Copyright and AI – It's not just about the cultural industries

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What is AI?

Most of the current interest by the public stems from the remarkable progress in generative AI, including several popular Large Language Models including but not limited to services like ChatGPT, Gemini, Meta AI, Grok/XAI, Claude, DeepSeek and a growing number of impressive services to create images and audio.

The rise is share prices for companies associated with generative AI has led to an extensive rebranding of a wide range of computer enabled services as “AI”, including many older technologies.

Copyright disputes involve a variety of topics, on both the input (training) and output side.

Text and data mining exceptions

Text and data mining exceptions for copyright have been a highly contentious issue around the world.

Is it an infringement to use a copyrighted work to training AI, and if there are exceptions for text and data mining, do they provide for opt-outs, apply to commercial uses, or make other distinctions?

“As laws and regulations emerge, care should be exercised to avoid a one-size-fits-all approach, in which the rules that apply to recorded music or art also carry over to the scientific papers and data used for medical research and development.”

> *We Need Smart Intellectual Property Laws for Artificial Intelligence: “One-size-fits-all” regulation will sideline medical and research benefits promised by the advent of artificial intelligence, Scientific American, August 7, 2023.*
>
> *https://www.scientificamerican.com/article/we-need-smart-intellectual-property-laws-for-artificial-intelligence/*

Some recent KEI comments:

- February 2025 submission to the UK IP office consultation on AI and Copyright (available here: https://www.keionline.org/40558)
- February 3, 2025 comments to USTR regarding its Special 301 list (Available here: https://www.regulations.gov/comment/USTR-2024-0023-0051)
- March 15, 2025. Respond to NSF Request for Information on the Development of an Artificial Intelligence (AI) Action Plan. https://www.keionline.org/wp-content/uploads/KEI-RFC-AI-Action-Plan-15March2025.pdf

KNOWLEDGE ECOLOGY INTERNATIONAL

UK Intellectual Property Office
Copyright and AI: Consultation 2025

Data spaces

Data spaces are an emerging concept designed to facilitate the secure, trusted and efficient exchange or other use of data across different organizations, sectors, and countries, while protect norms regarding privacy or other safeguards.

In some implementations data is controlled by non-commercial entities, sanctioned by governments, and researchers can query data held by multiple decentralized data sets.

REGULATION (EU) 2025/327 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L_202500327

(Text with EEA relevance)

5.3.2025

Health data holder

The EHDS Regulation introduces the concept of “health data holder,” which can include any legal person operating in the healthcare sector, developing health products or services, or conducting health-related research, as well as public authorities, agencies, and bodies, including reimbursement services that either:

Key obligations for health data holders include:

Obligation to share health data: When access to health data is granted by the health data access body (HDAB, a national body responsible for assessing health data access requests and applications), health data holders must share the requested health data, unless the patients concerned have opted out of sharing.

https://www.arnoldporter.com/en/perspectives/advisories/2025/03/european-health-data-space-regulation-published

Health Data Categories Concerned by the EHDS Regulation

The EHDS Regulation specifies the categories of health data that health data holders must share, and which may be requested for access, including:

- Genetic, epigenomic, genomic, proteomic, transcriptomic, metabolomic, lipidomic, and other omic data
- Data from clinical trials, clinical studies, clinical investigations, and performance studies (note that clinical trial and clinical investigations data may be shared once the trial has ended)
- Personal health data automatically generated through medical devices and “other” health data from medical devices (note that it is not specified what “other” means)
- Health data from biobanks and associated databases
- Healthcare-related administrative data, including on dispensations, reimbursement claims, and reimbursements
- Data from registries for medicinal products and medical devices
- Data from medical and mortality registries
- Data from population-based health data registries (i.e., public health registries)
- Data from health research cohorts, questionnaires, and surveys after the first publication of the results
- Data on professional status, and on the specialization and institution of health professionals involved in the treatment of a natural person
  Data from wellness applications

These are the minimum categories of health data concerned by the EHDS Regulation, though EU Member States may add additional categories of health data at the national level.

https://www.arnoldporter.com/en/perspectives/advisories/2025/03/european-health-data-space-regulation-published

The EHDS Regulation allows health data to be used for “secondary purposes.”

- Public interest in the areas of public or occupational health
- Policy-making
- Statistics
- Education
- Scientific research
- Health treatment optimization

(61) . . . Access to data for secondary use should contribute to the general interest of society. In particular, the secondary use of health data for research and development purposes should contribute to benefiting society in the form of **new medicines, medical devices, and healthcare products and services at affordable and fair prices** for Union citizens, as well as to enhancing access to and the availability of such products and services in all Member States. . . .

The notion of scientific research purposes should be interpreted in a broad manner, including technological development and demonstration, fundamental research, applied research and privately funded research. Activities related to scientific research include innovation activities such as **training of AI algorithms** that could be used in healthcare or the care of natural persons, as well as the evaluation and further development of existing algorithms and products for such purposes. It is necessary that the EHDS also contribute to fundamental research, and, although its benefits to end-users and patients might be less direct, such fundamental research is crucial for societal benefits in the longer term. In some cases, the information of some natural persons, such as genomic information of natural persons with a certain disease, could contribute to the diagnosis or treatment of other natural persons.

Article 52 -Intellectual property rights and trade secrets

1. **Electronic health data protected by intellectual property rights, trade secrets or covered by the regulatory data protection right** laid down in Article 10(1) of Directive 2001/83/EC of the European Parliament and of the Council (36) or Article 14(11) of Regulation (EC) No 726/2004 of the European Parliament and of the Council (37) **shall be made available for secondary use in accordance with the rules laid down in this Regulation.**

2. Health data holders shall inform the health data access body of any electronic health data containing content or information protected by intellectual property rights, trade secrets or covered by the regulatory data protection right laid down in Article 10(1) of Directive 2001/83/EC or Article 14(11) of Regulation (EC) No 726/2004. Health data holders shall identify which parts of the datasets are concerned and justify the need for the specific protection of the data. Health data holders shall provide that information when communicating to the health data access body the description of the dataset they hold pursuant to Article 60(3) of this Regulation or, at the latest, following a request received from the health data access body.

3. Health data access bodies shall take all specific appropriate and proportionate measures, including of a legal, organisational and technical nature, they deem necessary to protect the intellectual property rights, trade secrets or the regulatory data protection right laid down in Article 10(1) of Directive 2001/83/EC or Article 14(11) of Regulation (EC) No 726/2004. Health data access bodies shall remain responsible for determining whether such measures are necessary and appropriate.

4. When issuing data permits in accordance with Article 68, health data access bodies may make the access to certain electronic health data conditional on legal, organisational and technical measures, which may include contractual arrangements between health data holders and health data users for the sharing of data containing information or content protected by intellectual property rights or trade secrets. The Commission shall develop and recommend non-binding models of contractual terms for such arrangements.

5. Where the granting of access to electronic health data for secondary use **entails a serious risk of infringing intellectual property rights, trade secrets or the regulatory data protection right** laid down in Article 10(1) of Directive 2001/83/EC or Article 14(11) of Regulation (EC) No 726/2004 **which cannot be addressed in a satisfactory manner, the health data access body shall refuse access to the health data applicant to such data.** The health data access body shall inform the health data applicant of, and provide to the health data applicant a justification for, that refusal. Health data holders and health data applicants shall have the right to lodge a complaint in accordance with Article 81 of this Regulation.

Article 53 Purposes for which electronic health data can be processed for secondary use

1. Health data access bodies shall only grant access to electronic health data referred to in Article 51 for secondary use to a health data user where the processing of the data by that health data user is necessary for one of the following purposes:

(a) the public interest in the areas of public or occupational health, such as activities to protect against serious cross-border threats to health, public health surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety, and of medicinal products or medical devices;
(b) policymaking and regulatory activities to support public sector bodies or Union institutions, bodies, offices or agencies, including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;
(c) statistics as defined in Article 3, point (1), of Regulation (EC) No 223/2009, such as national, multi-national and Union-level official statistics, related to health or care sectors;
(d) education or teaching activities in health or care sectors at vocational or higher education level;
(e) scientific research related to health or care sectors that contributes to public health or health technology assessments, or ensures high levels of quality and safety of healthcare, of medicinal products or of medical devices, with the aim of benefiting end-users, such as patients, health professionals and health administrators, including:
    (i) development and innovation activities for products or services;
    (ii) training, testing and evaluation of algorithms, including in medical devices, in vitro diagnostic medical devices, AI systems and digital health applications;
(f) improvement of the delivery of care, of the optimisation of treatment and of the provision of healthcare, based on the electronic health data of other natural persons.

2. Access to electronic health data for the purposes referred to in paragraph 1, points (a), (b) and (c), shall be reserved for public sector bodies and Union institutions, bodies, offices and agencies exercising the tasks conferred on them by Union or national law, including where processing of data for carrying out those tasks is done by a third party on behalf of those public sector bodies or of Union institutions, bodies, offices and agencies.

Article 54 Prohibited secondary use

Health data users shall only process electronic health data for secondary use on the basis of and in accordance with the purposes contained in a data permit issued pursuant to Article 68, health data requests approved pursuant to Article 69 or, in situations referred to in Article 67(3), an access approval from the relevant authorised participant in HealthData@EU referred to in Article 75.

In particular, seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 68 or a health data request approved pursuant to Article 69 for the following uses shall be prohibited:

(a) taking decisions detrimental to a natural person or a group of natural persons based on their electronic health data; in order to qualify as ‘decisions’ for the purposes of this point, they have to produce legal, social or economic effects or similarly significantly affect those natural persons;
(b) taking decisions in relation to a natural person or a group of natural persons in relation to job offers, offering less favourable terms in the provision of goods or services, including exclusion of such persons or groups from the benefit of an insurance or credit contract, the modification of their contributions and insurance premiums or conditions of loans, or taking any other decisions in relation to a natural person or a group of natural persons which result in discriminating against them on the basis of the health data obtained;
(c) carrying out advertising or marketing activities;
(d) developing products or services that may harm individuals, public health or society at large, such as illicit drugs, alcoholic beverages, tobacco and nicotine products, weaponry or products or services which are designed or modified in such a way that they create addiction, contravene public order or cause a risk for human health;
(e) carrying out activities in conflict with ethical provisions laid down in national law.

Article 55 Health data access bodies

1. Member States shall designate one or more health data access bodies responsible for carrying out the tasks and obligations set out in Articles 57, 58 and 59. Member States may either establish one or more new public sector bodies or rely on existing public sector bodies or on internal services of public sector bodies that fulfil the conditions set out in this Article. The tasks set out in Article 57 may be distributed between different health data access bodies. Where a Member State designates several health data access bodies, it shall designate one health data access body to act as coordinator, with responsibility for coordinating tasks with the other health data access bodies both within the territory of that Member State and in other Member States. . . .

. . .

3. Member States shall ensure that any conflicts of interest between the organisational parts of health data access bodies performing the different tasks of such bodies is avoided by, for example, providing for organisational safeguards such as segregation between health data access bodies' different functions, including assessing applications, the reception and preparation of datasets, for example pseudonymisation and anonymisation of datasets, and the provision of data in secure processing environments.

4. In the performance of their tasks, health data access bodies shall actively cooperate with relevant stakeholders' representatives, especially with representatives of patients, health data holders and health data users and shall avoid any conflicts of interest.

5. In the performance of their tasks and exercise of their powers, health data access bodies shall avoid any conflicts of interest. Health data access bodies' staff shall act in the public interest and in an independent manner.

. . .

Fees and other barriers to sharing for secondary use

(69) In order to support secondary use, health data holders should refrain from withholding the data, requesting unjustified fees that are not transparent or proportionate to the costs of making the data available or, where relevant, to marginal costs of data collection, requesting the health data users to co-publish the research or other practices that could dissuade the health data users from requesting the data. Where a health data holder is a public sector body, the part of the fees linked to its costs should not cover the costs of the initial collection of the data. Where ethical approval is necessary for providing a data permit, the evaluation related to ethical approval should be based on its own merits.

More on EHDS fees

(70) Health data access bodies should be allowed to charge fees, taking into account the horizontal rules provided by Regulation (EU) 2022/868, in relation to their tasks. Such fees could take into account the situation and interest of small and medium-sized enterprises (SMEs), individual researchers or public sector bodies. In particular, Member States should be able to establish measures for health data access bodies in their jurisdiction which make it possible to charge certain categories of health data users reduced fees. Health data access bodies should be able to cover the costs of their operations with fees set up in a proportionate, justified and transparent manner. This could result in higher fees for some health data users, if handling their health data access applications and health data requests requires more work. Health data holders should be allowed to also ask for fees for making data available which reflect their costs. Health data access bodies should decide on the amount of such fees, which could also include the fees requested by health data holders. The health data user ought to be charged such fees by the health data access body in a single invoice. The health data access body should then transfer the relevant part of the paid fees to the health data holder. In order to ensure a harmonised approach concerning fee policies and structure, implementing powers should be conferred on the Commission. Article 10 of Regulation (EU) 2023/2854 should apply to fees charged under this Regulation.

Concluding comments

Or some types of AI services, it will be important to have robust exceptions for text and data.

In some cases, the evolving market structure can be shaped by public policy.

Competition policy, standards, meta data, interoperability and countless other issues need to be addressed, and in some cases, cross border norms will be important.

fyi

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