Lyrica in the Supreme Court: broader lessons for pharmaceuticals

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The issues before the Supreme Court

- Construction
- Sufficiency and plausibility
- Amendment
- **Infringement**

Infringement – the problem

- How to protect the patented market while giving access to non-patented market
  - Patent grants “monopoly” for manufacture of a product for the designated purpose, not use of the product for the purpose
- 4 objectives to be achieved
  1. Reasonable protection to patentee to reward and incentivise “valuable” new uses
  2. Allow public access to the product for original use
  3. Reasonable legal certainty for those in the Gx manufacturing and supply chain
  4. Autonomy of clinical judgments
     - *Per* Lord Sumption at 82. (Lord Briggs at 155 mentions 1-3)

Infringement – the parties' contentions

- WL - intent relevant - objective test
  - was it foreseeable to Gx manufacturer that more than *de minimis* amounts of product would be used for patented use (with fall back of Gx took all (reasonable) steps to prevent this)
  - problems arising could be dealt with in remedies
- Actavis – intent relevant – subjective test
  - Gx manufacturer must be making the product targeting the patented use

The courts below

- 1st instance – Arnold J – subjective test (not satisfied here)
- CA – foreseeability creates required intention but this is negated where manufacturer takes all reasonable steps to prevent use for patented indication

What did the Supreme Court decide?

- Nothing
- Two (and a bit) tests emerging

Lords Sumption and Reed reject any intent-based test

- Any test based on intention, subjective or objective, "contrary to principle and productive of arbitrary and absurd results"
- If intention of manufacturer is relevant, liability of those downstream is dependent on intent of manufacturer
- If foreseeability is the test, where leakage into patented market is foreseeable (as here), all stock infringes, all subsequent dealings infringe and patentee gets *de facto* extension of expired patent (and this can't be cured in remedies) (Other judges agree)
- CA caveat of "all reasonable steps to prevent leakage negates intention" is a non-statutory defence to infringement which may be desirable but not for Courts to create

The “outward presentation” test of Lords Sumption and Reed

- “The physical characteristics of the product as it emerges from the relevant process, including its formulation and dosage, packaging and labelling and the patient information leaflet …”
- “It strikes a fair balance between the public interest in rewarding the invention by allowing the patentee to exploit his monopoly and the public interest in the free use of the invention for therapeutic uses which do not have, or no longer have, patent protection. In my opinion, it satisfies all four policy objectives …which I summarised …above”
- Accepts that this may give insufficient protection to patentee (a concern expressed by the Court of Appeal) “but there is no perfect solution”

Outward presentation test rejected by Lords Briggs and Hodge

- Purpose limitation in Swiss form claim involves a mental element on the part of the manufacturer
- “Striking” that not advocated by any parties/interveners until prompted by the Court after the hearing.
- “Plainly” affords inadequate protection the patentee.

The “subjective intention” test of Lords Briggs and Hodge

- What was Gx manufacturer’s intent? Was it to “serve (and profit from” the patented market?
- “Packaging, labelling and patient information leaflets will in most cases be the best evidence” but other evidence (eg documentary disclosure, quantities manufactured) might prove the requisite intent.

Lord Mance doesn’t want to give a view

- I am the “swing” voice, and it is with some unwillingness that I pronounce on the issue at all. All our remarks on it will be obiter, and it is often better to leave a truly contentious and difficult issue to a case where it matters… My own view has swung between the two sides”
- Rejects subjective intention and foreseeability for reasons given by Lords Sumption and Reed
- “A process leading to a composition or product, which does not make clear that its permitted use is limited will infringe”
- Doesn’t fully endorse outward presentation, apparently (but not expressly) because it can lead to patentee’s interests being ignored
- “I prefer however to leave open whether there might be some circumstances in which a generic manufacturer could or should be expected to go further, by a notice positively excluding the patent-protected use” (if permitted by regulatory law)”

Lord Mance sees the problems but doesn't have a solution

- "The delicate and difficult question is how far surrounding circumstances or general knowledge may be relevant, if in their light it is obvious or easily ascertainable that the process results in a product which, despite packaging and instructions making clear that it is for the non-patent-protected use, is destined for such use."
- "Because context is all in the law, I also think that we should be careful about committing ourselves in obiter remarks in relation to other extreme cases not now before us."
- How "extreme" are these cases? How different from the subjective intention test is this approach likely to be in practice?

So what are the lessons to be learned?

- Foreseeability (and mitigation of its problems through remedies) is not the test
- If “skinny label” approach is used by Gx, in many cases that will suffice to avoid liability under either outward presentation or subjective intention test
- There may be cases where the facts will justify liability being found but the burden will be heavy
- It’s really hard

Policy implications/other issues

- Will there be prescribing guidance in future from Secretary of State?
- Will cross-undertakings in favour of GX and/or Government be enforced and, if so, with what result?
- Will there be further cases and how will future case law develop? The importance of disclosure.
- How will the elevation of Lord Kitchin influence future case law?
- Will the approach be different with EPC 2000 claims?
- How will the UPC deal with this?
- Will the Government take steps (eg by changing prescribing/dispensing rules) to achieve the balance required?
- Will the decision undermine development of second medical uses?