Life Sciences & eHealth – Legal Key Issues

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eHealth potpourri

- Patients' Electronic Health Records (EHR) and health information exchange (HIE) networks

- eHealth and pharma

- Challenges for the patent system

- Diagnosis tools

- Software as medical device

Patients' Electronic Health Records (EHR) and health information exchange (HIE) networks: Key legal issues

- Data protection and privacy: written and informed consent of patient.

- Competences between Confederation and Cantons.

- Financing.

- Liabilities in case of violation of data protection obligations and wrong entries.

- Secondary use of EHR data (e.g. for scientific research).

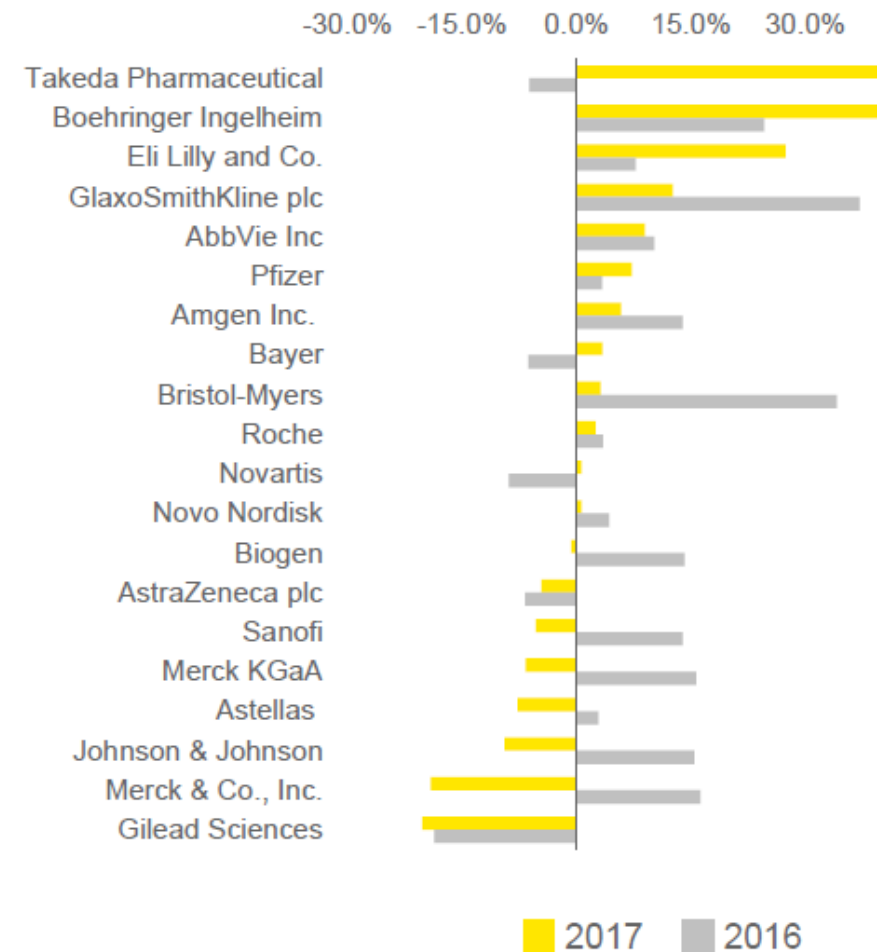- Criminal sanctions in in the event of intrusion into data system.

Challenges of pharmaceutical companies

- Increasing costs for R&D and for marketing approval (preclinical studies and clinical studies, see study of the Center for the Study of Drug Development (CSDD)).

Cost, $ millions

Preclinical
Clinical

1,500
1,200
900
600
300
0

1970s   1980s   1990–2000   2000–2010
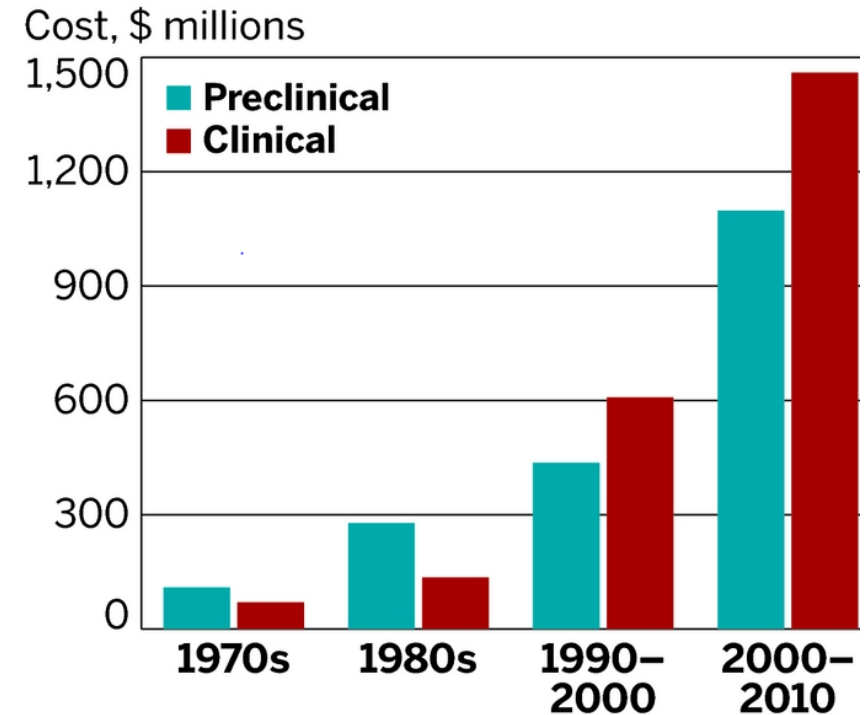
Challenges of pharmaceutical companies

- Stagnating EBIT (EY report of 2018)

Possible solution: cooperations between high-tech and pharma

- Since 2014 AbbVie has been in cooperation with Google's subsidiary Calico.

- In 2015, Johnson & Johnson announced cooperation with IBM's Watson platform.

- In December 2016, IBM announced that Pfizer would use the Watson platform.

- In June 2017, Genentech, a member of the Roche group, announced a collaboration with GNS Healthcare (a precision medicine company) focused on cancer therapy.

- At the same time Novartis announced its collaboration with IBM's Watson platform for the purpose of improving breast cancer treatments. Novartis also cooperates with Google, Microsoft, Qualcomm.

- Biogen and Sanofi have announced cooperations with Google.

Challenges for patent system

Questions under patent law:

- Patentability of algorithms (computer implemented inventions)?

- Patentability of output of algorithms?

  - Inventorship?

  - Definition of person skilled in the art?

  - How to examine inventive step?

Position of the European Patent Office

- Amended guidelines on mathematical methods, AI and machine learning (October 2018)

- Two-hurdle approach
  - Technical character of the invention.
  - Technical contribution to inventive step.
  - Algorithm as such cannot be patented but

- Two main options to overcome the two-hurdle approach:
  - Restrict claims to a specific technical purpose or application (see e.g. decision T 1227/05 "INFINEON")
  - Claiming a specific technical implementation of a mathematical method that has been specifically adapted to run on a particular hardware configuration (in the words of the EPO: "the design of the mathematical method is motivated by technical considerations of the internal functioning of the computer").


Patenting Artificial Intelligence

Conference summary
30 May 2018, EPO Munich

Diagnosis tools: Stanford's skin cancer diagnosis algorithm

- In February 2017, researchers of Stanford University published an article in NATURE and announced to have trained an algorithm for the **diagnosis of skin cancer** that outperforms expert dermatologists.

- Stanford algorithm is based on Google's Convolutional Neural Network (CNN) (93.33% accuracy on 1,000 object classes (1.28 million images) of 2014 ImageNet Challenge).

- Fine tuning: 130,000 images of skin lesions representing over 2,000 different skin diseases taken from the Internet.

- Testing conditions: Biopsy-proven pictures from ISIC (International Skin Imaging Collaboration) Dermoscopic Archive, Edinburgh Dermofit Library and Stanford Hospital.
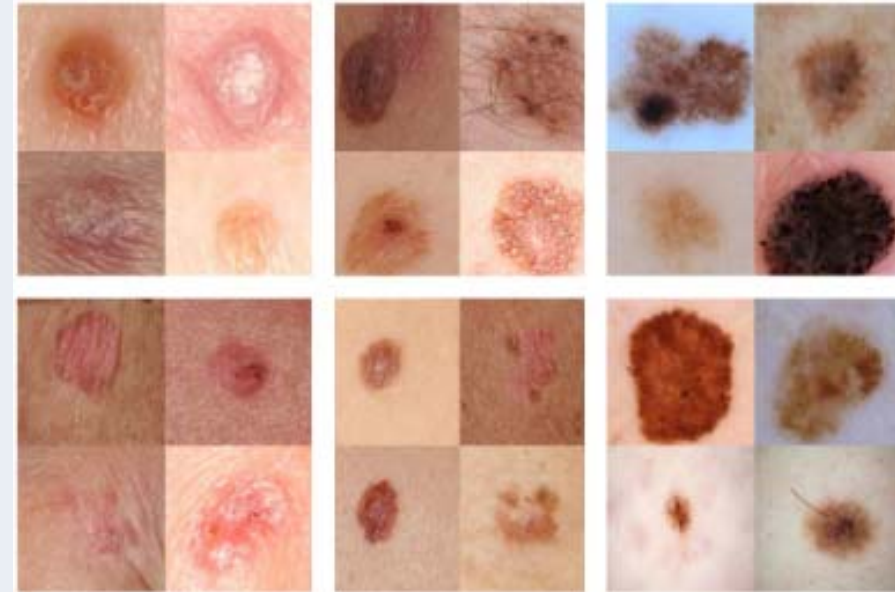
Stanford's skin cancer diagnosis algorithm: legal issues

- Use of pictures from the Internet for training:
    - Personal rights
    - Copyrights of photographers
    - Database rights
    - Others?
- Patentability of software and diagnosis tools? Copyright protection?
- Inventorship?
    - Programmers of Google's CNN?
    - Google staff for pre-training?
    - Stanford researchers for fine-tuning?
    - Others?

![mll logo]

Software as medical device: ECJ decision C-329/16 and decision of the Swiss Federal Administrative Court (C-669/2016)

- Software is key to e-health.

- **ECJ decision C-329/16** of 7 December 2017: French Syndicat national de l'industrie des technologies médicales (Snitem) versus Philips France.

- Decision of the **Swiss Federal Administrative Court (C-669/2016)** of 17 September 2018

Definition of medical devices according to EU Directive

- **Software of Philips France** compares patient data with drugs and is able to provide doctor with automated analysis that detects, among other things, possible contraindications, drug interactions and overdoses.

- Purpose of software is to prevent, monitor, treat or alleviate diseases. Therefore, software = medical device.

- Irrelevant, whether software directly acts in or on the human body.

Definition of medical devices under Swiss law

- **Sympto App**: By evaluating the personal data of the users, the app can help determine the fertile days of women.

- Swissmedic prohibited marketing and sales of Sympto App in Switzerland. Swiss Federal Administrative Court confirmed.

- Requirements of EU (Directive 93/42/EEC of 14 June 1993 concerning medical devices) and Switzerland (Medical Devices Ordinance) are identical.

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Besten Dank

Wir danken für Ihre Zeit und Ihr Interesse.