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EXCLUSIONS TO PATENTABILITY

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USEFUL RESOURCES

- UKIPO Manual of Patent Practice (MOPP)
 - Section 1: Patentability
 - Section 4: Industrial application
 - Section 4A: Methods of treatment and diagnosis
 - Section 76A and Schedule A2: Biotechnological inventions
 - See also <https://www.gov.uk/government/publications/examining-patent-applications-for-biotechnological-inventions>
- EPO Guidelines for Examination
 - B-VIII, 2: Subject-matter excluded from patentability under Art. 52(2) and (3) [to be excluded from search]
 - G-II: Patentability of inventions (exclusions and exceptions)
 - G-III, 3: Industrial application vs. exclusions under Art. 52(2)
- PCT Applicant's Guide
 - Chapter 7 of Intro to International Phase: Limitations on International Search
- USPTO Manual of Patent Examining Procedure
 - Chapter 2100, Sections 2104-2107

SECTION 1(2), PA 1977

It is hereby declared that the following (among other things) **are not inventions** for the purposes of this Act, that is to say, anything which consists of –

- (a) a discovery, scientific theory or mathematical method;
- (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;
- (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;
- (d) the presentation of information;

but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act **only to the extent that a patent or application for a patent relates to that thing as such.**

ART 52, EPC

(2)The following in particular **shall not be regarded as inventions** within the meaning of paragraph 1:

- (a)discoveries, scientific theories and mathematical methods;
- (b)aesthetic creations;
- (c)schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- (d)presentations of information.

(3)Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein **only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.**

SOME BACKGROUND ON EXCLUDED SUBJECT MATTER IN THE UK

- Aerotel/Macrossan leading case in this area: [Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1 \[2007\] RPC 7](#)
- Selected quotes from Aerotel/Macrossan Judgment:
 - “**The provisions about what are not to be "regarded as inventions" are not easy.** Over the years there has been and continues to be much debate about them and about decisions on them given by national courts and the Boards of Appeal of the EPO. They form the basis of a distinct industry of conferences and are the foundation of a plethora of academic theses and publications. There has also been much political debate too: some urging removal or reduction of the categories, others their retention or enlargement. With the political debate we have no concern – it is our job to interpret them as they stand”.
 - “As the decisions show this is not an easy task. There are several reasons for this:
 - i) In the first place there is no evident underlying purpose lying behind the provisions as a group – a purpose to guide the construction. **The categories are there, but there is nothing to tell you one way or the other whether they should be read widely or narrowly.**
 - iii) Some categories are given protection by other intellectual property laws. **Most importantly, of course, aesthetic creations and computer programs have protection under the law of copyright.** So the legislator may well have formed the view that additional protection by way of patentability was unnecessary or less appropriate.
 - iv) Further, some categories are so abstract that they are unnecessary or meaningless”.

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- Selected quotes from Aerotel/Macrossan Judgment:
 - “The position is different in Europe from that in the USA. Not only is there no equivalent of Art.52(2) in the US Statute but the courts have positively held that the types of patentable invention should be given “wide scope“... The Committee Reports accompanying the 1952 Act inform us that **Congress intended statutory subject matter to “include anything under the sun that is made by man.”** S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)...The endorsement of the “anything under the sun that is made by man” approach led to further expansion of what is patentable in the US. In 1994 the Court of Appeals for the Federal Circuit **decided that computer programs were patentable**, *Re Alappat*, (1994) 33 F.3d 1526, 31 USPQ2d 1545. Then, in 1998, it decided in *State Street Bank v Signature Financial Group*, (1998) 149 F.3d 1368, 47 U.S.P.Q.2D (BNA) 1596 that **business methods as such were too**”.
- Some context: the above quote refers to a time **before US practice became more restrictive**, e.g., see the “**Alice/Mayo test**”.

SOME BACKGROUND ON EXCLUDED SUBJECT MATTER IN THE UK

- Aerotel/Macrossan leading case in this area: [Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1 \[2007\] RPC 7](#)
- Selected quotes from Aerotel/Macrossan Judgment:
 - “The decisions of the EPO Boards of Appeal are mutually contradictory. To say that is not to criticise anyone. On the contrary the Boards of Appeal have each done what they think is right in law – as befits tribunals exercising a judicial function... Our summary of the various approaches which have been adopted is as follows:
 - (1) **The contribution approach**: Ask whether the inventive step resides only in the contribution of excluded matter – if yes, Art.52(2) applies.
 - (2) **The technical effect approach**: Ask whether the invention as defined in the claim **makes a technical contribution to the known art** – if no, Art.52(2) applies. A possible clarification (at least by way of exclusion) of this approach is to add the rider that novel or inventive purely excluded matter does not count as a “technical contribution”. This is the approach (with the rider) adopted by this Court in Merrill Lynch. **It has been followed in the subsequent decisions of this Court, Gale and Fujitsu**. The approach (without the rider as an express caution) was that first adopted by the EPO Boards of Appeal, see Vicom, IBM/Text processing and IBM/Data processor network.
 - (3) The “any hardware” approach: Ask whether the claim involves the use of or is to a piece of physical hardware, however mundane (whether a computer or a pencil and paper). If yes, Art.52(2) does not apply”.
 - **“The fact is that this court is bound by its own precedent: that decided in Merrill Lynch, Gale and Fujitsu – the technical effect approach with the rider**. We think we must apply it as we understand it, namely as set out above. That we will proceed to do”.

THE 4-STEP APPROACH OF AEROTEL / MACROSSAN

- Aerotel/Macrossan leading case in this area: [Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1 \[2007\] RPC 7](#)
- Selected quotes from Aerotel/Macrossan Judgment:
 - *"The approach is in 4 steps:*
 - *"(1) properly construe the claim*
 - *(2) identify the actual contribution;*
 - *(3) ask whether it falls solely within the excluded subject matter;*
 - *(4) check whether the actual or alleged contribution is actually technical in nature".*

THE 4-STEP APPROACH OF AEROTEL / MACROSSAN

- Aerotel/Macrossan leading case in this area: [Aerotel Ltd v Telco Holdings Ltd & Ors Rev 1 \[2007\] RPC 7](#)
- Selected quotes from Aerotel/Macrossan Judgment:
 - “(1) properly construe the claim:
 - No-one could quarrel with the first step – construction. *You first have to decide what the monopoly is before going on the question of whether it is excluded.* Any test must involve this first step”
 - (2) identify the actual contribution;
 - The second step – identify the contribution – is said to be more problematical. How do you assess the contribution? Mr Birss submits the test is workable – it is an exercise in judgment probably involving the problem said to be solved, how the invention works, what its advantages are. *What has the inventor really added to human knowledge perhaps best sums up the exercise.* The formulation involves looking at substance not form – which is surely what the legislator intended.
 - (3) ask whether it falls solely within the excluded subject matter;
 - The third step – is the contribution solely of excluded matter? – *is merely an expression of the "as such" qualification of Art.52(3).*
 - (4) check whether the actual or alleged contribution is actually technical in nature".
 - The fourth step – check whether the contribution is "technical" – may not be necessary because the third step should have covered that. It is a necessary check however if one is to follow Merrill Lynch as we must”.

RELATIONSHIP WITH THE EPC AND DECISIONS OF THE EPO

- The EBoA considered a referral from the President of the EPO on the patentability of computer programs in G3/08. The referral was inadmissible because the prior EPO decisions were not considered to be “divergent”.
- “although in methodological terms the approach in the UK and the approach in the EPO may look different, *in practice they reach the same result, at least usually*”, paragraph 9 of *Lenovo (Singapore) PTE Ltd v Comptroller General of Patents* [2020] EWHC 1706 (Pat).
- “As the Office is *bound by the judgments in Aerotel/Macrossan and HTC v Apple*, it cannot choose to depart from the Aerotel/Macrossan test in order to adopt EPO practice”, MOPP.

PRACTICAL ISSUES

- “When determining if an invention falls foul of the exclusions, **it is critical that the examiner consider the substance of the invention rather than the form of claim provided, by looking beyond the strict literal wording of the claims.** For example, when a claim is directed to a computer program, the examiner must look at what the computer program will do when run, as established in paragraph 49 of *Astron Clinica Ltd & Ors v The Comptroller General of Patents, Designs and Trade Marks* [2008] EWHC 85 RPC 14”. (MOPP).
- “It is not the nature of a single embodiment of an invention which is important when determining whether it is excluded, **but the nature of the central idea or invention which is embodied in the claims.** To determine this, the invention claimed should be assessed and construed as a whole to see whether it comprises an advance that lies in a non-excluded field. However, as Floyd J observed in paragraph 23 of *Kapur v Comptroller-General of Patents* [2008] EWHC 649 (Pat), **if there are embodiments of a claim that fall within excluded subject matter, the fact that the claim is wide enough to encompass embodiments that are not excluded under s. 1(2) will not be sufficient to save it.** The exclusion “will still bite to the extent that excluded subject matter is claimed”. (MOPP).

- “In *Lantana v Comptroller-General of Patents* [2014] EWCA Civ 1463 the Court of Appeal reiterated that the requirements of s.1(1) and s.1(2) are separate, and that **claims to novel and inventive subject matter may still be excluded**”. (MOPP).

RELATIONSHIP
TO NOVELTY /
INVENTIVE
STEP

DISCOVERIES, SCIENTIFIC THEORIES AND MATHEMATICAL METHODS

- “In Genentech Inc’s Patent [1989] RPC 147, the Court of Appeal held that the **discovery of an amino acid sequence** for the substance tPA **led to a valid claim when incorporated into a conventional manufacturing process for the manufacture of tPA**. Similarly, in Kirin-Amgen v Hoechst Marion Roussel [2005] RPC 9, the House of Lords held that **a DNA sequence of a gene was not an invention on its own**, but if it were necessary to isolate and extract it, then **a process developed for this purpose and the material when obtained by this process could both be patentable** (see also 76A.05). (MOPP).
- “In Vicom Systems Inc T0208/84 [1987], the EPO Board of Appeal defined a mathematical method as one which “is carried out on numbers and provides a result in numerical form”. A mathematical method was therefore merely **an abstract concept prescribing how to operate on the numbers**, and a claim directed solely to the mathematical method was excluded from patentability as a result of its abstract nature.
- However, **if an invention provides a technical contribution, it may avoid exclusion even though the underlying idea may reside in a mathematical method**; a claim to a method of enhancing digital images by software processing that implemented a mathematical method was considered to provide such a contribution in Vicom and allowed”. (MOPP).

DISCOVERIES, SCIENTIFIC THEORIES AND MATHEMATICAL METHODS

- “In Gale’s Application [1991] RPC 305 the applicant had devised a new and better algorithm for calculating square roots and claimed it on a read only memory (ROM). In holding the invention to be excluded, Nicholls LJ stated on page 328: “Mr. Gale has devised an improvement in programming. What his instructions do, but it is all they do, is to prescribe for the CPU in a conventional computer a different set of calculations from those normally prescribed when the user wants a square root”. Nicholls LJ also held that the instructions did not embody a technical process and did not solve a technical problem within a computer. Thus, carrying out a mathematical method by a program will not, in general, be enough to avoid exclusion. Similarly, an improvement in programming or an improved algorithm will not generally be enough to avoid exclusion **unless there is something more to it in the form of a technical contribution**”. (MOPP).

AESTHETIC CREATIONS

- “If an article is distinguished from the prior art solely by its design, ornamentation or colour, then it will be excluded if this has a purely aesthetic function, **but if the distinction has a practical effect then this could save it from the exclusion**. For example, if a serving tray were characterised solely by having a particular embossed pattern on its surface, then it would fall within the exclusion, **but if it were found that this particular pattern had non-slip attributes unexpectedly superior to those normally associated with embossment, this could provide a patentable feature**”. (MOPP).

MENTAL ACT, PLAYING A GAME, BUSINESS METHODS, AND COMPUTER PROGRAMS

- “The decision in Halliburton Energy Services Inc’s Applications [2012] RPC 129 confirmed (in paragraphs 57 and 63) that the mental act exclusion **is to be interpreted narrowly** – it only covers acts that are carried out by “purely mental means”, and **does not extend to those which are merely capable of being performed mentally**. HHJ Birss QC (sitting as a Judge of the High Court) considered that the aim of the exclusion was to prevent patents being granted which could be infringed “by thought alone”. (MOPP).
- “The patentability of schemes, rules or methods for playing a game was considered by the Patents Court in Shopalotto.com Ltd’s Application [2006] RPC 7, where the application related to a computer lottery game played over the internet. The Court held that **the patentability of games should be assessed using the general approach for excluded matter, putting it in line with the other exclusions**. Following Aerotel/Macrossan, this means that the patentability of games should be assessed using the Aerotel test... In relation to non-computer based games, apparatus which involves a combination of standard game items, such as a board, playing pieces, a random outcome generator (e.g. dice), chance cards and the like, **which are united by the nature of the game played will usually be excluded, since the actual contribution lies in the game that the apparatus is used to play**”. (MOPP).

MENTAL ACT, PLAYING A GAME, BUSINESS METHODS, AND COMPUTER PROGRAMS

- The fact that an application may provide a better way of conducting business is not relevant:
- “The business method cases can be tricky to analyse by just asking whether the invention has a technical effect or makes a technical contribution. The reason is that computers **are self evidently technical in nature**. Thus when a business method is implemented on a computer, the patentee has a rich vein of arguments to deploy in seeking to contend that his invention gives rise to a technical effect or makes a technical contribution. **For example the computer is said to be a faster, more efficient computerized book keeper than before and surely, says the patentee, that is a technical effect or technical advance. And so it is, in a way, but the law has resolutely sought to hold the line at excluding such things from patents**”. (Halliburton Energy Services Inc’s Applications [2012] RPC 129).

MENTAL ACT,
PLAYING A
GAME,
BUSINESS
METHODS, AND
COMPUTER
PROGRAMS

- “Where a claim involves the use of a computer program, *it does not naturally follow that the claim must be excluded*”. (MOPP).
- “Instead, the contribution of a claim to a computer program *must be assessed by reference to the process the program will cause a computer to perform*, because the assessment is based on the substance of the invention”. (MOPP).

AT&T SIGNPOSTS

AT&T signposts:-

- (i). whether the claimed technical effect has a technical effect on a process which is carried on **outside the computer** (from Vicom)
- (ii). whether the claimed technical effect operates **at the level of the architecture of the computer**; that is to say whether the effect is produced irrespective of the data being processed or the applications being run (from IBM T 0006/83, IBM T 0115/85, Merrill Lynch, Symbian)
- (iii). whether the claimed technical effect results in the computer being made to **operate in a new way** (from Gale)
- (iv). whether the program makes the computer a better computer in the sense of running **more efficiently and effectively as a computer** (from Vicom, Symbian; as reworded in HTC v Apple)
- (v). whether the perceived problem is overcome by the claimed invention **as opposed to merely being circumvented** (from Hitachi T 0258/03)

ARTIFICIAL NEURAL NETWORKS

- “The definition of ‘a computer’ and ‘a program for a computer’ were set out in *Comptroller-General of Patents, Designs and Trade Marks v Emotional Perception AI Ltd* [2024] EWCA Civ 825 (see [61]). A computer is “a machine which processes information”. **A program for a computer is “a set of instructions for a computer to do something”.** These two definitions work together, so one can say that a computer is a machine which does something, and that thing it does is to process information in a particular way. The program is the set of instructions which cause the machine to process the information in that particular way, rather than in another way.
- *The exclusion is not limited to digital computers”, MOPP*

ARTIFICIAL NEURAL NETWORKS

- “Case law with respect to the computer program exclusion has developed largely in the context of digital computers that have a processor to execute programs (software) that are stored in memory. However, for the purposes of the exclusion, computers are not restricted to these types of computers. This was clarified in *Emotional Perception*, where an Artificial Neural Network (ANN) was found to be a computer. The weights applied to the neurons of the network were found to be the computer program because the set of weights as a whole instruct the machine to process information it is presented with in a particular way. **Thus ANN-implemented inventions are in no better and no worse position than other computer implemented inventions** (see [71]). There is no requirement for the program to be written by a human programmer (see [64]), nor is there any requirement for the problem addressed by the program to be tractable to a human programmer (see [65]). How the program came into being is irrelevant (see [66])”.
- For more: see *Examining patent applications relating to artificial intelligence (AI) inventions*

PRESENTATION OF INFORMATION

- “Any manner, means or method of expressing information which is characterised solely by the content of the information is excluded, regardless of how it is represented”. (MOPP).
- “Gemstar-TV Guide International Inc v Virgin Media Limited [2010] RPC 10 considered the question of computerised methods for presenting information. The case related to three EP(UK) patents covering various aspects of Electronic Program Guides (EPGs). In his judgment, Mann J emphasised that the exclusion was not solely confined to the content of information, and that, in order for the exclusion not to apply, **there must be some technical effect beyond the information being presented**. The court also stated that **if the contribution is defined only in terms of the information to be presented, then that is a presentation of information - the presence of a display does not change this**. In particular, a better (or new) user interface was not considered to be a relevant technical effect - the rearrangement of information was nothing more than the presentation of information; simply having something different displayed was not sufficient to overcome the exclusion. Two of the three patents were found to be excluded as they lacked the required technical effect; the third presented a physical effect, namely the movement of data between hard disks, such that there was more than merely the presentation of information”. (MOPP).

EPO EXAMPLES

- “For example, the physical theory of semiconductivity would not be patentable. However, new semiconductor devices and processes for manufacturing these may be patentable”. (EPO Guidelines).
- “Examples of technical contributions of a mathematical method are:
 - **controlling** a specific technical system or process, e.g. an X-ray apparatus or a steel cooling process;
 - digital audio, image or video **enhancement or analysis**, e.g. de-noising, detecting persons in a digital image, estimating the quality of a transmitted digital audio signal;
 - encoding data **for reliable and/or efficient transmission or storage** (and corresponding decoding), e.g. error-correction coding of data for transmission over a noisy channel, compression of audio, image, video or sensor data;
 - **encrypting/decrypting** or signing electronic communications; generating keys in an RSA cryptographic system;
 - **optimising** load distribution in a computer network;
 - determining the energy expenditure of a subject by processing data obtained from **physiological sensors**; deriving the body temperature of a subject from data obtained from an ear temperature detector;
 - providing a medical diagnosis by an **automated system** processing **physiological measurements**”. (EPO Guidelines).

EPO EXAMPLES

- “Artificial intelligence and machine learning find applications in various fields of technology. For example, the use of a neural network in a heart monitoring apparatus **for the purpose of identifying irregular heartbeats makes a technical contribution**. The classification of digital images, videos, audio or speech signals **based on low-level features** (e.g. edges or pixel attributes for images) are further typical technical applications of classification algorithms... Classifying text documents **solely in respect of their textual content is however not regarded to be per se a technical purpose but a linguistic one** (T 1358/09). Classifying abstract data records or even “telecommunication network data records” without any indication of a technical use being made of the resulting classification is also not per se a technical purpose, even if the classification algorithm may be considered to have valuable mathematical properties such as robustness (T 1784/06). Where a classification method serves a technical purpose, **the steps of generating the training set and training the classifier may also contribute to the technical character of the invention if they support achieving that technical purpose**”. (EPO Guidelines).

EPO EXAMPLES

- “Computer-implemented simulations that comprise features representing **an interaction with an external physical reality at the level of their input or output may provide a technical effect** related to this interaction. A computer-implemented simulation that **uses measurements as input may form part of an indirect measurement method that calculates or predicts the physical state of an existing real object** and thus make a technical contribution regardless of what use is made of the results...
- A computer-implemented simulation **without an input or output having a direct link with physical reality may still solve a technical problem**. In such a "purely numerical" simulation, the underlying models and algorithms may contribute to the technical character of the invention **by their adaptation to a specific technical implementation or by an intended technical use of the data resulting from the simulation**.
- Models and algorithms that do not make a contribution to the technical character of the invention form constraints that may be included in the formulation of the objective technical problem when following the COMVIK approach outlined in G-VII, 5.4". (EPO Guidelines).

- “Once it is established that the claimed subject-matter **as a whole** is not excluded from patentability under Art. 52(2) and (3), it is examined with respect to novelty and inventive step (G-I, 1). The examination of inventive step requires an assessment of **which features contribute to the technical character of the invention** (G-VII, 5.4).”. (EPO Guidelines).

EPO EXAMPLES

EPO EXAMPLES

- “The **activity of programming**, in the sense of writing code, is an intellectual, **non-technical activity**, to the extent that it is not used in the context of a concrete application or environment to contribute in a causal manner to the production of a technical effect (G 3/08, T 1539/09)...
- Defining and **providing a programming language** or a programming paradigm such as object-oriented programming **does not per se solve a technical problem**, even if its particular syntax and semantics enable the programmer to develop a program with greater ease. Easing the intellectual effort of the programmer is per se not a technical effect.
- When assessing an invention relating to a programming environment, the features pertaining to the programming language do not normally contribute to its technical character. For example, in a visual programming environment, the provision of specific graphical building blocks is part of the programming language and makes no technical contribution **if the only effect is easing the intellectual effort of the programmer**”. (EPO Guidelines).

EPO EXAMPLES

- “A computer-implemented **data structure or data format** embodied on a **medium or as an electromagnetic carrier wave** has technical character as a whole and thus is an invention within the meaning of Art. 52(1)...
- A data structure or format contributes to the technical character of the invention **if it has an intended technical use and it causes a technical effect when used according to this intended technical use...** This may happen if the data structure or format is functional data, i.e. if it has a technical function in a technical system, such as controlling the operation of the device processing the data...
- Similarly, an index structure used for searching a record in a database produces a technical effect **since it controls the way the computer performs the search operation** (T 1351/04)”. (EPO Guidelines).

EPO EXAMPLES

- “Digital data is used to control devices in additive manufacturing (AM).... If the data defines the instructions **for operating the AM device**, it makes a technical contribution as illustrated in the following example:
- Example:
 - A computer-readable medium storing data which defines both a digital representation of the product of claim 1 and operating instructions adapted to control an AM device to fabricate the product using the digital representation of the product when said data is relayed to the AM device.
- A computer-readable medium is a technical object, so no objection under Art. 52(2) and (3) arises”. (EPO Guidelines).

EPO EXAMPLES

- “A feature defining a presentation of information produces a technical effect if it **credibly assists the user in performing a technical task** by means of a continued and/or **guided human-machine interaction process** (T 336/14 and T 1802/13). Such a technical effect is considered credibly achieved if the assistance to the user in performing the technical task is objectively, reliably and causally linked to the feature. This would not be the case if the alleged effect **depends on subjective interests or preferences of the user**. For example, for some users it is easier to understand data when it is displayed as numerical values, whereas others might prefer a colour-coded display. **The choice of the one or other manner of displaying the data is thus not considered to have a technical effect** (T 1567/05). Similarly, whether or not it is easier to understand audio information conveyed as a musical scale instead of spoken words is a matter concerned only with the cognitive abilities of the user. As another example, allowing the user to set parameters determining the information to be presented or to select the manner of its presentation does not make a technical contribution **if it merely accommodates subjective user preferences**”. (EPO Guidelines).

EPO EXAMPLES

- “For example, displaying several images side by side in low resolution and allowing selection and display of an image at higher resolution conveys information to the user in the form of a technical tool **that enables the user to perform the technical task of interactively searching and retrieving stored images more efficiently**. Storing digital images at different resolutions gives rise to the technical effect of allowing the simultaneous overview display of several images (T 643/00). As another example, in a video soccer game, the particular manner of conveying to the user the location of the nearest teammate **by dynamically displaying** a guide mark on the edge of the screen when the teammate is off-screen **produces the technical effect of facilitating a continued human-machine interaction by resolving conflicting technical requirements: displaying an enlarged portion of an image and maintaining an overview of a zone of interest which is larger than the display area** (T 928/03)”. (EPO Guidelines).

SECTIONS 1(3)-(4), PA 1977

1(3) A patent shall not be granted for an invention the commercial exploitation of which would be **contrary to public policy or morality**.

1(4) For the purposes of subsection (3) above exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it.

→ The above wording reflects Article 27(2) of the TRIPS agreement.

ART. 53(A) EPC

inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

MORALITY

- “In practical terms, the effect of s.1(3)... is to prevent the grant of patent rights for inventions **which the general public would regard as abhorrent or from which the public need protection**. It provides a reasonably objective test which has to be applied to each invention and its particular set of facts and circumstances. Clearly what is to be regarded as contrary to public policy or morality will vary according to changes in social attitudes and on no account ought examiners to allow their own personal and individual beliefs to colour their judgment on this matter”. (MOPP).
- “The corresponding provision of the EPC (see 1.06) refers to “inventions the publication or exploitation of which would be contrary to ‘ordre public’ or morality”. In the **Harvard “oncomouse” case** T 315/03 ([2006] 1 OJEP 15, [2005] EPOR 31) (see also 76A.02.1 and 76A.05), the Board of Appeal endorsed the definitions of “ordre public” and morality provided in Plant Genetic Systems T 356/93 [1995] 8 OJEP 393 and held that the assessment of these concepts **should be made as of the filing or priority date of the application**. The concept of “ordre public” was accepted as covering the protection of public security and the physical integrity of individuals as part of society and encompassed the protection of the environment”. (MOPP).

MORALITY

- “Section 1(4) is a rider to section 1(3) to make it clear that an act or action prohibited by a law **is not to be considered as necessarily the same thing as contrary to public policy or morality**. (One reason for this is that a product which could not lawfully be used in the UK **may be manufactured lawfully in the UK for export to countries where its use is not illegal**)”. (MOPP).
- Example technologies that are prohibited: landmines (Ottawa convention) and cluster munitions.
- Example technologies that might be prohibited: chemical and biological weapons. “However, it should be noted that both these Acts recognise that agents capable of use as a chemical or biological weapon **may have legitimate purposes**. In cases in which an invention can be exploited legally albeit **in accordance with stringent regulations**, it would be very difficult to argue that s.1(3) applies and the application for a patent refused”. (MOPP).

SCHEDULE A2, PA 1977

1. An invention shall not be considered unpatentable **solely on the ground** that it concerns—
 - (a) a product consisting of or containing biological material; or
 - (b) a process by which biological material is produced, processed or used.
 2. Biological material which **is isolated from its natural environment or produced by means of a technical process** may be the subject of an invention **even if it previously occurred in nature.**
-

SCHEDULE A2, PA 1977

3. The following are **not** patentable inventions—

(a) the **human body**, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;

(b) processes for **cloning human** beings;

(c) processes for modifying the germ line genetic identity of **human** beings;

(d) uses of **human embryos** for industrial or commercial purposes;

(e) 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;

(f) any **variety of animal or plant** or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.

SCHEDULE A2, PA 1977

4. Inventions which concern plants or animals may be patentable if the technical feasibility of the invention **is not confined to a particular plant or animal variety**.

5. An element isolated from the human body **or otherwise produced by means of a technical process**, including the sequence or partial sequence of a gene, may constitute a patentable invention, **even if the structure of that element is identical to that of a natural element**.

SECTION 4(A), PA 1977

- (1) A patent shall not be granted for the invention of-
- (a) a **method of treatment** of the human or animal body **by surgery or therapy**, or
 - (b) a **method of diagnosis** practised **on the human or animal body**.
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METHODS OF TREATMENT OR DIAGNOSIS

- “The term “therapy” includes the prevention as well as the treatment or cure **of disease...** for a treatment to constitute therapy there must be **a direct link between the treatment and disease state being cured, prevented or alleviated...** The EPO Board of Appeal in another case, T74/93 (OJEPO headnote 4/95), confirmed that methods of contraception in general are not considered to be therapeutic, as pregnancy is not a disease. The Board held that the claimed method in this case lacked industrial applicability as it was a purely personal method carried out in private. In the UK methods of contraception are not considered to lack industrial application merely because they are for “private and personal use”. Under 60(5)(a) of the Patents Act 1977 the private use of such a method would not constitute an infringing act, and so a patent to such a method is allowable”. (MOPP).
- “It appears that any medical treatment of a disease, ailment, injury or disability, **ie anything that is wrong with a patient and for which they would consult a doctor, as well as prophylactic treatments such as vaccination and inoculation, is to be regarded as therapy.** The same considerations apply for animals as for human patients, so that for example prophylaxis and immunotherapy in animals are regarded as therapy”.

METHODS OF TREATMENT OR DIAGNOSIS

- “Section 4A(1) excludes only treatment by surgery or therapy, and it follows that other methods of treatment of live human beings or animals, eg treatment of a sheep in order to promote growth, to improve the quality of mutton or to increase the yield of wool, **are patentable provided that (as would probably be the case) such methods are of a technical, and not essentially biological, character**. However, where an increase in meat yield or other industrial benefit is merely an inevitable consequence of improved health through therapeutic treatment, then such a method is unpatentable. On the other hand, a claim to the **non-therapeutic use** of antibiotics or other drugs may be acceptable if the claimed effect is not a mere consequence of improved health. Where the method set out in the claim may be patentable **but could also cover non-patentable embodiments, a claim must be clearly limited (e.g. by a disclaimer) to methods which are patentable**, and there must be support in the description for a non-therapeutic method. **If necessary, the description should be amended to clarify that therapeutic methods do not form the invention**”. (MOPP).

METHODS OF TREATMENT OR DIAGNOSIS

- “Application of substances to the body **for purely cosmetic purposes** is not therapy”. (MOPP).
- “In Oral Health Products Inc (Halstead’s) Application, [1977] RPC 612, claims to a method of removing dental plaque and/or caries were refused, as was a claim to a method of cleaning teeth which embraced both curative and cosmetic effects. This decision has been followed under the 1977 Act in ICI Ltd’s Application No 7827383 (BL O/73/82), where a claim was refused to a method of cleaning teeth which removed both plaque and stains; it was argued that when applied to perfectly healthy teeth the method was purely cosmetic, **but the hearing officer observed that practically all medical treatments which are preventative in nature (such as vaccination) must at times be applied to people who would have remained healthy anyway, but they remained medical treatments**”. (MOPP).

METHODS OF TREATMENT OR DIAGNOSIS

- “Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests. Determination of the general physical state of an individual (e.g. a fitness test) is not considered to be diagnostic if it is not intended to identify or uncover a pathology. *Section 4A(1) relates to methods of diagnosis practised on the human or animal body; diagnosis in itself is a method of performing a mental act and is excluded from patentability* under section 1(2)(c)”. (MOPP).

METHODS OF TREATMENT OR DIAGNOSIS

- “Typically, the process of diagnosis involves a number of steps leading towards identification of a condition. The Enlarged Board characterised these steps as being: (i) **the examination and collection of data**, (ii) **comparison of the data with normal values**, (iii) **finding any deviation from the norm**, and finally (iv) **attributing the deviation to a particular clinical picture**. The Enlarged Board held that for a claim to fall under this prohibition, **it must include** both the deductive step of making the diagnosis (step iv) and the preceding steps constructive for making that diagnosis involving specific interactions of a technical nature with the human or animal body. The exclusion is therefore a narrow one, and also requires all the method steps of a technical nature to be practised on the body. However, the Board pointed out that the exclusion **could not be circumvented by omitting one of the essential features of the diagnostic method as the claim would then not satisfy Article 84 EPC** (equivalent to section 14(5)(a) to (c)), since this requires that all the essential features necessary for clearly and completely defining a particular invention are present in the claim”. (MOPP).

METHODS OF TREATMENT OR DIAGNOSIS

- “Methods of diagnosis performed on tissues or fluids which have been **permanently removed from the body** are not excluded, and so, for example, genetic or immunological tests on blood or urine samples are patentable. “Body” should be taken to mean living body, and a method practised on a dead body, for example in order to determine the cause of death, would not be excluded”. (MOPP).

METHODS OF TREATMENT OR DIAGNOSIS

- “Surgery is defined as the treatment of disease or injury by operation or manipulation. It is not limited to cutting the body but includes manipulation such as the setting of broken bones or relocating dislocated joints (sometimes called “closed surgery”), and also dental surgery. **In general, any operation on the body which required the skill and knowledge of a surgeon would be regarded as surgery** (see also 4A.10). The Enlarged Board of Appeal in G 01/07 MEDI-PHYSICS/Treatment by surgery [2011] 3 OJEP 134 held that a method should be excluded if it comprises or encompasses an invasive step **which constitutes a substantial physical intervention on the body, and which entails a significant health risk even when carried out by a medical professional**”. (MOPP).
- “It may often be helpful, in deciding whether or not a method is excluded under s.4A(1) to consider **who would in practice carry out the method**. The apparent purpose of s.4A(1) is to prevent a medical practitioner being inhibited by legal monopolies. Thus for example bone setting is regarded as surgery, while applying a plaster cast is not, since the former is carried out by a doctor, the latter by a technician”. (MOPP).

METHODS OF TREATMENT OR DIAGNOSIS

- “Claims objected to under section 4A(1) are often in the form “A method (or process) **for treating medical or veterinary condition** Y by”, but other forms of claim are also objected to such as “The use of substance (or composition) X **in treating medical condition** Y by”, “A compound (or composition) X **when used in the treatment of medical condition** Y by” and “The use of substance (or composition) X as a pharmaceutical”. The last of these claims is interpreted as a method claim to the use of the substance in therapeutic treatment, rather than simply a claim to its use in a pharmaceutical formulation”.
- “Patents may, however, be obtained for surgical, therapeutic or diagnostic **instruments or apparatus intended for use in such methods**. Also the manufacture of prostheses or artificial limbs and taking measurements therefore on the human body are patentable. In addition, tests on human or animal bodies should be regarded as patentable inventions if they do not meet the criteria for “methods of diagnosis” set out in 4.06”. (MOPP).

SECTION 4(A), PA 1977

(2) Subsection (1) above does not apply to an invention consisting of **a substance or composition for use in any such method**.

(3) In the case of an invention consisting of a substance or composition for use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art. (“First medical use”).

(4) In the case of an invention consisting of a substance or composition for a specific use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new **if that specific use** does not form part of the state of the art. (“Second medical use”).

EXAMPLE EXAM QUESTIONS ON EXCLUDED SUBJECT MATTER

1. “According to Section 1(2), what are not inventions for the purposes of the UK Patents Act 1977”? 8 marks. FC1, 2022.
2. “Your client claims to have invented a perpetual motion machine. List three grounds on which the UKIPO might raise an objection”. 3 marks. FC1, 2021.
3. “With reference to Section 1 of the UK Patents Act 1977 (Patentable inventions), list six things which are not inventions for the purposes of the Act”. 3 marks. FC1, 2020.
4. “According to Section 1 UK Patents Act 1977 (Patentable inventions), a scheme, rule or method for performing a mental act as such is not patentable. Explain how this exclusion is interpreted in practice, the aim of the exclusion and how a claim may avoid the exclusion”. 4 marks, FC1, 2019.
5. “With reference to Schedule A2, Section 76A UK Patents Act 1977 (Biotechnological Inventions), state three biotechnical inventions which are not patentable”. 6 marks. FC1, 2019.

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