BRISTOWS

# Fordham IP Conference 2013

# Supplementary Protection Certificates

## Part Two: Other Issues

Friday 5th April

Brian Cordery, Partner
Bristows, London

# Other Contentious Issues Relating to Supplementary Protection Certificates

- SPCs for Second Medical Uses?
- SPCs based on others' Marketing Authorisations
- Suspended MAs/Adjuvants
- Article 3 of the SPC Regulation – lost in translation?

# SPCs for Second Medical Uses

- It is beyond any doubt that **patents** can be obtained in Europe for further medical uses of known drugs

- But the SPC Regulation would appear on its face not to contemplate SPCs for second and further medical uses:

  " *An SPC may be granted where:*

  *3a...*

  *3b: A **valid authorisation** to place the **[active ingredient]** on the market as a [medicine] has been granted...*

  *3c...*

  *3d: The **authorisation** referred to in (b) is the **first authorisation** to place the [active ingredient] or market as a [medicine]*"

- Early CJEU jurisprudence seemed to confirm this:
  Pharmacia Italia; MIT and Yissum

# SPCs for Second Medical Uses – Neurim Pharmaceuticals

What were the facts?

- Melatonin is a natural hormone – the product *per se* has never been patented
- Melatonin was first authorised for veterinary use in sheep in a medicine called REGULIN®
- Neurim owned an EP containing claims to formulations containing melatonin for treating insomnia in humans
- Neurim marketed a melatonin product under the brand name CIRCADIN®
- The MA for CIRCADIN® was granted in June 2007, less than 5 years before patent expiry
- Neurim applied to the UK IPO for an SPC based on the CIRCADIN® MA

# Neurim Pharmaceuticals – the English Judges disagree

- UK IPO rejected the SPC application on the basis that Neurim failed to fulfil Article 3(d) – the first MA for melatonin related to REGULIN® and so there could be no SPC for CIRCADIN®

Arnold J agreed with the UKIPO:

"*I conclude that the IPO were correct to interpret Article 3(d) as requiring the authorisation in 3(b) to be the first authorisation*"

Jacob LJ disagreed:

"*If Neurim are wrong the SPC will not have achieved its key objects for large areas of pharmaceutical research. It will not be fit for purpose*"

# Neurim

CJEU Decision

- Followed Jacob LJ's view and applied a teleological interpretation to Article 3(d)
- Existence of an earlier MA covering a particular product does not preclude grant of an SPC for the same product which is the subject of a later MA, provided the medicinal product which is the subject of the earlier MA does not fall within the limits of the patent relied on for the SPC application.
- So because the medicinal product (i.e. REGULIN® for sheep breeding regulation) was outside of the scope of the CIRCADIN® patent. Neurim could have its SPC.

Why is the case important?

- Opens the door to second medical use SPCs – "*relevant*" MA is the first MA within the scope of the basic patent

# Is it possible to obtain an SPC based on another's MA?


The issue:

- A has a patent covering drug X
- B obtains an MA for X
- Can A obtain an SPC for X, even if it has no connection to B (it may be a competitor)?

| Reasons for | Reasons against |
|---|---|
| • SPCs purpose is to extend the life of the patent<br><br>• How can IPOs tell if A and B are in a commercial relationship or not? | • A has not been delayed in getting X to market and therefore does not need to be compensated |

# SPCs based on others' MAs
# Eli Lilly v HGS (decision of Warren J dated 3 August 2012)

- HGS have a patent to neutrokine-alpha (upheld by the Supreme Court). The patent has very broad claims.

- Lilly are developing an antibody LY2127399 and applied for a declaration that any application by HGS for an SPC on an MA for this antibody would be invalid

- Lilly sought a reference on two points:
  (i) an SPC could not be sought on the basis for a third party MA;
  (ii) Lilly's antibody was not "*specified or identified*" in the claims of the HGS patent.

# Eli Lilly v HGS

- Strike out refused

- Warren J considered that it was reasonably clear that SPCs could be obtained on third party MAs but decided to tag a reference on to the reference on to the ‘specified’ issue after the trial

- Then the plan was “hijacked” by the Sanofi decision and so a reference was made on ‘specified’ but not on third party MAs

# Other Issues

Suspended MAs

- What is the status of a Swiss MA which took effect in Lichtenstein but which was:

  (a) not accepted by European Medicines Agency?; and
  (b) suspended in Switzerland after grant (AstraZeneca – reference from Arnold J dated 19 October 2012)?

Adjuvants

- Should adjuvants, which have no therapeutic effect of their own, but enhance the therapeutic effect of an antibody, be regarded as "active ingredients"? (GSK – reference from Arnold J dated 21 March 2013)

  (German Court has also made a reference in relation to the meaning of "product" in the Plant Protection Products Regulation – is a "safener", which is added to prevent the harmful action of a herbicide in plants, an "active substance" (Bayer Cropscience AG C-11/13)

# Article 3
# Conditions for obtaining an SPC – lost in translation

# Anglo-Dutch translation guide

| What the British say | What the British mean | What the Dutch understand |
|---|---|---|
| I hear what you say | I disagree and do not want to discuss it any further | He accepts my point of view |
| Quite good | A bit disappointing | Quite good |
| Oh, by the way... Incidentally... | The primary purpose of our discussion is... | This is not very important |
| I was a bit disappointed that... It is a pity you... | I am most upset and cross | It doesn't really matter |
| Very interesting | I don't agree/ don't believe you | They are impressed |
| I'll bear it in mind | I will do nothing about it | They will probably do it |
| Please think about that some more | It's a bad idea: don't do it | It's a good idea: keep developing it |
| I'm sure it's my fault | It is your fault! | It was their fault |
| That is an original point of view | You must be crazy | They like my ideas! |
| You must come for dinner sometime | Not an invitation, just being polite | I will get an invitation soon |

# Article 3 of the SPC Regulation

| What the article says | What most people thought it meant | What the CJEU has now said it means | Comments |
|---|---|---|---|
| a) The product is **protected** by a basic patent in force | Since a product A+B would **infringe** a patent for A, A+B was protected by a patent for A | The product must be **"specified/ identified in the wording"** of the claims of the basic patent | •What does "specified" mean?<br>•Does the inventive concept play any role?<br>•Markush formulae – functional groupings e.g. diuretic |
| b) A **valid authorisation** to place the product on the market as a medicinal product has been granted | For an **SPC for A**, an **MA for A** (alone) had to exist | **Any MA** for any medicinal product containing A (i.e. **an MA for 'A', 'A+B', 'A+C', 'A+B+C')** will suffice | •Is this the correct approach?<br>•What is the basis in the regulation for this? |
| c) The product has not already been the **subject of a certificate** | **One SPC per product per patent (**Biogen) | **One SPC per patent?** | •Did the CJEU mean to change the law?<br>•Reference by Dutch Court in Georgetown |
| d) The authorisation in (b) is the **first authorisation** to place the product on the market | Any earlier MA for the product would be fatal to a later SPC | It is possible to **ignore the first MA** if the medicinal product to which it relates would **fall outside the scope** of the basic patent relied on for the second SPC (Neurim) | •Second medical use SPCs are now a possibility |

# Thank you for your attention

Bristows
100 Victoria Embankment
London EC4Y 0DH
T +44(0)20 7400 8000
F +44(0)20 7400 8050

brian.cordery@bristows.com
www.bristows.com

*"...this is the third time in 6 months that I have had to refer questions of the interpretation of the SPC Regulation to the CJEU... that this should be necessary demonstrates the dysfunctional state of the SPC system at present. This is primarily due to the poor drafting of the SPC Regulation and the failure of the Commission, Council and Parliament to revise it.* ***Matters have not been assisted, however, by the fact that CJ's recent case law has not provided the level of clarity and consistency that is required****."*

BRISTOWS