

# & The unbearable pleasures of patenting in life sciences



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# & The issues

- There are three developments in patenting in life sciences which are worth discussing:
  - Statutory harmonization
  - How statutory harmonization leads to diversity in case law
  - How use of the patent system is perceived as being unfair and what is even more, anticompetitive

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## & Statutory harmonization

- Apart from the unifying influence of the European Patent Convention (EPC) and the Community Patent Convention (CPC), there was also a perceived need to harmonize patentability of certain categories of inventions:
  - Biotechnological inventions (Dir. 98/44/EC)
  - Computer-related inventions (draft directive which never became directive)
- Why only those categories one may wonder?

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## & Statutory harmonization

- Has harmonization in specific technology sectors led to actual and effective harmonization?
- No, in view of unclear provisions of the statute (political compromise)
- Example: biotechnological inventions

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## Plants

- Art. 4 Directive 98/44/EC:
- "1. The following shall not be patentable:
  - (a) plant and animal varieties,
  - (b) essentially biological processes for the production of plants and animals.
- 2. Inventions which concern plants or animals may be patented if the technical feasibility of the invention is not confined to a particular plant or animal variety.
- 3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process."

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## Essentially biological processes for the production of plants

- Art. 2 Directive 98/44/EC:
- "1. For the purposes of this Directive,
  - (a) 'Biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.
  - (b) 'Microbiological process' means any process involving or performed upon or resulting in microbiological material.
- 2. **A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.**
- 3. [...]"

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## Relevant provisions

- Art. 53(b) EPC: [European patents shall not be granted in respect of:]  
(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.
- Rule 23(b)(5) EPC1973 (Rule 26(5) EPC 2000): A process for the production of plants or animals is essentially biological **if it consists entirely of natural phenomena such as crossing or selection.**

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## Referral EBA

- T 0083/05, EP 1069819
- Claim 1 main request oral proceedings TBA:
  - “A method for the production of Brassica oleracea with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, which comprises:
    - (a) **crossing wild Brassica oleracea** species selected from the group consisting of Brassica villosa and Brassica drepanensis with broccoli double haploid breeding lines;
    - (b) **selecting hybrids** with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, elevated above that initially found in broccoli double haploid breeding lines;

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## Referral EBA

- (c) **backcrossing and selecting plants** with the genetic combination encoding the expression of elevated levels of 4methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both; and
- (d) **selecting a broccoli line** with elevated levels of 4methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, capable of causing a strong induction of phase II enzymes,

**Wherein molecular markers are used** in steps (b) and (c) to select hybrids with genetic combination encoding expression of elevated levels of 4methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, capable of causing a strong induction of phase II enzymes

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## Referral EBA

- T 0083/05 -> G 2/07
- 1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?
- 2. If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

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## Another referral

- Yet another referral - EP 1 211 926, T 1242/06, G 1/08
- 1. Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?
- 2. If question 1 is answered in the negative, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?
- 3. If question 2 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

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## EP 1 211 926

- Claim 1 main request:
- "A method for breeding tomato plants that produce tomatoes with reduced fruit water content comprising the steps of:
  - crossing at least one *Lycopersicon esculentum* plant with a *Lycopersicon* spp. to produce hybrid seed;
  - collecting the first generation of hybrid seeds;
  - growing plants from the first generation of hybrid seeds;
  - pollinating the plants of the most recent hybrid generation;
  - collecting the seeds produced by the most recent hybrid generation;
  - growing plants from the seeds of the most recent hybrid generation;
  - allowing fruit to remain on the vine past the point of normal ripening; and
  - screening for reduced fruit water content as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin."

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## EP 1 211 926

- "15. A tomato fruit of the species *Lycopersicon esculentum* which is naturally dehydrated, wherein natural dehydration is defined as wrinkling of skin of the tomato fruit when the fruit is allowed to remain on the plant after a normal ripe harvest stage, said natural dehydration being generally unaccompanied by microbial spoilage.
- 16. A tomato fruit of the species *Lycopersicon esculentum* characterized by an untreated skin, dehydration of the fruit and wrinkling of the skin, said dehydration being generally unaccompanied by microbial spoilage.
- 17. A tomato plant having the tomato fruit of claim 15 or 16 on the vine."

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## New referrals EBA

- Problem with Rule 23b(5) EO (Rule 26(5) EPC 2000) is:
  - Reference to "essentially biological" in combination with "consists entirely of natural phenomena such as crossing or selection"
  - Two different concepts: essentially  $\neq$  entirely
  - Crossing and selection are not necessarily natural phenomena

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## Morality provisions

- Art. 6 Biotech directive
- Rule 23d EPC (Rule 28 EPC 2000): Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:
  - (a) processes for cloning human beings;
  - (b) processes for modifying the germ line genetic identity of human beings;
  - **(c) uses of human embryos for industrial or commercial purposes;**
  - (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

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## Morality provisions

- Rule 29(1) EPC2000 (Rule 23e(1) EPC1973):
  - The human body, at the various stages of its formation and development ... cannot constitute patentable inventions.

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## Stem cells - WARF

- T1374/04–338, Wisconsin Alumni Research Foundation (WARF) patent application EP 96903521.1 reads:
  - 1. *A cell culture comprising primate embryonic stem cells which (i) are capable of proliferation in vitro culture for over one year, (ii) maintain a karyotype in which all chromosomes normally characteristic of the primate species are present and are not noticeably altered through culture for over one year, (iii) maintain the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) are prevented from differentiating when cultured on a fibroblast feeder layer.*

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## Stem cells to EBA (G 2/06)

- 4 questions to EBA in case T1374/04, Wisconsin Alumni Research Foundation (WARF):
  - 1. Does Rule 23d(c) EPC apply to an application filed before the entry into force of the rule?
  - 2. If the answer to question 1 is yes, does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which - as described in the application — at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?
  - 3. If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?
  - 4. In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: eg derivation from available human embryonic cell lines)?

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## Question 2

- EBA: *"On its face, the provision of Article 6(2) (c) of the Directive and thus also of Rule 28(c) (formerly 23d(c)) EPC is straightforward and **prohibits the patenting if a human embryo is used for industrial or commercial purposes. Such a reading is also in line with the concern of the legislator to prevent a misuse in the sense of a commodification of human embryos** (see the decision of the German Bundespatentgericht (BPatG) of 5 December, 2006, 3 Ni 42/04, point IV 2.2 i.f.) and with one of the essential objectives of the whole Directive to protect human dignity. This concern is also evidenced by the selective policy of the Community in funding stem cell research."*

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## Question 2

- EBA: *"**What needs to be looked at is not just the explicit wording of the claims but the technical teaching of the application as a whole as to how the invention is to be performed. Before human embryonic stem cell cultures can be used they have to be made.** Since in the case referred to the Enlarged Board the only teaching of how to perform the invention to make human embryonic stem cell cultures is the use (involving their destruction) of human embryos, this invention falls under the prohibition of Rule 28(c) (formerly 23d(c)) EPC (compare also the decision of the BPatG of 5 December 2006, 1c cit., points IV 2.1 to 2.3) **To restrict the application of Rule 28(c) (formerly 23d(c)) EPC to what an applicant chooses explicitly to put in his claim would have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claim.** In a case like the present one, where the teaching to obtain the embryonic human stem cells claimed is confined to the use (involving their destruction) of human embryos, the argument raised by the Appellant, namely that the exclusion from patentability would go much too far if one would consider all the steps preceding an invention for the purposes of Rule 28(c) (formerly 23d(c)) EPC, is not relevant."*

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## Question 2

- EBA: *"for the reasons given above, the Enlarged Board of Appeal comes to the conclusion that **the legislators (both the legislator of the Implementing Regulations to the EPC and of the Directive) wanted to exclude inventions such as the one underlying this referral from patentability and that in doing so, they have remained within the scope of Article 53 (a) EPC and of the TRIPS Agreement.***
- *In view of this result, it is not necessary nor indeed appropriate to discuss further arguments and points of view put forward in these proceedings such as whether the standard of ordre public or morality should be a European one or not, whether it matters if research in certain European countries involving the destruction of human embryos to obtain stem cells is permitted, whether the benefits of the invention for humanity should be balanced against the prejudice to the embryo, or what the point in time is to assess ordre public or morality under Article 53a EPC. The legislators have decided, remaining within the ambit of Article 53(a) EPC, and there is no room for manoeuvre."*

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## Question 4

- EBA: *"**When assessing whether a claim contravenes Rule 28(c) (formerly 23d(c)) EPC, technical developments which became publicly available only, after the filing date cannot be taken into consideration.** It cannot be relevant whether later either the applicant himself or others made something further available that would then have allowed the product' to be made in an innocuous manner. Similarly to the case of an invention 'which is insufficiently described in the application as filed to be carried out, lack of any disclosure in the application as filed putting the skilled person in possession of a way to carry out the invention complying with Rule. 28(c) (formerly 23d(c)) EPC cannot be cured by the occurrence of subsequent technical developments.*
- *Thus question 4 must be answered to the effect that it is not of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos."*

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## Stem cells

- Conclusion:
  - An ambiguous provision is susceptible to divergent interpretations
  - EBA has been forced to interpret a provision which was primarily aimed at the member states
  - The interpretation given by the EBA deems hESC research to be contrary to ordre public or morality
  - The EU legislator has expressly declined from making such statements, in view of the subsidiarity principle, and stem cell research as falling within that category

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## Divergent interpretations in case law

- Apart from issues with statutory harmonization, there is also the issue of divergent interpretation by national courts of patentability criteria and/or scope of a particular patent
- Is especially unhelpful in enforcing patents Europe-wide

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## Case

- Example: Angiotech taxol medicated stent patent EP 0 706 376
- Claims at issue:
  - 1. A stent for expanding the lumen of a body passageway, comprising a generally tubular structure coated with a composition comprising an anti-angiogenic factor and a polymeric carrier, the factor being anti-angiogenic by the CAM assay, and wherein said anti-angiogenic factor is taxol, or an analogue or derivative thereof.
  - 6. A stent according to any one of claims 1 to 5 wherein said stent is a vascular stent.
  - 11. A stent according to any one of claims 1 to 5 for treating narrowing of a body passageway.
  - 12. A stent according to claim 11 for treating or preventing recurrent stenosis.

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## Case

- At EPO: patent amended after Opposition
- In UK:
  - first instance -> patent held to lack inventive step (was it obvious to try without any expectation of success)
  - Appeal -> patent lacked inventive step (contained no disclosure saying that taxol was specially suitable for preventing restenosis)
  - House of Lords -> patent is inventive (was it obvious to use a taxol-coated stent to prevent restenosis)
- In NL:
  - In a first case in first instance -> held novel and inventive
  - In another case in first instance -> held novel but partially invalid for lack of inventive step
  - In the first case in appeal -> held novel and inventive, but to lack industrial application, claims can still be amended

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## What is the problem?

- Lack of centralised judiciary leads to divergent and contradictory decisions
- Not only divergent interpretations on questions of fact, but also on questions of law, interpretation of patentability criteria identical in all EPO member states
- Does not create legal certainty
- Brings extra costs with it for patent holders and alleged infringers alike
- Is a cost unduly burdening SME's, and affordable but wasted to multinational companies

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## Anticompetitive practices using the patent system

- On 28 November 2008, the European Commission has presented its Preliminary Report on the Pharmaceutical Sector Inquiry.
- The main findings are that competition in this industry does not work as well as it should. According to the preliminary report there is evidence that originator companies have engaged in practices with the objective of delaying or blocking market entry of competing medicines.

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## & Pharmaceutical inquiry EC

- Nelie Kroes, 28 November 2008:
  - Today the Commission publishes its preliminary report on the competition sector inquiry into the pharmaceutical sector – and we find that competition in this industry **does not** work as well as it should.
  - What could summarise our concerns better than the internal strategy document of a large originator company. It reads: "We identify options to obtain or acquire patents for the **sole** purpose of limiting the freedom of operation by our competitors."

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## & Anticompetitive practices using the patent system

- The report also finds that originator companies have designed and implemented strategies (a "tool-box" of instruments) aimed at ensuring continued revenue streams for their medicines.
- The strategies observed include filing for up to 1,300 patents EU wide in relation to a single medicine (so-called "patent clusters"),
- engaging in disputes with generic companies leading to nearly 700 cases of reported patent litigation,
- concluding settlement agreements with generic companies which may delay generic entry and intervening in national procedures for the approval of generic medicines.
- The preliminary findings of the inquiry also suggest that originator companies develop and practice defensive patenting strategies primarily in order to block the development of new competing products. This can lead to obstacles to innovation, in form of higher costs for competing pharmaceutical companies (e.g. for royalties), or in delays.

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## & Filing patent applications

- Abuse?
- How to tackle through competition law?
- Artificial distinction made by EC between “primary” strong and “secondary” weak patents is not very well substantiated

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## & Litigation

- When is litigation anticompetitive (abuse of dominant position)?
  - Very rare
  - ITT Promedia (T-111/96)
    - Manifestly unfounded
    - Conceived as part of a plan to eliminate competition
  - Astra Zeneca case (abuse of SPC and regulatory procedures)

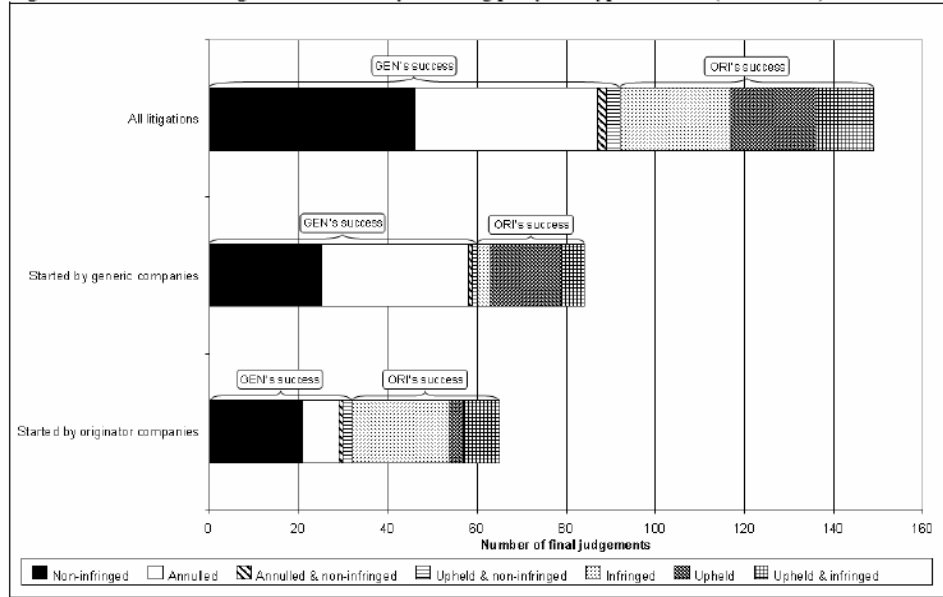
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Figure 72: Outcome of litigation in the EU by initiating party and type of action (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

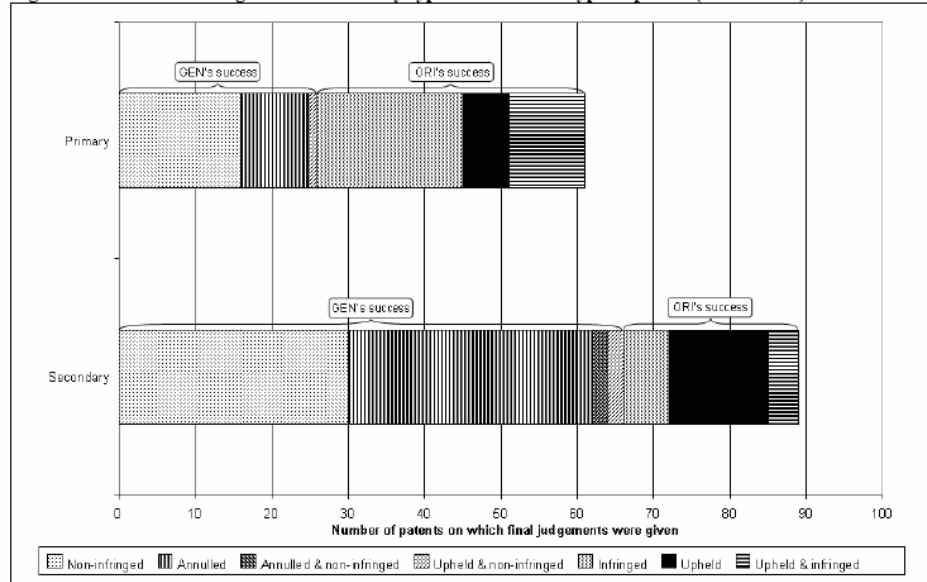
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Figure 73: Outcome of litigation in the EU by type of action and type of patent (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

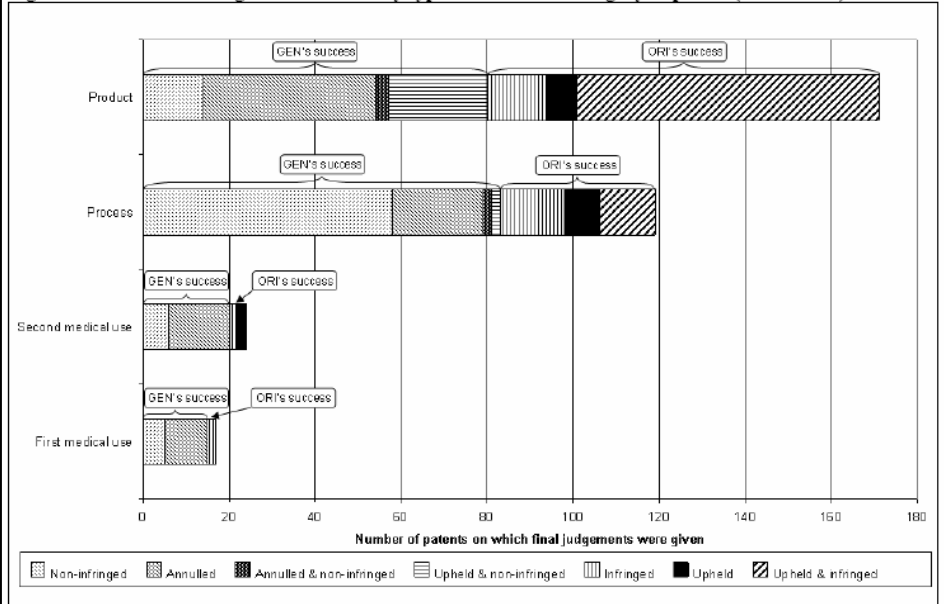
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Figure 74: Outcome of litigation in the EU by type of action and category of patent (2000 - 2007)



Source: Pharmaceutical Sector Inquiry

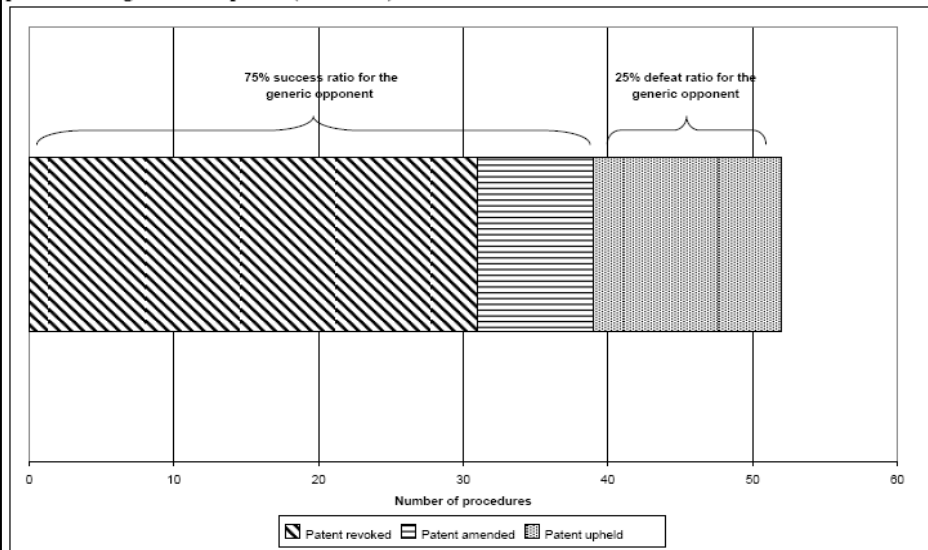
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Figure 88: Final outcomes of opposition and appeal procedures involving generic companies against the patents of originator companies (2000-2007)



Source: Pharmaceutical Sector Inquiry

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## & Regulatory interventions

- Originators writing to marketing authorization bodies expressing concerns about:
  - Infringing of patent rights
  - Generic medicines not equivalent
  - Health risks for patients
- Sometimes requesting that no authorization is granted or that the application is not examined
- Is said to be a tactic to delay generic market entry
- Commission claims to have evidence of patent linkage practices

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## & Settlements

- Issue is so-called "reverse payments" in settlement -> payments by patent holder to generic challenging the validity of the patent
- Is that a competition law issue?
  - The argument made is that with reverse payment, originator profits will be lower than with full monopoly, but higher than in a situation of full competition between originator and generic

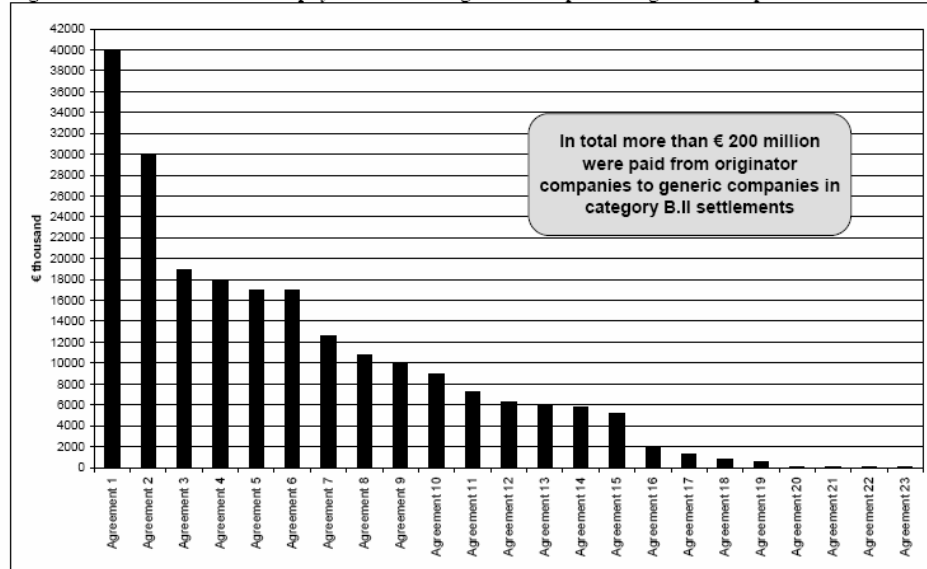
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Figure 104: Total value of direct payments from originator companies to generic companies



Source: Pharmaceutical Sector Inquiry

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## & Anticompetitive practices using the patent system

- Will the EC be able to carry out the ambitious agenda?
- How will it carry out the agenda?
- What will be the consequences for the patent system?
- Where will the solution be found?
  - In the patent system
  - In the regulatory system
  - In competition law
  - Combination of the above

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Thank you for your attention!

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