedural agreement, withdrawing its original procedural objections) – is that of IBSA's *legitimatio ad processum*, with regard to Art. 122 CIP 2005 for what concerns *legitimatio ad processum* for a patent nullity action.

As is well-known, the (sparse) case law on the matter, using far from rigorous criteria, has identified interest in bringing a nullity action, assuming – on the one hand – the decisive nature of the plaintiff's statement of facts contained in the writ of summons and – on the other hand – considering a general relationship of competition between the companies as sufficient to render credible the usefulness of removing the patent for (even future) activity from the party asking for the nullity declaration.

The defendant (from now on, Pfizer) has repeated throughout the proceedings its full argumentation against <u>IBSA's *legitimatio ad processum*</u>, also citing rulings and criteria more properly related to Antitrust (the so-called "relevant market") which are extraneous to the instant dispute. The Court holds that – beyond the eccentric nature of IBSA production prior to 2006 in relation to the prevention of heart attacks – the (undisputed) pharmacological nature of the plaintiff's field of activity makes it, in law, unrealistic to exclude an interest in the removal of Pfizer's patents, IBSA's potential entering of the specific sector being viable by means of a number of industrial and legal forms (realization of active principles or final formulations, distribution, licences granted to third parties): so that even the economic analysis of the defendant as to the reliability of the hypothesis of that entrance on a economic/financial level (doc.26 – *studio ZSA Associates*) are pointless.

The *legitimatio ad processum* of the plaintiff having been confirmed we move on to the <u>merits of the case</u>.

As stated in the narrative, the evidence-gathering stage consisted in the submission of

documentation and a patent Expertise which examined the validity of the disputed patents.

In a report of 16 July 2008 the Expert panel failed to agree on the novelty of Claims 1-3 of the Italian patent, whilst it (unanimously) recognized the novelty and inventive step of the Italian part of the European patent only as regards 1 to 6, as well as Claims 4-5-6 of the Italian patent. As for the relationship between the two patents, the subject matter of the Italian patent for what concerns claims was broader as – what is more – the two descriptions are identical (see letter b) p. 74, moreover not particularly well-written or summarized: see pp 8/10 and 72/73 Expert's Report).

Generally speaking and very briefly it may be observed that:

a) the patents concern compositions containing fatty acids (EPA and DHA) in the form of ethyl esters (of said acids), proposed as a medication to prevent death in post-infarct patients;

b) it is undisputed (and was, in any case, so during the Expertise) that the patented substances were already known, also in the form of the pharmaceutical product (on the market) and that the invention concerned the specific therapeutic use above, assuming that for the earlier it was non-existent;

c) the description relates «a clinical study lasting around 3.5 years» conducted following a certain administration protocol for (4) groups of patients, only two of which were administered the treatment with the patented principle. The results confirmed the aim given in the patent text (preparation of «an <u>effective</u> drug... for the prevention of subsequent heart attacks» in the face of a State of the Art characterized by «treatment... which was <u>insufficient</u> for the prevention of heart attacks ... more specifically death, which occur in post-infarct patients, due to heart attacks following a first acute myocardial heart attack»: pp. 3/4 description).

The clinical data listed in the patent speak of «around 20% of the total mortality» as the percentage reduction, as well as «a reduction of around 40% in sudden deaths», without the description (or the Court Experts) lingering on the relative concepts, on the importance of the time interval considered or on the criteria for assessing the causal link between death and the original heart attack (sudden death is – in any case – death without any prior symptoms – p. 69 of the report – but it is supposed that it has a clear cardiologic origin).

The clinical experimental study (again according to the patent text) was conducted by administering ethyl esters of EPA + DHA whose weight was 85% of the total fatty acids, in a daily dose of 1 gram. Only this mix was therapeutically effective and the technical problem raised by the inventor can be said to have been resolved: the correct approach of the Panel of Experts (pp. 63 ff. report 16 July 2008) was not followed up by an equally rigorous handling of the matter, where (after a complete examination of the relevant priority) it confirmed *tout court* the inventive step of Claim 1/6 of the European patent despite the fact that the principal claim simply speaks of a «content of EPA + DHA of that mix ...more than 25% in weight» of the entire composition. This problem shall be examined later.

In order to confirm the reliability of the clinical experimental data (found in the description without an analytical illustration of the course of the protocol) – the Court Experts state that the results were «confirmed......... [by the] GISSI study published after the filing of the Italian patent application with all the procedural details...» (The Lancet, vol. 354, August 99): see p. 66 report of the defendant's Expert included in the First Exchange Brief («the study was then published in full ...», in loc. cit., where «the study» is the «*clinical triab*» referred to in the patent text – pp. 14/15 Court Expert).

Both patent claims carry a series of claims (independent, according to the Court Experts) concerning the use – naturally for the same therapeutical purpose as indicated above – of fatty acids containing exclusively one of the ethyl esters *de quibus* (EPA and DHA), with various weight indications: these are claims 8 to 13 of Italian patent '613 and claims 7 to 9 of EP '755 (which – it must be stressed – came into effect in Italy with filing 49742BE2002 – on 16 June 2002 – Chamber of Commerce, Industry and Crafts, Rome).

The Court Expert's report states (pp. 54/55 for what concerns the Italian patent; p. 59 for the

EP) that not even the patent text «reports any therapeutic efficacy for formulations containing only ethyl esters of EPA or of DHA», and thus «the patent cannot extend protection to aspects for which technical progress has not been demonstrated»; finally, as such claims of use of a type of acid ethyl ester (of the two considered) «... are not supported by any attestation of functionality, they are to be considered as if they did not contain the therapeutic use limitation ...», and are therefore fully anticipated by numerous prior patents, including US '667. Although the approach to the issue from a perspective of (extrinsic) novelty is acceptable at juridical level, it seems manifestly clear that – as the invention is based on a result which ameliorates the problem of preventing post-heart attack deaths - the omission in the patent text of any indication in this regard for one or more of the (independent) claims means that there is either a lack of description or a lack of inventive step, as the patent does not possess the fundamental pre-requisite for the legal protection assigned by law (improvement in technique). Since there has been no clinical trial involving pharmaceutical compositions containing only EPA EE or only DHA EE, the option seems to be the latter, i.e. the two patents' lack of inventive step for what concerns the indicated claims. The issue is, what is more, merely theoretical as there is no actual doubt as to the nullity of claims 8 to 13 of patent 1308613 and 8 to 9 of EP 1152755 whatever the precise grounds. On this point the Pfizer defense is rather weak (pp. 42/43 final brief), with the defendant emphasizing the marginal nature of such ways of realizing the invention and the lack of prejudice for the validity of the prior claims based on the known mix of both acids.

The Court believes it would be inopportune to immediately tackle (and therefore shall invert the logical order of its handling of the question) the constitutive point of the (extrinsic) novely of claims 1/3 of Pfizer's Italian patent on which the two Court Experts do not agree, nevertheless providing the Court with sufficient data to rule in this regard (pp. 48 ff. report). At a general level, the Panel cannot but note how difficult it is to assess the validity of such general claims, particularly no.1, which does not even indicate a relationship between ethyl ester EPA + DHA and the total substance used in the pharmaceutical composition. What is more, as this is the same criterion as that used by the Court Experts (see above) with reference to the independent claims concerning the use of a single acid (EPA EE or DHA EE), i.e. the absence of clinical data in relation to an appreciable therapeutic effect (which in the description exclusively concerns the 85% of the two ethyl esters in the mix). This observation of the Court Expert Dr. Capasso, what is more, also extends to Italian claims 2 and 3 (p. 52 report) which are not particularly dissimilar to claims 1/3 of the European patent (considered, on the contrary, undoubtedly new by the Court Experts: p. 59), apart from the condition of oral administration (which the Experts mention only briefly and not conclusively - p.73 of the report).

In actual fact, the Panel believes – thus disregarding the conclusions of the Court Experts – that the Pfizer patents do not possess sufficient inventive step even for the claims which are considered to be new or – in any case –, in the wake of the Expertise, reputed to lead to innovation; furthermore Claim 5 in combination with Claim 4 of the European patent (obviously taking into consideration the aims, uses and structure indicated by Claims 1 and 2) is definitely new as it is completely consistent with the clinical study indicated in the description.

Therefore, for what concerns inventive step the Panel of Experts carried out a correct analytical examination in the light of the priorities at their disposition and the technical discussion, following a juridical approach which was essentially exact (technical problem announced, solution proposed, evidence or lack of evidence of the solution with respect to the State of the Art). What was also impeccable – from an abstract point of view – was their identification of the indicators in favor of inventive step, including the possible technical prejudice which the State of the Art would have demonstrated for the solution proposed by the inventor (the use of EPA and DHA in ethyl ester form instead of in the form of triglycerides for the therapeutic aim of prevention declared many times).

The panel identifies a number of firm points which emerge from the Expertise (albeit not always undisputed *inter partes*: see the full and well-written summary of the respective positions on pp. 9/45 of the report, indispensable for fully understanding the assessment of the Court Experts, which

follow the same) and summarized as follows.

1) The State of the Art knew of the <u>use of EPA + DHA in the form of triglycerides</u> – natural or re-esterized – in the prevention of mortality in post-infarct patients, it being understood that the ethyl ester molecule is structurally different; thus the Court Experts overcame a number of procedural objections of the Pfizer technical defense (e.g. with regard to the use of the medicinal product MAXEPA in the 1989 Burr study, whose primary aim was to connect a fish rich diet to the prevention of subsequent heart attacks in post-infarct patients) and – at the same time – rushed observations of inventive banality on the part of the plaintiff's Expert (thus, again with reference to the Burr/DART study, the possibility of replacing MAXEPA with the ethyl esters of EPA + DHA indicated in Ackman, which, however, according to the defendant was not a study with pharmaceutical and therapeutic aims but a pure investigation of chemical analysis): pp. 31 ff. Court Expert's Report.

2) The researcher had at his disposition <u>drugs which were completely homogeneous at structural-chemical level</u> to that described in the (now) Pfizer patents, drugs which were cited many times in the report (with regard to the GISSI Protocol: see above) with the commercial names of ESAPENT, ESKIM and SEACOR, all «comprising ethyl esters of fatty acids ... with a content of EPA+DHA not less than 85% and a ratio between them of 0.9-1.5 ...» (p. 25 report). Although the Court Experts relate the datum as a given (p. 56 and p. 69) the therapeutic aim of these drugs as being limited to the «reduction of triglycerides» was fully discussed by the technical defence team,. The discussion was essentially based on a number of illustrative leaflets regarding the drugs in question and on their dating: the plaintiff was not able to demonstrate that the indications of the illustrative leaflets resulting from the 2000-2001 revisions, indications which speak of secondary prevention, of reduction in the risk of mortality (i.e. subsequent to the patents in suit and to the consequent publication of the GISSI study on the complete experimental procedure: see above) could also be placed at a prior date, as shown by the original Marketing Authorizations of the drugs (early 1990s): pp. 25/30 Court Expert's Report.

3) <u>The protocol published by the Group Italiano Studio Sopravvivenza Infarto</u> (GISSI) in G. Ital. Cardiologia, vol. 23, October 1993 (pp. 18 ff., pp. 56 ff. report) has been known since 1993. The Court Experts define it as a «protocol used to give rise to the results covered by the invention», i.e. contemplating experimental procedures consistent with the patent description, as confirmed also by the subsequent explanatory GISSI publication (p. 64 report).

According to the Court Experts this protocol does not constitute a priority which can affect the assessment of novelty (as it indicates not therapeutic outcomes achieved but a project) but <u>adds to</u> the State of the Art for the purposes of the inventive step of the patent in suit (pp. 57/59) also in the light of the case law of the EPO Opposition Division and of the (obvious) consideration that «the State of the Art comprises all that is accessible to the public at the date of priority», therefore including the protocols of clinical trials. The GISSI document indicated the drugs (1 capsule of Esagent or equivalent as shown above), oral administration and dosage (1 capsule = 1000 mg a day), the effect of reducing mortality in post-infarct patients and the expected statistical data (20% reduction): see – for correspondence – pp. 5/6 Pfizer (now) patent description.

This State of the Art raises the problem of the inventive step of the patent – which pertains to the <u>second therapeutic use of known substances</u> (Art. 14.4 Patent Law 1939; now Art. 46.4, CIP 2005; on this point see p. 47 of the Court Expert's Report) – as a problem of the reliability of substituting ethyl esters of EPA + DHA for triglycerides in order to prevent recurrence of heart attacks, given that this was already the aim of studies on (EPA + DHA) triglycerides and that drugs (ethyl esters) had long been on the market for generally preventive aims (lowering the level of triglycerides in the blood).

At this point, the Experts – as anticipated, completely correctly – examine a couple of documents evocative of technical prejudice with respect to said modification of the formulation (Smith et al – Swahn et al) in that they indicated a worsening of some intermediate parameters (the so-called surrogate end points), above all in relation to LDL cholesterol (the so-called bad

cholesterol), which increased in post-infarct patients treated with ethyl esters of EPA +DHA of -5% (Smith) or 7% (Swahn).

As the Experts acknowledge, the parties' Experts debated at length on the statistical and clinical importance of these studies and their results. Albeit admitting theoretically that the surrogate «end points (favourable: writer's note) are not always indicative of therapeutic efficacy» as is the final or real end point (decrease in mortality), while «if a particular treatment leads to a worsening of some intermediate parameters this cannot be ignored, even less so in ... post-infarct patients» (p. 66 report), it is clear that the technical prejudice deduced from the above modest variations of the indices of cholesterolemia is the result of a rather rough clinical induction, essentially lacking references to the literature, all the more so as Swahn indicated a parallel increase in HDL of 9% (p. 67 report) and that the importance of the LDL/HDL ratio for the purposes of heart disease has long been known.

A further cause for perplexity is the actual diffusion within the scientific community of the above studies, the debate which they actually gave rise to and the general reception of their results among workers in the sector, bearing in mind the legal theory and the EPO case law cited by the plaintiff (pp. 27 ff. final brief) as regards the concept of technical prejudice and its pre-requisites.

The Court Experts – however – once more supply the Court with rather a complete picture at a technical level, indicating – within the context of the discussion on possible technical prejudice – US priority 5,656,667, submitted by the plaintiff as proof to the contrary.

The patent concerns the usual «mix of ethyl esters of EPA + DHA at a concentration of at least 80% in weight to be administered orally for the treatment or prophylaxis of the multiple factors of cardiovascular illnesses». However, the results it supplies are not mortality rates but various «surrogate end points» (blood pressure, pulse rate, levels of triglycerides, seric cholesterol and HDL) not including LDL. Even in the face of this disquieting prior patent, the Court Experts keep to their reconstruction of the technical prejudice. In their opinion US '667 does not give clear indication of the use of ethyl esters in the prevention of mortality.

Here too the Court cannot but express extreme perplexity with regard to the reasoning of the Court Experts. The postulate of the non-decisiveness of the favourable «surrogate end points» (see above) is, in actual fact, taken to its extreme limits, a question not only of a number of intermediate parameters which are clearly connected at pathological and clinical level but of data which would suffice to decide that the Smith and Swahn studies are counterbalancing for the purposes of announcing the much cited technical prejudice. In conclusion – it being understood that the argumentation would not be (per se) decisive in order to refute the inventive step of the discovery – it is difficult to understand why an expert, tackling the technical problem of improving survival rates which can be achieved with treatment, should not have taken the teaching of the US patent into the slightest consideration simply because various experiments indicated (modest) increases in the levels of LDL cholesterol: in fact, the (indicated) lack of awareness of the US patent could reasonably give rise to a comparative study of the various «surrogate end points», if not the real clinical trial on the primary end point (mortality).

That clinical study protocol is the above GISSI '93 protocol, which the Court Experts finally discuss on pp. 70 ff. of the Report, as State of the Art (see above), for the purposes of deciding on inventive step and – in particular – always taking into consideration the question of the technical prejudice on the use of the EE of known fatty acids: nevertheless, discussion of the question has a superficial dialectic outcome (confirming prejudice), given the absence of therapeutic checks in the protocol (which is merely a project) and the failure of the protocol to refer to the Smith and Swahn studies, so that the authors of the GISSI did not demonstrate that they knew and wanted to overcome (by independent experimental checks) such dissuasive antecedents.

However, this is not the exact conceptual plane of relevance of GISSI '93. <u>The protocol is</u> nothing but the proceduralization followed by the inventor in the patents in suit, as stated clearly by the Court Experts (see above) in the face of a timid rebuttal on the part of the defendant's expert (which highlighted how the result on sudden death was not even programmed by the protocol – an

observation which, however, does not disprove in any way the objective datum of procedural correspondence: see pp. 4/5 of the minutes of the meeting 27 June 2008 Court Expert attachment 12). The inventor – i.e. the party which currently has exploitation rights – wishes to demonstrate in these proceedings that (its) discovery is not invalidated by the fact that it followed a clinical research programme belonging to the known art, stating in this way that the invention is (the fruit of) mere experimentation. The patent text refers to «surprising and very significant reduction in post-infarct mortality» but the 20% reduction in total mortality indicated by GISSI is clearly lower than that indicated (29%) by Burr 1989 (p. 69 Report): actually disparaged by the defendant's expert who stated (p. 5 Court Record 27.6.08 cit.) that «the 20% reduction in mortality following a diet was a figure which had long been referred to in the literature» (*ibid*, for further points); and thus the only thing remaining is the data regarding the so-called sudden deaths, which even the Court Experts did not precisely understand (in loc. cit. p. 11), but – above all – on which there were no reliable statistical studies («Moreover, a comparative study of the % reduction in sudden deaths following administration of esters and triglycerides is not included in the documents submitted to the Courts: p. 69 Report).

Therefore, there is nothing «surprising» about the results of the experiment which form the basis of the patent and, what is more, the discussion did not particularly deal with that evidence of inventive step (i.e. non-evidence).

The actual proceduralization of GISSI '93 placed importance not on overcoming technical prejudices but on financial resources, in all likelihood supplied by the patenting company to the group, which – immediately after the filing of the Italian priority – rushed to publish details of the experiment (Lancet '99).

The defendant was, in any case, obliged to prove such prejudice since the indicated series (protocol – corresponding patent – publication of the clinical trial which formed the basis of the patent) was (and is) strong evidence of the invention's lack of inventive step according to what has been observed thus far: an obligation which was not carried out given US priority which indicated key results in terms of «surrogate end points» (enormously significant for cardiovascular illnesses, as a whole) in the face of contrasting results from Smith and Swahn, at the most counterbalancing the prior patent (after a rigorous prior validity check). US 5656667, on p 2 of the patent description, is actually listed among the priorities concerning «essential fatty acids ...[with] a therapeutic effect in the prevention and treatment of cardiovascular illnesses, for example the treatment of thrombosis, hypercholesterolemia,......hyperlipidemia», confirming that the technical prejudice attributed to ethyl esters – of which the patent makes no mention – is a mere *«a posteriori»* reconstruction, inspired by the need to save an inadmissible patent of pure experimentation on an (already) known project: moreover (that project) being based on relevant prior patents (also) involving the use of ethyl esters and on the use of drugs which, in any case, pertain to the sector in discussion (level of triglycerides in the blood, which cannot be reduced by diet).

The case in question does not seem to need further arguments.

The above demonstrates the nullity of the Pfizer patents in suit and the plaintiff's petition is admitted.

The losing party to pay court costs assessed at Euro 14.171,82, of which Euro 8.600 for counsel fees and expenses.

For these reasons

Deciding on the petition submitted by S.A. IBSA Institut Biochimique by Writ of Summons served on 22 March 2006 on SpA Pharmacia & Upjohn and by Writ of Summons served on 15 June 2006 on srl Pfizer Italia, thus rules:

a) declares the matter in suit ceased for what concerns proceedings between the plaintiff and Pharmacia & Upjohn, setting off correlative case costs;

b) declares the nullity of Italian patent 1308613 of 9 January 2002 as well as the Italian part of EP 1152755B1, made effective in Italy by filing 499428E 2002 of 14 June 2002 Chamber of

Commerce, Industry and Crafts, Rome;

c) orders Pfizer Italia – holder of the patents under point b) – to reimburse the plaintiff's case expenses, assessed as Euro 14.171,82, plus 12.5% lump sum on duties and fees, Expertise costs if paid in advance by IBSA in these proceedings and subsequent proceedings if necessary.

Court Clerk Office's communication to the UIBM pursuant to Art 122, last paragraph, CIP 2005.

Thus decided in Milan, in Chambers 14 May 2009.

The President Rapporteur Dr. Stefano Rosa

THE ARTICLE

✓ The Trade Mark as a sign and distinctive capacity – an article by Professor Cesare Galli published in Il Diritto Industriale

In June 2008 the Italian Group of AIPPI organized an international meeting in Milan, the scientific project of which was drawn up by Professor Cesare Galli, on «*Marchi e diritto comunitario: l'evoluzione giurisprudenziale e le ricadute sui diritti nazionali*» (*Trademarks and EC Law: the evolution in case law and its effects in the national jurisdictions*); in the course of which Professor Galli presented a paper entitled *La nozione di segno e la capacità distintiva del marchio (The Trade Mark as a sign and distinctive capacity* – cfr. IP_LAW_GALLI Newsletter, September 2008). The review *Il Diritto Industriale* subsequently asked Professor Cesare Galli to develop his paper into an article. The article was then published by the review.

There follows an updated version of this article. It reconsiders the notion of distinctive capacity and that of sign on the basis of Community case law, framing it within a vision of the Trade Mark connected to the meaning and value which it actually has in the contemporary economic world and in contemporary life.

CESARE GALLI

THE TRADE MARK AS A SIGN AND DISTINCTIVE CAPACITY

SUMMARY: 1. Trade Mark Law and Community Law: the reasons for convergence/clash. -2. The Trade Mark in the economic world and how it is viewed by the EU Legislator. -3. The Trade Mark as a sign, ahead of a distinctive sign. -4. Distinctive capacity in ECJ Case Law. -5. Strong and weak trade marks: the need for a "case-by-case" assessment. -6. Shape trade marks and questions regarding the acquisition and loss of distinctive capacity. -7. Conclusions: the "realistic" approach to the Trade Mark in the reality of the market as a fundamental contribution made by Community Law to distinctive sign matters.

1. The **competitive** – and, at least potentially, anti-competitive – **relevance** of Industrial Property rights, and more generally Intellectual Property Rights, has received particular attention in Community Law since the very outset.

What has led EU Law to directly tackle the content of IP rights, significantly contributing to their development, is the **territoriality principle** which governs them and which, of necessity, sets them on a collision course with one of the fundamental principles of Community Law, that of the **free movement of goods within the Community**. It is, in fact, clear that on the basis of the territoriality principle, which governs IP matters, even within the Community goods risk coming up against an IP right at each border crossing, which differs from and is independent of that in force in the State from which they originate, a right which, as such, could be invoked to stop further movement of the goods and thus become an instrument for **market compartimentalization**.

This conflict has been tackled and resolved first by Community case law and then by EC Directive 89/104 to Approximate the Laws of the Member States relating to Trade Marks,

establishing the principle of **Community Exhaustion of** IP rights¹. This stops the holder of any such right opposing further movement of goods placed on the market within the Community by him or with his consent. At the same time Community case law has established the notion of «specific subject-matter» of the right, as a criterion for determining when bans and restrictions on importation deriving from IP rights and commercial rights can be considered justified²; thus such bans and restrictions are considered justified when they comply with that specific subject-matter and unjustified when they go beyond the bounds of the subject-matter. There is, however, a significant development: according to the most traditional ECJ case law the specific subject-matter of protection of a trade mark only concerned the mark's distinctive function³, while in more recent Community case law the specific subject-matter of the trade mark right seems to go beyond this function and to extend to the other components of the message communicated by the trade mark, including its suggestive components⁴, with a view – which represents the consistent line of Community IP Law and also underlies the policy of harmonization which led to the introduction first of EC Directive 89/104 to Approximate the laws of the Member States relating to Trade Marks and then of EC Regulation 94/40 on the Community Trade Mark (henceforth CTMR) – to avoiding a trade mark right becoming an instrument with which to distort the market, adjusting the juridical discipline to the reality of the trade mark in the contemporary economic world and in contemporary life.

2. In fact, on an economic level the Trade Mark is today the fundamental instrument of business communication, since it is used (and promoted) not only to inform the public as to the origin of the goods and services for which it is used by a certain company and, therefore, as to the existence of the exclusive right of this company to use it in a certain sector (the traditional «indication of origin function» of the Trade Mark), but also as a symbol of all the other components of the «message» which the public connects, through the Trade Mark, to the goods or services for which it is used: a message which comprises both the data which consumers have deduced from (direct or indirect) examination and use of these goods or services; and – above all – the information and suggestions spread directly by the business through advertising.

It is on the last components of the message connected to the Trade Mark, and in particular on the capacity of the Mark to evoke gratifying images for the purchaser of the good or services bearing it, that **market value** is mainly concentrated today, in terms of the so-called selling power⁵, of the most famous Trade Marks – and thus economists prefer to speak of **«brands»** –, in that thanks to this evocative capacity they confer a **significant added value amongst the public**⁶ on the good. In fact, the purchase of goods or services bearing a Trade Mark, which in addition to carrying out an identifying function also has a symbolic value, is often a form of **«investment in reputation capital»**, since by using (and sporting) these goods or services and their Trade Marks consumers transmit a certain image of themselves to the outside world, consistent with the «style» connected to these Trade Marks⁷. It seems, therefore, that the ideological criticism which is often levelled against

¹ A particularly clear ruling is that of the ECJ in Centrafarm/Winthrop ECJ, 31 October 1974, in *Giur. ann. dir. ind.*, 1974, 1480 ff. and in *Racc. giur. Corte*, 1974, 1183 ff.

² On this point see, in particular, ECJ, 17 October 1990, C-10/89 (Hag 2), in *Giur. ann. dir. ind.*, 1991, 844 ff.

³ See, for example, ECJ, 25 May 1978, C-102/77.

⁴ ECJ, 11 July 1996, in joined proceedings C-94 and C-73/94, in *Giur. ann. dir. ind.*, 1996, 1255 ff. See also ECJ, 11 July 1996, in joined proceedings C-427/93, C-429/93 and C-436/93, in *Racc. giur. Corte*, 1996, 3457 ff. and ECJ, 4 November 1997, C-337/95, in *Giur. ann. dir. ind.*, 1997, 1131 ff.

⁵ See D. PREDOVIC, *La valutazione del marchio*, Milan, 2004; and Various Authors, *Brand*, (edited by) D. PREDOVIC, Milan, 2004.

⁶ On this point see, in particular, N. ECONOMIDES, *The Economics of Trademark*, in 78 TMR (1988), p. 523 ff, especially pp. 532-535

⁷ W. LANDES - R. POSNER had already called attention to this point in *Trademark Law: an Economic Perspective*, in 30 *Journ. of Law and Econ.* (1987), pp. 265 ff, later republished with amendments as *The Economics of Trademark Law*, in 78 *TMR* (1988), pp. 267 ff, especially pp. 304-306.

Trade Marks⁸, starting from the assumption that, when the image components connected to famous Trade Marks give added value to the intrinsic qualities of the good, consumers are induced to pay more for goods which are in essence exactly the same as cheaper ones (or actually worse), can be refuted on the basis of the **recognition of the value which these image components may also have for consumers on today's market**, and correlatively of the fact that the success or lack of success of a product, and thus also of brand goods, at the end of the day still depends on choices of the market i.e. of consumers.

This development of the Trade Mark in economic practice⁹ has been accompanied by legislative development, which has led – in Italy following implementation of EC Directive 89/104 and the introduction of the CTMR – to legislative recognition of the role played by the Trade Mark as an instrument of communication, and therefore to the protection of trade marks against all parasitic exploitation, whether this be in the form of likelihood of confusion or linkage, i.e. against all uses of identical or similar signs which involve the unauthorized appropriation of the «external economy» of the Trade Mark which is linked to the incorporated message¹⁰. However, acting as a foil to this recognition, especially in the Italian legal system, is the responsibility borne by the trade mark holder for what concerns information and other elements of that message perceived by the public as connected to that Trade Mark. The holder must guarantee that the goods or services bearing the trade mark comply with this message (in this regard we speak of the «statute of the non-deceptiveness» of the Trade Mark and in Anglo-Saxon legal theory of «*consumer trademark*»¹¹).

3. Even before this, however, the Community development of Trade Mark Law has led to the enhancement from a juridical (and also specifically legislative) perspective of aspects which had never been fully grasped by Italian case law or even by Italian legal theory, in relation to the **premises for protection** of distinctive signs.

Precisely because the Trade Mark is essentially an **instrument of communication**, an element of the language (albeit not necessarily verbal), i.e. the **symbol** of a message which is inherent in the product or service for which registration is requested, it must consist of something **which consumers perceive as a «sign»**, i.e. as the bearer of meaning, thus ideally_distinguishing it from the product or service bearing the mark: this may seem banal, but is in fact not so, if we think that traditionally in Italy the question of distinctive capacity was read purely **negatively**, excluding from registration those Trade Marks consisting of general names and descriptive indications, raising the problem therefore essentially for denominative Trade Marks and essentially to **exclude distinctive capacity and not to confirm it**.

Hence, only that which is a sign can be a trade mark, but this is obviously not enough: in order to be able to speak of Trade Mark, the significance of which, as a sign, it is the bearer must be «distinctive», i.e. the sign must (also) be perceived as indicating the **existence of an exclusive right** on its use in a certain sector and, therefore, as indicating that in that sector there is only one party which may use it or authorize others to use it and which assumes **responsability** for the characteristics of the goods or services bearing the mark. Thus, Trade Marks (and other distinctive

⁸ The radical criticism of «brands» is one of the battle horses of the *no global*, movement, one of whose «sacred texts» is the best seller N. KLEIN, *No Logo: Taking Aim at the Brand Bullies*, Toronto, 2000 (Italian edition: *No Logo, economia globale e nuova contestazione*, Milan, 2001). For a reply to this stance conducted from a juridical perspective see C. GALLI, *Protezione del marchio e interessi del mercato*, in *Studi Vanzetti*, Milan, 2004, pp. 661 ff.

⁹ On this development see, in particular, T. DRESCHER, *The Transformation and Evolution of Trademarks – from Signals to Symbols to Myth*, in 82 *TMR* (1992), pp. 301 ff.; and in Italian legal theory C. GALLI, *Funzione del marchio e ampiezza della tutela*, Milan, 1996.

¹⁰ For this see once more W. LANDES - R. POSNER, *The Economics of Trademark Law, cit.*, p. 304. See also G. GHIDINI, *Profili evolutivi del diritto industriale*, Milan, 2001, pp. 145-146.

¹¹ See A. KAMPERMANN SANDERS - S. MANIATIS, A Consumer Trade Mark: Protection Based on Origin and Quality, in EIPR, 1993, pp. 406 ff., p. 415.

signs), on the one hand, contrast with elements which are not signs i.e. that the public does not perceive as bearers of a message, but appreciate per se, as usually happens with shapes and colours, which only exceptionally constitute Trade Marks i.e. only in that they are actually perceived by the public as signs¹²; on the other, as **«specific» signs**, they contrast with **«generic» signs**, i.e. the names and symbols which in common (verbal and non-verbal) language exclusively express one or more characteristics of the product or services for which they are used, or are actually the common name for them or constitute symbols in general use, and which, as such, do not (also) communicate the existence of an exclusive right but must remain at the disposition of whoever intends to use them with their «generic» meaning. This too seems banal but it continues to escape a part of Italian case law which, when dealing with the question of strengthening due to the use of signs containing one of these «generic» components, states that extension of the «strengthened» trade mark protection to the conceptual significance also involves that component, which, on the other hand cannot be monopolized in its generic meaning, on the basis of the **anti-monopoly rationale** which underlies this rule and had already been dealt with in Italian legal theory¹³.

For registered trade marks, these two fundamental requisites – without which we could not even speak of trade marks, or more generally distinctive signs – are accompanied by a third, of an essentially practical nature, i.e. the ability of the sign to be **graphically represented**: and again this is a question which, albeit not new, has been particularly well-examined in Community case law. As the ECJ stated, this requisite meets the need for third parties, competent authorities and traders to *«know with clarity and precision the nature of the signs of which a mark consists in order to be able to fulfil their obligations in relation to the prior examination of registration applications»* and *«with clarity and precision be able to find out about registrations or applications for registration made by their current or potential competitors»*¹⁴; on this basis the Court (questionably) excluded from registration as trade marks a sign constituted by a particular **fragrance** to be applied to the goods intended to be distinguished, ruling that the ways used by the applicant to graphically represent the fragrance did not meet these requisites¹⁵.

4. In the CIP – which, on this question, has essentially taken up the provisions of the Trade Mark Law amended in 1992 following implementation of EC Directive 89/104 – these basic requisites are provided and disciplined by articles 7 (subject-matter of the registration), 13 (distinctive capacity) and 12.1.*a*) (customary use signs), to which articles 4 and 7. 1 letters *a*, *b*, *c* and *d* CTMR correspond. The first article, in particular, also contains an **exemplicative** (and thus not exhaustive) **list**, of what may, individually or in combination (in which case we speak of complex marks), constitute a sign and thus be protected as a trade mark. The list covers *«words, including personal names, designs, letters, numerals, sounds, the shape of goods or of their packaging, colour combinations or tones».*

Art. 13 CIP excludes from protection as a trade mark signs which «lack distinctive capacity», and «in particular» those constituted «exclusively» by **generic names** and by **descriptive indications** relating to the goods or services for which the trade mark is requested. The article (like the corresponding article of the CTMR) gives a series of examples of these signs (*«signs which may serve, in trade, to designate the kind, quality, quantity, intended purpose, value, geographical origin or the time of production of the goods or of rendering of the service, or other characteristics of the goods or service*»); of these examples those signs relating to «**geographical origin**» are of particular importance and give rise to a number of problems of interpretation. An extreme interpretation would, in fact, lead to signs constituted

¹² See in particular, for colour trade marks, the rulings of the ECJ, 6 May 2003, C-104/01 and ECJ, 24 June 2004, C-49/02; and for shape trade marks that of the ECJ, 7 October 2004, C-136/02.

¹³ See the famous article of A. SRAFFA, *Monopoli di segni distintivi o monopoli di fabbricazione?*, in *Claim dir. comm.*, 1930, II, p. 1 ff.

¹⁴ ECJ, 12 December 2002, C-273/00, points 50 and 51 of the decision.

¹⁵ The Court did not rule on the possibility of using spectrographic techniques to describe smell, as some legal theory had suggested (in particular L. MANSANI, *Marchi olfattivi*, in *Claim dir. ind.*, 1996, I, p. 262 ff.). Prior to this, the OHIM Boards of Appeal ruled in favour of eligibility for registration with a decision of 11 February 1999, in *Giur. ann. dir. ind.*, 1999.

exclusively by geographical names being excluded *tout court* from registration as individual Trade Marks; however, militating against this interpretation is the fact that generic or descriptive signs, the monopolization of which the legislator aims to avoid, are obviously not all those which may abstractly define or describe any product or service or their characteristics, but only those which **carry out this function in relation to the specific goods or services for which the trade mark is requested**. This seems to leave open the possibility of protecting as trade marks geographical names of regions or places which, in the perception of consumers, **do not affect** the characteristics of the goods or services bearing the mark, and which are thus seen by the public as fantasy names even when they indicate the actual origin of these goods or services¹⁶. On this issue too the ECJ has ruled, stating that the bar applies not only to geographical denominations which currently influence the judgment of the public as to the quality of the goods bearing the mark but also to those which **may only potentially** be able to designate the geographical origin of the category of goods for which the trade mark is requested¹⁷; however, the Court does not seem to go so far as to exclude from registration as trade marks geographical names which have, for the target public, an evocative value which prescinds from geographical origin in a strict sense.

Traditionally, Italian legal theory and case law held that this hypothesis of generic names and descriptive indications exhausted the list of signs lacking distinctive capacity and, therefore, in practice interpreted this requisite «in negative» - as existing only if the trade mark did not concern the generic name of the product or service bearing the mark or a related descriptive indication. This approach, however, seems **reductive** from various perspectives and has, in fact, been **abandoned**. Firstly it is clear that the rationale which forbids the monopolization of generic names and descriptive indications also holds for **non-denominative signs** which likewise express, in a general manner, the characteristics of the product or service bearing the mark, like the images which represent it or the packaging which assumes the shape of the goods inside. The risk to be avoided by barring appropriation as a trade mark of generic signs is, in fact, that whereby **monopoly on a sign may turn into monopoly on the product:** just as EC case law has stressed, this bar «*pursues an aim which is in the public interest, namely that such signs or indications descriptive of the characteristics of the goods or services in respect of which registration is applied for may be freely used by alb¹⁸.*

Secondly, under Art. 12.1. *a*) CIP, regarding novelty (according to the proposal for revision of the CIP this provision will be placed in Art. 13, in a more systematically correct way) trade marks which *«consist exclusively of signs which have become customary in the common language or in the bona fide and established practices of the trade*» also lack distinctive capacity. According to the traditional teaching of Italian case law and legal theory, these signs are constituted by denominations or (bidimensional or tridimensional) symbols which, albeit lacking descriptive value, are *«commonly used in trade and in daily life for goods of any type (and hence) words such as 'super', 'extra', 'standard'*»¹⁹, including the lower numbers and the letters of the alphabet. The rationale behind this lies in that these signs are **customarily used** to indicate various «series» of the goods, and as such do not seem monopolizable, unless in relation to the particular way in which they are written, or the combination in which they are used and other verbal or figurative elements²⁰. However, for numbers and letters there was an ambiguity in this argument: it is, in fact, clear that this «generic» use of letters and numbers may well be permitted even when another party has registered a number or a letter, as it comes within the ambit of lawfulness which has been recognized for the descriptive use

¹⁶ Comm. Brevetti 7 October 1994, in Il dir. ind., 1995, pp. 151-152.

¹⁷ ECJ, 4 May 1999, C-108/97 and C-109/97.

¹⁸ ECJ, 12 February 2004, C-363/99 and ECJ, 12 February 2004, C-265/00.

¹⁹ See V. DI CATALDO, *I segni distintivi*², Milan, 1993, p. 69. The ECJ has broadened this definition, stating that signs which, albeit not descriptive, have also come to be used customarily in the (only) specific sector for which the trade mark is requested must be considered non-monopolizable: ECJ, 4 October 2001, C-517/99. On this issue see M. AMMENDOLA, *I segni divenuti di «uso comune» e la loro inappropriabilità come marchi*, in *Studi in onore di A. Vanzetti*, Milan, 2004, pp. 1 ff.

²⁰ In this sense see Supreme Court 7 May 1983, 3109, in *Giur. ann. dir. ind.*, 1983, no. 1595.

of another's sign by Art. 1-*bis*, paragraph 1 Trade Mark Law and now by Art. 21, paragraph 1 CIP and Art. 12 CTMR, provided this use is *«in accordance with honest practices»*; on the other hand, just as with all other cases of lawful use of another's trade mark, what will be forbidden will be the improper use of such signs, i.e. that realized in such a way as to cause a likelihood of confusion or linkage to the trade mark. A trade mark constituted by a single letter or number will, therefore, have to be **admitted each time, in a certain context, the single letter or number is actually perceived as a distinctive sign**, i.e. as the bearer of a message also relating to the existence of an exclusive right; and shall be protected against any use which brings to mind that «specific» message, and not (or not only) against the «generic» message relating to the series of goods²¹. In fact, it is precisely the fact that another's use causes the imitated sign to be brought to mind may constitute – in this as in other cases of signs whose distinctive capacity is in doubt – the **litmus test for the existence of this «specific» message**, and therefore of the existence of a valid trade mark.

These two hypotheses, however, do not exhaust the list of signs without distinctive capacity. As has also been stated by the ECJ, other signs may exist which, albeit neither descriptive nor in general use, are not actually able to communicate a message and, in particular, a distinctive message, in the above sense, i.e. to be perceived by the target public as distinctive signs; according to the ECI the existence of the requisite of distinctive capacity also needs to be checked *positively*, rather than considered only negatively, in relation to bars on the registration of signs in customary use and those constituted exclusively by the generic name of the product or service for which the trade mark is registered or by a relative descriptive indication, as was traditional in Italian case law and legal theory. Again it appears clear from Community case law that this is, in a certain sense, a «residual» impediment, considered essentially for trade marks constituted by realities which, in the eyes of the public, do not normally effect a distinctive function. This problem arises, in particular, for trade marks constituted by colours, the shapes of the product and its packaging and - as the ECJ highlighted - also by slogans, in that, according to the Court, «average consumers are not in the habit of making assumptions about the origin of products on the basis of such slogans»²². However, this statement too conceals, a least in part, an ambiguity: it may apply only to signs which «are born» as slogans, i.e. which, due to their structure, the public cannot plausibly perceive in any other way; when, on the contrary it is only the actual use which the holder makes of them which allows us to define a denominative sign as a slogan or as a distinctive sign proper, the process is, to some extent, reversed, i.e. it is, if anything, this use which may lead to the loss of distinctive capacity (if the public does not perceive the sign as such, i.e. as able to communicate also the message as to the existence of an exclusive right), and not the contrary.

²¹ The author who was most reluctant to admit eligibility for registration of letters and numbers considered per se has also reached this conclusion, changing his previously expressed opinion (VANZETTI, in VANZETTI-DI CATALDO, Manuale di diritto industriale⁵, Milan, 2005, pp. 183-184); as has, in ruling no. 14684 of 25 June 2007, the Supreme Court, which annulled a decision of the Appeal Court of Florence, stating that the Appeal Court had «mixed up letters of the alphabet considered per se, as signs normally intended – alone or combined with other letters of the alphabet, in single words or in more complex sentences/periods - for a communicative function as an instrument of language, even if belonging hypothetically to a foreign language, with letters of the alphabet used (regardless of any graphic characterization conferred on them) as signs identifying goods or activity, i.e., for a distinctive function, which is not theirs and which can be effected precisely by virtue of the original association to the product, and for this reason does not preclude anyone who wishes to continue to employ that same letter according to its natural use as an instrument of language»; and concluding that the valid eligibility for registration of a trade mark constituted by a single letter of the alphabet must be «confirmed or refuted not by reason of the fact that letters of the alphabet belong to the signs of language, but by reason of the distinctive capacity which the specific sign possessed or did not possess, once - beyond its normal and conventional intended use - it had managed to create a link with the goods of the company which made use of that certain letter, and registered it as a trade mark, precisely by way of its distinguishing the goods, and not as a means of communication according to the natural and typical intended use of alphabetical and word signs».

²² ECJ, 21 October 2004, C-64/02 P. See also ECJ, 7 July 2005, C-353/03.

For **colours** (the same reasoning, however, could apply to letters and the lower numbers) there is also a further problem: as the ECJ has again stressed, in *«assessing the potential distinctiveness of a given* colour», account must be taken of the fact that «the number of colours actually available is limited» meaning that «a small number of trade mark registrations for certain services or goods could exhaust the entire range of the colours available», creating «an extensive monopoly (which) would be incompatible with a system of undistorted competition, in particular because it could have the effect of creating an unjustified competitive advantage for the single tradem²³: it being understood that the wider the product ambit of protection of the trade mark, the stronger this need is, and thus it must be held that even a primary color mey be protected, when the range of goods or services to which protection should extend is particularly limited; and that more generally speaking we may say that there is protection when there is actually (also for numbers, letters and colours) an element which is perceived as the bearer of a distinctive message, but at the same time this protection exists only against that which in the actual market situation leads to this message really being brought to mind. The criterion of public perception, therefore, also allows the anti-monopolistic needs expressed by Community case law to be overcome or, at least, brought back to their right proportions: all things, in fact, and thus also goods, cannot be without colour (from this perspective transparency is also a colour), and this colour or these colours which is/are «natural», or in customary use, remain at the disposition of any trader, precisely because they lack distinctive character; the protection of *specific colours*, also pure colours, different to that or those colour(s) which are natural or in customary use and which actually effect a distinctive function, i.e. they are perceived by the public as signs, does not therefore create any unreasonable prejudice for other traders, precisely because, by definition, these colours cannot «exhaust the entire range of the colours available», to use the words of the ECJ^{24} .

5. In any case, these impediments only regard trade marks which are constituted «*exclusively*» by the elements that we have so far considered. This adverb, inserted into the Italian Law on the occasion of its harmonization with EC Directive 89/104 and naturally also to be found in the CTMR, expressly excludes from the bar on registration signs which contain not only generic or descriptive elements or, in any case, elements which are not distinctive, but also other elements which are more properly distinctive: this means, for example, that even words consisting in generic names or descriptive indications may be valid trade marks of the goods or services to which they refer, if they are used in combination with other elements in such a way that the resulting sign appears to possess distinctive capacity; and confirms a conclusion which Italian case law has always

²³ ECJ, 6 May 2003, C-104/01 (Libertel case).

²⁴ These principles have recently been correctly applied in Italy in a number of rulings of the Court of Milan, which accorded protection as a trade mark - and indeed as a renowned trade marks - of Ferrari to the colour red, extensively understood (not therefore in a particular tone), used for Formula 1 cars and scale models of such cars, highlighting the actual perception of the target public, which in this field recognizes that colour used as the background colour for or, in any case, the predominant colour of the car as a distinctive sign unequivocally linked to Ferrari; in this regard the Court carried out a concrete analysis, stressing all the elements of the case in question and noting in particular that «the 'similarity' of the car (of all the cars) of Formula 1, dictated by functional needs and by regulations, leads to fundamental importance being attributed, for distinctive purposes, to the colour and signs, even should they not be registered, used to identify the car», with the result that the «red 'Formula 1' models ... immediately evoke Ferrari cars» (Court of Milan, interim order 5 August 2008, in IP_Law_Galli Newsletter, September 2008, p. 24 ff., which upheld a previous order issued ex parte). The decision in question was then upheld by the Appeal Court of Milan, order 12 September 2008, which stated, in more general terms, that «the actual use of that colour (red: writer's note) - which has been used for decades by the Ferrari stable, in a given sporting sector - ... has assumed an absolute qualifying value», so that it «actually appears inadmissible to hypothesize that, even for the most unwary consumer, the colour red in question, within the field of Formula 1 and car racing, is not an element which characterizes the Ferrari Stable». This seems to signify that the exclusive right thus recognized on the colour is «transversal» to the various product classes, being conditional upon the fact that red goods possess elements which link them to the world «of Formula 1 and car racing», here too following the boundaries of distinctiveness as it is perceived by the public.

considered undisputed²⁵, the corollary being drawn, moreover, that protection of the trade mark is, in any case, **limited to its distinctive elements**²⁶.

Italian case law has developed, in this regard, the already mentioned countraposition, often mechanically applied, between «strong» and «weak» trade marks. The former are said to be those constituted by signs all of whose components are distinctive and the latter, on the other hand, those of which only some components are distinctive, usually because they are constructed on a descriptive base which is modified by truncations and elisions (for example, «Mesulid» for a nimesulide-based drug), the addition of letters («Panem» for bakery products - in Italian: pane -) or the merging of words («Lemonsoda» for a fizzy lemon drink); according to this countraposition strong trade marks are even protected against imitations which are only partial and more distant from the original model (in particular, when they are not signs of pure fantasy, against imitations which copy the **conceptual nucleus** of the original trade mark), weak marks only against complete or almost complete copying, and in any case only against copying also of their distinctive components. However, in actual fact, the rules for ascertaining infringement of another's trade mark always require case by case assessment, on the basis of the criteria indicated by the legislator. Such an assessment does not lend itself to generalizations or mechanical application, and the limitation on the protection of trade marks containing non-distinctive components derives rather from the procompetition need to leave these components (and in particular descriptive components) at the disposition of all traders in the sector²⁷.

6. An **anti-monopoly need** underlies the **«special» discipline** – also of European Community origin – of shape trade marks which the CIP and the CTMR provide respectively in articles 9 and 7, paragraph 1, letter *e*, forbidding the registration of *«signs which consist exclusively of the shape which results from the nature of the goods, the shape of goods which is necessary to obtain a technical result or the shape which gives substantial value to the goods. As the ECJ has stated, in this case too, the rationale behind these bars is in fact again of a pro-competition nature, since the question here is that of avoiding monopoly of the shape er se possesses²⁸: the exclusive right on a trade mark is, in fact, potentially perpetual unlike that of a patent and that accorded by copyright which are always temporary; and perpetual protection of these substantial values would be anti-competitive. However, this rationale marks the limit of the bar: it seems reasonable to believe, therefore, that it must be only these substantial values which fall within the public domain, while if the same utility or substantial value (be it an aesthetic or a market value) can be attained by means of infinite variants, each of these variants could be protected as a trade mark without such values being monopolized and thus, in this case, the bar on registration should not apply.*

Therefore, these bars have **nothing to do with the distinctive capacity and with the nature itself of a sign** of shapes, to which the rules that already for all other signs apply, it being understood that such rules apply to shapes (just as to colours) in a rather singular way, on the basis of the already mentioned – and much cited in Community case law – experience rule, whereby the shapes of products are not usually perceived by the public as signs and, in particular, as distinctive signs. It is precisely for this reason that the possibility that previously non-existent distinctive capacity can be **acquired through use** takes on special importance for shapes. Generally speaking it is admitted (and this too is the result of Community Law) that a trade mark which originally lacked distinctive capacity may acquire it, even after registration, through use of the sign on the market, and in that case its original invalidity is remedied (Art. 13.3 CIP and Art. 51.2 CTMR). The phenomenon

²⁵ In this sense see, from among the others, Supreme Court 12 May 1975, no. 1839, in *Giur. ann. dir. ind.*, 1975, p. 54 ff.; Supreme Court 29 May 1998, no. 5338, *ibid*, 1998, p. 82 ff..

²⁶ According to the Italian case law, if a trade mark comprises a number of distinctive features, protection is given to each of them, individually considered: see for example Appeal Court of Bologna 29 May 2002, in *Giur. ann. dir. ind.*, 2002, p. 913 ff.

²⁷ C. GALLI, Problemi attuali in materia di marchi farmaceutici, in Riv. dir. ind., 1992, I, p. 14 ff.

²⁸ See in particular ECJ, 18 June 2002, C-299/99 (Philips/Remington case).

is rare for denominative trade marks (the sign must acquire a **distinctive «secondary meaning**», which replaces or at least flanks the original general meaning), while it is more common for **shape or colour trade marks** which, although not usually perceived as signs, can become signs when they are used as such and **«loaded» with a distinctive message**, in particular by advertising; what is required, in any case, is that *«in consequence of such use, the relevant class of persons actually perceive the product or service, designated exclusively by the mark applied for, as originating from a given undertaking»²⁹, and proof of this may be given using the statements of expert workers in the fields concerned or opinion polls.*

On the contrary, if distinctive capacity is lost after registration, a trade mark which was originally valid lapses. To this end Art. 13 CIP and Art. 50 CTMR state that the loss of distinctive capacity must be caused by *«acts or inactivity of the proprietory»*; it has therefore been argued in Italy that a trade mark would not lapse, even when the sign has lost its distinctive capacity, if the proprietor has not used his sign with a general meaning and has not failed to take action against general use of his sign by third parties. The ECJ has, however, recently stated that **inactivity of the proprietor** *«may also take the form of a failure on the part of the proprietor of a mark to have recourse … in due time for the purposes of applying to the competent authority to prevent third parties from using the sign»³⁰: which seems to indicate that only an effective reaction on the part of the proprietor may serve to avoid lapse, and that what really counts, also from this perspective, is once again the perception of the public.*

7. These points, therefore, allow some conclusions to be drawn. A systematic and coordinated reading of the rules, in line with the way in which they have been interpreted in both Italian and Community case law, seems to indicate the wish of the Community Legislator to make the exclusive right accorded by distinctive signs subject (and commensurate with) the **meaning which it presents to the public**, highlighting this perception of the public as a linchpin of the system, in countrast with «formalistic» interpretations, particularly common in Italy (but also in other States: we may think of certain presumptive rules of German case law which the ECJ struck down³¹), which recall the same interpretations which were made by some of the German Trade Mark Law of 1894, in the sense that on the basis of the Law *«there was no legitimacy outside registration; and that with registration, preceded by rather careful official scrutiny, there could only be legitimacy*», all because *«in this way the security of trade, it was said, was assured to the greatest degree»*; these interpretations too, however, were **abandoned** in the space of a few years, and there arose a new and more modern consideration of distinctive signs *«from a more straightforwardly private law perspective*», which saw in a trade mark not a privilege granted by the State, but a **sign born of the market** which had to be **protected as such**, in relation to the needs of commercial life³².

Thus the circle closes: in fact we have seen that the interest demonstrated by Community Law for Intellectual Property in general and for distinctive signs in particular, arises from a need to promote and protect competition or rather to defend (and develop) the free market. It is therefore completely in line with this approach that the sacrifices which these exclusive rights impose on the freedom of traders are closely correlated with the **function that the rights which form their subject-matter actually effect on the market**.

CESARE GALLI

²⁹ ECJ, 7 July 2005, C-353/03, *cit*..

³⁰ ECJ, 27 April 2006, C-145/05.

³¹ See, for example, ECJ, 6 October 2005, C-120/04, in matters of likelihood of confusion, and ECJ, 14 September 1999, C-375/97, in matters of ascertaining renown. Precisely in matters of distinctive capacity, this time criticizing a «formalistic» criterion followed in the UK, see ECJ, 16 September 2004, C-404/02, which stated clearly that «*The distinctive character of a trade mark, in whatever category, must be the subject of a specific assessment»*.

³² Hence the memorable essay of M. GHIRON, *Il marchio nel sistema del diritto industriale italiano*, in *Claim dir. civ.*, 1915, p. 150 ff, pp. 162-163 and ID., *La riforma delle leggi industriali in Germania*, in *Riv. dir. comm.*, 1914, I, p. 436 ff., especially pp. 437-438.

ABOUT US

The activity of Professor Cesare Galli on the new Meeting Tables between the Government and private companies on the fight against infringement and the strengthening of IP protection

Professor Cesare Galli – who has been a member of the **Technical Committee at the High Commission for the Fight against Infringement** (a small group of experts who assist the Commissioner in his activity) since its inception – has also been called to participate in the Meeting Tables set up by the new Director General of the Italian Patent and Trade Mark Office and of the Fight against infringement. In particular Professor Cesare Galli has been appointed a member of the **Consultative Committee on New Legislation** created within the ambit of the Meeting Tables with private businesses and the **Table on the problems of infringement by means of Internet**.

In particular Professor Cesare Galli went back to the proposal to **strengthen** the civil and criminal protection of intellectual property, drawn up within the ambit of the High Commission, and in part already adopted in Law no. 99/2009, formulating specific proposals aimed at improving the CIP, both at substantive and procedural level, changing it into a **more modern and above all more functional instrument** for the protection of intellectual property and for countering counterfeiting, in particular counterfeiting originating abroad.

Professor Cesare Galli was then consulted by the Director General's Office for the drafting of an **interpretative circular** aimed at limiting the negative impact of the new provision relating to the affixing of Italian trade marks on goods made abroad, a circular whose guidelines aimed at protecting the past activity of Italian businesses he suggested.

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✓ The «Legal 500», «Chambers Global», «Which Lawyer» and «Top Legal» guides once more rank Professor Cesare Galli and our Firm among the excellent IP firms in Italy

As has happened each year since its foundation (and also in the previous years for its name partner), our firm and Professor Cesare Galli have been placed by the leading independent international guides in top positions among Italian IP Law specialists. In particular the **Chambers Global** Guide for the third year running has listed **Professor Cesare Galli among the «Number 1» IP practitioners in Italy** in Band 1 of the lawyers indicated and the firm as a whole has also been **ranked among the top ten Italian firms** in Band 2, and has even improved its rating with respect to the already excellent rating of 2008 (Band 3).

Likewise, the other well-known international guides **«Legal 500**» and **«Which Lawyer**» have also once again ranked Professor Cesare Galli and our firm among the **excellent IP practices** – respectively among the top thirteen and the top eight Italian IP practitioners –, confirming and improving the judgment already expressed in their previous editions; the Italian review **«Top Legal»** did likewise, placing us among the top ten Italian IP firms). Here are the comments of these publications on our firm:

<u>Legal 500</u>: «The 'straight to the point' <u>IP Law Galli</u> is run by the 'excellent' and deeply experienced <u>Cesare Galli</u> who clients describe as 'the absolute top in IP matters among scholars and practitioners of his generation'. Offices are run from Milan, Brescia and Parma, and the practice recently won an important trade mark colour case for Ferrari and has strong patent capabilities both at local and international levels. De Longhi, GlaxoSmithKline and Bulgari are clients».

<u>Chambers Global</u>: «Mainly based in Milan and with offices in Brescia, Parma and Verona, this highly specialised boutique has recently expanded to meet an increasing workload. Its areas of activity range from the food industry to design and new technology; it

also acts for many Italian fashion companies, including Luciano Padovan, Gaudì and Coccinelle. The team of *"young and aggressive"* Lawyers is led by <u>Cesare Galli</u>. *"A true litigator and a strong reference point in the sector"*, Galli is one of the most prominent of the younger generation of IP Lawyers».

<u>Which Lawyer</u>: «Established player in the market with a particularly strong practice on biotech patents. Widely respected by his peers, he is best known for his litigation skills in the life sciences arena, although he is increasingly making his name known in trade mark».

<u>Top Legal</u>: «Firms such as the <u>Galli</u> practice (...) boast hyper-specialization in all branches of IP Law (Trade Marks, Patents, Copyright). They have a pragmatic approach, less academic than the old guard and directed more at negotiation rather than litigation, their prerogative being to act as quickly as possible».

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Professor Cesare Galli called onto the Working Group on Trade Marks and the Fight against Infringement of Confindustria (Confederation of Italian Industry)

The new President of the Working Group on Trade Marks and the Fight against Infringement, Dr. Carlo Guglielmi, invited Professor Cesare Galli to be a member of the group. He asked him to present – at the meeting held on 8 July last to meet the new Director General of the UIBM, Loredana Gulino – a report on the contents of Law 99/2009, which was passed by the Senate on that day.

In his report Professor Cesare Galli stressed the **problematic aspects of the new provisions**, particularly in relation to the article which discriminates to the detriment of Italian businesses with regard to the use of their trade marks on goods produced abroad and to the interim provision on design, both of which conflict with Community legislation and are of doubtful constitutionality. He also repeated the need to strengthen **protection against «new infringement» and the look-alike phenomenon**.

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✓ *Recent IP rulings obtained by our Firm*

Trade Marks: interim protection of renowned trade marks even against the nonconfusing use of similar signs: expansion of the concept of urgency in the IP field

With a panel order of 19 September 2008 the Court of Naples – Specialized IP Division – recognized protection, at interim stage, for the extremely famous trade marks of Champion Products Europe Ltd., represented by our firm, against the use of a trade mark «Equi Champion» for specialized sporting goods and clothing in the equestrian sports sector. The ruling first of all emphasized the «extremely strong distinctive capacity» and the «diffusion and renown of the sign (which) has given rise to a definite case of 'secondarization', of strengthening» the trade mark Champion. The ruling recognized the renown of the mark and therefore the possibility of it enjoying in full the «strengthened protection for all classes of goods/services» under Art. 21.1. letter c) C.I.P.: and thus the panel ruled that the mark was infringed, emphasizing the perception of the public and in particular the fact that the imitator's sign could «give the impression that Equi Champion is (was) a special trade mark of Champion, or at any rate connected to it, in the field of equestrian sports», and, in any case, the fact that the use of that sign constituted «improper linkage to and thus exploitation of the renown» of the Champion trade marks.

Of particular importance is the assertion in the order relating to the requisite of **urgency** required for interim IP measures: in fact, the Court of Naples correctly observed that these measures have «pre-requisites which are very different to and less rigid than Art. 700 Code of Civil Procedure», and this especially following implementation of the «Enforcement» EC Directive,

which «attenuated ... the link of instrumentality between pre-trial interim proceedings and proceedings into the merits, in that there is no obligation to bring the latter for anticipatory measures and for those pursuant to art. 700 CCP», with the result that in this field the requisite of urgency «has been strongly attenuated» and «can never again... be identified with the 'imminent and irreparable harm' required by Art. 700 Code of Civil Procedure»; the Court found «textual confirmation (for this conclusion) in the new text of the fundamental Art. 131 C.I.P., which makes adoption of an interim measure, with clear breadth, conditional upon there being 'imminent violation of the right and continuation or repetition of the violation'».

This ruling – fully commented upon in the international IP review *World Trademark* Review Daily – thus constitutes the recognition and consecration of the significant **strengthening on the interim protection** of IP rights effected, upon the proposal of Professor Cesare Galli, by Legislative Decree. no. 140/2006.

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Trade Marks: Interim protection of registered and non-registered renowned trade marks (including colour trade marks) against linkage

The Court of Rome – Specialized IP Division, with an *ex parte* order of 15 December 2008 recognized protection for the extremely famous trade marks of Ferrari, represented by our firm, and in particular the «rampant horse», against infringement effected by placing fantasy variants of this sign on **toy Formula 1 cars with the typical red and red-white livery of Ferrari racing cars**. The Court of Rome stated in particular that the *«replacing the horse with other animals or the word Ferrari with other names, what is more written in the same characters and colours as Ferrari*» gave rise to *«secondary variants*», which could not exclude likelihood of confusion and parasitical linkage.

The order – which led to the **seizure of a many counterfeit goods** and to the dismantling of the large distribution network for said goods – follows in the wake of the decrees and orders issued by the Court of Milan which were covered fully in a previous issue of this Newsletter (September 2008), and is an important **confirmation** of them.

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Trade Marks: Protection of renowned trade marks against damage to their renown

The Court of Milan – Specialized IP Division, ruling 16 January 2009, ruled that the famous trade mark Bulgari, belonging to the company of the same name, represented by our firm, had been infringed by the use in the business activity of a pornographic actress (calendars, films and shows) of a nom d'art (Brigitta Bulgari), in that said use could give rise to improper exploitation of the renown of the trade mark and, at the same time, caused *«particularly serious harm to the prestige of a trade mark renowned for elegance, refinement and style»*.

All the parties implicated in this activity who used the nom d'art in relation to their goods or services were found guilty of infringement. These parties were, in particular, the producer and publishers of the calendars, the distributor of the pornographic films and the producers of the shows in addition, naturally, to the pornographic actress personally. The ruling expressly stated that the distributor of the counterfeit published goods, albeit not liable as it was a necessary intermediary in this distribution, could still be «sued and was a necessary party in the interim proceedings».

The Court also established a fine (of 100.000 Euro) for violation of the interim injunction, issued in favour of Bulgari by way of an interim award, as only a petition for a general order to pay compensation, with the sum to be assessed in separate proceedings, had been submitted, in order to shorten the case.

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Patents: Ex ante evaluation of inventive step and recognition of validity and infringement contrary to the conclusions of the Court Expert

The Court of Turin - Specialized IP Division, ruling 10/23 February 2009, declared valid and

infringed, with all consequent orders, a patent relating to the use of Boswellic acids or their mixtures for the production of a cosmetic and/or dermatological preparation for the eudermic and/or trophic treatment of cutaneous biochimism, held by Pharmaland S.A., represented by our firm. The Court thus decided to deviate, with full and well-articulated grounds, from the negative conclusions of the Court Expert as to the validity of the patent in suit.

In particular, the ruling admitted our argument whereby stating, as the Court Expert had done, that a series of prior art documents, all constituted by products in which the properties of the Boswellic acids were not considered but said acids were at times present only as components of a natural substance (olibanum) which in turn was one of the many (hundreds of) components, could anticipate the patent, constitutes an inadmissible ex post facto judgment, which presupposes knowledge of the teaching of the patent. The Court thus confirmed the validity of the patent, stating that «with an *ex ante* judgment an average technician (had) no reason to believe, when the patent was filed, that there was a clear cosmetic use for this component (Boswellic acids: writer's note) of olibanum (of which, on the other hand, without specification of its components, various curative and cosmetic uses were known)».

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Patents: «Ever-greening» of pharmaceutical patents and nullity

The Court of Milan – Specialized IP Division, in a decision of 14/26 May 2009 admitted a petition of nullity – submitted by the Swiss company IBSA S.A., represented by our firm – with regard to two **pharmaceutical patents relating to a particular therapeutic indication of an already known substance**. The Court admitted our arguments, here too deviating from the conclusions reached by the Court Experts and ruling on the one hand that **the «new» indication was the same as the ones already known**, and on the other **that there was no technical prejudice** so as to discourage use with the specific indication which was then patented, which the patent holder claimed it had overcome.

On this last point, in particular, the ruling clarified the importance of the **notion of technical prejudice**, stating that it existed only when there was a **widespread and deep-rooted conviction**, which may not be demonstrated on the basis of simple individual opinions. The Court also explored more deeply the issue of **legitimatio ad processum with regard to patent nullity**, stating that it existed for **any entrepreneur of the sector**.

The full text of the ruling, preceded by our final reply brief, is published in the "The Case" section of this Newsletter.

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Patents: New technical problem and inventive step: interim measures protecting patents

The Court of Milan – Specialized IP Division, with an order of 29/30 December 2008, not appealed, admitted a petition for **interim measures to protect a patent**, submitted by an Italian company operating in the mobile telephone sector (Drin.it s.r.l., represented by our firm), against the Italian subsidiary of a large South Korean company in the same sector.

The protected patent solves the technical problem of **allowing at least two distinct SIM cards to work** so that the user, by managing them selectively, can simultaneously and effectively exploit all their possibilities. The validity of the patent was recognized in an **interim stage expertise** which highlighted, for the purposes of recognizing inventive nature, the fact that the patent in question **identified and resolved a new technical problem for the first time**. This issue too has been tackled for the first time in Italy and resolved in line with the thinking of the EPO Boards of Appeal.

The ruling is highlighted also because, in addition to issuing an injunction and a seizure order (the latter also in relation to accounting books), also laying down a fine of 1.000 Euro for each violation of the injunction, it admitted, for the first time after the introduction of the Law implementing the «Enforcement» Directive, the requested **formal questioning of the legal representative of the defendant**, in order to obtain information as to distribution of counterfeit goods.

Even taking into account the Expertise stage, the requested measures were **issued in less than eight months** from the start of proceedings. This confirms the level of efficiency which the Italian procedural system has achieved at interim stage also with regard to the protection of patents, when the procedural instruments available are used in the best way.

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Patents: Use of discovery in patent matters

By an order of 16-19 January 2008, the Court of Venice – Specialized IP Division, admitted *ex parte* a petition for patent discovery submitted by a well-known mechanics company of the Veneto region (Meccanica Breganzese s.r.l.), represented by our firm. The measure was expressly extended to the defendant's accounting books, and it allowed both infringement and the level of infringement to be proved, leading to an **out-of-court settlement**, reached very quickly, based on the defendant's undertaking to respect the patent.

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Patents: Patent Expertise at interim appeal stage

By an order of 1/14 July 2009, the Court of Venice – Specialized IP Division, admitted the petition of a very well-known German producer of white goods, represented by our firm. The German company claimed that a number of its patents had been infringed and requested **an Expertise to decide on the question of infringement at interim appeal stage**, after a single Judge had initially awarded *ex parte* an injunction and seizure order only to revoke these measures later, on the basis of the mere expounding of claims of non-infringement by the defendant.

This order is important because in published case law there are no previous examples of a patent Expertise being ordered at interim appeal stage, even though an Expertise at appeal stage is indisputably admissible, on the basis of the decisions of the Supreme Court and the Constitutional Court which we fully cited in this case.

Therefore, this order also confirms the orientation of Italian courts as being increasingly in favour of protection at interim stage also for patent rights.

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Designs and models: a question of pre-judicial interpretation of EC Directive 2001/6 referred to the ECJ in order to clarify the scope of Art. 239 Code of Industrial Property (CIP)

By an order of 12 March/30 April 2009 the Court of Milan – Specialized IP Division, admitting a petition submitted by Assoluce, the Italian Association of Domestic Lighting, represented by our firm, referred to the ECJ three questions which essentially propose to ascertain that copyright protection for designs and models, which Art. 17 of EC Directive 98/71 obliged Member States to introduce (by 31 October 2001 as provided by Art. 9 of the Directive) can neither be postponed in its application for a substantial period (ten years), nor completely excluded or, at any rate, excluded for an entire category of users, for the simple fact that the designs and models were not protected by another right in the Member State when the Directive was implemented.

The question is of specific interest in Italy – in particular in the case within the ambit of which the Court to which the case had been sent drew up the questions, but also from a more general perspective, which justifies the intervention of Assoluce –, because the Italian legislator, after correctly implementing EC Directive 98/71, intervened three times in order to limit its effects (in 2001, 2007 and 2009), by means of transitory rules introduced over time but always aimed at disapplying, completely or partially, Art. 17 of the Directive in relation to the majority of the designs and models produced prior to 2001, the year in which Italy implemented the Directive: designs and models which include real masterpieces of industrial design, as is certainly the design (as the Court of Milan also recognized) which forms the subject-matter of the principal case i.e. the «Arco» lamp, designed by the brothers Achille and Pier Giacomo Castiglioni in 1962.

The order – which was discussed at length in the first section of this Newsletter – has also been commented on in the latest issue of *AIPPI News* and in the international review IP *World Trademark*. *Review Daily*.

Designs and models: Relations between registered and non-registered designs and models

By an order of 29 January/12 February 2009 the Court of Milan – Specialized IP Division ruled **valid and infringed** a Community model of a lamp registered by Slide s.r.l., a well-known company operating in the sector of contemporary decorative lamps made of molded plastic, represented by our firm, confirming at appeal stage the **injunction and seizure order** already issued by the Appointed Judge, first by means of an *ex parte* decree and then with an order issued after the defendant appeared.

The order has deepened the relationship between registered and non-registered community model and the effects of the divulgation carried out by the holder in the year of grace prior to registration, admitting our arguments and correctly stating that the counterfeiting activity of a non-registered model prior to its registration could not destroy the novelty of the subsequent registration made in good time.

This order has also been commented on in the international IP review World Trademark Review Daily.

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Designs and models: Validity of «combination models» and the informed user criterion

By an order of 18 December 2008 the Court of Milan – Specialized IP Division recognized as **valid and infringed** the registered Community model of the «Outline» door of Lualdi s.p.a., world leader in the field of design doors, represented by our firm, admitting our application for an interim injunction, fine and order to reimburse case costs; as there were no following proceedings into the merits the order became **final**, as provided by Art. 131.1 *quater* C.I.P.

The Court of Milan reached this conclusion by admitting our arguments in relation to two aspects whose importance goes well beyond the confines of the case in question. Firstly, the Court defined «the informed user» as a purchaser who pays particular attention to the goods to which the model refers and compares them with other goods before making his purchase, being, however, an ordinary consumer, not an architect or designer.

Secondly, the Court ruled that the individual character of the *design* may be the fruit of the pure combination of characteristics of other prior models, provided the general impression brought about by the design in question differs to that brought about by each of the individually considered priorities. This assertion, for which there is no published precedent in Italy, is in line with the rationale of design protection, since the combination of features belonging to prior products may be a significant part of the work of the designer.

The international IP review *World Trademark*. *Review Daily* has also dedicated an article to the order in question.

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Trade Secrets: Use of discovery and designation as officially secret of documents submitted by the plaintiff

The President of the Court of Milan – Specialized IP Division, by an *ex parte* decree of 30 December 2008, ordered a discovery of the equipment, production plans, production books and accounting books of a chemical company, in order to check the extent to which secrets had been taken to the detriment of a US multi-national operating in the sector, represented by our firm.

Balance between breadth of the order – in which the surprise-effect was essential for the success of the operation – and protection of the confidential information of the defendant was achieved by forbidding *«persons other than the experts and defence teams of the parties to participate in the discovery»* and ordering the *«filing of acquired documentation in the Court Clerk's Office, without any copies being issued»*.

Before this, upon the petition being submitted, the President expressly ordered that some of the

documents submitted by plaintiff to demonstrate that secrets had been taken be kept confidential, since such documents were naturally also secret. This decree was confirmed by the Examining Magistrate of the ensuing case into the merits, who allowed access only to the defendants' defence teams and experts and forbade them to reveal anything of the documents to their respective clients.

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Competition: Parasitical imitation of a series of lamps

With its already mentioned order of 29 January/12 February 2009 the Court of Milan – Specialized IP Division, in addition to recognizing a Community lamp model registered by Slide s.r.l., represented by our firm, as valid and infringed, also admitted our application for an interim injunction based on the acts of parasitical competition being committed.

Admitting our case, the Court gave importance to the fact that a *«significant number»* of the goods of the plaintiff were copied and that *«doubtlessly original aspects relating to presentation of the goods… pertaining to characteristics connected to the various sizes of the products or to the setting of same and their presentation to the client … extrinsic with respect to the shape per se of each» had been copied, with the result that there was <i>«systematic exploitation of the ideas and initiatives of the plaintiff*», unlawful pursuant to Art. 2598, no. 3 Civil Code.

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Competition: Slavish imitation of the packaging of cosmetic products

By an order of 6/7 August 2009 the Court of Naples – Specialized IP Division admitted, on the grounds of **unfair competition due to slavish imitation** (but also citing the provisions of the C.I.P. and thus implicitly protecting imitated shapes also as **de facto distinctive signs**), a petition for an interim injunction submitted by Deborah Italia s.p.a., a market leader in the field of cosmetics, represented by our firm. The Court of Naples, in fact, ascertained, in line with our arguments, «*imitation of the exterior individuating characteristics*» of some **types of cosmetics packaging** and thus recognized their distinctive character.

The order is important also because, in addition to the injunction, withdrawal from the market order and a fine, **publication of the ruling was ordered**.

This order too has been commented on both in the international IP review *World Trademark*. *Review Daily* and in the most important Italian economic newspaper *Il Sole-24 Ore*.

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International activity of the Firm in the IP field

Our firm has continued to handle the **co-ordination and supervision of a number of important pieces of international IP litigation**. Professor Cesare Galli has, *inter alia*, **organized two key actions**, in **Austria** and in **Germany**, in order to protect some of the most famous world trade marks in the car industry, supervising the activity of the lawyers of those countries.

For some Italian companies, clients of our firm, a number of important pieces of litigation in Germany and Switzerland have likewise been co-ordinated and various international technology transfer agreements entered into, also in relation to developing countries of the Far East, in particular China. A leading US multinational in the car industry called Professor Cesare Galli as an *expert witness* on Italian IP Law, within the ambit of a case pending before the District Court of the Central District of California; and in this capacity he was heard by the lawyers of the parties in the US.

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Our latest publications and Meetings

The Rivista dell'Ordine dei Consulenti in Proprietà Industriale has published a long article by Professor Cesare Galli and Ms Mariangela Bogni, the latter of our firm, entitled *I «nuovi» livelli di tutela* della forma dei prodotti tra comunicazione e innovazione (The «new» ways of protecting the shape of

products, between communication and innovation).

As has happened every year since 1996, *AIDA* has published an essay by Professor Galli, this year dedicated to *Segni distintivi e industria culturale* (*Distinctive signs and the culture industry*).

Professor Cesare Cesare Galli has edited the Italian section of the *Anti-Counterfeting Guide*, published by the *World Trademark* Review, and a series of articles dedicated to important Italian court decisions in the *World Trademark* Review Daily.

An **Editorial** by Professor Cesare Galli is due to appear in *AIPPI News*, the on-line review of the Italian AIPPI group. The article, entitled *Luci ed ombre del «pacchetto anticontraffazione»* (*Light and shadows of the anti-infringement package*), is written in his capacity of member of the Executive Committee of AIPPI Italy.

The law review *Themis* has also asked Professor Cesare Galli to contribute an article entitled *La* nuova protezione della proprietà industriale in Italia (The new IP rights protection in Italy).

Professor Galli has also continued to publish his reflections in matters of *design* in his regular column in the specialized sectoral review *Luce e Design*.

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On 5 February 2009 Professor Cesare Galli participated in the 2009 Meeting of AIPPI Italia held in Milan, giving a **Report on the activity of the AIPPI Trade Marks group**, which he chaired.

On 11 March 2009 Professor Cesare Galli gave a paper in Bologna at the Congress «Quanto costa non brevettare», speaking of *Gli svantaggi della tutela del segreto rispetto a quella brevettuale* (*The disvantages of the protection of trade secrets in comparison with patents*).

On 6 May 2009 Professor Cesare Galli was invited to take part in the National Assembly of the College of IP Consultants (*Assemblea Nazionale del Collegio dei Consulenti in Proprietà Industriale*), held in Milan, at which he gave a paper on **II marchio comunitario alla luce della recente** giurisprudenza (The Community trademark in the light of the recent case law).

On 18 May 2009 Professor Cesare Galli took part in a course organized in Bologna by the Fondazione Forense Bolognese, giving a paper entitled **Denominazioni di origine e marchi geografici,** individuali e collettivi. Le problematiche legate all'applicazione delle biotecnologie in agricoltura (Geographical indications and trademarks, collective and individual. The IP problems linked to the use of biotech inventions in the agricultural field).

On 4 June 2009 Professor Cesare Galli participated in the *«Fashion Law»* meeting held in Genova, giving a paper entitled *Logo, forma e marchio di forma nel mondo della moda fra rinomanza, capacità distintiva e carattere individuale* (Logos, shapes and shape trademark in the fashion world: renown, distinctiveness and individual character).

On 14 September 2009 Professor Cesare Galli will participate in a workshop in Milan organized by AICIPI, giving a paper on *La nuova disciplina dell'apposizione dei marchi italiani sui prodotti realizzati all'estero* (*The new rules on the use of Italian trademarks on products manufactured abroad*) and take part in the debate on *Le prospettive di riforma del Codice della Proprietà Industriale e le proposte di AICIPI* (*The revision of the Italian Code of Industrial Property and the proposals coming from AICIPI*).

On 22 September 2009 Professor Cesare Galli will speak in Milan during the public part of the INDICAM meeting, as Rapporteur at a **Round Table on infringement**.

On 25 September 2009 Professor Cesare Galli will partecipate in the 2009 AIDA Conference in Pavia «Le garanzie su diritti IP», giving a paper on *Le garanzie sui marchi comunitari (Warrants on CTMs)*.

On 23 October 2009, as every year, Professor Cesare Galli chaired the National IP Congress in Parma under the auspices of INDICAM, AIPPI and LES Italia, entitled «Innovazione e Internazionalizzazione: competere con i brevetti sul mercato globale» (Innovation and

Internationalization. How to compete with patents on the global market), in the course of which he will give a paper entitled Difendere i brevetti veri e difendersi dai brevetti falsi: aspetti sostanziali e strategie processuali (How to protect the valid patents and defend the business from invalid patents. Substantive rules and procedural strategies).

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If you wish to receive more information on the Congress of 23 October 2009 or the Abstracts of the papers given by Professor Galli at the above events, email GALLI.PR@IPLAWGALLI.TT.

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