# Free-riding with Impunity?

## Generics, biosimilars and originator trademarks in France

**Markus Rouvinen**

mmhr@thomsentrampedach.com

https://www.thomsentrampedach.com/

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# Introduction

- References to originator trademarks may be useful in promoting generics through advertising
- Special characteristics of generic medicines render such references likely to be considered prohibited free-riding under the EU rules on comparative advertising
- Particularities of the French market has led the French courts to treat generics with particular leniency, an approach perpetuated by regulatory means for fiscal gain
- Problems for the uniformity of EU law, notably the uniform protection of the EU trademark
- Is the French approach analogously applicable to biosimilars?

REFERENCES TO ORIGINATOR MARKS – RECIPE FOR FREE-RIDING?

FRANCE

IMPUNITY FOR FISCAL GAIN?

WHAT ABOUT BIOSIMILARS?

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# References to Originator Marks – Recipe for Free-riding?

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# MCAD

- Pharmaceutical advertising heavily regulated in EU by the Human Medicines Directive
- But Recital (42) makes saving for applicability of Directive 2006/114/EC on Misleading and Comparative Advertising (MCAD)

    - Joint Cases C-544/13 and C-545/13 *Abcur* (16.6.2015)

- MCAD intended to legalise comparative advertising across the EU and subject it to common rules:

    - Comparative advertising seen as desirable to allow advertising to objectively demonstrate the merits of comparable products to better provide an outlet for goods and services in the single market (Recital (6), MCAD)

    - Simultaneous need to protect consumer and competitor interests (Recital (9), MCAD)

# MCAD and Trademarks

- **Legitimate** comparative advertising not infringing:
  - *O2 Holdings*, Case C-533/06, 12.6.2008 **vs.** Article 10 (3)(f) Trademark Directive, 2015/2436 & Article 9 (3)(f) Trademark Regulation, 2017/1001)


- 2 of the 8 conditions in Article 4 MCAD relate to the prevention of free-riding:

**(f) it does not take unfair advantage of the reputation of a trade mark, trade name or other distinguishing marks of a competitor or of the designation of origin of competing products;**

**(g) it does not present goods or services as imitations or replicas of goods or services bearing a protected trade mark or trade name;**

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# References to originator marks and free-riding

- **Unfair advantage (Article 4 (f) MCAD)**:
  - ”Riding on the coat-tails of a mark with a reputation” (Case C-487/07 *L'Oréal and others*, 18.6.2009*)*
  - “Transfer of the image of the mark or of the characteristics which it projects” (*L'Oréal and others)*
  - “Associate the reputation of the manufacturer's products with the products of the competing supplier” (Case C-112/99 *Toshiba Europe*, 25.10.2001)


→ Reference to originator allows generic to take advantage of originator’s pre-established reputation, reducing marketing efforts

→ Image/reputation transfer seems likely since the legal definition of generics and substitution presuppose the equivalent quality and safety of generic *vis-à-vis* originator

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# References to originator marks and free-riding

- **Imitation advertising (Article 4 (g) MCAD**, *L'Oréal and others*):
  - Open admission, whether explicit or implicit, of the fact that an essential characteristic is arrived through a process of imitation
  - Overall presentation and economic context

→ Active composition of generics is developed on the basis of the reference medicine – reference to originator mark likely to constitute open admission

- **But overall purpose of MCAD is to increase available objective information:**
  - Use originator TM unlikely to be illegitimate where doing so has informative/functional significance (*Toshiba Europe*; Case C-59/05 *Siemens*, 23.2.2006)
  - But informational benefit to professional public familiar with INNs can be questioned
- Use of the originator trademark should in any case be **minimised** given special characteristics of generics and the legitimate interests of trademark proprietor

# Spain - *Prozac®* (STS 204/2010, 7.4.2010) Eli Lilly/Ratiopharm

- Use of the statement ”bioequivalent of Prozac®” was held to be parasitic and distinct from legitimate comparative advertising
- Instead of comparing the two products to highlight the advantages of the generic, the statement sought to emphasise the equivalence of the generic and Prozac®, attaching itself to the reputation of that brand.


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# Spain - *Exelón®* (AAP M 853/2015, 9.1.2015) Novartis/Teva


- Use of Exelón® mark seen to take unfair advantage of its reputation
- Use considered unduly intensive:
  - Mark highlighted
  - Multiple mentions
  - Not merely informative

→ A single informative mention would have been permitted

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# Spain - *Singulair®* (SJM A 3304/2016, 15.06.2016) MSD/Sandoz


- References to Singulair® and Nasonex® sought to transfer the reputation of the originator medicines to the generic/hybrid medicines, which was aided by references to bioequivalence
- Reference to the originator unnecessary as INN sufficient
- Emphasis on similarity between pills held to constitute imitation advertising

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# Germany – *Prograf®* (OLG Hamburg, 28.06.2012, 3 U 17/11)

Astellas Pharma


- A reputation transfer is a necessary consequence of using brand name in a bioequivalence claim, and is inherent to the process of substitution
- Repetitive use of Prograf® trademark was unduly intensive and beyond what was needed to inform medical professionals
- Was not justified by providing *direct* information

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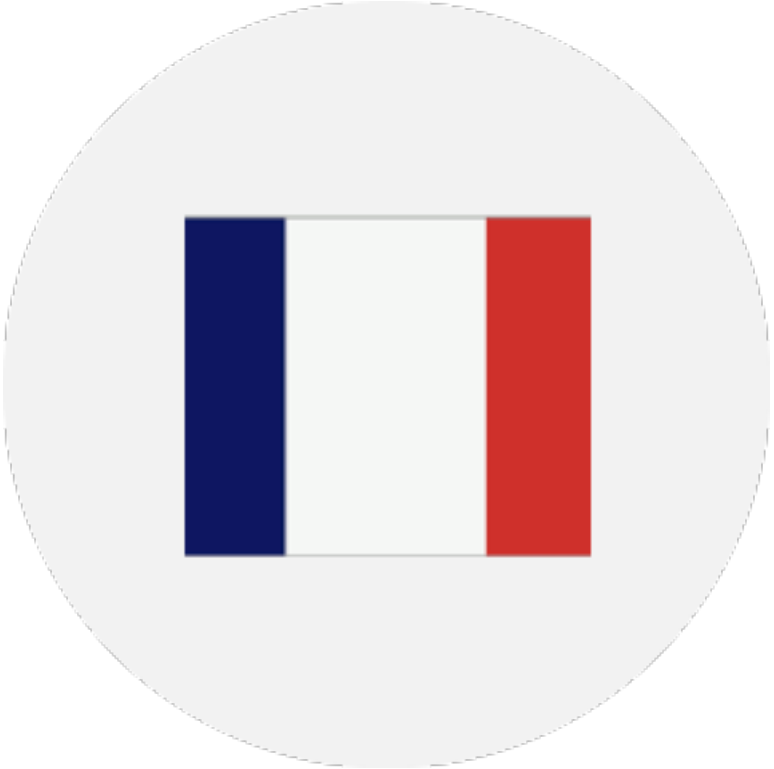

# France – Impunity for Fiscal Gain?

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# *Diamicron®* (CA Paris, 8.10.2010, n° 09/10708) Laboratoires Servier/Teva


- The **effective commercialisation** of generics depends on reference to originator trademark as it provides information that is **necessary even for the pharmacists targeted** by the advert

- The highlighting of the Diamicron® mark was for the purpose of **direct and easy readability**, and did not take unfair advantage of its reputation

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# *Deroxat®* (Cass. com., 24.5.2011, n° 09-70.722) GSK/Sandoz


- A generic is guaranteed by statute to be an equivalent to the originator (with the same active ingredient, dosage and pharmacological form), but does not imitate it.
    - The concept of **bioequivalence must be distinguished from the idea of reproduction** used in the MCAD.
- **Limited** use of the Deroxat® trademark was aimed at providing **direct information** to medical professionals, and **was necessary for the existence of proper competition on the market.**

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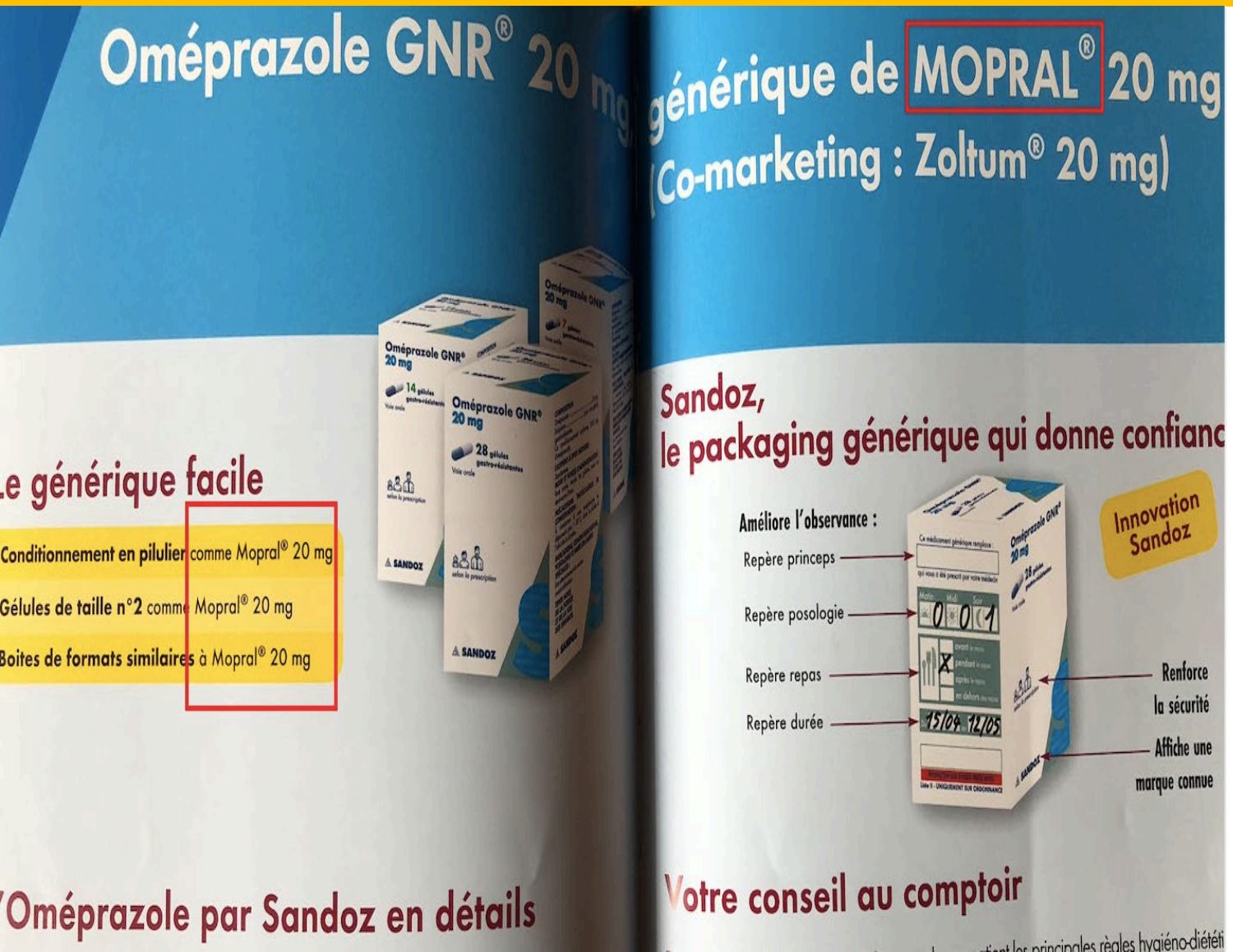
# *Mopral®* (CA Versailles, 13.12.2011, n° 10/05084) AstraZeneca/Sandoz




- The use of Mopral® when emphasising the similarities in the packaging of the Omeprazole generic did not present the generic as an imitation
  - Based on report from French medical regulator, encouraging generics with packaging as close as possible to originator
- The emphasis on Mopral® did not take unfair advantage of the reputation of the mark, but was rather aimed at providing **direct information** to medical professionals

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# Regulatory Aftermath

- The approach of the courts has been perpetuated through regulatory means for fiscal gain
- Cases used to justify Decree n° 2012-741 of 9th May 2012, which introduced new provisions to the *Code de la santé publique* (Arts R.5122-3 and R.5122-8):
    - All advertising for generic medicines **must** contain a reference to the brand name of the originator, its pharmacological form and to its dosage.
- Motivated by desire to use advertising as a means **to increase the uptake of generics**, to counterbalance the marketing efforts of originator brands and brand loyalty
- Requires that originator marks are used even where this has no informational value to target audience
- Intensive use encouraged indirectly?


Recent examples…


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# Analysis

- Contrary to what CJEU case law would seem to require, French courts have treated special characteristics of generics as *decreasing* the likelihood of free-riding taking place

  - No concern for whether reputation/image transfer has taken place
    - Only limited concern for the interest of the trademark proprietor in minimising use

  - Generics excluded from the scope of application of the imitation advertising prohibition (including outer characteristics)
    - Seems inconsistent with *L'Oréal and others*

  - The goal of increasing substitution seen as inherent to effective competition

    → Concern for fiscal policy objective of increasing generic uptake (cf. CA Versailles, 29.3.2001, 1998-5727)

# Analysis

- At the time of the decisions, originator trademarks arguably had ”functional significance”:
    - Prescriptions were written almost exclusively using the originator brand name, and generics were not listed in medical reference works

→ Risk a pharmacist might not immediately recognise the function of the generic without reference to originator (”double verification”)

→ Even prominent references seen as acceptable on the grounds that this provides direct, accessible information to medical professionals

# Approach still valid?

- Subsequent changes call into question the continued validity of this approach:
  - Since 2015, prescriptions must always be written using the INN name (Art. L. 5121-1-2 Code of Public Health; Art. 4 Decree n° 2014-1359 of 14th November 2014)
    - Follows that pharmacists must be familiar with INN name to be able to fulfil prescriptions
  - This, together with increased use of prescribing software, has considerably diminished informative value of originator brand names
  - → Argument that reference to originator is functionally necessary for effective competition on French market is **now substantially weakened**

# Comment

- French approach difficult to reconcile with the interpretation given to MCAD by CJEU:
  - Preliminary reference procedure should have been used in Deroxat® case as unclear whether a generic can be an “imitation” under MCAD (Case C-283/81 *CILFIT*, 6.10.1982)
  - Fiscal policy goal of increasing generic uptake would seem to have limited relevance when applying MCAD
- Divergent interpretation in Member States problematic:
  - **Uniform protection conferred by the EU trademark → Generics seem exempted from imitation advertising prohibition *in principle***
- **Need for CJEU guidance**

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# What about biosimilars?

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# Biosimilars, originator marks and comparative advertising

- In France increasing use of biosimilars is seen as an important component in further reduction of health care costs
  - The French National Health Strategy for 2018-2022 calls for 80% biosimilar market share
  - Strong incentive for measures favourable to substitution, especially on the outpatient market where pharmacies play a key role

- Comparative advertising using references to originator brand name useful in encouraging substitution:

  → The originator brand name often benefits from established reputation among medical professionals

  → Biosimilars with a mode of administration as close to the originator as possible more likely to be substituted

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- Enoxaparine Crusia® was approved as a biosimilar of Lovenox® in May 2018

- Heavily promoted to pharmacists and prescribers as substitutable for Lovenox®

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# Biosimilars and MCAD

- Use of originator brand names to encourage substitution problematic in light of MCAD:

→ Advertising aiming to equate biosimilar with the originator exposes itself to risk that reference would constitute a taking of unfair advantage or imitation advertising.

# Does *Deroxat®* rationale apply to Biosimilars?

→ The considerations for effective competition seen in Deroxat® seem even less applicable to biosimilars:

- Unlike generics, biosimilars are listed under their own name in medical reference works (e.g. Vidal)
- Indications of a biosimilar not necessarily identical to reference medicine
- Importance of distinguishing between biosimilars and originators highlighted by fact that long-latent provision allowing the substitutability of biosimilars was removed on 24th December 2019 (Art. L.5125-23-3 Code of Public Health repealed)

→ Suggests that use of originator marks in a similar way to what is seen with generics would be unjustified from a “functional” perspective

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Questions?

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