



Napp Pharmaceutical Holdings Ltd v ratiopharm GmbH  
Napp Pharmaceutical Holdings Ltd v Sandoz Ltd

RSC Law Group  
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## Facts

- EP (UK) 1258246 a Divisional Application from EP (UK) 722730
- 12 hour controlled release form of oxycodone – OxyContin®
- Sales of £32 million per annum in UK
- Generics houses about to receive marketing authorisation
- “Clearing the Way” before launch of the product
- Did generic product infringe?
- Were the claims valid?



## Divisional Applications

- Break up content of original filings into multiple applications
- Generally same text for practicable purposes
- Different claims and corresponding variations of text
- Subject matter of divisional must not extend beyond content of parent
- Each divisional must have different claims
- 9 divisionals stemming from original filing
- Court of Appeal noted problems with current divisional system



## Claim 1 EP (UK) 722730:

A controlled release oxycodone formulation for oral administration to human patients, comprising:

(a) oxycodone salt in an amount equivalent to 10 mg to 160 mg of the oxycodone hydrochloride salt, and

(b) a controlled release dosage matrix, other than an acrylic resin matrix selected so that formulation provides pH-independent dissolution characteristics,

(c) wherein said formulation provides, at steady state after repeat administration at 12-hour intervals, a mean maximum plasma concentration of oxycodone of 6 to 240 ng/ml at 2 to 4.5 hours after administration and a mean minimum plasma concentration of oxycodone of 3 to 120 ng/ml at 10 to 14 hours after administration.



## High Court – Validity – Obviousness

- Useful practical guide as to how to approach the issue of obviousness
- Cites the restatement of the *Windsurfing* questions in *Pozzoli v BDMO SA*
- Sends a message to IP lawyers as to how to plead “common general knowledge”
  - CPD Part 63 PD 11.3(1) and 11.4(1)
  - Need formal exposition in advance of expert evidence stage
  - Cannot follow the Pozzoli approach without this



## High Court – Validity – Obviousness

- It is essential that the starting point of the plea is established to be CGK
- Need to be precise about what is asserted to be CGK
- What are the requirements for something to be CGK?
- Allegations of obviousness in light of CGK alone need to be treated with a certain amount of care
- The CGK does not include knowledge which does not inform the skilled person's approach from the outset
- Dispute in this case centred around what was known about oxycodone
- The risk of hindsight
- Held that the inventive concept of the claims was not obvious in light of the common general knowledge



## C of A - Validity – Added Matter

- Disclaimer added to distinguish from claims of the original application
- Sandoz argued the disclaimer of added matter as it was prohibited by case law of the EPO
- Mere exclusions of subject matter excluded from patentability or accidental anticipations allowable by G01/03
- Court of Appeal agreed with first instance decision
- Acrylic resin matrix disclosed in examples as one suitable matrix
- A divisional disclaimer that just excludes subject matter cannot offend against added matter provisions



## C of A - Infringement

### Claim 6 EP (UK) 722730:

A controlled release oxycodone formulation for oral administration to human patients, comprising:

- (a) an analgesically effective amount of spheroids comprising oxycodone or a salt thereof and a spheronising agent,
- (b) each spheroid being coated with a film coating which controls the release of the oxycodone or oxycodone salt at a controlled rate in a medium.



## C of A - Infringement

- Construction of terms “spheroid” and “spheronising agent” key
- First instance applied purposive construction to “spheroid” but applied a narrow definition to “spheronising agent”
- Court of appeal decide that this approach was inconsistent
- Broad construction applied to both terms
- Generic product satisfied both features on broad construction
- Infringed



## Costs

- Usual starting point - loser pays the winners costs
- An issue based costs award should be applied where practicable in a patent case
- Three questions:
  - Who has won?
  - Has the party who has won lost on a suitably circumscribed issue to make it appropriate to deprive it of costs?
  - Is the case suitably exceptional to go further and make a costs order against the party who has won overall?
- Floyd held that even though Napp were the losing party overall the net result should be that 20% of its costs be paid by Ratiopharm and Sandoz



## Conclusion

- Raises interesting questions on divisionals / added matter / inventive step / costs and infringement
- Issue with divisionals highlighted by the Court of Appeal may well be addressed by changes in procedure at the European Patent Office
- Interesting to note reference to German proceedings in the Court of Appeal



## Any Questions?

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