# New French exception to pharmaceutical IP rights

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***A new French Law of December 29, 2011, has introduced article L. 5121-10-3 in the Public Health Code. Its provisions exclude generic drugs from trademarks and designs monopolies that relate to the appearance, shape or color of a reference pharmaceutical product.***

French Law No. 2011-2012 relating to the '*reinforcement of sanitary safety of medicines and health products'* of December 29, 2011 (published in the Official Journal on December 30, 2012) has introduced a new article L. 5121-10-3 in the Public Health Code which gives prevalence of Generics over trademarks and other IP right by providing the following:

*"The owner of an intellectual property right protecting the appearance and the texture of oral pharmaceutical forms of a reference product […] cannot prohibit the oral pharmaceutical forms of a generic drug substitutable to this products [...] from showing a similar or an identical texture and appearance".*

This is the third time article L. 5121-10-3 is seen in France under this very same and invariable wording but this time it is for real.

This provision first appeared on November 26, 2009, as part of French law *'Financing the National Social Security for 2010'.* French Constitutional Council however upheld on December 22, 2009, that Article L. 5121-10-3 was contrary to the French Constitution and decided that it could not be enacted in the context of a Social Security law.

Article L. 5121-10-3 was introduced back again last May by French Parliament in a proposition of law reforming the health system. Again also, the French Constitutional Council upheld on August 4, 2011, that the provisions at hands were contrary to the French Constitution and could not be enacted because they did not bear a sufficient link with the specific law in concerns.

The main 'alleged' reasons behind the adoption of Article L. 5121-10-3 are first to avoid or at least significantly reduce mistakes from end users during their drug therapy when generics have been substituted to brand-name drugs (the substitution principle being applied under French practice). Other considerations such as 20% of the hospitalizations of over 80 years old patients being caused by drugs or overdoses and therapy interruptions leading to serious illnesses also leaded French authorities to be willing to include the provision above with the view to increase public health.

The immediate result of this new provision is to allow an expired patent for a drug to prevent valid trademark and/or design registrations from being enforced against manufacturers of generics who can freely reproduce or imitate the overall shape, color(s) and/or taste of the original pharmaceutical products without infringing these trademarks or designs.

This however leads to a couple of questions. The consequences on recordation with Customs and the seizures they may perform are still uncertain at the moment. One can particularly wonder whether this new provision strictly and only applies to national intellectual IP rights or extends to IP rights having effects in France as Community Regulations on Trademarks and on Designs both establish that Community rights *'[…]shall have equal effect throughout the Community'.*

This being said, as an exception to IP monopolies it should rather be strictly interpreted. Only time and practice over the next months will allow seeing how this new provision can concretely and properly be handled.

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