

October 2005

Germany Implements EU Biotechnology Directive with a Twist

After more than five years of delay, and long battles with pressure groups such as Greenpeace, the European Union (EU) Biotechnology Directive (Directive 98/44/EC) has been implemented in Germany by a new German Patents Act.

The new provisions on patentability in Germany are largely identical to Rules 23b-e of the European Patent Convention (EPC). However, the new German law imposes an additional claim requirement for human sequences. Whereas Rule 23e EPC provides that "The industrial application of a sequence or a partial sequence of a gene must be disclosed in the **patent application**", the new German law also requires that "If the subject-matter of the invention is a sequence or partial sequence of a gene, whose structure is identical with the structure of a **natural** sequence or partial sequence of a **human gene**, then its **use**, for which the industrial application has been concretely described ..., must be **incorporated in the claim**".

It is currently the subject of debate in Germany, whether this provision applies only to newly granted German and European patents designating Germany or whether it affects all existing national German patents and European patents validated in Germany. We will keep you informed of developments, as the effects of the new German law are clarified and the practice in both the German and European Patent Offices develops. We recommend that all new patent applications relating to a new nucleotide sequence include use-limited claims in addition to claims to the nucleotide sequence *per se*.

Ulrich Benedum – For further information email ubenedum@haseltinelake.com

Claims defined by Parameters at Risk of Invalidity in the EPO

The EPO Boards of Appeal have been showing themselves very ready to revoke – or require restrictive amendment to – chemical, pharmaceutical and biotech patents/applications on the ground of insufficient disclosure or lack of clarity, in cases where the invention is claimed by reference to parameters of a product and those parameters are indefinite or difficult to measure reproducibly.

Recent examples are:

- oxidative exotherm of polyethylene (missing details: cooling time, sample particle size and viscosity) (T1288/01)
- tensile strength of a web (missing details: rate of extension to be applied in the test method) (T611/02)
- cup crush energy and cup crush peak load of a fabric (missing details: number of pleats and wrinkles and general shape of the cup-shaped fabric piece, relative arrangement of the surrounding guide cylinder, distance of descent of the pressure foot on the fabric cup) (T252/02)
- volume-weighted geometric mean particle diameter of emulsified water droplets in a fatty foodstuff (missing details: all measurement information) (T83/01)
- molecular weight of proteins and other large molecules (missing details: all measurement information) (T285/01)
- melt tension and melt flow rate of a polymer (missing details: the operating temperature and load to be applied in the test methods) (T412/02)

Decision T412/02 is interesting because the problems arose when the patentee **introduced** the parameters into the main claim from the description during opposition proceedings, in an attempt to define a patentable invention.

These decisions show that considerable care must be taken when drafting a patent application which refers to any parameter of a product in the **description, examples or claims**, or which seeks to define a functional descriptive term by reference to a parameter. All the critical details for measurement of every parameter must be fully set out. It is not enough to refer merely to a standard test method or a commercial apparatus if critical conditions must be selected arbitrarily or subjectively for the test. In that event, the conditions to be used in the test method must be stated, so that the test is reproducible as intended by the patentee.

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

→ for links to cases go to http://legal.european-patent-office.org/dg3/search_dg3.htm

Suspension of European Patent Application Reviewed in Entitlement Dispute

The European Patent Convention (EPC) provides that European patent application or opposition proceedings must be suspended when proof is provided that a litigated dispute as to entitlement to ownership has arisen, unless the third party claimant agrees otherwise (Rule 13 EPC). Rule 13(3) EPC, however, provides for the possibility of resumption of the proceedings before conclusion of the entitlement litigation, at the discretion of the EPO.

There exists a clear potential for third parties to use this provision of the EPC to cause unfair damage to a legitimate applicant or opponent through false claims to entitlement.

The EPO Legal Board of Appeal was recently called on to review a suspended application, to judge whether - balancing the interests of the parties - the suspension should continue (Decision J10/02). The applicant had asserted that the entitlement litigation had been brought solely to delay grant of the commercially important patent.

The Oral Proceedings took place before the Board of Appeal nearly four years after the entitlement proceedings had been launched in an Italian court, during which time the application proceedings had remained in suspension following the decision of the Legal Division of the EPO, shortly after the suspension had been ordered, to maintain the suspension.

The Board reviewed the circumstances and issued an order to the Legal Division to check on progress of the Italian litigation and "if appropriate" to lift the suspension and resume the EPO proceedings.

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

→ <http://legal.european-patent-office.org/dg3/pdf/j02001eu1.pdf>



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, Attorney – Bristol

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

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



JOHN HUTCHISON, Attorney-in-training

Trainee 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



MARK ROWLAND, Attorney-in-training

Trainee Patent Attorney
BA Chemical Engineering MEng Chemical Engineering
Cambridge University

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

Please visit our new website at
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: Rosenheimer Strasse 30, D-81669 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