EPLAW Congress
Brussels
22 November, 2013

Second Medical Use Claims

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Outline

- Background to second medical use claims
  - Penny Gilbert
- Validity of claims for second medical use
  - Albert Lindner
- Some issues that remain to be resolved……
  - Scope and construction of Swiss form vs EPC 2000 form claims
  - Infringement (on-label and cross-label use)
  - Appropriate relief for cross-label infringement
- and case law from UK, NL, DK
  - Alex Wilson
  - Mark Van Gardingen
  - Sture Rygaard
- Report on the Venice Mock Trial on these issues

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Background

- Invention of a new drug (NCE)

  - Compound per se claims

  ➔strongest protection = compound however used.

  - First medical use

  Art 54(3) EPC 1973:

  Even if a substance or composition is part of the state of the art, its use in a method of treatment of humans or animals is not excluded from patentability provided that its use for any method of treatment is not part of the state of the art.

  ➔protection for compound known in non-medical field

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New use for old drug – patentable?

- Further research into use in a different disease/ more favourable dosing regimen/ new patient population – research and cost. Patent protection available?
- **G5/83 (Esai)**

Legal fiction of first medical use claim should be extended "by analogy" to new therapeutic use of a medicament irrespective of whether any pharmaceutical use already known. Claims should be drafted in "Swiss-type form":

"Use of a compound X in the manufacture of a medicament for the treatment of Y"

- **G2/08 (Kos / Abbott Resporatory)**

The second medical use may be the identification of a new, useful dosing regimen

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EPC 2000:
A new approach to second medical use claims

- **Art 54(5)**

Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition..for any specific use or method…provided that such use is not comprised in the state of the art.

- No longer need to use Swiss- claim format since EPC 2000:

"x for use in the treatment of Y"

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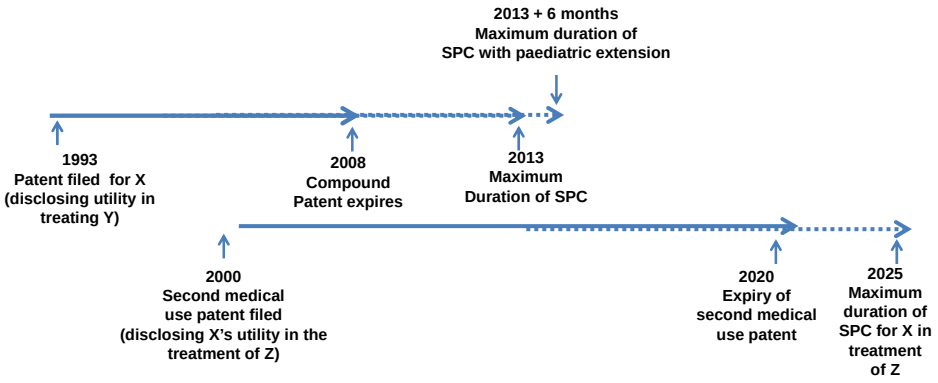
Drug Development Timeline



- The original compound patent will protect all uses of X until 2013
- The SPC will protect all medical uses of X (whether alone or in combination with other drugs) until up to 2013
- Generics should be free to sell X for use in treating Y after 2013
- The Second Medical Use patent should protect all use of X in condition Z until 2025

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Decision G 02/08 and Claims relating to a Further Medical Use

Dr. Albert K. Lindner

Date: 22 November 2013

Consequences of decision G 02/08

New therapeutic applications can be based on

1. a new patient group to be treated
2. a different technical effect
3. a different dosage regimen
4. a different mode of drug administration

New patient group (1/4)

Requirements for a new therapeutic application

1. The patient group is distinguishable by its physiological or pathological status (T 0019/86, T 0893/90, T0233/96)
2. There must exist a functional relationship between the particular physiological or pathological status of the patient group and the therapeutic or pharmacological effect achieved (T 0233/96)
3. The choice of the patient group must not be arbitrary (T0233/96)
4. There must be no overlap between the chosen patient group and the previously treated group (T 0233/96).

New patient group (2/4)

Claim defining a new patient group (T0893/90)

A method of producing a pharmaceutical composition for

controlling bleeding

in

non-hemophilic mammals

characterized by forming a mixture of phospholipid vesicles and mammalian blood Factor Xa in a form suitable for administration, the phospholipid and Factor Xa being present in amounts and in proportions just sufficient to arrest bleeding, said mixture excluding other physiologically-active materials.

New patient group (3/4)

Claim defining a new type of tumour (T0108/09)

Claim:

Use of fulvestrant in the preparation of a medicament
for the treatment of a patient with breast cancer
who previously has been treated with an aromatase inhibitor and tamoxifen and has failed with such previous treatment.

Argument of the opponent:

The previous treatment with an aromatase inhibitor and tamoxifen merely constitutes the medical history of the patient which is irrelevant for the claimed use.

New patient group (4/4)

Claim defining a new type of tumour (T0108/09)

Reasoning of the board:

1. It is known from the prior art that tamoxifen resistance leads to physiological changes in the tumour, which means that **this tumour can be distinguished from the same tumour before tamoxifen resistance set in**
2. **Physiological changes in the tumour** would also occur when resistance against aromatase inhibitors would set in
3. As a consequence, the tumours of the prior art, being only resistant to tamoxifen, can be distinguished from the tumours as claimed.
4. **This distinction means that two different diseases or two subsets of a disease (tumour) are concerned, which establishes novelty**."

New effect (mechanism of action) (1/4)

Decision T 0290/86

Claim:

The use of a salt of lanthanum for the manufacture of a ... toothpaste ... for cleaning plaque and/or stains from human teeth...

Prior art:

Use of a salt of lanthanum for depressing the solubility of tooth enamel in organic acids, thus strengthening the enamel

Common disease to be treated:

Inhibition of tooth decay

New effect (mechanism of action) (2/4)

Decision T 0290/86

Reasoning of the board:

"When a prior document and a claimed invention are both concerned with a similar treatment of the human body for the same therapeutic purpose ... the claimed invention represents a further medical indication as compared to the prior document ... if it is based upon a different technical effect which is both new and inventive over the disclosure of the prior document."

New effect (mechanism of action) (3/4)

Decision T 0486/01

Claim:

The use of IGF-1 ... in the manufacture of a medicament for use **in reducing the loss of glial cells** suffered after a CNS insult.

Prior art:

Use of IGF-1 for treating Parkinson's disease (CNS insult) **by rescuing neuronal and/or cholinergic neuronal cells**.

New effect (mechanism of action) (4/4)

Decision T 0486/01

Reasoning of the board:

1. a new property or a new technical effect of a known substance do not necessarily translate into a novel medical or non-medical use
2. there is no evidence for the existence of CNS injuries affecting only glial cells while leaving other populations of CNS cells unscathed
3. no new sub-group of patients (**i.e. patients to be treated for "glial cell dependent Parkinson's disease"**) can be recognised as distinguishable from the patients of the prior art
4. as a consequence, there is lack of novelty

Administration regimen (1/2)

Decision T 1319/04

Claim:

The use of nicotinic acid ... for the manufacture of a sustained release medicament for use in the treatment by oral administration **once per day prior to sleep**, of hyperlipidaemia.

Inventive step:

An inventive step was acknowledged as the claimed dosage regimen "once per day prior to sleep" reduced hepatotoxic side effects of nicotinic acid.

Administration regimen (2/2)

Decision T 1409/06

"The board is of the opinion that **the mere determination of the dosage which yields the best effect does not involve an inventive step when, as in the present case, the effect as such is already known or obvious**. The person skilled in the art is aware that the intensity of a pharmacological effect depends inter alia on the concentration of the active agent. **Finding the optimum dosage is a matter of routine experimentation, which does not require inventive skill**."

Mode of administration

Decision T 0051/93

Claim:

Use of HCG for the manufacture of a non- depot medicament for use in the treatment **by subcutaneous administration** of infertility or male sexual disorders

Prior art:

Use of HCG for the treatment of infertility of male sexual disorders by **intramuscular administration**

Inventive step:

As compared to intramuscular administration, the same therapeutic effect was achieved despite lower HCG blood levels, which was considered non-obvious.

Issues on the enforcement of second medical use claims

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Issues on enforcement

- Are EPC 2000 format claims identical in scope to Swiss-type claims?
- How should the issue of infringement be assessed in (i) the on-label scenario and (ii) the cross-label scenario?
- Relief – Should injunctions be available when infringement is by cross-label use?

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On-label vs cross-label use - How it can arise

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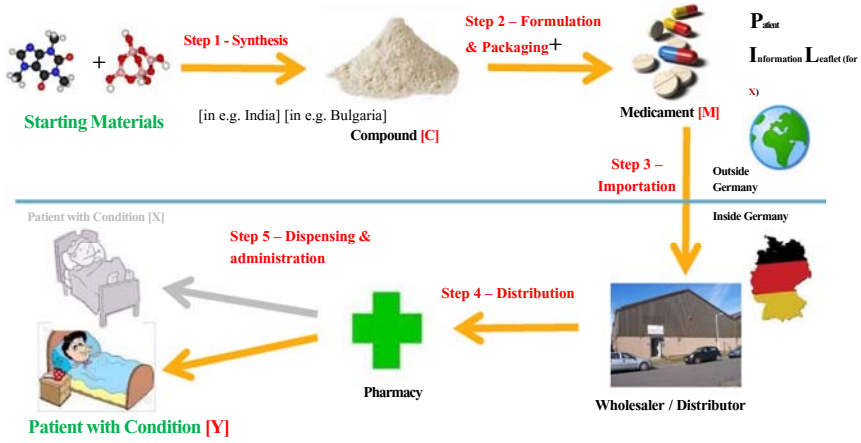
Slide courtesy of Brian Cordery, Bristows

From Starting Materials to Patient:

"Use of compound [C] in the manufacture of a medicament [M] to treat Y"



Second Medical Use Claims UK Case Law

EPLAW Congress

Alex Wilson
Powell Gilbert LLP
22 November 2013

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Construction and infringement of Swiss Form Claims and EPC 2000 Format Claims

- Swiss Form claims are process claims:-

  "use of product X in the manufacture of a medicament for the treatment of indication Y"

- EPC 2000 Claims are product claims:-

  "product X for use in the treatment of indication Y".

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INFRINGEMENT

- **Product claims**:-

  s60(1)(a) Patents Act 1977 (corresponds to Art 25(a) UPCA)

  - by disposing, offering to dispose of using, importing or keeping the product.

- **Process claims**:-

  s60(1)(b) Patents Act 1977 (corresponds to Art. 25(b) UPCA)

  - by using or offering for use the claimed process (subject to knowledge requirements)

  s60(1)(c) (corresponds to Art. 25(c) UPCA)

  - by disposing, offering to dispose of, using keeping or importing a product obtained directly by means of the claimed process.

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Ranbaxy v AstraZeneca [2011]

- Patent covering AstraZeneca (AZ) drug Nexium for treating gastric disorders
- Active ingredient of Nexium is magnesium esomeprazole, a pure isomer of omeprazole (omeprazole is an "old" compound, marketed by AZ as Losec and is a racemic mixture of isomers)
- Patent claims in both Swiss Form and EPC 2000 Form
  - Use of >99.8% [optically pure magnesium esomeprazole] for the manufacture of a medicament for the treatment of a gastric acid- related disease
  - >99.8% [optically pure magnesium esomeprazole] for use in the treatment of a gastric acid-related disease
- Ranbaxy wished to import a generic product with less than 99.8% of the pure isomer
- BUT during manufacture (done outside UK), Ranbaxy used pure isomer before mixing with prior art racemic mixture to reduce its purity.

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Ranbaxy v AZ (contd.)

- Astrazeneca accepted that Ranbaxy product would not infringe EPC 2000 claims
- BUT alleged infringement of Swiss Form claims based on use of optically pure isomer during the process of manufacture
- Infringement on basis of s60(1)(c) Importing a product obtained directly by means of the claimed process
- Question – *is the scope of a Swiss Form claim broad enough to cover the use of the claimed compound during the manufacture of a medicament, even if the claimed compound is no longer present in the medicament itself?*

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Ranbaxy v AZ- Decided

- Skilled reader of patent would know about drafting convention of Swiss Form claims
- EPO jurisprudence on Swiss Form claims: the medicament must contain the claimed ingredient
- The specification of the patent also demonstrated that the invention was the use of the pure isomer (with a conventional carrier) in a medicament
- Conclusion: AZ's broad construction of Swiss Form claims rejected.

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On-label vs. cross-label use

- UK – medical practitioners are encouraged to prescribe by reference to the active ingredient rather than originator brand
- Pharmacist dispenses by reference to ingredient- incentivised by drug reimbursement policy to use generic substitutions
- Where originator has:
  a) expired patent to product *per se*
  b) unexpired patent to a second medical use of the product
  - Can the originator block the supply of the generic drug for the patented use?

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On-label vs cross-label use (contd.)

- On-label use
  - Product information leaflet (PIL) of generic specifically refers to patented use
  - Straightforward: Potentially direct infringement and contributory infringement of the second medical use claims
- Cross-label use
  - Generic carves out of its label any reference to the patented use
  - Limits label to approved indications that are old/not patent protected
  - No **regulatory** prohibition on pharmacist from dispensing generic for all approved indications
  - Is there contributory infringement under s60(2) Patents Act 1977?

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Contributory Infringement

s60(2) infringement by the supply of:-

> "means, relating to an essential element of the invention for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and intended to put, the invention into effect"

(corresponds to Article 26(1) UPCA)

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Cross-label Use (contd.)

- Contributory infringement considered by Court of Appeal in *Grimme Maschinenfabrik v Scott* [2010] EWCA Civ 1110
  - Intention of the ultimate uses important for determining infringement
  - It is enough that it is "inherently probable" that some ultimate users will use the product in the claimed manner
- Also *KCI v Smith & Nephew* [2010] EWCA Civ 1260
  - Claim required use of a clamp on a tube draining fluid from a wound to prevent leakage
  - Defendant supplied apparatus without a clamp and argued that it used a different method to prevent leakage
  - But infringement as court found it probable that some hospital practitioners would use clamps when operating the Defendant's device.
- Suggests that carving out the patented use from the label will NOT be sufficient to avoid infringement?

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Could refusal of injunction be the answer?

- Generally if infringement→injunction granted
- BUT injunctions are equitable and can be refused (eg *Navitaire v Easyjet)* where:
  - Injury to plaintiff's right is small and capable of being estimated in small £
  - Injunction would be oppressive and grossly disproportionate to right protected
- THEN Damages can be awarded instead
- Would require a lowering of the current threshold

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Brinkhof

ADVOCATEN

Second medical use claims

Dutch case law

Mark van Gardingen

Construction Swiss type claims

DC The Hague 29-3-2000 (Judges Du Pon, Bonneur, Driessen), AHP v. Novartis (rapamycine)

—AHP's claim: use of rapamycine for the preparation of a medicament for inhibiting organ/tissue transplant rejection

—Novartis' product: a rapamycine-*derivative* for inhibiting rejection

—Literal direct infringement? AHP: Novartis uses rapamycine to make a derivate for the preparation of a medicament for the patented indication.

Rapamycine (c'd)

—Court: Swiss type claim is a purpose-limited product claim: protects (only) the use of rapamycine (not of a derivative) as the active ingredient (not as an intermediate product) of a medicament for the patented indication.

—The fact that the derivative was made by using rapamycine as an intermediate product was irrelevant, therefore.

—Seems in line with UK High Court (Kitchin J) in Ranbaxy v. AstraZeneca (esomeprazole)

Scope: when infringement?

DC The Hague 10 November 2010 (Judges Van Peursem, Kalden, Van Walderveen), Schering v. Teva (ribavirine):

—Schering's claim (summarized): use of ribavirine in combination with pegylated interferon alpha for the manufacture of a pharmaceutical composition for treating a specific subset of patients (naïve patients) having a specific type of hepatitis C infection (genotype 1 with a certain 'viral load' in serum), according to a specific administration regimen (40-50 weeks).

Ribavirine (c'd)

- Teva's product: ribavirine for treating patients with chronic hepatitis C infection. Teva 'carved-out' the patented indication from the SmPC under the heading "approved indications": (i.a.) *"... except for genotype 1"*.
- But: clinical trials relating to the patented indication were mentioned under the heading "pharmacodynamic properties".
- Schering: referring to the patented indication qualifies as direct infringement.

Ribavirine (c'd)

Court:

"Teva does nothing more than practicing the prior art. The current market authorizations allow her to trade generic ribavirine for use in a known combination therapy in a known dosage regimen of 6-12 months, but she has excluded the specific patient category (naïve and having genotype 1 infection) claimed by Schering. That is sufficient to fall outside the protective scope of the patent. In other words: Teva does not have a market authorization to manufacture generic ribavirine for the specific indication claimed in the patent."

(intermezzo: Carve-out)

- Carve-out of patented indications allowed ex Art. 11 Directive 2004/27/EC (amending 2001/83).
- Exception to the rule that the SmPC should provide for complete and sufficient information about known activity/-ies of a substance, for reasons of adequate patient information and public health.
- Dutch MEB requires a standard passage in case of carve-out (drafted by CMD(h)): "*This substance is also authorised to treat other conditions not mentioned here. Ask your doctor or pharmacist.*"
- DC Arnhem 11 February 2012 (lansoprazole): standard passage necessary for adequate information, no invitation to infringe a patent.

Back to ribavirine (c'd)

BUT:

Court also mentions:

"This [=non-infringement] could be different in the hypothetical situation – which is not the case here – that it had been proven that because of the clinical research mentioned in [the the pharmacodynamic chapter of the SmPC] and the conclusions from that research, Teva's generic ribavirine – induced to it or not – would nevertheless also be prescribed for naïve patients having a genotype 1 infection".

Indirect infringement: intention

PI Judge DC The Hague 18 October 2010 (Judge Blok), Safeway v. Kedge (glued roof anchor)

—Kedge's claim (summarized): a safety device for fall protection (roof anchor) comprising a flexible floppy flap to be glued to roof to bring about a firm and reliable connection *without puncturing the roof*.

—Safeway's product: a roof anchor with a flexible floppy flap and a pre-punctured metal plate with screw bolds, and user instructions explicitly requiring the user to screw the anchor in the roof.

Glued roof anchor (c'd)

- PI Judge: If it would turn out and become known to Safeway that end-users go against the instructions and just glue the anchor to the roof, Safeway could still *indirectly* infringe Kedges patent. Not because Safeway can be blamed for her end-users not following the instructions, but because Safeway then trades a product of which it knows or it is obvious that end-users despite the strict user instructions will nevertheless use the product to infringe Kedge's patent.
- Seems in line with UK CoA in Grimme v. Scott

How to avoid infringement?

If non-infringing use is possible (no compound protection), is an order to refrain from *any and all* trade of the product appropiate/proportional?

What more could be done to avoid infringement?

—Consider 'compound patent-free' substances as 'staple goods' (incitement required for indirect infringement)?

—(If possible) sales volume cap for generic products, to stay within objective and reasonable predictions/forecasts?

—Informing doctors, pharmacists, insurers?

Denmark – Preliminary Injunction
Second medical use claim

Danish Preliminary Injunction (PI) Claims

•PI claims must be clear enough to directly enforce

•Violation of PI subject to penalty – clarity required

•PI claims normally specify injuncted acts

PI obtained for second medical use claim

•Terfinadine was a compound known

DK – PI obtained – "on-label" (non-medical)

PI obtained for second medical use claim

•Terfinadine was a known anti-histamine (allergy) pharmaceutical but suspicion that it could cause heart arrhythmia

•Patent claim obtained for metabolite fexofenadine known for allergy treatment:

"Use of a composition comprising [fexofenadine] for the preparation of a medicament for use in a treatment of allergic rhinitis in which the induction of cardiac arrhythmia is avoided, said treatment comprising administering a pharmaceutically effective amount of [fexofenadine] to a human patient whose hepatic function is not impaired".

DK – PI obtained – "on-label"

SmPC for Gx product

•Stated *inter alia*:

•"doses up to 800mg/day did not show adverse"

•"Maximum dose has not been determined"

•"No QTc-interval changes were seen" at certain doses

•"32 times the therapeutic dose did not affect the delayed corrected K+-chanel cloned from a human being"

•

PI obtained

The Bailiff's reasoning and PI ordered

•PI could not cover use of fexofenadine as it was known

•Gx SmPC did not state that it was for hepatically impaired patients so it was directed to patients which are not hepatically impaired

•Only use whereby the induction of cardiac arrhythmia is avoided is covered by the patent, as use as anti-histamine was known

•General statements about doses without adverse effects and maximum doses not found to infringe, as they did not specifically concern heart arrhythmia

•Statements about QTc-intervals and K+-channel not affected found to infringe, as they referred to avoidance of heart arrhythmia

PI proceedings AstraZeneca v. KRKA
Swiss type claim interpreted as method claim

Patent covering AstraZeneca (AZ) drug Nexium for treating gastric disorders

•Patent claims in both Swiss Form and EPC 2000 Form:

"Use of >99.8% [optically pure magnesium esomeprazole] for the manufacture of a medicament for the treatment of a gastric acid- related disease"

">99.8% [optically pure magnesium esomeprazole] for use in the treatment of a gastric acid-related disease"

•KRKA imported a generic product with less than 99.8% of the pure isomer

•BUT it was disputed whether during manufacture KRKA reached pure isomer before ending at <99.8% pure product

PI proceedings AstraZeneca v. KRKA
Swiss type claim interpreted as method claim

Bailiff reasoned

•That the Swiss type claim was to be considered a process for the manufacture of a product

•This was apparently based on her finding that the process for manufacture of the optically pure API was described and that she considered that the API was the main element in the manufacture of the product

•So the Bailiff awarded the Swiss type claim indirect product protection (i.e. for products manufactured by the patented process)

•As it was a process for a *new product*, there was even reversed burden of proof

•But – the bailiff found that KRKA had lifted the burden of proving that they did not reach the 99.8% optical purity during their manufacture, and thus they were not found to infringe

Would cross label use infringe in Denmark Indirect patent infringement

Novozymes v. Danisco - PI

•Patent claim covered (in short) use of specific enzyme granules in steam pelleting of feed

•Danisco delivered such specific enzyme granules to feed mills and promoted their use for steam pelleting – which the mills did

•The enzymes granules could also be used for non-steam pelleted feed (mash) which would not infringe

•Bailiff refused to give PI order for delivery and offering of the enzyme granules as such, because "not all" of the granules were used in an infringing way

Would cross label use infringe in Denmark Indirect patent infringement

Novozymes v. Danisco - PI

•PI ordered against delivery and offering of the enzymes granules while Danisco describe or recommend the patented use (steam pelleting)

•The Bailiff *refused* to give PI order for delivery and offers of the specific enzyme granules *without clearly stating on the products and in marketing that the granules may not be used for manufacture of steam pelleted feed*

•Indicates that cross label use would not infringe

Indirect patent infringement - considerations

What should "intended for" mean in relation to indirect infringement

•The "inherently probable" view of Grimme v. Scott (UK CoA) seems right:

"it was enough if the supplier knew (or it was obvious in the circumstances) at the time of his offer to supply or supply that some (disregarding freak use) ultimate users would intend to use, adapt or alter the "means essential" so as to infringe" (para 112)

•The patent holder should be able to require the alleged infringer to state explicitly that the product may not be used for the patented purpose

•If infringement continues by some customers, perhaps a license/damages should be ordered for that part

European Judges' Forum Venice, 2013

Mock Trial

26 October 2013

Powell Gilbert

IN THE UNIFIED PATENT COURT **File no. UPC (Venice .0001)**
LOCAL DIVISION OF VENICE
BETWEEN:

PHOENIX PHARMACEUTICALS

Claimant

-and-

(1) GENERIKA INTERNATIONAL SPA
(2) GENERIKA IMMUNOLOGY GMBH
(3) GENERIKA METABOLIKA LIMITED

Defendants

UPC Agreement and Rules of Procedure (Draft No 15 / 31 May 2013)

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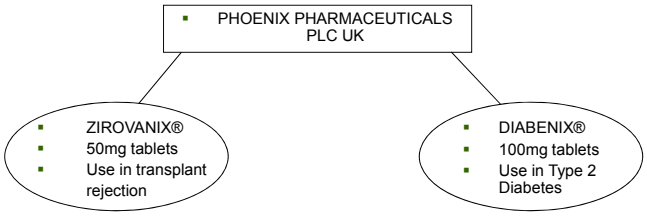
Phoenix

- MAs granted for Zirolimus use in transplant rejection and Type 2 Diabetes
- Patent EP 0 789 123 – second medical use: type 2 diabetes



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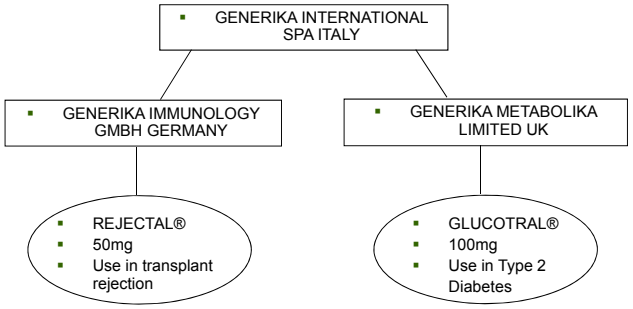
The Generika Defendants



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Cross Label use….

- Pharmacists dispensing 2x 50mg tablets of REJECTAL for use to treat Type 2 Diabetes (= cheaper than 100mg DIABENIX)

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Infringement

- In relation to each Defendant, namely:
  - Generika
  - Immuno
  - Metabolika
- Is the patent infringed, either directly (Art 25) or indirectly (Art 26), by:
  - Manufacture/ supply of Zirolimus?
  - Manufacture/supply of REJECTAL?
  - Manufacture/supply of GLUCOTRAL?
- In the event of infringement should an injunction be granted?

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Invalidity counterclaim

- Lack of novelty / obviousness over
  - "News & Views" article
  - Oral disclosure by inventor Dr Kahn
- Insufficiency ("squeeze")
  - The patent is no more enabling than the prior art disclosures.

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The Local Division of Venice

- **Robert van Peursem (NL) (Presiding)**
- **Véronique Renard (FR)**
- **Eurico dos Reis (PT)**
- **Lotte Wetterling (DK)**
- **Hermann Deichfuß (DE) (Judge Rapporteur)**

Parties represented by:

Claimant / patentee – Dominique Menard, Hogan Lovells, Paris
Defendants / generics - Alan Johnson, Bristows, London

- **The interim decisions….**

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Case Management Issues

- Bifurcation requested - with validity to be referred to the CD and infringement decided (without a stay) (Art 33(3)(b); r 37(4))?
- Evidence be admitted at trial (Art 53)?
  - Production of documents; and/or
  - Cross examination (r 176)
    - Professor Kahn (an inventor)
    - Professor Nodder (Defendant's expert)
    - Dr Whittaker (author of "News & Views" article)
    - Mr Cordery (Defendant's fact witness)
- Leave for late filing of submissions in response
- Arrangements for conduct of the oral proceedings (Art 52(3);r112-113)

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Case management decisions

Venice Division		Group 1	Group 2	Group 3
Bifurcation?	X	X	X	X
Evidence:				
Kahn	Yes	Yes	Yes	Yes
Whittaker	Yes	Yes	Yes	Yes
Nodder	No	No	No	No
Cordery	No	Yes	Yes	No

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Validity

	Venice Division	Group 1	Group 2	Group 3
Validity	Yes Novelty: Evidence of Whittaker/Kahn did not establish that all integers disclosed Obviousness: Evidence not obvious to assume type 2 diabetes from prior disclosure	Yes	No All claims obvious	Yes

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Infringement

	Venice Division	Group 1	Group 2	Group 3
Generika (manufacture of API Zirolimus)	Indirect infringement re supply to Metabolika	Indirect	Indirect + liable for direct inf by Metabolika as knew of use	Indirect + liable for direct inf by Metabolika as knew of use
Metabolika (Glucotral)	Direct infringement claims 1,2,3			
Immuno (Rejectal)	**No infringement.** Knowledge not proven.	Indirect inf. Had knowledge x-label use	Either direct or indirect Had knowledge x-label use	Indirect inf Majority viewed knowledge proven

Relief for cross-label infringement?

- Concern that injunction not appropriate, should be able to supply for non-infringing use
- Agreement that discretion should be applied re grant of injunction
- Various options:
  - Cap on sales per annum to cover non-infringing use
  - Payment of royalty on non-permitted use
  - Warning label to pharmacists ….

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Any better suggestions ?

PS….**Lessons from applying the UPC Agreement /draft RoP**

- None of the (mixed nationality) groups of judges would bifurcate
- Many of the differences in the decisions depended on the approach to admitting evidence – indicates the importance of the case management decisions (judge rapporteur) in the interim stage.

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