

# International News

Security Act whose purpose was to introduce in French law a provision rather similar to the US 'Bolar provision' also known as the Waxman-Hatch Act [35 USC 271 (e) (i)]. This Act results from a proposal by a Member of Parliament and is also supported by the Government. It aimed at allowing generic drugs to be marketed more quickly; and it reads as follows:

- Marketing authorisation for a generic drug – within the meaning of Article L601-6 of Social Security Code – may be granted before expiration of intellectual property rights attached to the original drug.
- However, actual marketing of the generic drug may not be started before expiration of such rights.
- When it grants a marketing authorisation in such a case, the French Agency for Drug Security shall inform the owner of the marketing authorisation for the original drug.
- Biodisponibility studies conducted to show bioequivalency with an original drug for the purpose of obtaining a marketing authorisation for a generic drug are regarded as acts of experimental use within the meaning of Article L613-5 of French Intellectual Property Code. (*Note: This last sentence has been held invalid by the French Conseil Constitutionnel and is therefore not contained in the Act such as in force, as explained below.*)

The first and second sentences do not bring any change in French law, since the *Cour de Cassation* (highest French court) had already decided on March 24, 1998 (*Promedica & Chiesi v Allen & Handburys*) that the mere filing of an application for a marketing authorisation was not *per se* an act of infringement. The main change was in the last sentence, which said that it would not be an infringement to conduct clinical studies for the purpose of obtaining a marketing authorisation for a generic drug. This provision was a departure from the present law in France and in the major European Union countries. It will not come in

## France

### **Clinical trials not regarded as experimental use**

The French Parliament adopted on December 29, 1999 a new Social

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force in France, at least for the time being, since the French *Conseil Constitutionnel* (the highest court in France for constitutional matters) held that it was contrary to the French Constitution.

The reason has nothing to do with patent law; it lies in the fact that the proposed Act, since aiming at dealing with the funding of Social Security, could not include provisions which had no *direct* impact on Social Security finance. It may happen, however, that the French Government will propose a new specific bill for the introduction of a Bolar provision in French law. Such a move could cause the European Commission to speed up the enactment of a Regulation on generics. It could also cause some concern to the French Government if another state member of the WTO starts proceedings against France, arguing that the new regulation violates Articles 27 and 28 of TRIPs, as the European Commission has challenged similar provisions of Canada's legislation.

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