Intellectual Property in the Life Sciences - France

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1 Small molecules

1.1 Product and process claims

Product claims under French law are traditionally protected *per se*. Thus, any use, disposal, sale, offer for sale or importation will be an infringing act (Article L 613-3 of the Intellectual Property Code (IPC)).

Similarly, the protection of process claims follows the common system adopted in the rest of the European Union, according to which the direct product of a process is protected (Article L 613-3 IPC).

Acts of infringement of process claims by direct products are defined in Article L 613-3(c) of the IPC under which the "Offering, putting on the market or using the product obtained directly by a process which is the subject matter of the patent or importing or storing for such purposes" are prohibited. The definition of a direct product has not been settled or even appreciably discussed by French case law.

It should be noted that, for biotechnology products, specific legislation derived from the Biotechnology Directive 98/44 has been put in place (Articles L 613-2-2 and L 613-2-3 of the IPC). This states that:

> *"[..] the protection conferred by a patent on a product containing or consisting of genetic information shall extend to any material in which the product is incorporated and in which the genetic information is contained and performs its stated function."*
>
> And
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> *"The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material, derived from the latter, by reproduction or multiplication and possessing those same characteristics."*

As a result, it is clear that in a biotechnology context, the protection afforded to the direct product of a process is extended to various acts of propagation.

It should also be noted that the protection afforded to a biotechnological product (especially a DNA sequence) could be limited to the specific use disclosed in the description under Article L 613-2-1 of the IPC which provides:

> "*The scope of a claim concerning a gene sequence shall be confined to the part of such sequence that is directly related to the specific function disclosed concretely in the description.*
>
> *The rights created by the grant of a patent including a gene sequence may not be called upon against a later claim on the same sequence if this claim satisfies the requirements of Article L. 611-18 and if it discloses any other particular application of this sequence."*

This provision clearly departs from the normal rules on the protection of products *per se*.

While there is still some debate as to whether these provisions constitute a proper implementation of the provisions of the Biotechnology Directive, there is currently no case precedent that has tested these provisions.

1.2 Scope of protection of claims and Markush formulae

Claims have to be interpreted as understood by the skilled worker on the basis of the description and his common general knowledge, pursuant to both Article L 613-2 of the IPC and Article 69 of the European Patent Convention (EPC).

While this proposition does not depart much from the position in other member states, it should be noted that this commonly results in the patent being interpreted by French courts as limited to specific examples disclosed in the description (*Sofresud v Bertin* Court of Appeal of Paris, September 8 2006).

Similarly, when faced with a claim that potentially encompasses a wide subject matter, the approach of the French courts is not to deal with this issue under the assessment of validity, but rather of infringement.

Thus, a claim that may be infringed solely because it is drafted so widely that it also encompasses embodiments that do not solve the technical problem forming the subject mater of the patent, will not lead to an issue with the validity of the claim, but rather to limitation in the scope of the claim.[1]

Thus, the French courts will not deal with such issues under sufficiency or inventive step, but rather as a matter of claim interpretation and restriction of scope. As a result a court could limit a Markush claim that is deemed too wide to describe embodiments.

1.3 Metabolites

While there is no specific case law on metabolites or precursors, the issue of whether there could be an infringement of a patent over a drug, merely by providing a precursor of a drug, would be dealt with either through the issue of claim interpretation (as described in the previous section), or the issue of contributory infringement.

Indeed, under the provision of Article L 613-4, there can be contributory infringement if one provides the essential means to work an invention. Thus, under certain circumstances it is conceivable that the provision of a precursor of a drug could be seen as the provision of an essential means to work the invention.

However, such interpretation could be defeated by considerations involving the proper interpretation of the claims based on the description. Indeed if the description of the relevant patent does not provide any description of the use of a precursor of a drug, then conceivably the French courts may reject an interpretation of the patent that would cover an undisclosed metabolite.

The issue of active metabolite is largely untried in France, however, any interpretation of the claims that substantially departs from what is actually described by the patent, is unlikely to be met favourably by the French courts.

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[1] See *'HILITI'* case, Court of cassation, Commercial chamber, June 4 2002, Number of appeal: 00-11857. See also *'SDP'* case, Court of Appeal of Douai, Chamber 1, section 2, December 15 2010, Docket number 09/05106, dismissing the appeal lodged against High Court of Lille, June 18 2009, Chamber 1, Docket number 08/04156.

2 Second generation inventions

2.1 Combinations

Combination patents are afforded protection and thus there is no impediment *per se* to patenting a combination and enforcing such a patent, provided that the combination satisfies all the requirements of patentability.

However, it should be noted that the French courts often apply an 'obvious to try' doctrine which frequently results in combination or selection patents being revoked.

As an example in the *Solvay* case, it was held that an invention which resulted from the selection of a molecule on which to operate a substitution from a list of over 30 molecules and then the selection of a substitution position, was not inventive on the ground that the combination was obvious to try.[2]

Similarly, in the *Teva v Merck* (Alendronate 10 mg) case, the court held that there was no inventive step involved in the selection and the testing of several combinations of potential modifications to an existing molecule.[3]

In these cases, even the existence of a surprising effect in the combination was not sufficient to overturn such a finding of obviousness to try. Thus, under such case precedents, a patent protecting a combination of products, will have to overcome the hurdle of such combination being not only novel, but also not obvious to try in light of the prior art.

2.2 Enantiomers

Several cases have dealt with enantiomers such as *Teva v Sepracor* and *Hexal AG* and *Sandoz v Boehringer Ingelheim Pharma*.[4]

These cases have ruled that it was necessary for a patent claiming specific enantiomers, to contain some experimental results supporting the alleged effects, in order to avoid the nullity of the patent, either for lack of inventive step or for lack of sufficient description.

Nevertheless the *Lundbeck* case confirmed that enantiomers can be patented under French law, provided they satisfy the requirements of patentability.[5]

2.3 Selection inventions

The case law discussed above for combinations applies equally to selection inventions.

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[2] High Court of Paris, 3rd chamber, 1st section, July 1 2008, *SAS Solvay-Fluores France and Company Solvay Fluor GmbH v Company EI Dupont de Nemours and Company*, Docket number 05/09022.
[3] High Court of Paris, 3rd chamber, 2nd section, *Company MSD Somerset Ltd v Company Teva Classics and Company Teva Sante*, Docket number 05/07130, p 9 of the ruling.
[4] *Company Hexal AG and SAS Sandoz v Company Boehringer Ingelheim Pharma GmbH & CoKG*, Docket number 08/12537; High Court of Paris, 3rd chamber, 1st section, October 6 2009, *Companies Teva v Sepracor*, Docket number 07/16446.
[5] See for instance, High Court of Paris, 3rd chamber, 4th section, September 30 2010, *Company Ratiopharm GmbH v Company H Lundbeck A/S*, Docket number 10/08089, judging valid litigious claims of patent EP 0 347 066 B1.

In addition, the older Amoxicillin case[6] held, in 1980, that to select from six different combinations, one combination that conferred an improved effect was obvious. Thus, selection inventions will have to face the high hurdle that the selection should not have been obvious to try.

2.4 Methods of use and secondary indications

While there may have been some controversy in the past about whether second medical use claims could be valid,[7] this issue is regarded as settled following the adoption of the new European Patent Convention 2000. Nevertheless, this issue may still be arguable for patents that were issued before the new patent convention.

The recent case of *Actavis v Merck*[8] has however indicated that the French courts may not be ready to follow the enlarged Board of Appeal decision Enlarged Board G2/08[9] and may disregard dosage regimen from secondary indications. Thus, under this case precedent, features belonging to a dosage regimen cannot be taken into consideration when assessing patentability.

2.5 Methods of treatment

Methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded from patentability under both the application of the European Patent Convention (Article 53(c) of the EPC) and national law (Article L 611-16 of the IPC).

This exclusion is largely based on public interest, public health and ethical considerations.[10] It aims notably at preventing an eventual hindrance in the practice of such methods by physicians or veterinaries.[11] Thus, it is likely that the French courts will continue to uphold these exclusions vigorously.

2.6 Formulations and physical forms

Under the recent case law of *Laboratoires Negma v Biogaran*, concerning the purity of chemical compounds, it was held that a product is not deemed novel only because it is prepared in a purer form.

This was confirmed by the case *Hexal AG & Sandoz v Boehringer Ingelheim Pharma*,[12] which held that "a known compound does not become novel only because of the fact that it is prepared in a form more pure":

It is arguable that such doctrine could apply to biotechnological products, such as proteins for which purity is both a relevant and complex issue.

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[6] Court of Appeal of Paris, 4th chamber, October 17 1980, PIBD, III, 267.
[7] Frédéric Pollaud-Dulian, 'La Propriété Industrielle' (Industrial Property), *Economica*, 2011, n° 239 and following, p 168 and following.
[8] High Court of Paris, 3rd chamber, 1st section, *Company Actavis Group and Company Alfred E Tiefenbacher GMBH v Company Merck Sharp & Dohme Corp*, Docket number 07/16296; see pp 7 to 9.
[9] *Abbott Respiratory*, Official Journal EPO, 10/2010, p 456.
[10] *Ibid*., p 139.
[11] Jacques Azema et Jean-Christophe Galloux, *Droit de la propriété industrielle*, Dalloz, 6ème édition, 2006, n° 211, p 132.
[12] High Court of Paris, 3rd chamber, 3rd section, May 7 2010, *Company Hexal AG and SAS Sandoz v Company Boehringer Ingelheim Pharma GmbH & CoKG*, Docket number 08/12537, p 15 of the ruling.

2.7 Reach-through claims

There is no specific case law on reach-through claims in France. However, in the field of biotechnology, the issues discussed above for product and process claims are relevant.

3 DNA biologicals and personalised medicine

3.1 Discoveries

Under French law, discoveries are not patentable as such. This principle is solidly stated in Article L 611-10 of the IPC.

This was reiterated by the High Court of Paris in the case *Institut Pasteur v Chiron Blood Testing*, where it was held that a virus was not patentable in itself but that all or part of its genome was patentable inasmuch as it enables the manufacture of a product used for diagnosis or treatment.[13]

In addition following the Biotechnology Directive 98/44, Article L 611-18 of the IPC was incorporated expressly to exclude from patentability the discovery of elements of human body.

No ruling has interpreted this provision or its relationship to patents covering cells or genes.

3.2 Gene patents and industrial application

The provisions governing biotechnology patents and industrial applicability are derived from the Biotechnology Directive and are discussed in the Intellectual Property Code (Article L 611-18 IPC).

Although there is no case law on the industrial applicability of gene patents, it should be noted that France may have diverged in its implementation of the Biotechnology Directive, in that it has indeed excluded from patentability discoveries of components of the human body, but has not expressly provided for the patentability of isolated gene sequences, as provided for under the Biotechnology Directive. As a result, the proper scope of patents covering genetic material is still an untried legal issue.

3.3 Stem cells and other organic material

The leading case at the European Patent Office is decision G 2/06.[14] This decision has interpreted the provisions of the Biotechnology Directive on public order and morality.

Under this decision, the Enlarged Board held that, under the Biotechnology Directive, claims directed to products which at the filing date could be prepared exclusively by a method which necessarily involved the destruction of human embryos would not be patentable.

This prohibition is in fact wide ranging, as the destructive step, need not even be part of the claims. Thus, inventions such as cell lines that may historically have arisen from the destruction of embryos would be unpatentable.

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[13] HCP, February 7 2007, *Institut Pasteur* 05/11023, p 6.

[14] *Wisconsin Alumni Research Foundation*, November 25 2008, G 2/06, Official Journal EPO, 5/2009, p 306 and following.

In view of the France's implementation of the Biotechnology Directive, and as the IPC expressly refers to the concept of human dignity (L 611-17) which is in effect a wider concept, it is expected that French courts and the French Patent Office will apply a regimen at least as stringent as that used at the European Patent Office.

3.4 Bioinformatics systems

It should be noted as a preliminary point that computer programs may be patented under certain conditions. In order to be patentable, they need to posses a technical character.[15] In addition, in a ruling of the Court of Appeal of Paris, it was held that a valid claim should not cover a program, as such.[16]

Thus, while the decisions of the French courts are not as developed as those of the EPO, they are nevertheless broadly consistent with them. As such, there is no absolute impediment *per se* to patenting a program in France.

The issue relating to the patenting of product obtained from a computer system, such as a DNA sequence with a postulated function presents specific difficulties.

First, sufficiency would be an issue in as much as it could be argued that no real invention had been made at the priority date. If, as in the *Sepracor* case,[17] it is held that the patentee was not in possession of the invention at the time of filing, or if use that is put forward in the description was speculative or mere conjecture, a finding of insufficiency could be made by the courts.

The sequence information, however, could itself conceivably be protected under copyright. An essential requirement of copyright is originality. Originality can be defined as the mark of the author's personality or, in the area of computer programs, as the mark of intellectual contribution.[18]

However, in the recent case of *Dassault Systems*, it was held that there could be no copyright lying in the mere product of a computer program.[19] Thus the patentability of the products of such computer programs may be doubtful.

3.5 Databases and search engines

Databases may be protected by a *sui generis* right under Article L 341-1 of the IPC, or by general copyright. However, it is doubtful that copyright could protect a genetic sequence in its actual physical form or in its biochemical function.

4 Acts of patent infringement

4.1 Infringement

[15] See EPO, Case Law of the Boards of Appeal of the European Patent Office, 6th edition, 2010, p 23.
[16] Court of Appeal of Paris, 4th chamber, section B, June 5 2009, *Kone v Azpitarte*, Docket number 2007/20589, PIBD n° 903, III, p 1331 and following, see p 1336.
[17] High Court of Paris, 3rd chamber, 1st section, October 6 2009, *Companies Teva v Sepracor Inc*, Docket number 07/16446.
[18] Court of cassation, Full Court, March 7 1986 (*Pachot Case*).
[19] Court of Appeal of Paris, Pole 5, chamber 1, February 24, 2010, Docket number 08/11742.

Please see the section on product and process claims for an overview of direct infringement in France.

4.2 Contributory infringement

Contributory infringement is provided for in Article L 613-4 of IPC, which prevents the supply or offer to supply, in France, of the means of implementing, in France, an invention with respect to an essential element of it. There are no specific provisions concerning contributory infringement for biotechnological products.

Thus, Article L 613-4 of the IPC could apply to such subject matter. Various cases in the field of biotechnology have applied the provisions of this article.

The case *Institut Pasteur v Chiron Blood Testing and Company Chiron Healthcare Ireland Ltd*,[20] ruled that contributory infringement constitutes an act of infringement, provided that the supplied means relate to an essential element of the invention. According to this decision, an essential element of the invention should be understood as an element contributing to its result.

The similar case of *Institut Pasteur v Siemens Healthcare Diagnostics*[21] confirmed this position and further held that the means supplied did not necessarily have to be claimed in themselves.

4.3 Experimental use exemptions

Under Article L 613-5 of the IPC, there is an experimental use exemption which has recently been amended to include an express exemption for acts performed for the purpose of obtaining a marketing authorisation.

Article L 613.5 of the French intellectual property code (IPC) states that there is no infringement of a patent right where the invention is used for experiments on the subject matter of the invention. Thus, there are two elements for this exception to apply:

- there must be an experiment (namely to gain knowledge); and
- the experiment must be on the subject matter of the invention.

Thus, using the invention for experimentation unrelated to the invention is not exempted.

Experiments with patented drugs for the purpose of finding new modes of administration were held not to constitute infringements (*Wellcome Foundation v Perexel International and Flamel*, Court of Appeal January 27 1999).

In *Wellcome Foundation v Perexel International and Flamel* (Paris High Court, February 20 2001), it was held that the experimental use exemption did not apply to commercial or industrial acts, but that bioequivalence testing for the purpose of obtaining a marketing authorisation were not industrial or commercial acts and thus were exempted.

In *Science Union & Laboratoires Servier v AJC Pharma* (Paris High Court October 12 2001), it was held that experiments involving the semi-industrial manufacture of batches for the grant of an MA

[20] High Court of Paris, 3rd chamber, 3rd section, February 7, 2007, *Institut Pasteur v Chiron Blood Testing and Chiron Healthcare Ireland Ltd*, Docket number 05/11023, p 11 of the judgment; Court of Appeal of Paris, 4th chamber, section A, March 4, 2009, *Institut Pasteur v SAS Chiron Healthcare*.
[21] High Court of Paris, 3rd chamber, 2nd section, May 28 2010, *Institut Pasteur v Company Siemens Healthcare Diagnostics*, Docket number 08/08679, p 16 of the judgment.

were exempted under experimental use. More recently, in the other *Union & Laboratoires Servier v AJC Pharma* case (Paris High Court January 25 2002), the above position was confirmed.

In addition to these exemptions, the Directive 2004/27/EC added a specific exemption related to marketing authorisations. Thus, the position of French courts is necessarily predominantly to construe all experiments performed for the purpose of obtaining an MA as covered by the experimental use exemption. Once the MA is obtained, any further production is unlikely to constitute research and would thus infringe.

4.4 Offers to supply

Offering within the meaning of Article L 613-3 of IPC is widely interpreted by case law.

Under the ruling of the High Court of Paris, *Bayer Healthcare AG v Zhejiang Jingxin Pharmaceutical Co*,[22] an offer includes all acts and especially promotional acts aiming to present the allegedly infringing product to clients. It does not matter that the product has not been physically presented to clients, nor that it cannot yet be marketed because it lacks the relevant authorisations.

Marketing can result from any material operation intended for bringing a product into contact with the relevant public and thus covers all acts of presentation of the product, even if marketing cannot immediately occur (*Evysio Medical Devices v Guidant*).[23]

Thus, under French law, marketing is a very general act defined as any material operation tending to place a product in circulation.[24]

4.5 Summaries of product characteristics (SmPCs)

In the case *Abbott v Wyeth*,[25] the Court of Appeal of Paris held that the fact that a product could inherently be used for a specified use could not constitute an infringement of use claim. Thus there was a requirement of a material act on the part of the infringer for the use claim to be infringed.

It is likely that a statement contained in a leaflet or a summary of product characteristics would constitute a sufficient material act that could result in the infringement of a use patent.

5 Patent enforcement

5.1 Obtaining information on the infringer and the infringement

[22] High Court of Paris, 3rd chamber, 3rd section, *Bayer Healthcare AG v Company Zhejiang Jingxin Pharmaceutical Co, Ltd*, Docket number 06/16242, p 4 of the judgment.
[23] High Court of Paris, 3rd chamber, 2nd section, *Evysio Medical Devices ULC v Guidant France, Guidant Europe NV/SA, Abbott France and Abbott Vascular Devices*, Docket number 06/08499.
[24] Court of Appeal of Paris, 4th chamber, section A, April 4, 2004,
High Court of Paris, 3rd chamber, 2nd section, September 19 1997, *Aktiebolaget Hassle and Laboratoires Astra France v Chong Kun Dang*, Docket number 26297/94, p 7 of the judgment.
[25] Court of Appeal of Paris, October 29 2004, 4th chamber, section B, *Abbott Laboratories v Wyeth Nutrition and SA Candia*, Docket number 2003/01748; High Court of Paris, 3rd chamber, 3rd section, March 14 2000, Docket number 98/9979.

The predominant method of obtaining evidence on infringement in France is by way of seizure proceedings (Article L 615-5 of the IPC). Under this procedure, it is possible to obtain a court order to effect a search of premises and the seizure of goods for the purpose of evidencing infringement.

Following the implementation of the EC Directive 2004/48 on the enforcement of intellectual property rights, further evidential means were provided such, as the right of information, which enables a court to compel the disclosure of documents required to determine the origin and the distribution networks of the infringing goods.

This provision has led to varying uses by the courts. A court may reject such a request on the ground of the preservation of commercial secrets and competition.[26] Conversely, a court may rule that the 'commercial secret' and the 'considerable harm' relied on by the defendant does not constitute a legitimate impediment.[27]

In addition, the existence and the conduct of prior seizure proceedings can influence a court's willingness to grant such remedy.[28]

5.2 Interim relief

Under French law, it is possible for a patentee to request the court to grant an interim injunction, if there is an infringement, or an immediate threat of an infringement. The criterion for granting an interim injunction is that an infringement must appear likely. It should be noted that such an assessment involves a full review of validity and infringement.

Thus, proceedings for an interim injunction appear similar to a full trial on the merits, except that they are held in a much shorter time frame. Typically, interim injunctions will last between four and 12 weeks.

5.3 Other remedies such as *ex parte* injunctions and custom seizures

It should be noted also that *ex parte* proceedings exist under French law, thus enabling a patentee to obtain an injunction against an infringer without the infringer being aware of the proceedings. However, while these proceedings have already been used in trade-mark matters, they are still extremely rare for patents.

In addition, the existence of Customs seizures should be noted. Such seizures are carried out by French Customs and are effective against goods entering the European Community through France.[29]

5.4 Post-patent expiry injunctions

It is generally accepted that injunctions can only be granted and take effect while the infringed intellectual property right is still in force.

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[26] *Ibid*, p 5.
[27] High Court of Paris, 3rd chamber, 2nd section, Order of the pre-trial judge, September 25 2009, *Company Promiles and Company Decathlon v Company Trading Innovations*, Docket number 07/13634, p 4.
[28] For an example concerning the production of accounting elements, see High Court of Paris, 3rd chamber, 1st section, Order of the pre-trial judge, April 29 2009, aforementioned, p 5 last paragraph) and 6 (first paragraph) of the order.
[29] See in particular Council Regulation (EC) No 1383/2003.

This doctrine is indirectly confirmed by a recent Supreme Court decision which held that even seizures cannot be carried out after the patent has expired, notwithstanding the fact that the patentee still had a legitimate interest in carrying out the seizure to evidence past infringement.[30]

5.5 Unjustified threats

Liability for threats of infringement arises from the general law of unfair competition under Article 1382 of the French Civil Code. There are no specific provisions governing such threats and thus any guidance can only be found in specific case precedents. In certain circumstances, such threats of infringement can constitute acts of unfair competition. As an example, the intimidation of the clients of a competitor through threats of infringement proceedings was deemed to be an act of unfair competition.[31]

However, unfair competition can also arise even in the absence of an express threat. Thus, the act of informing distributors of the defendants of the existence of an infringement action and presenting the defendants' products as being infringing products, while the proceedings were still ongoing, can constitute an act of disparagement and thus of unfair competition.[32]

Any form of communication with customers of a suspected infringer should, therefore, be handled with caution.

5.6 Remedies

The main remedies available under French law include damages and injunctions.

Damages are computed on the basis of a loss of profits assessment, or an indemnifying royalty. Loss of profits equate to the profits that the patentee could have made by working the invention in the place of the infringer.

The indemnifying royalty is available upon request by the patentee, or if the patentee could not have exploited the patent. This royalty is often set above a commercial royalty negotiated at arm's length.

Article 13 of the EC Directive 2004/48 (the Enforcement Directive) has been transposed in Article L 615-7 of the IPC and has *inter alia* provided that the courts may take into account the profits made by the infringer when awarding damages.

While there is no possibility for a patentee directly to recover the profits of the infringer, this provision nevertheless enables the courts to take such evidence into account.

This provision has recently been applied the Court of Appeal of Paris in a ruling dated March 19 2010, in which profits made by the manufacturer were expressly taken into consideration for setting the damages awarded.[33]

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[30] Court of Cassation, Commercial chamber, December 14 2010, Number of appeal: 09-72946.
[31] Court of Appeal of Paris, 4th chamber, section B, January 12 2007, SARL *Cabac Logistique and Mr Jean-Michel Falieres v Company Sevim*, Docket number 05/08799, p 5 of the ruling.
[32] High Court of Paris, 3rd chamber, 4th section, May 14 2009, *Company Quest Technologies Inc and Company Distrisud v SARL AHT Sud* and Mr Sylvain C, Docket number 09/03665.
[33] Court of Appeal of Paris, [Pole 5], 2nd chamber, *SAS Sempa and SA* of Spanish law *Zumex Maquinas y Elementos*, Docket number 06/16476.

5.7 Injunctions

Injunctions are available as of right when the court finds in favour of the patentee. If the court so provides, such injunctions can be enforceable pending appeal.

It should be noted that breaching an injunction in France does not result in criminal liability, but in the award of high damages designed to deter non-compliance.

5.8 Other remedies

Further remedies are provided for by Article L 615-7-1 of the IPC, which partially transposed Articles 10 and 15 of the EC Directive 2004/48. These provide for the delivery of infringing products and the recall of such products from commercial channels. In addition, the court may order publication of the judgment (or extracts from it) at the infringer's expense.

6 Compulsory licensing

Compulsory licences are provided for in Articles L 613-11 to L 613-19 of the IPC. There are two types of compulsory licence:

- judicial licences granted upon application by third parties;
- *ex officio* licences granted at the initiative of the French state.

There are three sub-types of compulsory judicial licence. These can be granted by courts on the grounds of a lack of exploitation of the patented invention, or because a patent cannot be worked without a licence of a dominant patent.

Ex officio licences are provided for by Articles L 613-16 to L 613-19-1 of the IPC and in Article L 5141-13 of the Public Health Code. These provide for licences being ordered by the state on the ground of public health, export of drugs to countries with public health problems, for the good of the economy, national defence or specifically in the field of semiconductors.

However, in spite of the existence of several distinct legal provisions allowing for various compulsory licences, in practice these provisions are almost never used. Therefore, such licences are exceedingly rare.

7 Ownership, inventors and compensation

In practice, inventors are afforded extensive protection and rights to share in the benefits of their inventions. Article L 611-7 of the IPC, which is the relevant provision concerning inventions made by employees defines two broad categories of invention:

- Mission inventions, defined as inventions created in the normal course of the employee's duties, or expressly requested by the employer. Such inventions belong to the employer.
- All other inventions – on a first analysis, these belong to the employee.

As regards mission inventions, the employee shall enjoy 'additional remuneration' (Article L 611-7, (1) of the IPC).

However, included with those inventions which are not regarded as mission inventions, the law provides two further categories:

- assignable inventions;
- non-assignable inventions.

Assignable inventions are defined by Article L 611-7(2) IPC as inventions which were made either in the course of the employee's work, or within the field of activity of the employer, or by using the resources of the employer. In such circumstances, the employer will be entitled to have the invention assigned to him. On the other hand, the employee shall be entitled to obtain a 'fair price' in exchange for the assignment of his rights.

All other inventions, which are non-assignable inventions, belong to the employee.

In practice, there has been a convergence between the fair price and the additional remuneration provided either for mission inventions or assignable inventions. Both can now be substantial.

8 Branding and designs

The name of a drug may be protected by trade-mark law provided that such name meets traditional requirements of trade-mark law and complies with specific legal requirements, under the Health Public Code.

For instance, under Article R 5121-2, of the Health Public Code, the invented trade-mark name of a drug should not be such that it may be confused with its common name. Likewise, the shape of a drug may also be protected by trade-mark law. However, a shape which has a technical effect cannot be protected as a trade mark.

The cases *Lego*[34] and *Lexomil*[35] in the field of pharmaceuticals, have expressly denied the possibility of protection by trade marks of a shape having a technical effect.

9 Protecting valuable information

9.1 Preserving confidentiality

While some case precedents have ruled that under certain circumstances an obligation of confidentiality can arise in the course of business, obligations of confidentiality are not readily implied into contracts. It is thus necessary for contacting parties to make express provision for confidentiality.

9.2 Know-how and ex-employees

Know-how can be protected by rules of civil liability. It may also be protected by criminal law, if it can be held to constitute a 'manufacturing secret' (Article L 1227-1 of the Labour Code). Know-how which is not expressly protected by any intellectual property right may be protected by Article 1382 of the French Civil Code.

[34] Court of Cassation, Commercial chamber, October 7 2007, Number of appeal: 95-15859.
[35] Court of cassation, Commercial chamber, January 21 2004, Number of appeal: 02-12335.

To obtain compensation, the holder of the know-how must prove a tortious act, a loss and a causal relation between the wrongful act and the loss.

A tortious act may, for instance, take the form of the misappropriation of another company's know-how. Under the *Chantelle* case,[36] it should further be noted that the misappropriation is sufficient to trigger liability and damages, even if *no use* is made of that know-how.

9.3 The disclosure of manufacturing secrets

Even after they leave the company, employees are subject to a general, but *limited* obligation of confidentiality under employment law. Thus, it is necessary to include explicit confidentiality provisions in employment contracts. Separately, under L 621-1 of the IPC, it is a criminal offence for an employee or a director of a company to reveal trade secrets.

In practice, however, the use of such criminal remedies is extremely rare.

9.4 Copyright patient information leaflets and packaging

Patient information leaflets and packaging can be protected under all intellectual property rights including copyright, trade marks and designs.

10 Counterfeiting

Patent infringement potentially carries a criminal penalty (Articles L 615-12 to L 615-16 of the IPC). Thus, under Article L 615-14 of the IPC, "any person who has knowingly infringed the rights of the owner of a patent as defined in Articles L 613-3 to L 613-6 shall be liable to a three-year imprisonment and a fine of €300.000".

These penalties are increased, if the infringement was committed by an organised criminal group or if the counterfeit goods are dangerous to health, or to human or animal safety.

However, cases involving criminal penalties are extremely rare. The reason for such limited use of penal provisions may arise from the fact that it is necessary to prove that the alleged infringer knowingly infringed the patent and also from the complexity of the relevant facts.[37]

It should also be noted that it is possible for Customs to effect seizures under their general powers or under the regulation EC 1383/2003.

11 Collaborative models

Any collaborative model should include clear and unambiguous contracts dealing with intellectual property. An obvious risk is that a contributor could claim co-ownership of any inventions or other intellectual properties rights.

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[36] Court of cassation, Commercial chamber, February 25 2003, Number of appeal: 00-21542, dismissing the appeal lodged against a ruling handed down by the Court of Appeal of Paris on September 27 2000. See also: Court of Cassation, Criminal chamber, June 20 1973, Number of appeal: 72-92270.

[37] Frédéric Pollaud-Dulian, 'La Propriété Industrielle' (Industrial Property), *Economica*, 2011, n° 837, p 435.

It should be noted that in French law, even remuneration for services rendered often does not imply the assignment of any intellectual property rights. Similarly, a general assignment of copyright is not permitted in French law.[38]

It should also be noted that the validity of such contracts can be called into question if proper consideration is not given. Thus, contracts should be drafted in such a way as to deal with each intellectual property right that might be created through the collaboration.

12 Hot topics

The field of Supplementary Protection Certificates (SPC) constitutes an area of law 'in turmoil'. Recent cases have helped, or will help, to clarify both the requirements for the grant of such additional intellectual property rights and their scope.

12.1 The requirements for the grant of an SPC over a combination of active ingredients

Under Article 3(a) of Regulation 469/2009, an SPC shall be granted if the product is protected by a basic patent in force. The issue of whether a product was indeed 'covered' by a basic patent has caused many difficulties.

Under several rulings of the Court of Appeal, including the recent *Daiichi Sankyo* case, it was held that a combination of active ingredients would meet this requirement only if this combination was claimed as such (and thus disclosed by the patent).[39]

Thus, so far the Court of Appeal has always refused to apply the 'infringement test'. Under such test, a combination of active ingredients may be deemed as 'protected by a basic patent' in force, if using such a combination would infringe the basic patent. This test diverges from that applied by the Court of Appeal, notably when a product could be protected by a basic patent through the infringement of a process claim or when a combination could be protected, even if it is not described in the basic patent.

The *Daiichi Sankyo* case has been appealed to the Supreme Court. In addition, there are several pending references for preliminary rulings from national courts to the European Court of Justice concerning this issue, in cases involving medicinal products comprising more than one active ingredient.[40]

Finally, in a recent case where the infringement test was relied on, in order to obtain the nullity of a decision of the French PTO refusing to issue an SPC on a vaccine comprising multiple antigens, the aforementioned appeals and references led the Court of Appeal (*Medeva* BV, 10/16069, 10/16063, 10/16059 and 10/1605511 May 2011,) to order a stay of proceedings pending the decision of the French Supreme Court concerning such appeal and the ruling of the ECJ in the *Medeva* case.

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[38] See Article L 131-3 of the IPC; see also L 131-1.

[39] Court of Appeal, November 6 2009, *Daiichi Sankyo*, 09/06530; Court of Appeal, January 19 2005, *Abbott Laboratories*, 04/14435; Court of Appeal, February 8 2006, *EI du Pont de Nemours*, 05/20525.

[40] Case C-6/11, January 5 2011, *Daiichi Sankyo Company*, Case C-630/10, December 24 2010 *University of Queensland, CSL Ltd*, Case C-322/10, July 5 2010, *Medeva BV* (joined with Case C-422/10, *Georgetown University*).

12.2 The requirements for the grant of a paediatric extension

In the *Losartan* case,[41] the Court of Appeal ruled on the question of the validity of a pediatric extension granted by the French Patent Office on the ground that the company Dupont did not demonstrate that all pediatric marketing authorisations had been issued in the 27 states of the European Union at the time of filing the application for the pediatric extension.

The Court of Appeal ruled that Article 36 of the Regulation EC No 1901/2006 on pediatric extensions does not provide that when submitting an application, all the marketing authorisations must have been obtained. According to the Court of Appeal, to require the production of all 27 pediatric marketing authorisations on the day of filing of the application would be impracticable in the absence of a centralised procedure for registration.

Thus, the Court ruled that Article 36 can only be concerned with the requirement to provide the initial marketing authorisations. Consequently, pediatric marketing authorisations can be provided in the course of the procedure for granting the extension.

12.3 Scope of protection of an SPC protecting a single active ingredient

The *Losartan*[42] and *Valsartan*[43] cases have held that the holder of an SPC concerning a single active ingredient may prohibit the exploitation of a drug consisting of a combination of active ingredients containing the active ingredient.

Thus, these rulings demonstrate that, under ordinary patent law, it is necessary to distinguish what is protected by the patent (the subject matter of the patent – in these cases the single active ingredient) from the scope of the patent (that is to say the effects of the patent or the rights conferred by the patent).

It should be noted that in the *Losartan* case,[44] the Court of Appeal has further held that only the marketing of the generic drugs before the expiration of the protection could be prevented.[45]

Thus, this case suggests that the production and storing of a generic drug may not infringe the SPC, even if the basic patent could have been infringed by such actions.

[41] High Court February 12 2010 *EI Dupont de Nemours and Company* 10/51453.
[42] High Court, February 12 2010, *EI Dupont de Nemours and Company* 10/51453.
[43] High Court, January 28 2011, *Novartis AG* 11/50892.
[44] High Court of Paris, February 12 2010, *EI Dupont de Nemours and Company* 10/51453.
[45] Court of Appeal March 15 2011, *SAS Mylan* 10/03075.