Competition Cases on Product Denigration: What Can You Say About Competing Products?

EU Pharmaceutical Law Forum

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Key Cases by the French Competition Authority

Sanofi-Aventis	Decision in May 2013 imposing a fine of €40.6 million
	Upheld by Paris Court of Appeal in December 2014
Schering-Plough	Decision in December 2013 imposing a fine of €15.4 million

Sanofi - Facts

Plavix (clopidrogrel) – blood thinner used to prevent blood clots and heart attacks

Sanofi had patent on a salt that extended beyond basic patent, so generic had to use a different salt

Sanofi had a patent on use in combination with aspirin to treat acute coronary syndrome (ACS)

Sanofi - What Can You Say?

Generic has different salt.

Generic has different salt because we have a patent on our salt.

Generic has different salt and does not have indication for ACS.

Generic has different salt, but the health authority has found that this difference does not affect the efficacy or safety profile of the generic.

Schering-Plough – Facts

Subutex (high-dosage buprenorphine or HDB) – used to treat heroine addiction

Generic used different excipients

Schering-Plough – What Can You Say?

Generic has different excipients

Generic is more soluble because it has different excipients, so a greater risk that it may be dissolved and injected rather than swallowed as a pill.

Generic is more soluble, so a greater risk that it may be dissolved and injected rather than swallowed as a pill. We have supporting evidence.

Key Points for Competition Authorities

Key Points	
	Doctors are risk averse and sceptical about new drugs or generic versions of new drugs; they do not understand pharmacology or laws on generic marketing approvals and intellectual property.
	Detailing visits are a key source of information for doctors.
	Information should be “objective, complete and reliable.”

Criticisms of Denigration Cases

Criticisms	**Inconsistent with regulatory regime, which recognizes that generics may be different – no automatic substitution in some Member States and doctors retain final say in some Member States.**
	Differences between products may exist even after finding of bioequivalence.
	If discussions with health authorities about differences could give rise to competition issues, risk of restricting information made available to HCPs.
	Is this really a competition law problem? Laws on misleading and comparative advertising and unfair trade practices deal with these practices.

Golden Rules

Practical Guidance	Statements should be objective, complete and reliable; they should not be incorrect or misleading.
	Do not suggest problem with safety or efficacy of generic without supporting evidence.
	If contradictory evidence exists (such as a finding of bioequivalence), this should be mentioned.