Società Italiana Brevetti
Intellectual and Industrial Property in Italy and the European Union

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società italiana brevetti's updates on intellectual and industrial property in Italy and the EU

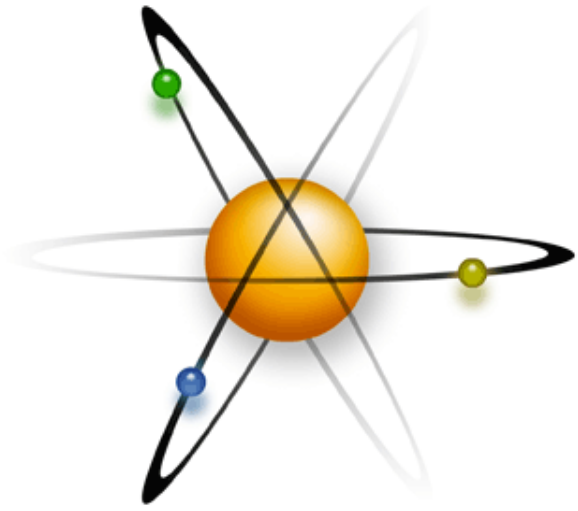
July 2009 patents

ITALY - LEGISLATION UPDATE

NEW WEAPONS FOR THE FIGHT AGAINST PATENT COUNTERFEITING

A freshly approved law concerning economic development and nuclear energy also introduces stiffer fines and penalties for patent counterfeiters as well as new tools to fight organised counterfeiting activities, including confiscation of the means of production, sales profits and premises used for storage or sale.

A new Italian decree, aiming inter alia to allow the domestic production of nuclear energy, includes several provisions concerning intellectual property. Definitively approved on 9 July 2009, the decree has not been published, therefore its date of entry into force is not yet known.



Stepping up Criminal Sanctions

The new decree amends several provisions of the Italian Criminal Code, drastically increasing fines and introducing imprisonment for patent and design counterfeiting, although terms of punishment are diminished for counterfeiters who collaborate with justice.

Confiscation of Storage and Sales Premises

A new provision introduces "landord liability" - unless good faith is proved - which may lead to the administrative confiscation of the premises where patent-infringing products are warehoused, stored for sale or sold.

Internal Priority for Patents and Utility Models

The decree amends Article 47 of the Industrial Property Code in order to introduce an internal priority for patents and utility models, meaning that filing a patent or utility model application in Italy gives rise to priority rights also with respect to a later Italian application concerning elements already included in the application for which priority is claimed.

Universities Acquire Right to File Patents

Within one year from the decree's entry into force, the Italian government may issue a provision allowing universities to file patents for inventions made by their own researchers.

The new decree also includes provisions on trademarks (*see trademarks section of this newsletter*).

ITALY - CASE LAW

PROVING PATENT ANNUITY PAYMENTS

The Italian Supreme Court confirms that payment of a patent annuity may be proved only by producing a receipt of payment, not by witness testimony or by an assumption based on the payment of subsequent annuities.

The Italian Patent and Trademark Office (IPTO) had asked the holder of an Italian patent to provide proof of the payment of annuities for several years. The patent holder was unable to produce a receipt of payment for one of the annuities. The IPTO declared the patent forfeited as from the year for which the receipt had not been produced by the holder of the patent.

The patent holder appealed to the IPTO's Board of Appeals (the Board), essentially on the ground that over several years the IPTO had never requested payment of the annuity for which the receipt was missing. The Board upheld the appeal, finding that the payment of patent annuities can be proved without documentary evidence. The IPTO brought the case before the Italian Supreme Court.

On 4 May 2009 the Supreme Court issued decision No. 10219 finding in favour of the IPTO's arguments and annulling the decision of the Board.

The Court confirmed that failure to pay a patent annuity within the term set by law causes the forfeiture of patent rights. According to the decision, only documentary evidence is considered sufficient proof of payment of a patent annuity: the testimony of witnesses or mere assumptions are not admissible as proof. The Board had therefore erred in holding that the IPTO can assume that a patent annuity has been paid if proof of payments for subsequent annuities is produced, and the Court consequently annulled the Board's decision in the case.

Or your Italian patent could be forfeited.

Since the case required no further investigation, the Court was also able to confirm the forfeiture of the patent.

ITALY - CASE LAW

REQUEST FOR MARKETING AUTHORISATION DOES NOT INFRINGE PATENT

Requesting a marketing authorisation for a product covered by patent rights before those rights have expired cannot in itself be considered an act of infringement, according to the Court of Milan.

Eli Lilly and Company Ltd. (Eli Lilly) is the holder of a European patent validated in Italy, as well as of an Italian Supplementary Protection Certificate concerning the same patent, for the active principle known as "olanzapin". Eli Lilly brought an action before the Court of Milan (the Court) against several companies, including Ratiopharm GmbH, Ratiopharm Italia and Sandoz International, claiming that the defendants had infringed its patent rights by filing an application for an Italian marketing authorisation concerning olanzapin-based products more than one year before the expiry date of said patent rights. Eli Lilly essentially asked the Court for a declaration of patent infringement, and to award the payment of damages.

The Court rejected both requests. In its decision No. 7645 of 2 April 2009, the Court found that the mere filing of an application for a marketing authorisation cannot be considered as proof either of an infringement of patent rights, or of acts preparatory to infringement.

Referring to its own case law, the Court conceded that obtaining a marketing authorisation may be considered a condition for the subsequent marketing of infringing products; however, where no actual manufacturing and marketing have taken place, and the possibility cannot be ruled out that such manufacturing and marketing may never take place, the obtainment of a marketing authorisation is to be considered a mere administrative act that cannot, in itself, be considered to infringe patent rights.

The Court also found that in the circumstances of the case, no proof had been produced that acts

preparatory to manufacturing or marketing the patented product had actually taken place, such as the purchase, manufacturing or storage of the product, or the organisation of distribution or advertising campaigns. Lastly, the decision points out that according to Article 68 of the Italian Industrial Property Code, exclusive rights granted by a patent do not extend to acts carried out privately and for non-commercial purposes, including acts aimed at obtaining a marketing authorisation for a pharmaceutical product.

This decision touches on one of the issues addressed by the European Commission's inquiry into competition in the pharmaceutical sector, whose recently published results (*see news item on page 5*) indicate that approval procedures for generic medicines should be "significantly accelerated" throughout the European Union.

EUROPEAN PATENT UPDATE

EUROPEAN PATENT CONVENTION AMENDMENTS OF 2010: WHAT TO EXPECT

Applicants should be aware in particular that the time allowed for responses to reports and for providing additional information will be considerably shorter, and that precise time limits will be introduced for filing divisional applications.

Important amendments of European Patent Convention (EPC) rules will take effect on 1 April 2010, pursuant to two decisions of the Administrative Council of the European Patent Organisation, both issued on 25 March 2009. At first glance, the new rules would appear to introduce useful tools enabling the applicant to provide the European Patent Office (EPO) with information prior to the issuance of the search report. It could be argued, on the contrary, that the amendments are intended to speed up procedures merely by shifting a considerable amount of work from the EPO onto the applicant, who will have shorter time limits both to respond to the EPO's invitations to submit information before the search report is issued, and to reply to objections raised in the search report itself.

It will be up to expert European patent attorneys to devise strategies to "work around" the new rules creatively to the applicant's advantage. Essentially, it will be a question of getting most of the claims reach examination stage as filed, and of reversing some of the burden of work back on to the EPO. It should be noted, however, that as more professional work is likely to be required in the initial phase of the procedure, the corresponding costs will probably increase.

Time Limits for Divisional Applications

Rule 36 EPC

Time limits will be introduced for the filing of divisional applications. The current legal framework only requires that the parent application is pending at the time when the divisional application is filed.

As from 1 April 2010, the following time limits will apply:

* voluntary divisional applications: two years from the first communication by the examining division in respect of the parent or earlier application;

* mandatory divisional applications: 24 months from the communication in which the relevant objection is raised by the examining division for the first time.

One Independent Claim Per Category

Rule 43(2) EPC

Save for exceptions clearly listed in the EPC, a European patent application may not contain more than one independent claim per category. As from 1 April 2010, compliance of applications with this requirement will be examined at the search stage (it is currently checked at substantive examination stage) and where applications do not comply applicants will be invited to indicate which claims fall within the exceptions.

Where the applicant fails to answer within two months, the EPO will search only the first independent claim in each category. Examination will only be carried out for the searched subject matter.

Clear and Concise Claims

Rule 63 EPC

Where at search stage an application is found lacking support, clarity or conciseness to the point of making the prior art search impossible in the EPO's view, the EPO will ask the applicant to provide a statement indicating the subject matter to be searched. If such a statement is not submitted within two months or is not sufficient to overcome deficiencies, the EPO will issue:

* a partial search report and invite the applicant to restrict the claims to the subject matter searched, or

* a reasoned declaration that it is impossible to carry out a search.

Mandatory Response to Extended European Search Report

Rule 70a EPC

Applicants will be required to submit a response to extended European search reports before filing the request for examination, which means within six months after the European search report is published.

The new rule will be applicable to applications for which the European search report is issued on or after 1 April 2010.

Identification of Amendments

Rule 137(4) EPC

When filing any amendments to a European Patent application, the applicant shall identify them and indicate the basis for them in the application as filed. If the examining division notes a failure to meet either requirement, it may request the correction of this deficiency within a period of one month, and if no response is filed in time, the application will be deemed withdrawn.

It must be noted that this change will have little impact since indicating amendments and their basis is a current practice of most European patent attorneys.

Mandatory Response to PCT Report

Rule 161 EPC

The EPO will invite Euro-PCT applicants to submit a response to written opinions or international preliminary reports within one month after receiving such an invitation. If the applicant does not comply with or comment on an invitation, the application shall be deemed to be withdrawn.

The new rule will be applicable to Euro-PCT applications for which a communication under current Rule 161 has not been issued before 1 April 2010.

SIB CONTRIBUTES TO EUROPEAN PATENT FORUM/PATINNOVA 2009

Claudio Germinario, European Patent Attorney with SIB.

SIB Società Italiana Brevetti was invited to contribute to this year's European Patent Forum / Patinnova 2009, held in Prague from 28 to 30 April 2009.

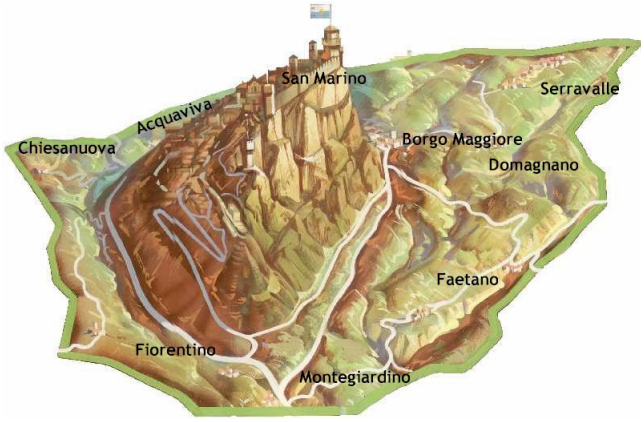
Organised by the European Patent Office (EPO) and the European Commission, the European Patent Forum / Patinnova is a conference on intellectual property rights in rapidly developing industries that brings together right holders, patent attorneys, innovation stakeholders and experts from research and politics.

Claudio Germinario, European Patent Attorney with SIB, spoke at the workshop "Nanotechnology: miracle or menace – is uniform IP protection feasible?".

EUROPEAN PATENT UPDATE

MINI-STATE OF SAN MARINO JOINS EUROPEAN PATENT ORGANISATION

The Republic of San Marino is a small city-state on Italy's north-eastern coast with a population of about 26,000. San Marino became the European Patent Organisation's 36th member state on 1 July 2009. As from that date, it is possible to designate San Marino in a European Patent application.



EUROPEAN UNION - ANTITRUST

DEFENSIVE PATENTING STRATEGIES LIMIT COMPETITION IN PHARMA SECTOR, SAYS EU COMMISSION

An official inquiry finds that competition in the pharmaceutical sector is not working as it should in the European Union, and points at company patenting strategies and regulatory deficiencies as possible causes.

On 8 July 2009, the European Commission issued the final report of its sector inquiry on competition in the pharmaceutical sector. The inquiry aimed to find out why market entry of generic drugs in the European Union is delayed, and why less novel medicines are reaching the market. The results suggests that competition in the sector is not working as it should, at the expense of European citizens and governments. Company patenting strategies may be to blame, but shortcomings in regulation are an additional cause.

On regulatory issues in particular, the Commission urges European Union member states to accelerate approval procedures for generic medicines. The report points out that almost a third of patent litigation is conducted in parallel in several member states whose national courts sometimes reach conflicting judgments; according to the Commission, establishing a Community patent and a specialised litigation system in Europe would contribute to improve this situation. The report also welcomes forthcoming changes in European Patent procedures aimed at ensuring a high quality of patents while limiting the filing of voluntary divisional applications (*see news item on page 2*).

The Commission has announced that on the basis of the inquiry's results it intends to monitor the respect of European antitrust rules and closely scrutinise "defensive patenting strategies", aimed merely at excluding competitors, as well as the settlements between originator and generic companies that limit or delay the market entry of generic drugs at the expense of consumers.

Read more
http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

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