

Tiptoeing around Restrictions in Biotechnology Inventions:

A Practitioner's Experience

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Who are we?

HARRISON GODDARD FOOTE (HGF)

One of the UK's largest firms of Patent and Trade Mark attorneys

HGF LAW

A specialist UK law firm focused solely on IP related matters

Aberdeen, Glasgow, Leeds, Manchester, Sheffield, York, London

Worldwide foreign associate network

International client base



Types of Intellectual Property



Copyright

Trademarks

Designs

Patents

Trade Secrets or Know How



WHAT CAN BE PATENTED

Products – pharmaceuticals

Uses of products - second medical indications “Swiss- style” claims G5/83 are obsolete now purpose limited claims G2/08

Genes – (isolated with function R27(a) & R29(3)) including modified genes, expression vectors and probes.

Proteins - including modified proteins, monoclonal antibodies and receptors

Other chemical compounds - such as small organic molecules

Cells - modified cells and cell lines

Methods – making the above

Dosing regimens - allowable G2/08



WHAT CAN'T BE PATENTED

- Methods of treatment on the human body by surgery or therapy and diagnostic methods practised on the human or animal body are not allowed in Europe (they are patentable in the United States)
- Processes for cloning human beings are not allowed
- Modification of germ line genetic identity of human beings not allowed
- Uses of human embryos for industrial or commercial purposes not allowed
- Animal suffering without substantial medical benefit is not allowed (Harvard Mouse, Knock-Outs)



“Dolly the Sheep” made by nuclear transfer



Edinburgh Patent, covered human stem cells and was limited to exclude human germ-line intervention.

1. A method of isolating and/or enriching and/or selectively propagating desired animal stem cells other than embryonic stem cells, which comprises maintaining a source of said cells under culture conditions conducive to cell survival, **characterised in that** the source of cells includes stem cells containing a selectable marker which is capable of differential expression in (a) desired stem cells of said source and (b) cells of said source other than the desired stem cells, whereby differential expression of said selectable marker results in preferential isolation and/or survival and/or division of the desired stem cells containing the said selectable marker.

2. A method according to Claim 1 wherein the desired stem cells are selected from unipotential stem cells, pluripotential stem cells, embryonic stem cells, gonadal stem cells, somatic stem/progenitor cells, haematopoietic stem cells, epidermal stem cells and neuronal stem cells.



Case Study 1

1. A method of treating type I hypersensitivity in a warm blooded animal sensitive to an allergen which comprises administering to the warm blooded animal a pharmaceutical composition comprising an effective amount of a refined detoxified endotoxin selected from the group consisting of monophosphoryl lipid A and 3-deacylated monophosphoryl lipid A, and a pharmaceutically acceptable carrier.

1. Use of a refined detoxified endotoxin selected from monophosphoryl lipid A and 3-deacylated monophosphoryl lipid A, for the manufacture of a medicament for use in treating type I hypersensitivity in a warm-blooded animal sensitive to an allergen.



Case Study 2

Can have claims in US to methods of replacing meniscus or treating meniscal injury but not in EP.

Can also have products obtainable by a process that can be used for transplantation but not use of products for transplantation .

Claim reads as “A product comprising meniscal tissue obtainable by the method of any preceding claim for use as a transplant tissue”
acceptable

Claim reads as “ Use of meniscal tissue obtainable by the method of any preceding claim as a transplant tissue” **not allowable** as considered method practised on the human body Art 53(c)



Case Study 3

<http://www.restorelite.co.uk/>

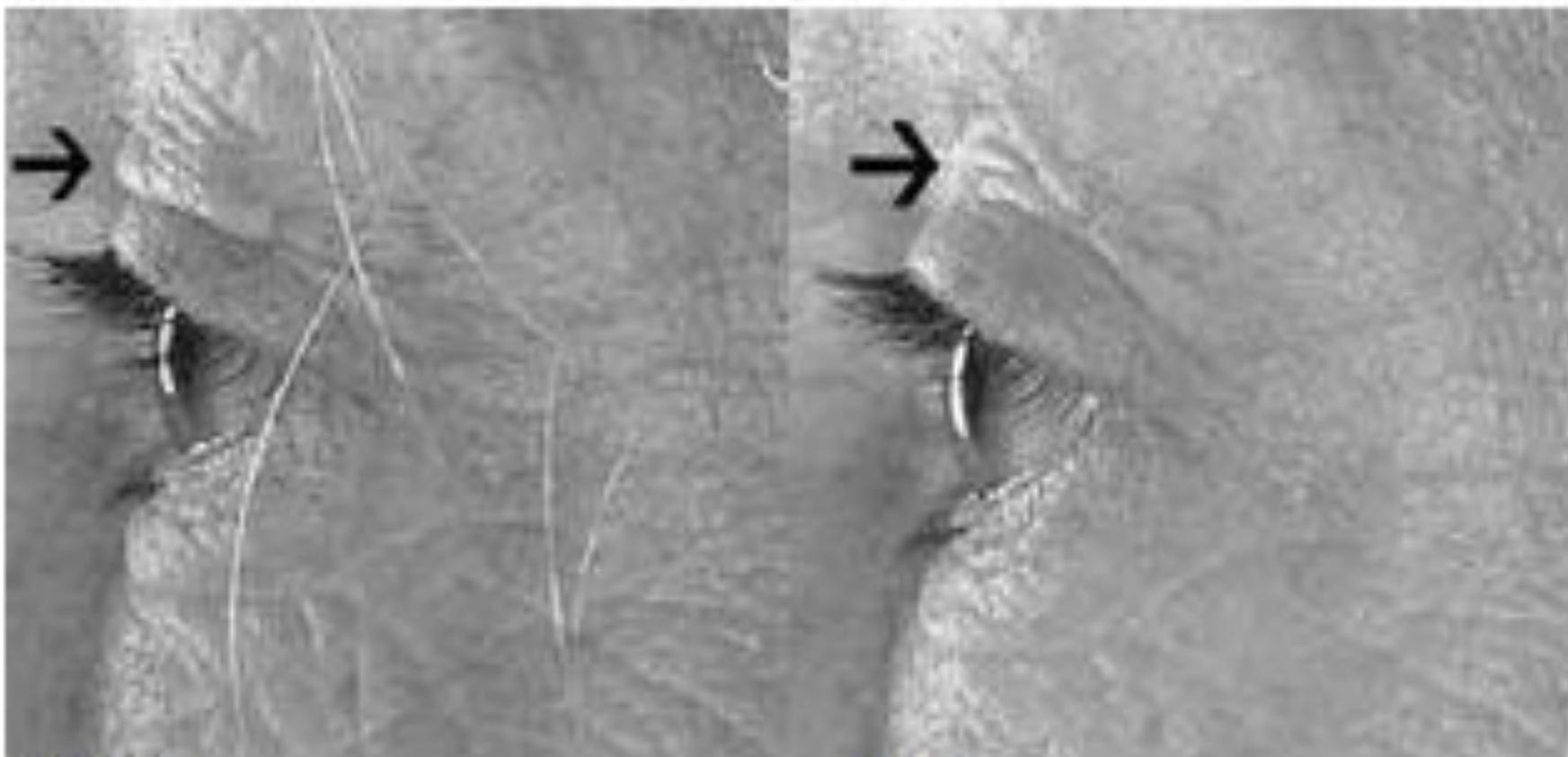
Anti-wrinkle breakthrough! Doctor has discovered a “cure” for wrinkles - Northern Echo Newspaper. Anti-ageing elixirs have been promised by alchemists throughout the ages. In modern times Alchemists have been replaced by pharmaceutical industry. Restorelite has discovered a completely new technology which has been proven to reverse the visible and invisible ravages of time.





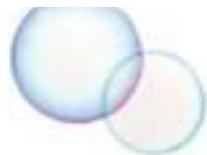


Harrison Goddard Foote
Patent and Trade Mark
Attorneys



Before

After





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Attorneys

Restorelite.



Photo 3 (Before)

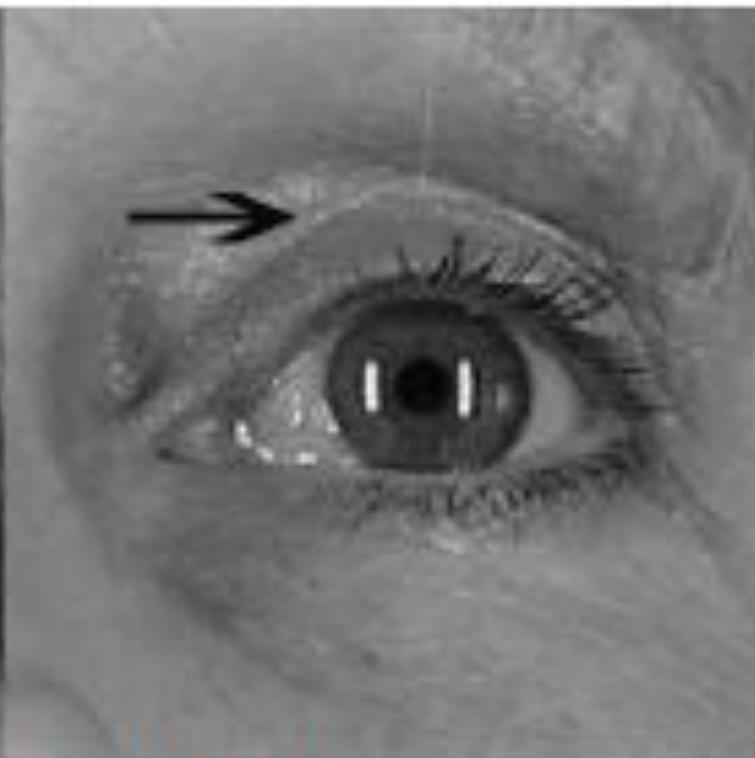


Photo 4 (After)

GB2415387B

1. A method of cosmetically treating a superficial area of mammalian skin around, above or below an eye by reducing or alleviating or removing or diminishing wrinkles that occur as a result of natural aging, the method comprising irradiating the skin with a source of divergent electromagnetic radiation centred at 1072nm and having a bandwidth of between 10 to 120nm with an intensity of at least 500 μ Watts/cm² and up to 500 mWatts/cm².



Section 4A

Methods of treatment or diagnosis

4A.-(1) A patent shall not be granted for the invention of-

- (a) a method of treatment of the human or animal body by surgery or therapy, or
- (b) a method of diagnosis practised on the human or animal body.



Potted History

UKIPO POSITION

“Your invention as claimed is in effect a method of treating the human body and this is not patentable under the law” 28 September 2005 and 20 October 2008.....plus lack of inventive step

COUNTER-ARGUMENTS

Claims which clearly cover a method of cosmetic use and are unrelated to the therapy of a human or animal body are acceptable (T144/83)

The term “cosmetic” is sufficiently precise to differentiate it from a product which also has a therapeutic use, claims for cosmetic use are sufficiently distinct even if the application might also incidentally involve a medical treatment (T36/83)

Herpes/bacterial infections versus wrinkles...no connection



Potted History..continued

UKIPO POSITION TAKING THERMAGE (T1172/03) AND EXAMINATION GUIDELINES INTO ACCOUNT

Considering the claims, it does not seem possible to distinguish them from methods of treatment that would be considered to have a therapeutic effect that use electromagnetic radiation” 8 July 2008,
5 August 2009

COUNTER-ARGUMENTS

T144/83 point 4 and Witness Statement

“To the best of my knowledge there are no medical conditions that would benefit from wrinkle reduction”



Cases Relied on in the Hearing Treatment by Surgery

T0383/03 (General Hospital Corporation ;Hair Removal) “treatments by surgery which are clearly neither suitable nor potentially for maintaining or restoring health, the physical integrity or the physical wellbeing of human beings or animals do not fall within the exclusion from patentability”.

In T0383/03 the underlying cause of excess unwanted hair was not treated.

The three Witness Statements backed this up as the only purpose of reducing wrinkles is to beautify. Also Medicines and Healthcare Regulatory Agency denial of application for registration.



Cases Relied on in the Hearing Treatment by Therapy



BL O/284/04 Commonwealth Scientific and Industrial Research Organization method for destroying sheep wool follicles

T1172/03 (Thermage; apparatus for skin resurfacing) thermal induction of scar collagen.

T1077/93 (L'Oreal; cupric complexes for reducing UV sun damage)



Hearing Officer's Decision

In regard to determining whether a treatment is excluded as a treatment by surgery it is a two step process (i) determine whether there is a “non—insignificant intentional physical intervention” and (ii) if there is, is the treatment suitable for restoring health, physical integrity or physical well-being”exclusion requires yes to both.

Therapy covers any treatment designed to cure, alleviate, remove or lessen the symptoms or prevent or reduce the possibility of contracting any disorder or malfunction.

Method does not interfere with the work of a medical practitioner.



Inventive Step

Conditions that did not benefit from light treatment

First application only relates to pathological conditions and genuine medical illnesses

Timescale of therapy

Counter-intuitive “like prescribing cigarettes to treat lung cancer”



Thank you...any questions?

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