European Communities Trade Mark Association

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ECTA LAW COMMITTEE POSITION PAPER
NEW FRENCH
LAW RESTRICTING IP RIGHTS ON THE APPEARANCE OF ORAL PHARMACEUTICALS[1]

1. *Introduction and Background on the New Article L. 5121-10-3*

It is the European Communities Trade Mark Association's (ECTA) objective to help safeguard the integrity of European trade mark law and the European trade mark legal system, as well as to support the respect of brand owners' trade mark rights. The comments contained in this paper therefore solely address the trade mark law issues associated with the new Public Health Law in France covering "*Intellectual Property rights."*

On 29 December 2011, the French government enacted a new provision of the Public Health Code, Article L. 5121-10-3, with the stated objective of reinforcing the "*sanitary security*" of medicine and other health products.
Among the different impacts of this new legislation, one provision appears to restrict certain IP rights with regard to pharmaceutical drugs by stating (English free translation):

"The owner of intellectual property rights protecting the appearance and the texture of oral pharmaceutical forms of a reference product within the meaning of article L.5121-1 [which defines a generic drug] may not prohibit the oral pharmaceutical forms of a generic drug substitutable to these products [...] from showing a similar or identical texture or appearance."

This new Article L.5121-10-03 appears to allow pharmaceutical companies to provide to their generic oral drugs with the same appearance as the referenced drug. For example if the originator's product is a yellow and green round pill, the equivalent generic product may be manufactured and sold in the same shape and colours.

In the comments provided herein, the ECTA addresses what it believes to be fundamental legal breaches with the new provision; ECTA does not provide an opinion or comment as to the purpose or objective of the provision addressing the appearance of generic pharmaceutical drugs.

[1] The paper was drafted under the lead of Caroline Casalonga, and with active contribution of Oscar Benito, Joao Pereira de Cruz, Myrtha Hurtado Rivas and Katherine Basile

2. *Fundamental Legal Breaches of the New Provision*

ECTA believes that Article L. 5121-10-3 of the French Public Health Code is (a) ambiguous and unclear and is therefore in breach with Article 7 of the European Convention for the Protection of Human Rights and the French Constitution (b) is in breach of the European Regulation for Intellectual Property rights.

A. The law is ambiguous and unclear

Article L. 5121-10-3 of the French Public Health Code is ambiguous and unclear and is therefore, according to ECTA's position, in breach with Article 7 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, and with Article 34 of the French Constitution. Both of these documents require that a law be clear and unambiguous in order to be enforceable and/or constitutional.

- THE TERM "IP RIGHTS" IS NOT SUFFICIENTLY DEFINED[2]

Article L. 5121-10-3 refers, without any clarity, to IP rights in general and to the "*appearance and the texture*" of oral pharmaceutical forms. However, it does not specify which IP rights are to be covered by this new provision. The reference to *"IP rights*" is extremely vague because the term could any form of intellectual property right, including patent rights as well as trademark, copyright and design rights.
For example, the appearance and texture of an oral pharmaceutical form may be protected by:
- a 3D mark,
- a device mark,
- a word and device mark,
- a design,
- a patent
- potentially a copyright, if the owner may demonstrate that such appearance is sufficiently original.

- THE PHRASE "APPEARANCE AND TEXTURE OF AN ORAL PHARMACEUTICAL FORM" IS NOT SUFFICIENTLY DEFINED

An oral pharmaceutical form may include:
- solid forms: pills, tablets, capsules, oral powder, solid crystals;
- liquid forms: syrups, liquids.

It is unclear what exactly is meant in the new law when it refers to "*the appearance*" of an oral pharmaceutical form. For example, it may consist of:
- a shape,
- a colour, a combination of colours
- a combination of a specific shape with a specific colour or colours
- any packaging material

[2] Under French law and jurisprudence, unfair competition is not included within the definition of "IP rights;" accordingly, ECTA is of the opinion that the law does not cover unfair competition and thus does not address unfair competition in these comments.

This is also true with regard to the use of the phrase "the texture" of an oral pharmaceutical form. For example, it may consist of:
- glassy,
- rugous,
- soft,
- any other texture.

The ambiguity of new Article is seen in the many questions that it raises but does not answer to the following:
Does the appearance of an oral pharmaceutical form include any word mark that may be placed on pills or tablets?
Does it include the appearance of the dose packet in which the oral powder is placed?
Does it include the appearance of the bottle in which the syrup is sold?
Does it include the product packaging?
Does the texture of an oral pharmaceutical form include the texture of syrup or the type of powder of an oral powder?

All the above questions help to demonstrate that the new Article is unclear on what is meant by "*appearance and texture*" that is meant to be covered by the exception to *"IP rights*" ownership.
Accordingly, ECTA is of the opinion that this new Article should be void for lack of clarity or should at least be revised to clearly define what type of form and texture it covers and what type of IP rights are covered.

B. The New Article is in Breach of CTM and Community design regulations and the trademark and design directives and of International IP conventions

Article L. 5121-10-3 of the French Public Health Code creates an exception to IP rights in France. This new Article appears to create an exception to otherwise valid IP rights such that upon the expiration of an owner's patent rights or at the expiration of the supplementary protection certificate on oral medical products, an IP rights holders will no longer be able to enforce their valid IP rights on the appearance and texture of the pharmaceutical oral form in France.
Because of this limitation on enforcement of IP rights in France, an IP holders' rights may be artificially limited to the duration of patent rights on the related medical product. Such exception is in contradiction with the unitary character of CTMs and RCDs and Unregistered CDs as the said right will not have the same effect in France as it will have in the other countries of the EU, and therefore it is in breach of the CTM Regulation (No. 207/2009) and Community Design Regulation (No 6/2002). It is also in breach with the trademark (2008/95/CE) and design (98/71/CE) directives that do not authorize such exception in relation to national French trademark and national French design rights.

The application of this Article creates a difference between the laws of the Member States that it is contrary to the principle of EU market harmonization and therefore affects the principle of free circulation of goods within the EU.

In addition, this Article does not comply with several provisions and principles of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and of the Paris Convention for the Protection of Industrial Property, which are binding signing parties to guarantee certain minimum standards on the protection of IPR. As an example, Article 17 of the TRIPS Agreement provides that exceptions to trademarks rights must "*take account of the legitimate interests of the owner of the trademark and of third parties"*, which is clearly not

the case in the present provision. Furthermore, Article 21 provides that compulsory licensing of a trademark shall not be permitted by the Parties.
It is also contrary to TRIPS Article 26-1, which provides that "*The owner of a protected industrial design shall have the right to prevent third parties not having the owner's consent from making, selling or importing articles bearing or embodying a design which is a copy, or substantially a copy, of the protected design, when such acts are undertaken for commercial purposes".*

Conclusion

ECTA, which does not wish to enter into the merits of the public policy objectives of article L. 5121-10-3 of the French Public Health Code, considers nonetheless that such objectives may not be achieved with a vague and unclear provision that is in breach with International conventions and European and French legislation.