

**Digital Health:
- Proprietary rights on software and other tools for the
processing of big data: Risks and Opportunities -**

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Dr. Alexander Dick, DESU

alexander.dick@hfp-ip.de

BÜRO MANNHEIM
Dudenstrasse 46
68167 Mannheim
mailman@hfp-ip.de

BÜRO MÜNCHEN
Isartorplatz 1
80331 München
mailmuc@hfp-ip.de

BÜRO DÜSSELDORF
Immermannstrasse 40
40210 Düsseldorf
maildus@hfp-ip.de

BÜRO BERLIN
Meineckestrasse 27
10719 Berlin
mailber@hfp-ip.de

Overview



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I Introduction



Digital health, a definition

“Digital health is the convergence of digital and genomic technologies with health, healthcare, living, and society to enhance the efficiency of healthcare delivery and make medicines more personalized and precise. ... These technologies include both hardware and software solutions and services, including telemedicine, web-based analysis, email, mobile phones and applications, text messages, and clinic or remote monitoring sensors. Generally, digital health is concerned about the development of interconnected health systems to improve the use of computational technologies, smart devices, computational analysis techniques and communication media to aid healthcare professionals and patients manage illnesses and health risks, as well as promote health and wellbeing. ...” From Wikipedia

I Introduction – cont.



Technical and non-technical aspects of digital health:

- Technical aspects: Analytics, data mining, computer networks & internet, diagnostics and therapy
- Non-technical aspects: Social & economic health care management, ethical aspects in medicine, social networking

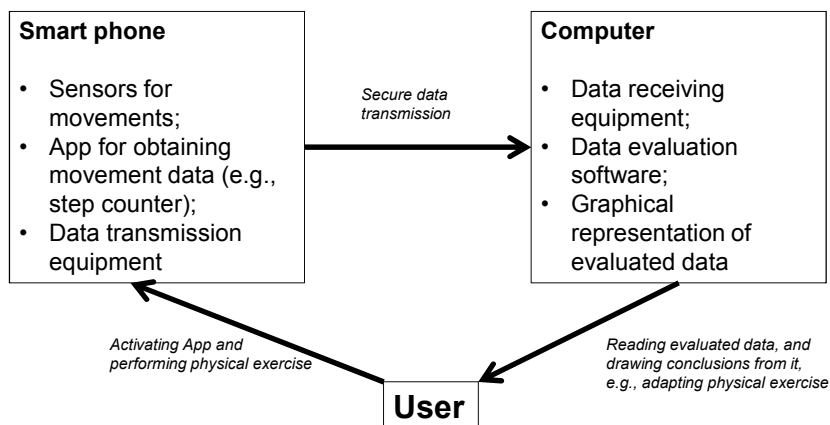
I Introduction – cont.



Examples of technical aspects in digital health:

- Analytics: stationary devices, e.g., MS-, NMR-, ELISA-devices, and robots, mobile devices, e.g., wearable sensors, smart devices, and mobile phones, biochemical assays, test suites, user interfaces
- Data mining: data processing device, e.g., computer devices, smart devices, and mobile phones, software for implementing data processing and evaluation algorithms, mobility data acquisition, graphical data representation
- Computer networks & internet: Laboratory and hospital information systems, health care management and knowledge networks, clinical trial support, software for data transmission and data security, graphical data representation
- Diagnostics and therapy: Diagnostic assays, personalized medicine (tests and therapeutic regime)

I Introduction – cont.



II Overview proprietary rights



Technical and non-technical intellectual property rights:

Technical IP rights:

- Patents;
- Utility models (in some countries)

Others:

- Know How;
- Unfair competition

Non-technical IP rights:

- Trademarks;
- Designs;
- Copyrights (registered/non-registered)

II Overview proprietary rights



Patents and Designs:

- Patents: Protection of technical inventions
 - Subject matter: Devices, composition of matter, and methods & uses
 - Requirements: Novelty, Inventive Step and Industrial Applicability
- Designs: Protection of appearance of items (3D or 2D)
 - Subject matter: Appearance of an item resulting from lines, contours, colors, shape, texture and/or materials of the item itself and/or its ornamentation
 - Requirements: Novelty and Individual Character

II Overview proprietary rights



Trademarks and Copyrights:

- Trademarks: Protection of signs and symbols signaling the origin of goods and services to the customer
 - Subject matter: Designations, names, numbers, slogans, drawings, logos, 3D structures, sounds, colors, etc.
 - Requirements: Not descriptive, distinct
- Copyrights: Protection of creative, intellectual or artistic works
 - Subject matter: Art, literature, music, motion pictures, etc. ... but also: Software!
 - Requirements: Originality

II Overview proprietary rights



Examples of IP-eligible subject matter in digital health:

- Patents: Analytic devices, wearable sensors, smart phones, diagnostic methods, data processing and evaluation software
- Designs: 3D structure of devices, graphical user interfaces
- Trademarks: Brands used for devices or methods, 3D structures of devices
- Copyrights: Software, database structures, graphics

III Patenting of digital health technology



Classical inventions in the health care and digital health field:

- Analytical devices, data processing devices, transmitters, receivers, sensors
 - Biochemical diagnostic assays
 - Therapeutic methods
- No particular problems to be expected, general patentability requirements of Novelty, Inventive step and Industrial applicability must be dealt with

III Patenting of digital health technology



Specific digital health inventions:

- Digital diagnostic methods
 - Test and evaluation software
 - User interaction
 - Health care assistance systems
- Specific patentability requirements or problems?

III Patenting of digital health technology



Requirements for patentable inventions:

Article 52 EPC:

(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.

(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.

...

III Patenting of digital health technology



Requirements for patentable inventions:

Article 53 EPC:

European **patents shall not be granted** in respect of:

- (a) 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;
- (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;
- (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods

III Patenting of digital health technology



Potential hurdles for specific digital health inventions:

Subject matter	Potential patentability problem	Conflicting Article
Digital diagnostic methods	Computer program, mental act and diagnostic method	Article 52 (2) EPC a) and c), Article 53 c) EPC
Test and evaluation software	Computer program, mathematical method, mental act and diagnostic method	Article 52 (2) a) and c) EPC, Article 53 c) EPC
User interface	Computer program and representation of information	Article 52 (2) a), c) and d) EPC
Health care assistance system	Computer program, doing business and diagnostic method	Article 52 (2) a) and c) EPC, Article 53 c) EPC

IV New technology, old problems



Exclusions under Article 52 EPC being potentially relevant for digital health inventions:

- Mathematical methods
- Mental acts
- Methods of doing business
- Computer programs as such
- Presentations of information

IV New technology, old problems



Case law on Article 52 EPC, in particular, computer programs:

T1173/97:

Relevant subject matter:

“20. A computer program product directly loadable into the internal memory of a digital computer, comprising software code portions for performing the steps of claim 1 when said product is run on a computer. “

“21. A computer program product stored on a computer usable medium, comprising: computer readable program means for causing a computer to ...”

Ruling:

“A computer program product is not excluded from patentability under Article 52(2) and (3) EPC if, when it is run on a computer, it produces a further technical effect which goes beyond the “normal” physical interactions between program (software) and computer (hardware)”.

IV New technology, old problems



Case law on Article 52 EPC, in particular, computer programs:

T641/00:

Relevant subject matter:

SIM card consisting of technical and non-technical features having a technical character as a whole

Approach taken by the EPO:

Assessing inventive step of all features which contribute to the technical character, whereas those who do not contribute are disregarded for the assessment

IV New technology, old problems



Case law on Article 52 EPC, in particular, computer programs:

T258/03:

Relevant subject matter:

A method for carrying out an auction in the internet

Findings of the EPO:

A method involving any kind of technical means is a technical invention.
However, inventive step was denied for other reasons in the case

IV New technology, old problems



Case law on Article 52 EPC, in particular, computer programs:

T1227/05:

Relevant subject matter:

A (computer-implemented, mathematical) simulation method for a circuit

Findings of the EPO:

A technical character was affirmed, since simulation methods are an essential part of the circuit manufacturing process

IV New technology, old problems



Case law on Article 52 EPC, in particular, computer programs:

T424/03:

Relevant subject matter:

A computer program on a storage medium

Findings of the EPO:

“The subject matter of claim 5 has technical character since it relates to a computer readable medium, i.e. a technical product involving a carrier...”

IV New technology, old problems



Case law on Article 52 EPC, in particular, computer programs:

G3/08:

- Affirmed the current case law and practice for patenting of computer-implemented inventions
- Pointed out a divergent logic applied in T1173/97 which was applied with regard to the technical character of a storage medium and the computer program itself

(Note: The Board in T1173/97 applied an “essence of the invention” approach in order to be able to disregard the technical character of the storage medium which is, however, not consistent with the general case law of the EPO)

IV New technology, old problems



Case law on Article 52 EPC, in particular, mental activity:

T643/00:

Relevant subject matter:

An image processing apparatus for hierarchically storing images and method for searching an image using it

Findings of the EPO:

*“An arrangement of menu items (or images) on a screen may be determined by **technical considerations**. Such considerations may aim at **enabling the user to manage a technical task**...in a more efficient or faster manner, even if an evaluation by the user on a mental level is involved. Although such evaluation per se does not fall within the meaning of “invention” pursuant to Article 52 EPC, the mere fact that mental activities are involved does not necessarily qualify subject matter as non-technical since any technical solutions in the end aim at **providing tools which serve, assist or replace human activities of different kinds**, including mental ones.*

IV New technology, old problems



Case law on Article 52 EPC, in particular, mental act and displaying information:

T49/04:

Relevant subject matter:

“Claim 1: A method for enhancing text presentation from a machine readable natural language text based on reader specific parameters including at least the viewing field dimensions ...”

Findings of the EPO:

“...the presentation of natural language text on a display in a manner which improves readability, enabling the user to perform their task more efficiently, relates to how, i.e. by what physical arrangement of the text, cognitive content is conveyed to the reader and can thus be considered as contributing to a technical solution to a technical problem ...”

IV New technology, old problems



Overcoming Article 52 EPC:

- No “further technical effect”, non-patentable:
 - Computer programs per se are considered non-technical
 - Simple displaying of information (per se) is considered non-technical
- With “further technical effect”, patentable: Examination practice:
 1. Identify technical features
 2. Is there at least one technical feature?
 - If No: No patentable invention, rejection on the basis of Art. 52 (1), (2) EPC
 - If Yes: technical character is given, generally patentable, but:
 3. Inventiveness: No inventive step arising from purely non-technical aspects!
 - Many computer-related applications are rejected for alleged lack of inventiveness! (Art. 52 (1) EPC in conjunction with Art. 56 EPC)

IV New technology, old problems



Overcoming hurdles for specific digital health inventions:

Subject matter	Potential patentability problem	Solution
Digital diagnostic methods	Computer program, mental act and diagnostic method	G3/08, further technical effect, i.e. diagnosis of a health condition
Test and evaluation software	Computer program, mathematical method, mental act and diagnostic method	G3/08, further technical effect, i.e. technical implementation on a computer, system storage device, typically adapted for performing digital diagnostic method
User interface	Computer program and representation of information	G3/08, further technical effect, i.e. involved in digital diagnostics
Health care assistance system	Computer program, doing business and diagnostic method	G3/08, difficult if no technical character (rare cases)

IV New technology, old problems



Exclusions under Article 53 c) EPC being potentially relevant for digital health inventions:

→ diagnostic methods practised on the human or animal body

IV New technology, old problems



**Case law on Article 53 c) EPC (formerly Article 52 (4) EPC),
diagnostic methods:**

G1/04:

**Exclusion as a diagnostic method requires that the claimed
method relates to**

*“(i) the diagnosis for curative purposes stricto sensu representing the
deductive medical or veterinary decision phase as a purely intellectual
exercise,*

(ii) the preceding steps which are constitutive for making that diagnosis, and

*(iii) the specific interactions with the human or animal body which occur when
carrying those out among these preceding steps which are of a technical
nature.”*

IV New technology, old problems



Case law on Article 53 c) EPC, diagnostic methods:

Diagnosis for curative purposes (G1/04):

„The diagnostic methods referred to in Article 52(4) EPC [now Article 53 c) EPC] include the method step related to the deductive medical or veterinary decision phase, i.e. the diagnosis stricto sensu representing a purely intellectual exercise.” (emphasis added)

Data generation, evaluation & mining without establishing the diagnosis for curative purposes is not encompassed by Article 53 c) EPC! – see, e.g., T330/03, however, care should be taken regarding a proper disclosure and claim drafting, see T143/04

IV New technology, old problems



Case law on Article 53 c) EPC, diagnostic methods:

Mandatory steps of a diagnostic method (G1/04):

- (i) examination phase involving **data collection**;
- (ii) **comparing** those data to **standards**;
- (iii) **finding significant deviations** during the comparison; and
- (iv) **attributing the deviation** to a clinical picture

IV New technology, old problems



Case law on Article 53 c) EPC, diagnostic methods:

Practised on the human or animal body (G1/04):

- applies only to steps of pure technical nature, i.e. the data collection phase;
- must not be fulfilled for the intellectual exercise of deducing a diagnosis
- must not be fulfilled for the steps of predominant non-technical nature, i.e. the data evaluation steps

IV New technology, old problems



Case law on Article 53 c) EPC, diagnostic methods:

Missing mandatory step (G1/04):

*“The method steps to be carried out prior to making a diagnosis as an intellectual exercise (cf. point 5.2 above) are related to **examination, data gathering and comparison** (cf. point 5 above). If only one of the preceding steps which are constitutive for making such a diagnosis is lacking, there is no diagnostic method, but at best a method of data acquisition or data processing that can be used in a diagnostic method (cf. T 385/86, point 3.3 of the Reasons). It follows that ... several method steps are required to define a diagnostic method within the meaning of Article 52(4) EPC due to the inherent and inescapable multi-step nature of such a method (cf. point 5 above).”*

IV New technology, old problems



Overcoming hurdles for specific digital health inventions:

Subject matter	Potential patentability problem	Solution
Digital diagnostic methods	Computer program, mental act and diagnostic method	G1/04, "in vitro" methods for analyzing data, i.e. examination step can be avoided
Test and evaluation software	Computer program, mathematical method, mental act and diagnostic method	G1/04, data generation, evaluation and mining not excluded, i.e. methods not aiming at a diagnosis <i>stricto sensu</i>
Health care assistance system	Computer program, doing business and diagnostic method	G1/04, data generation, evaluation and mining not excluded, i.e. methods not aiming at a diagnosis <i>stricto sensu</i> , examination step can be avoided

V Summary



Depending on the technology, problems of digital health inventions are either related to the field of computer-implemented inventions or the field of diagnostic methods

Digital health technologies involve new technologies facing old problems with existing solutions by the EPO's case law (see, e.g., G3/08 or G1/04)

VI Opportunities and risks



- Appropriate protection comparable to the field of classical biomarker diagnostics or software shall be available
- Particular aspects may need to be resolved by case law, however, the EPOs tendency was so far patent-friendly
- Other than in the field of classical biomarker diagnostics, more design-around options may exist in the field
- „Off label“ and private uses may be easier and more widespread than in classical biomarker diagnostics
- At least some technological aspects may be additionally protected by other IP-rights, such as designs (design of devices, graphical user interfaces) or copyrights (software or databases)

VII Discussion



... Thank you !!!