



# Patentable Subject Matter

## Recent and Upcoming EPO Enlarged Board of Appeal Decisions

**Andrew Bentham**

[abentham@jakemp.com](mailto:abentham@jakemp.com)

**J.A.KEMP & CO**

# Introduction

- Patentable/Unpatentable Subject-Matter under the EPC
- The EPO's Enlarged Board of Appeal
- Current/Recent Patentability issues
  - Stem Cells – Morality
  - Dosage Regimes
  - Methods of Surgery
  - Software (& Business Methods)
  - Plant Breeding
- Conclusions

# Patentable Subject-Matter

- 35 USC 101 – Patentable Inventions

*Whoever invents or discovers **any new and useful** process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor...*

- Canadian Patent Act, Section 2

*“invention” means **any new and useful** art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter ...*

- Compare with Article 52(1) EPC

*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 ...*

# Unpatentable Subject-Matter

- **But** – Articles 52(2) and 53 EPC: exclusions for (diverse) policy reasons
  - Discoveries, scientific theories and mathematical methods
  - Aesthetic creations
  - Schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers
  - Presentations of information
  - Inventions the commercial exploitation of which would be contrary to “ordre public” or morality
  - Plant or animal varieties or essentially biological processes for the production of plants or animals
  - Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body
- How are these interpreted as technology develops?

# Enlarged Board of Appeal

- “Supreme Court” for EPO
  - Widely followed/respected by National Courts
- Answers significant questions of law
  - Referred by Boards of Appeal
  - By EPO President if Boards “have given different decisions”
  - Not a further instance of Appeal as of right for parties
- Decides the issue, not the case *per se*
  - Regular Board then applies Decision to specific matter in question
  - Case acts as binding precedent going forward
  - “G” Decision codes, e.g. G3/08

# Enlarged Board of Appeal

- Approx 50 issues referred since EPO's inception
- Just 3/4 patentable subject-matter issues in 30yr
  - 2nd Medical Use 1984
  - Plant Varieties 1995, 1999
  - Diagnostic Methods 2005

# Enlarged Board of Appeal

- Recent/Upcoming Enlarged Board Decisions
  - Stem Cells – Morality (G2/06) November 2008
  - Dosage Regimes (G2/08) February 2010
  - Methods of Surgery (G1/07) February 2010
  - Software (G3/08) May 2010
  - Plant Breeding (G2/07, G1/08) Late 2010?
- 5/6 patentable subject-matter cases in just 2yr?
  - Diverse sectors: Biotech, Pharma, Med tech, Software, Agriculture

# Stem Cells – Morality

- Art 53(a) EPC excludes *inventions ... contrary to ‘ordre public’ or morality...*
- Rule 28(c) EPC implements this to preclude claims to *use of human embryos for industrial or commercial purposes*
- WARF/Thomson – basic case on human embryonic stem cells (hESCs)
  - No such uses **claimed**: claims were to cells as **products**
  - But only **method disclosed in application to obtain** hESCs required use of embryos
  - Examining Division: so claims to hESCs as products **do** constitute “use” of human embryo for industrial purposes



# Stem Cells – Morality

- Application refused, Appeal filed
- Questions to Enlarged Board from Technical Board

*... does [the] EPC forbid the patenting of claims directed to **products** ... 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?***

- Enlarged Board: **Yes**
  - products requiring destruction of human embryo unpatentable

# Stem Cells – Morality

- What about stem cell cases going forward?
  - Issue is not just what is **claimed** but also what was **invented**
- But otherwise, Enlarged Board Decision (deliberately) narrow
  - Rules out products that can **only** be obtained via the destruction of human embryos, not stem cell inventions in general
  - At WARF's filing date, destruction of embryo was required
- But banked stem cell lines later became available
  - If hESCs from a stem cell bank, claims allowable – no embryos destroyed to make invention?
  - Or unallowable – **creation of bank** originally required destruction
  - UK-IPO practice note – **allowable in UK national** filings
  - EPO examination – heterogeneous ...

# Dosage Regimes

- Art 53(c) EPC excludes *methods for treatment of the human or animal body by ... therapy*
- Imagine compound X known to relieve headaches, but is later found to be useful in treating cancer
- Two “second medical use” claim formats permitted

***G5/83\****                      *Use of X in the manufacture of a medicament for use in the treatment of cancer*  
(“*Swiss-style*”)

***EPC2000***                      *X for use in the treatment of cancer*

\* The Enlarged Board’s first case, consolidated with G1/83 and G6/83

# Dosage Regimes

- Now imagine
  - X known to relieve headaches,
  - Later found more effective against headaches if administered according to new dosage regime, say: 3 days on, 3 days off etc
- Will the EPO allow second medical use claims if the only new feature is the dosage regime?
- Contradictory case law prior to Enlarged Board referral

# Dosage Regimes

- Questions to Enlarged Board included

*Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented ... for use in a **different ... treatment ... of the same illness?***

*If ... yes, is such patenting also possible where the **only novel feature ... is a ... dosage regime?***

# Dosage Regimes

- Enlarged Board's answers

**Yes:** the second medical use does **not** have to relate to a different disease state

– So can now claim:

*X for use in the treatment of headaches, wherein treatment is according to the dosage regime: 3 days on, 3 days off, etc.*

# Dosage Regimes

- Enlarged Board also ruled out (after notice period yet to begin)
  - Original “Swiss-form” claims

*Use of compound X in the manufacture of a medicament for use in the treatment of disease Y*

- In favour of EPC2000 format

*X for use in the treatment of cancer*

Other countries have also adopted Swiss-form claims!

- UK-IPO has announced it will object (effective, 26 May) to Swiss-form for lack of clarity, allow replacement with EPC2000 format pre-grant
- Continue to draft both types for global prosecution

# Methods of Surgery

- Art 53(c) EPC excludes  
*... methods for **treatment** of the human or animal body by **surgery***
- Imaging methods raise questions
  - Direct injection of contrast agent to heart for real-time feedback in open-heart situations
  - Agent is imaged, serves **diagnostic purpose**
  - Injection into heart = surgical in nature ... possibly yes?
  - Is a method **of treatment by surgery** claimed... maybe no?



# Methods of Surgery

- Questions referred to Enlarged Board included:

*Is a claimed imaging method for a diagnostic purpose ... which comprises or encompasses a step [of] physical intervention practised on the human or animal body ...to be excluded ... as a ‘method for treatment of the human or animal body by surgery’ ... if such step does not per se aim at maintaining life and health?*

# Methods of Surgery

- Enlarged Board's answers – surgery defined as:

*A ... method, in which ... **maintaining the life and health** of the subject is important and which comprises or encompasses an **invasive step representing a substantial physical intervention** on the body which requires professional medical expertise ... and which entails a **substantial health risk even when carried out with the required professional care and expertise**, is excluded from patentability as a method for treatment ... by surgery ...*

- Exclusion defines **nature of intervention**, not its therapeutic purpose
  - **Non-therapeutic methods** (e.g cosmetic surgery, organ donation) may be excluded
  - Injection into the heart is a potentially risky surgical procedure
  - But **minor interventions** without substantial health risk are not methods of surgery (routine injection, tattooing, piercing, hair removal etc)
  - And methods concerning **only the operation of a device**, are not excluded (e.g. improved method of operation of a pacemaker)

# Software

- Article 52(2) EPC excludes
  - ... mathematical methods ... methods for performing mental acts,  
... or [methods of] doing business, and programs for computers;  
... presentations of information*
- But practice focuses on inventive step as much exclusion *per se*
  - Any “technical” feature satisfies Article 52(2)
  - So many computer-implemented inventions can be claimed in a non-excluded way, e.g. as a computer-implemented method or system
  - But **non-technical** problem/solution (e.g economic/administrative activity) **not part of technical contribution to the art**, only technical features contribute to inventive step
  - Applications that “computerise” a business method or other non-technical activity tend to fail on inventive step
  - What is left after non-technical elements are removed is obvious

# Software

- Referral made to Enlarged Board by **EPO President**
- President asserted Boards of Appeal had given different decisions
  - Required for referral from President rather than a Board
  - ~100 *amicus curiae* briefs!
  - Numerous questions posed
  - Always doubts re whether differences real or perceived ...

# Software

- ... And in fact, no answers given
  - Enlarged Board reviewed case law, found there **was** some divergence, but indicated that

*...case law in new ... fields does not always develop in a linear fashion ... earlier approaches may be abandoned or modified ...*
- So development of the law rather than a conflict within it
- Referral was inadmissible
  - But still some worthwhile commentary and confirmation that the current approach is correct, notably on inventive step
  - (Similar situation to G3/95 re plant varieties)

# Plant Breeding

- Art 53(b) EPC excludes
  - ... plant or animal varieties or essentially biological processes for the production of plants or animals ...*
- Two ongoing referrals to Enlarged Board
  - Broccoli
  - Tomatoes

# Plant Breeding

- “Broccoli” Case
  - Claims relate to method including breeding steps (crossing/selection)
  - But marker **analysis** to speed process up
- Questions to Enlarged Board, *inter alia*

*Does a ... process ... which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains ...an additional feature of a technical nature?*

# Plant Breeding

- “Tomato” Case

*A method for breeding tomato plants ... comprising ...crossing at least one *Lycopersicon esculentum* plant ...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*

- Again, recites steps of crossing/selection

- But (visual) screening at unusual time to determine success of process

- Further questions to Enlarged Board – conjoined with “broccoli”

*Does a ... process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion ... **only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?***



# Conclusions

- Considerable development recently
  - Possibly on broader front than in North America?
  - Less concrete news on software, more on life sciences
  - Impact across diverse technology sectors
  - Broadly good for those sectors, and for legal certainty?
- What next?
  - Plant breeding referrals still to be decided
  - Follow-up Technical Board cases, practice evolution
  - More Enlarged Board involvement to come?



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