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Patentability

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How can validity be challenged?

- Observations during application phase
- Oppositions
- Revocation proceedings
- Defence to infringement proceedings
- Patent office opinions (e.g. UK)

**GRANTED PATENT
=
VALID PATENT?**

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VALID PATENT?**

NO

(at least, not necessarily)

Europäisches Patentamt European Patent Office Office européen des brevets	
(11) EP 0 702 555 B1	
EUROPEAN PATENT SPECIFICATION	
(45) Date of publication and mention of the grant of the patent: 11.03.1998 Bulletin 1998/11	(51) Int. Cl. 5: A61K 31/505
(21) Application number: 94916236.6	(86) International application number: PCT/EP94/01580
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(54) PYRAZOLOPYRIMIDINONES FOR THE TREATMENT OF IMPOTENCE PYRAZOLOPYRIMIDINONE FÜR DIE BEHANDLUNG VON IMPOTENZ PYRAZOLOPYRIMIDINONES UTILISEES POUR TRAITER L'IMPUISSANCE	
(84) Designated Contracting States: AT BE CH DE DK ES FR GB GR IE IT LI LU NL PT SE	• TERRETT, Nicholas Kenneth Sandwich Kent CT13 9NJ (GB)
(30) Priority: 09.06.1993 GB 9311920	(74) Representative: Moore, James William, Dr. et al Pfizer Limited Ramsgate Road Sandwich Kent CT13 9NJ (GB)
(43) Date of publication of application: 27.03.1996 Bulletin 1996/13	(56) References cited: EP-A- 0 463 756 EP-A- 0 526 004 • BR. J. PHARMAC. vol. 81, no. 4, 1994 pages 665 • STJ A. BOWMANN ET AL. 'Cyclic GMP mediates neurogenic relaxation in the bovine retractor penis muscle' • AM. J. PHYSIOL. vol. 264, February 1993 pages H419-H422 P. TRIGO-ROCHA ET AL. 'Nitric oxide and cGMP: mediators of pelvic nerve-stimulated erection in dogs'
(73) Proprietors: • Pfizer Limited Sandwich Kent CT13 9NJ (GB) Designated Contracting States: GB • Pfizer Research and Development Company, N.V./S.A. Dublin 1 (IE) Designated Contracting States: BE CH DE DK ES FR GR IE IT LI LU NL PT SE AT	(72) Inventors: • ELLIS, Peter Ramsgate Road Sandwich Kent CT13 9NJ (GB)
Remarks: The file contains technical information submitted after the application was filed and not included in this specification	
Notes: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).	

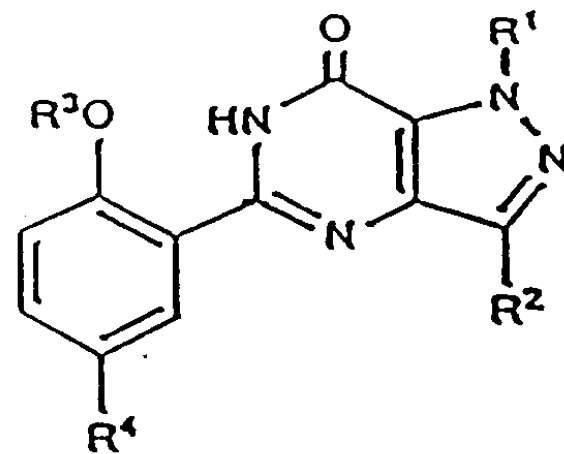
EP 0 702 555 B1



EP 0 702 555 B1 (Pfizer) – the Viagra patent

Claim 1:

“The use of a compound of formula (I):
... wherein R^1 is ... and R^{13} and R^{14}
are ...; or a pharmaceutically
acceptable salt thereof, ..., for the
manufacture of a medicament for the
... treatment of erectile dysfunction in
a male animal, including men.”



EP 0 702 555 B1 (Pfizer) – the Viagra claim

Claim 6:

“... wherein the compound of formula (I) is 5-[2-ethoxy-5-(4-methyl-1-piperazinylsulphonyl) phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7H-pyrazolo [4n,3-d] pyrimidin-7-one.”

(sildenafil)

Viagra: sildenafil citrate, i.e. a pharmaceutically acceptable salt

GB 2 451 598: “Method of weighing luggage”

CLAIMS

1. A method for notifying a passenger of overweight luggage comprising the steps of:
 - I. Entering information relating to a journey for which a passenger has a ticket into a processor;
 - II. Weighing the luggage;
 - III. Comparing the weight of the luggage with the maximum weight of luggage allowed for the particular ticket; and
 - IV. Indicating the level of overweight to the passenger.

How does the jurisdiction affect assessment of validity?

International Agreements

- TRIPS
- Paris Convention
- European Patent Convention
- Patent Co-operation Treaty
- Community Patent Convention
- EU directives and regulations

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

“Subject to [certain exceptions], patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application

European Patent Convention, Article 52(1)

“European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.”

Patentability in the UK: Section 1 Patents Act 1977

A patent may be granted for an invention provided:

- it is new
- involves an inventive step
- is capable of industrial application
- the grant of a patent is not excluded
(e.g. business methods, computer programmes, presentation of information, methods of treatment or diagnosis)

Where might proceedings take place?



European Patents:

A bundle of national patents

Over 30 member states of
the European Patent
Convention

Potential for conflicting
judgments relating to the
same “European” patent

Assessment of validity – legal issues

Novelty

- Does disclosure of a class disclose each of its members?
- Secondary use patents: does the prior art need to teach the secondary use expressly or is it enough that performing the prior art will achieve the benefit of the claimed secondary use?

Inventive step (obviousness)

- What does “obvious” mean? To whom?
- Is it enough to be obvious to try?
- To what extent does the patentee have to demonstrate that the claimed invention works to justify an inventive step?

Assessment of validity – procedural issues

- Disclosure (Keep good records!)
- Expert evidence (Will they say what you want them to?)
- Experiments (All too often useless. Always expensive.)
- Separate validity and infringement courts

Procedural issues – variation within a single jurisdiction

United Kingdom

- Patents Court
- Patents County Court
- Revocation proceedings in the Patent Office
- Patent Office opinions

EP 0 702 555 B1 (Pfizer)

Claim 6:

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UK patent no. GB 2 451 598 B “Method of weighing luggage”

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Thank you

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