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# Patchy report from a gynaecology conference is enough to put a bullet in Richter Gedeon's morning after pill patent

## The UK's High Court has decided that Richter Gedeon's patent for a single dose of the emergency contraceptive levonorgestrel is invalid in view of a report published a few months before the priority date revealing the preliminary results from an incomplete study of the drug.

### Background

Levonorgestrel is the active ingredient in the most commonly employed hormone-based emergency contraceptive. The drug is a synthetic version of the natural hormone progesterone.

Levonorgestrel is currently marketed in the UK by Bayer as Levonelle One Step®. Levonelle One Step® is a tablet containing 1.5 mg of levonorgestrel that is 84% effective as an emergency contraceptive when taken as a single dose 12–72 hours after unprotected intercourse.

Richter Gedeon's patent EP (UK) 1 448 207 had three claims. Claim 1 was directed to a pharmaceutical composition of 1.5 mg levonorgestrel (± 0.2 mg), for use as a single dose. Claim 2 was a claim directed to the same dose of levonorgestrel for use in emergency contraception (in 'Swiss' form in order to comply with EPO law against medical treatment claims), and dependent claim 3 limited that dosage regimen of claim 2 to a single application, administered within 72 hours of unprotected intercourse.

The European patent was granted in 2005 and not opposed centrally at the EPO. In order to kill the EP (UK) patent, Mylan launched an action in the UK High Court seeking revocation. The case dealt only with validity. There was no claim for infringement from Richter Gedeon.

### Arguments and judgment

Mylan attacked the patent on two grounds. The primary attack was obviousness, and the secondary attack was insufficiency (non-enabling disclosure). The insufficiency attack was an attempted 'squeeze' argument in case the obviousness attack failed, but since the obviousness attack succeeded, the judgment does not deal with the second attack in detail.

Levonorgestrel was known in the art as an emergency contraceptive. However, the drug was taken in two doses of 0.75 mg, 12 hours apart. The invention in the patent was taking 1.5 mg as one dose. The attack of obviousness concerned a single piece of prior art. This was a report in a special edition of the journal *Gynaecology Forum*, reporting the highlights of a world congress on gynaecology and obstetrics in Washington DC. The article included a short report of a presentation of the initial results of a medical study comparing the effectiveness of a single dose of 1.5 mg levonorgestrel against two other methods of emergency contraception: (i) two-dose treatment with levonorgestrel; and (ii) another contraceptive. Richter Gedeon had supported the study by providing levonorgestrel.

The subject of the report was noticeably close to the claims, but suffered from three deficiencies:

1. The three contraceptive methods compared in the study were simply named A, B, and C. The single dose of 1.5 mg levonorgestrel was not identified, presumably because the study was double-blind.

2. The report consistently stated that the dose of levonorgestrel was 1.5 g (not mg).

3. The report clearly stated that the study was incomplete, so the results could not be relied on. For example, the report stated:

- "This study is still in progress but an interim comparison between the groups was presented by Dr von Hertzen."

- "Dr Glasier advised great caution with [the assumption that a single dose of 1.5 g levonorgestrel was the preferred oral method] as the trial was still incomplete. The last few subjects could alter the data and it was wrong to try to guess which group was which, however tempting this might be."

As regards the unbroken code (formulations A, B and C), the court held that the report still showed that a single dose of levonorgestrel was effective, because the report said that all formulations had similar effectiveness.

As regards the erroneous dose of 1.5 g in the report, Mylan were not able to persuade the court that this would automatically have been read as 1.5 mg. However, Mylan successfully argued that the skilled person would have immediately identified the error and found the real dose elsewhere.

As regards the incomplete nature of the preliminary results, and the consequent caveats at the end of the report, Richter Gedeon attempted to argue that obviousness should be assessed from the view of a medical statistician, who would not have considered the single dose to be effective from these incomplete data. However, the court rejected this argument and held that obviousness should more accurately be assessed from the view of a medical practitioner rather than a statistician. The court held that a practitioner would have considered the one-dose regimen to be a viable form of emergency contraception in view of the report, and that there was then nothing inventive about completing the study. The court held that the invention had been "substantively revealed" as an "obvious likely way forward" by the report.

## Comment

The claims related to a specific dosage regimen (a single dose of 1.5 mg), for a specific medical use (emergency contraception). Notably, the court considered the claim to require the dosage regimen to be "reasonably effective" in the medical application. Inventive step then hinged on whether this effectiveness had been revealed in the prior art, with a reasonable expectation of success. Although the preliminary results in the prior art were not watertight, the court found that the conference disclosure had made the regimen seem viably useful, and the patent was revoked for lacking inventive step.

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