TRAINING SEMINAR

PHARMACEUTICALS AND INTELLECTUAL PROPERTY

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PRODUCT AND PATENT LIFECYCLE

by
Russell Bagnall and Danie Dohmen
Patent Litigation Department
Partners - Adams & Adams
“The law of capital punishment is far more complicated than I portrayed it … A Supreme Court Judge once remarked that the only thicket of similar legal obscurity is patent law”

Richard North Patterson
PRODUCT AND PATENT LIFECYCLE
Main requirements for patentability

- **novelty**—take into consideration all matter (whether a product, process, information about either, or any thing else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description by use or in any other way.

- **inventive step**—(the invention must not be obvious to a person of ordinary skill in the art)
PRODUCT AND PATENT LIFECYCLE

Priority date → Filing date in SA → Market entry → expiry

“R&D” → -1 → 0 → 20
It shall not be an act of infringement to exploit a patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.

Data package exclusivity not applicable in South Africa.
PRODUCT AND PATENT LIFECYCLE

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-1 | 0 | "R&D" | 20

Generic Registration

Grant
The interim interdict

a) A right which is at least prima facie established ("prospects of success at trial");

b) a well grounded apprehension of irreparable harm if the interim interdict is not granted and the ultimate relief is eventually granted;

c) that the balance of convenience favours the granting of interim relief; and

d) that the applicant has no other satisfactory remedy
Generic arguments

- prospects of success at trial weak (usually amounts to an attack on the validity – obviousness)
- do not need to respect invalid patents
- the generic is a company of substance that can pay damages and will keep accurate sales records
- spent money gearing up to launch (or have already launched) – generic will suffer greater prejudice if launched prevented or if removed from market
- trial imminent
- more affordable medicines will become available more quickly
Innovator arguments

- patent prima facie infringed and valid
- sales records of generic cold comfort because damages difficult to prove at trial
- Have to drop price to compete and cannot increase price later if successful at trial
- rapid market penetration that will destroy market created and maintained by innovator (unrecoverable costs)
- Redundancies, redeployment
- the generic will suffer less prejudice by waiting until expiry – should have cleared the way with a revocation application
PRODUCT AND PATENT LIFECYCLE

- 5 products @ R100m per annum
- 1 year left on patent /30% market share
- R2-3 million per case
- R 10-15 million costs to litigate them all
- One success R30 million
PRODUCT AND PATENT LIFECYCLE
PRODUCT AND PATENT LIFECYCLE

- Molecule
  - Crystalline form
  - New indication
  - Salt form
  - Process of Manufacture
  - Formulation
  - Dosing regimen
  - Patent 1
  - Patent 2
  - Patent 3
  - Patent 4
  - Patent 5
  - Patent 6
PRODUCT AND PATENT LIFECYCLE

“Extended life”
Sector inquiry-European Competition commission

- "...strategy documents of originator companies confirm that some of them aimed at developing strategies to extend the breadth and duration of their patent protection"
- "Filing numerous patent applications for the same medicine (forming so called "patent clusters" or "patent thickets") is a common practice"
- "Documents gathered in the course of the inquiry confirm that an important objective of this approach is to delay or block the market entry of generic medicines"
- "In this respect the inquiry finds that individual medicines are protected by up to nearly 100 product-specific patent families, which can lead to up to 1,300 patents and/or pending patent applications across the Member States"
Sector inquiry-European Competition commission

- "... looking from a commercial perspective, a challenger may, in the absence of a Community patent, need to analyse and possibly confront the sum of all existing patents and pending patent applications in those Member States in which the generic company wishes to enter"

- "When the number of patents and in particular of pending patent applications is high (patent clusters), this can lead to uncertainty for generic competitors – affecting their ability to enter the market"

- "Statements in internal documents collected in the context of the sector inquiry point at the awareness by patent holders that some of their patents might not be strong"
“The upshot of all this is that were the patent valid, X’s monopoly in practice would last until 2020. But, as the Judge held and we confirm, it is invalid. And very plainly so. It is the sort of patent which can give the patent system a bad name. I am not sure that much could have been done about this at the examination stage. There are other sorts of case where the Patent Office examination is seen to be too lenient. ... The only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation. Then it can be got rid of before it does too much harm to the public interest”
“It is right to observe that nothing X did was unlawful. It is the court's job to see that try-ons such as the present patent get nowhere. The only sanction (apart, perhaps, from competition law which thus far has had nothing or virtually nothing to say about unmeritorious patents) may, under the English litigation system, lie in an award of costs on the higher (indemnity) scale if the patent is defended unreasonably... “
“The judge had not erred in his approach to inventive step. He had taken into account that there were a number of avenues of research open to the skilled man seeking a solution to the problem and that he would not, therefore, have taken the diol route unless satisfied that there was a real prospect that the necessary reaction would work. The judge had rejected the respondents' evidence that there was a high expectation that the experiment would be a very easy ring closure which would work. Once he had done this, his conclusion that the diol route was not obvious was unassailable”
The essence of the respondents' case was that the skilled man could have come by the invention by doing a short and simple experiment. But that could be said, with hindsight, of many an invention. It was not enough for an experiment revealing an invention to be short and simple. There also had to be a reason why the skilled man would have carried it out. Normally that would require at least an expectation that something might come out of it. Otherwise, short and simple though it would have been, doing the experiment would have been pointless. The judge had rejected the evidence of the respondents' expert who had suggested there was a point, saying “the reaction looked promising”. There was clearly material upon which the judge could do so. The appeal on obviousness failed.”
A substance “for use”

- A new substance
- A first medical use of a known substance
- Second and subsequent uses of a known substance
“3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”
“In the long series of disputes that the implementation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in developing countries has seen, the controversy around protecting test data as provided for under Article 39.3 has few parallels in terms of enduring impact that it could have.”

Biswajit Dhar
None? Thank you!