

December 2006

HASELTINE LAKE 
EUROPEAN PATENT & TRADE MARK ATTORNEYS

Lipitor™ Appeal and Cross-Appeal Dismissed

In the November 2005 issue of this Newsletter, we reported the English High Court decision in *Ranbaxy UK Limited et al v. Warner-Lambert Company*, which held (a) that Warner-Lambert's master patent covering Lipitor™ (atorvastatin hemicalcium salt) is valid and would be infringed if Ranbaxy were to launch their imitation product before expiry of the patent and its supplementary protection certificate, and (b) that a later patent directed specifically to the hemicalcium salt is invalid.

Both sides appealed to the Court of Appeal, which has upheld the High Court decision by dismissing both appeals.

The appeal decision confirms that a pharmaceutical patent claim must not be given an over-meticulous interpretation but must be read in the context of the description of the invention and the examples in the patent, as they would be understood by a person skilled in the art. If – as in this case - a chemical formula appears to be a stereospecific representation of just one stereoisomer, yet the description clearly says that more than just that stereoisomer is contemplated (and that is rational in the context of the underlying inventive concept and the common general knowledge), then the patent covers all the relevant isomers whether in optically pure (resolved) form or as mixtures (racemates). Judgement of Jacob LJ, paragraphs 19 to 25.

Furthermore, Ranbaxy's argument that the skilled person, from his common general knowledge, would "know" that one of the stereoisomers would not have activity, and so interpret the claim narrowly, was dismissed. The evidence of such certain knowledge was lacking, so it was not necessary for the court to consider whether it could have affected the interpretation of the patent. Judgement of Jacob LJ, paragraphs 26 to 29.

→ <http://www.bailii.org/ew/cases/EWCA/Civ/2006/876.html>

David Brown – For further information email dbrown@haseltinelake.com

"Comprises" Not Always Amendable To "Consisting Essentially Of" in the EPO

It is often assumed that an amendment of claim language from "comprising" to "consisting essentially of" will be allowed in the European Patent Office (EPO) without a risk of an objection that the amendment adds new matter, where only the original wording "comprising" has explicit verbal basis in the application or patent.

Such an amendment can be very useful during examination or opposition, where for example the invention lies in the **omission** of certain components from a prior art composition.

Decision T868/04 of EPO Technical Board of Appeal 3.3.10 shows that such a general assumption is wrong, and that this amendment can indeed be refused if, in the circumstances of the case, new matter would be added.

The Board held that the original application disclosed an exhaustive list of ingredients as the only alternative to the more general "comprising" language, so that going to the intermediate position "consisting essentially of" added new matter.

We recommend that, when drafting applications in the chemical, pharmaceutical and biotech arts, in addition to "comprising" language, the alternative narrower options of "consisting essentially of" and "consisting of" are expressly stated as possible alternatives in the application, if it is desired to have them available as fall-back positions during examination or after grant.

In view of the strict approach of the EPO to issues of priority, this recommendation applies equally to priority-founding initial applications.

→ <http://legal.european-patent-office.org/dg3/pdf/t040868eu1.pdf>

David Nash – For further information email dnash@haseltinelake.com

“Characterised as...” Not Clear in EPO Composition Claims

In Decision T651/05, EPO Technical Board of Appeal 3.3.6 recently had the opportunity to consider how the term “characterised as...” should be interpreted in the context of a chemical composition.

The claim in question opened as follows: “A high purity solvent composition characterised as a mixture of *n*-paraffins and *iso*-paraffins...”, followed by a list of parameters to be met by the composition/mixture.

[It should be noted that the phrase was not being used in the way that the term “characterised in that” is used in the so-called “two-part” claim form preferred in the EPO, namely to demarcate the prior art features from the novel features, but was intended to mean something similar to “consisting essentially of”.]

The Board held that, in the absence of a definition, the phrase “characterised as...” used in this way lacked clarity, as it covered more than “consisting essentially of”. In particular, it covered compositions which “have the character” of a mixture of *n*-paraffins and *iso*-paraffins, but may not actually be such a mixture, and for example may exclude one or both components or may include others.

→ <http://legal.european-patent-office.org/dg3/pdf/t050651eu1.pdf>

David Rushton – For further information email drushton@haseltinlake.com

A Disclosed Embodiment Provides Basis for a Corresponding Specific Disclaimer

Given the strictness of the EPO’s examination of amendments for possible introduction of new matter, applicants and opposed patentees need to be resourceful when crafting successful amendments.

The recent Decision T1139/00 of EPO Technical Board of Appeal 3.2.2 has confirmed that a feature or combination of features originally **positively** claimed in a subsidiary claim can equally serve as the basis for an amendment to **exclude** that subject-matter from the main claim by way of disclaimer, without adding new matter. By disclosing a species within a genus, the balance of the genus is implicitly disclosed and can be claimed explicitly if desired.

→ <http://legal.european-patent-office.org/dg3/pdf/t001139eu1.pdf>

David Brown – For further information email dbrown@haseltinlake.com



DAVID NASH, Partner – Bristol

UK & European Patent Attorney
MA Natural Sciences
Cambridge University

Email: dnash@haseltinlake.com
Tel: +44 (0) 117 910 3200

DAVID BROWN, Partner – Bristol

UK & European Patent Attorney, UK & European Trade Mark Attorney
MA Natural Sciences
Cambridge University

Email: dbrown@haseltinlake.com
Tel: +44 (0) 117 910 3200



ULRICH BENEDUM, Partner – Munich

European Patent and Trade Mark Attorney
German Patentanwalt
Dipl.-Chem., PhD

Email: ubenedum@haseltinlake.com
Tel: +49 (0) 89 6227 1760

DAVID RUSHTON, Associate – Bristol

UK and European Patent Attorney
BSc Chemistry, PhD Chemistry
Newcastle University

Email: drushton@haseltinlake.com
Tel: +44 (0) 117 910 3200



CRISTINA REVERZANI, Attorney - Munich

Italian and European Patent Attorney
US Patent Agent (37C.F.R. §10.9(b))
Degree in Chemistry, Milan University

Email: creverzani@haseltinlake.com
Tel: +49 (0) 89 6227 1760

JOHN HUTCHISON, Attorney - Bristol

UK and European Patent Attorney
BSc Chemical Physics (Edinburgh University)
PhD Physical Chemistry (Cambridge University)

Email: jhutchison@haseltinlake.com
Tel: +44 (0) 117 910 3200



MAGNUS JOHNSTON, Attorney-in-training

Trainee Patent Attorney
BSc Chemistry with New Materials Technology, PhD Chemistry
Aberdeen University

Email: mjohnston@haseltinlake.com
Tel: +44 (0) 117 910 3200

MATTHEW GEORGIU, Attorney-in-training

Trainee Patent Attorney
MChem Chemistry
Oxford University

Email: mgeorgiou@haseltinlake.com
Tel: +44 (0) 117 910 3200



www.haseltinlake.com

London: Imperial House, 15 – 19 Kingsway, London WC2B 6UD
Tel: +44 (0) 20 7420 0500 Fax: +44 (0) 20 7420 0505

Leeds: West Riding House, 67 Albion Street, Leeds LS1 5AA
Tel: +44 (0) 113 233 9400 Fax: +44 (0) 113 233 9401

Munich: Theatinerstrasse, D-80333 Munchen, Germany
Tel: +49 (0) 89 6227 1760 Fax: +49 (0) 89 485 686

Bristol: Redcliff Quay, 120 Redcliff Street, Bristol BS1 6HU
Tel: +44 (0) 117 910 3200 Fax: +44 (0) 117 910 3201