Fordham IP Conference
1 April 2016
Second Medical Use

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Joint Head of Patent Litigation
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Agenda

1. Very brief reminder of the basics
2. Major European cases – status and future developments
3. How should second medical use claims be construed?
4. Remedies and Practical Solutions
Brief Reminder of the Fundamentals

Two types of claims for second medical use inventions in Europe:

1. **Swiss-type claims** (purpose-limited process claims)
   “Use of drug X in the manufacture/preparation of a medicament for the treatment of disease Y”

2. **EPC-2000 claims** (purpose-limited product claims)
   “Drug X for the treatment of disease Y”

- Claims are not the same in scope (T1780/12 – University of Texas)
- Cannot amend from one to another
- Swiss-type claims have not been granted in Europe from 2010 onwards (but will still be included in patents until circa 2035)
Status of Main European Cases (1)

Lyrica (pregabalin):
Pfizer’s patent with Swiss-type claims to the use of pregabalin in the treatment of pain

- PI refused by the High Court against Actavis (Jan 15); NHS Guidelines ordered by the High Court (Feb 15); PI considered and refused (by the Court of Appeal (May 15)); Patent held invalid (mostly) and not infringed (by the High Court (Sept 15); PI granted against Sandoz (Nov 15); Appeal starting 24 May 2016

- Several Gx submitted bids in “open house tenders” (not limited to non-patented indications). PI granted in April 15

- PI refused against Sandoz (Oct 15)

- PI against several generics refused by the Barcelona Court (June 15); Appeal decision expected in summer 2016.

- PI granted against several pharmacies to prevent cross-label use of Gx pregabalin for pain (June 15); PI rejected against Krka

- No litigation but guidance issued in September 15 that physicians should prescribe Lyrica for pain and appropriate reimbursement would be given
Status of Main European Cases (2)

Alimta (pemetrexed): Eli Lilly’s patent with Swiss-type claims to the use of pemetrexed disodium + Vitamin B12 for the treatment of cancer

- DNI granted by the High Court (May 2014); DNI refused by the Court of Appeal (June 2015); DNI granted re: remitted issue on dextrose by the High Court (February 2016); permission to appeal granted by the Supreme Court. Hearing early 2017?

- DNI refused by the Düsseldorf DC in April 2014; DNI granted by the Düsseldorf Court of Appeal in March 2015; Supreme Court hearing on 24 June 2016.
Status of Main European Cases (3)

Aclasta (5mg zoledronic acid): Novartis’ patent with Swiss-type claims patent to the use of zoledronic acid in a one-yearly i/v administration for the treatment of osteoporosis.

PI refused by the District Court of The Hague (April 2014); PI granted by the Court of Appeal (Jan 15); Main action decision (November 15) dismissed indirect infringement arguments and remitted issue of direct infringement (decision expected late spring 2016)
How Should Swiss-type Claims be Construed?

• Tension between Literal v Purposive construction (Eisai G5/83)

• The manufacturing element of the claim is not novel and not inventive; the invention lies in the new use

• Arnold J. (pregabalin) and Judge van Walderveen (zoledronic acid) are perhaps too focused on the wording “manufacture” and should perhaps see the claims as a multi-step process including manufacture; but also including packaging, labelling, distribution, storage and dispensing (but not the actual administration of the medicine)

• This would be consistent with the purpose of the second medical use regime

• It would avoid a debate about subjective/objective intention on the part of the manufacturer

• It would also obviate some of the otherwise curious results which result depending on when the “manufacture” actually takes place (see next slide)
Construction of Swiss-type claims (cont)

**Pemetrexed**

- Pemetrexed dipotassium made by Actavis; freeze-dried; packaged; labelled
- Supplied to UK wholesaler
- Supplied to pharmacist
- Supplied to Nurse
- Reconstituted with saline
- Administered to the Patient by the nurse

**Pregabalin**

- Pregabalin made by Actavis; packaged; labelled (for the non-patented indication)
- Supplied to UK wholesaler
- Supplied to pharmacist
- Dispensed to patient
- Generally self-administered
Construction of Swiss-type claims (cont)

- If the claim is viewed as a multi-step process claim then:
  i. It avoids the pregabalin/pemetrexed anomaly
  ii. It is more in line with the purpose of the law
  iii. It more closely aligns Swiss-type claims and EPC 2000 claims

- Such construction does not abuse the language of the claim (see s125 PA 1977 “unless the context otherwise requires, the invention shall be taken to be that specified in the claims”)

- Tying the claim to manufacture does not achieve the purpose of absolving the physician/patient anyway
Remedies – A: Remedies as against the generic manufacturer

- Carve-out the patented indication; but how skinny should the label be?
- Injunction for the generic not to sell its skinny label product?
- Financial relief?
- Labelling the product “not for use in [the patented indication]”?
- Restrictions in contracts with suppliers?
- Not to promote its product for the patented indication?
- Not to enter tenders to supply the product for the patented indication?
Remedies – B: Actions of other stakeholders

• Encourage prescription by brand for the patented indication (e.g. NHS Guidelines)

• Indications on prescriptions and appropriate reimbursement (confidentiality concerns are disproportionate?)

• Split tenders

• Software changes so that the HCPs are prompted to prescribe the correct medicine and dispense the correct medicine

• Communications to HCPs

• Access to patient records by pharmacists

• Advertisements placed in publications
Are patents the Appropriate Vehicle to Encourage Research into New Uses for Existing Medicines?

In a word...

NO!
You’re Infringing Several Patents

‘I’M AFRAID IT’S SERIOUS — YOU’RE INFRINGING SEVERAL PATENTS’
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Text in and around the red circle key but difficult to read