Criteria for patentability: a public health perspective

Karin Timmermans

Regional Consultation and Planning Workshop
'Use of TRIPS Flexibilities to Access Affordable ARVs in Asia'
29 May 2012

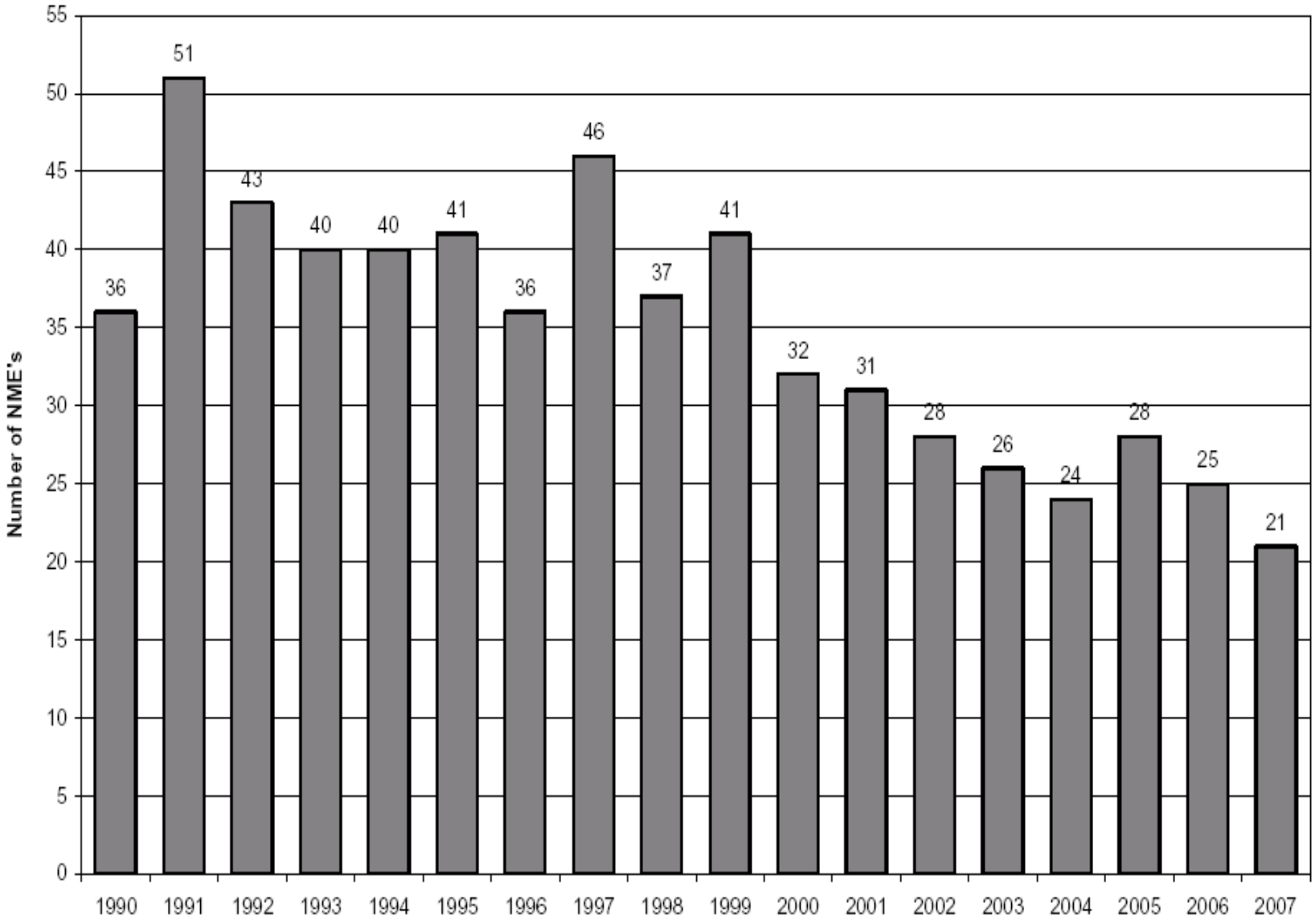
Patents are a public policy tool:

- to reward and promote innovation
- to disclose the invention in order to make it available

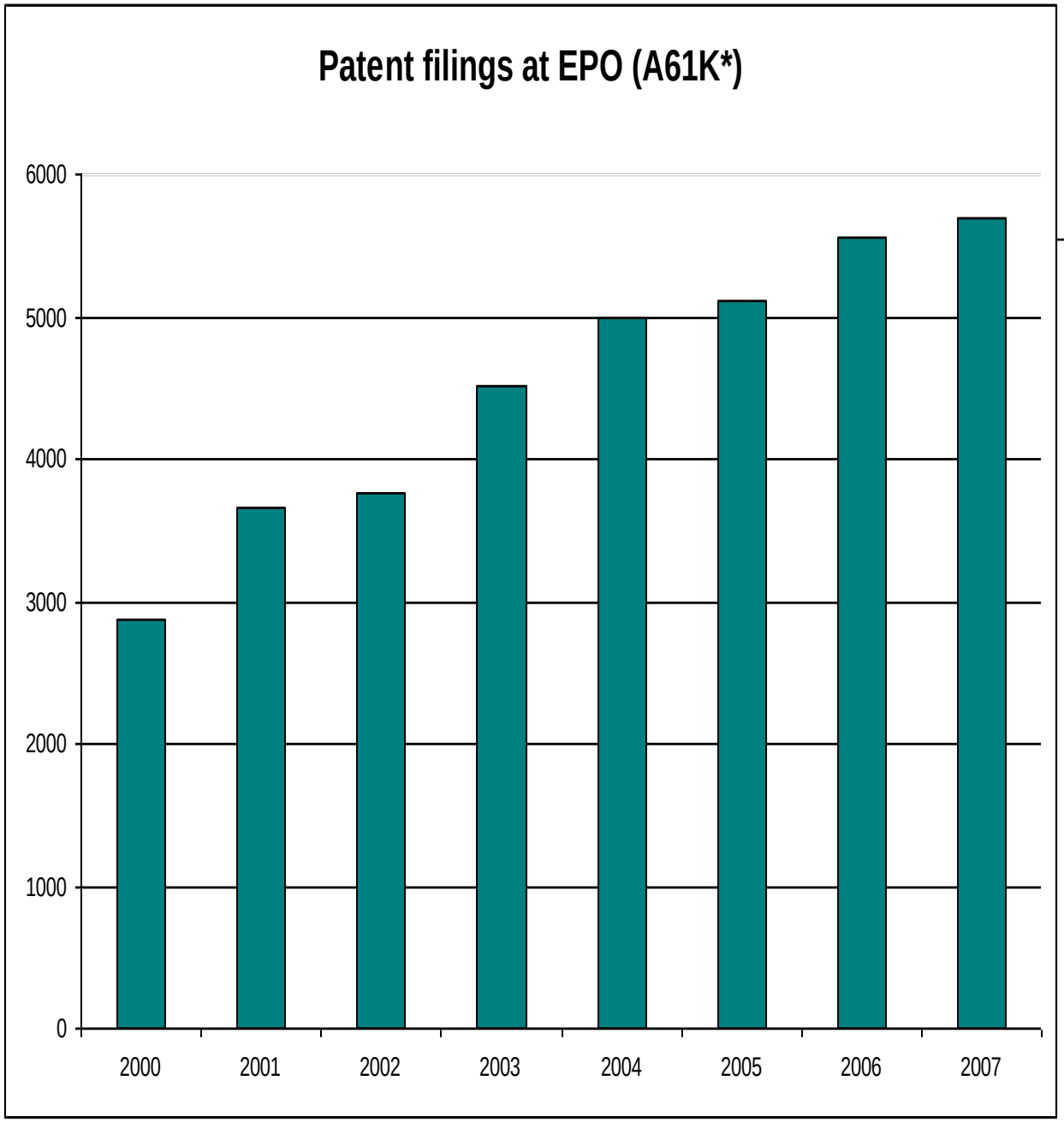
Of 1556 new products developed between 1975 and 2004, only 21 (1.3%) were for tropical diseases and tuberculosis.

Lancet, 2006

Number of new molecular entities (global figure)



From: European Comm. Pharmaceutical Sector Inquiry, Final Report (2009).



From: European Comm. Pharmaceutical Sector Inquiry, Final Report (2009).

Animal Hat Apparatus and Method

Patent Number: 4,969,317

Date of patent: Nov. 13, 1990

Inventor: April Ode, Lake Havasu City, AZ

Patents have been (and still are being?) granted for fairly trivial inventions…

- Patents for such trivial inventions are indicative of relatively low standards for patentability;
- It may be problematic if these same standards are applied to pharmaceutical inventions.

Example: Levofloxacin – patenting of isomers

Patent No.: US 4,382,892
In force until: 2 September 2003

Protects ofloxacin.

Patent No.: US 5,053,407
In force until: 1 October 2008

Claims levofloxacin, the S-(-)- isomer of ofloxacin.

TRIPS Article 27.1

"Subject to the provisions of paragraphs 2 and 3, 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.[5] …"

TRIPS Article 27.1

"Subject to the provisions of paragraphs 2 and 3, 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.[5] …"

TRIPS Article 27.1

"Subject to the provisions of paragraphs 2 and 3, 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.[5] …"

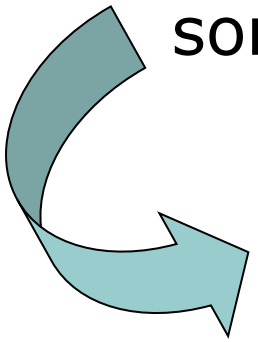
- Note: "inventions", not "discoveries".

Why are patentability criteria important?

- Once a patent is granted, it is presumed to be valid;
- Even a weak patent can “scare off” competitors, or researchers;
- Revoking a patent that should not have been granted usually requires significant expertise, is expensive and can take quite some time.

Why are patentability criteria important?

- Once a patent is granted, it is presumed to be valid;
- Even a weak patent can "scare off" competitors, or researchers;
- Revoking a patent that should not have been granted usually requires significant expertise, is expensive and can take quite some time.



In the meantime, patients may suffer due to lack of (access to) medicines.

Common pharmaceutical patent claims

- Formulations: claiming a particular dosage form or formulation (tablet, ointment, syrup, controlled release tablet, etc.) of an active ingredient
  - necessary to properly administer the drug
- Compositions: claiming the combination of an active ingredient with pharmaceutical carriers or excipients (binders, lubricants, fillers, disintegrants, etc.)
  - necessary for manufacturing
  - improve stability, disintegration, bioavailability

Examples

- Formulation claim:

  An encapsulated, extended release formulation of venlafaxine hydrochloride comprising a hard gelatin capsule containing a therapeutically effective amount of spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and hydroxypropylmethyl-cellulose coated with ethyl cellulose and hydroxypropylmethylcellulose.

- Composition claim:

  A pharmaceutical composition comprised of from 1% to 20% by weight of ezetimibe; from 1% to 80% by weight of simvastatin; and from 0. 01% to 2% by weight of BHA.

Common pharmaceutical patent claims

- Salts, ethers and esters: claiming a particular salt, ether or ester of a known active ingredient
  - salts/ethers/esters affect the solubility (in water/lipids) or stability of an active ingredient
  - thus they affect bioavailability

Common pharmaceutical patent claims

- Salts, ethers and esters: claiming a particular salt, ether or ester of a known active ingredient
  - salts/ethers/esters affect the solubility (in water/lipids) or stability of an active ingredient
  - thus they affect bioavailability

- ➔ These are well-known pharmaceutical techniques;
- ➔ Generally speaking they are not inventive;
- ➔ They should normally not be patentable

Common pharmaceutical patent claims

- Combinations: claiming combinations of known active ingredients.

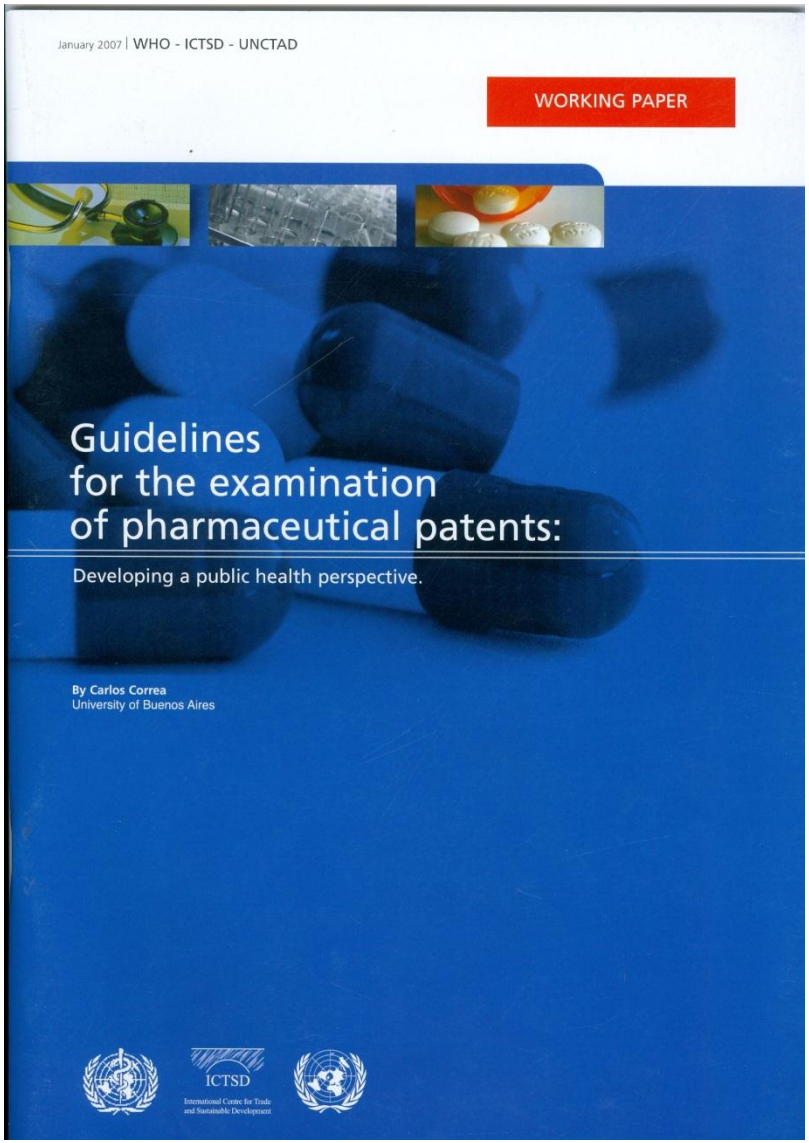
  Combinations can have a synergistic effect, which can be advantageous. Moreover, a combination product may be convenient for the patient (and thus enhance compliance).

- ➔ Often the advantages of a combination product (incl. synergy), as well as the techniques to produce it, are obvious;
- ➔ If so, they should not be considered patentable.

Other types of pharmaceutical patent applications that merit a critical look:

- dosage/dose
- active metabolites
- polymorphs
- isomers
- prodrugs
- method of treatment
- new use/new indications

For more detailed information and more examples, see working paper "Guidelines for the examination of pharmaceutical patents".



Available at:

http://ictsd.net/downloads/2008/06/correa_patentability20guidelines.pdf

To sum up:

Low (or flexible) patentability standards:

- may delay competition and complicate access to medicines;
- could perpetuate the problem of insufficient innovation in the pharmaceutical sector (by rewarding trivial inventions).

To sum up:

Low (or flexible) patentability standards:

- may delay competition and complicate access to medicines;
- could perpetuate the problem of insufficient innovation in the pharmaceutical sector (by rewarding trivial inventions).

Perhaps it is time to rethink??