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Artificial Intelligence: Moving the Needle

Cleary Gottlieb Pharmaceutical, Biotech and Healthcare Group

February 2024

Artificial Intelligence in Pharma, Biotech and Healthcare

1. **Industry overview** – Increased focus among Pharmaceutical, Biotech and Healthcare players on AI-related investments, and use of AI tools internally.

2. **Regulatory landscape** – Further scrutiny by global regulators of AI models and systems (particularly those used in the healthcare sector).

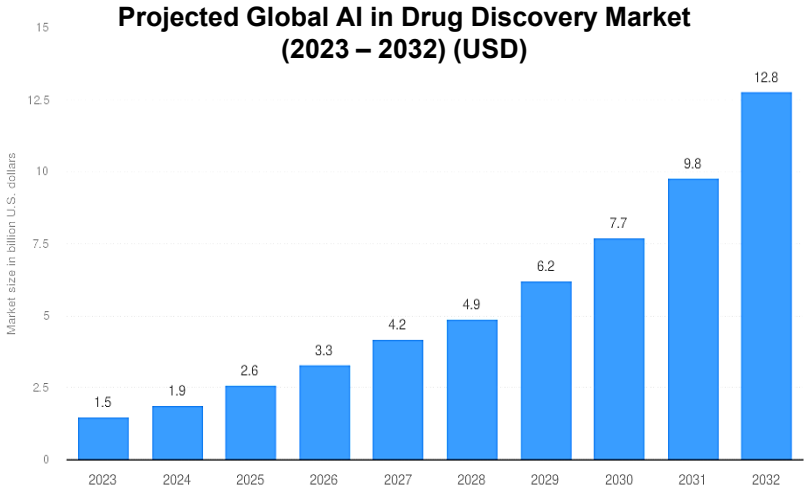
3. **Ownership of IP** – Legal uncertainty regarding the IP protection for AI-generated output.

4. **Practical considerations** for AI collaborations and for M&A.

1 Increase in AI-Related Investments in Pharma/Biotech

INDUSTRY TRENDS

- Artificial intelligence/machine learning are **key drivers** transforming the life sciences industry
- **Increase in AI use cases** e.g., in drug discovery, clinical trials, and manufacturing processes
- Big pharma hiring new talent, acquiring new technologies and implementing internal policies to be "AI ready"
- Growth in **AI-related investments** by Pharma/Biotech companies
- Over the next 10 years, the market for AI in drug discovery is expected to increase nearly ninefold (*Statista)*



Source: Statista (Dec 2023)

RECENT DEAL HIGHLIGHTS

- **Aqemia** closed €60m Series A funding round for new drug discovery technology (Jan 2024)
- **Bayer** partnering with Google to solve quantum chemistry problems in drug discovery (Sep 2023)
- **NVIDIA** partnering with Recursion to develop and expand AI applications for drug discovery (Aug 2023)
- **Eli Lilly** collaborating with XtalPi on AI drug discovery project leveraging XtalPi's integrated AI capabilities and robotics platform, ID4Inno, to design and deliver drug candidates (May 2023)
- **Moderna** collaborating with IBM to develop AI models to advance mRNA and quantum computing (Apr 2023)

1 AI Use Cases in Pharma and Life Sciences

Drug Discovery and Repurposing

Applying AI/ML to large datasets can (i) speed up discovery of new molecules, and (ii) identify existing drugs that may be used for different diseases

Clinical Trials

AI can significantly reduce trial times and costs e.g., by identifying suitable patient populations more quickly and efficiently

Patient Experience

Emerging AI technologies (e.g., chatbots) can enhance patient experiences, and help to deliver personalised treatments

Commercial and Marketing

AI can provide actionable insights based on patient journeys, advertising metrics, product trends etc. to improve marketing and messaging

Pharmacovigilance

Automating adverse event reports can reduce documentation workload and expedite investigation processes

Manufacturing and Supply Chain

Use of AI in the manufacturing process can help to detect and eliminate defects in real-time

2 A Patchwork of Emerging AI Regulation

INTERNATIONAL INITIATIVES AND GUIDANCE

- OECD AI principles (2019)
- G7 Hiroshima Process International Code of Conduct for Organizations Developing Advanced AI Systems and Guiding Principles for Advanced AI Systems (2023)
- The Bletchley Declaration by Countries Attending the UK AI Safety Summit (2023)
- United Nations Secretary-General's AI Advisory Body (2023)

KEY JURISDICTIONS IN FOCUS

AI BILL OF RIGHTS

EXECUTIVE ORDER

NIST AI RISK MANAGEMENT FRAMEWORK

FTC ENFORCEMENT

CCPA DRAFT AI REGULATION

AI ACT

AI LIABILITY DIRECTIVE

CYBER RESILIENCE ACT

DATA ACT

GDPR

EUROPEAN HEALTH DATA SPACE

AI WHITE PAPER

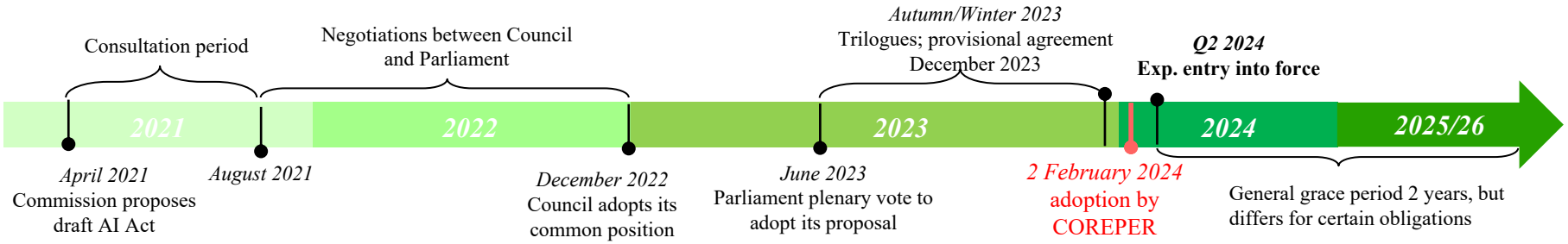
DIGITAL MARKETS, COMPETITION, & CONSUMERS BILL

DATA PROTECTION AND DIGITAL INFORMATION BILL

AI (REGULATION) BILL [HL]

2 The EU AI Act – Overview

THE ROAD TO REGULATION



APPLIES TO "PROVIDERS" BUT THE AI SUPPLY CHAIN IS IN FOCUS

*Providers** that develop AI systems or GPAI models, and *Deployers* using AI systems (including providers and deployers located outside EU where output produced by those systems is used in EU).

TIMING FOR IMPLEMENTATION

Expected timelines for effect (once approved) are:

- 2-year transitional period for most obligations
- 6 months for ban of unacceptable risk AI systems (i.e., prohibited AI practices)
- 36 months for obligations relating to high-risk AI systems and corresponding obligations (but special rules if already placed on market)
- 12 months for obligations relating to GPAI (or 2 years for GPAI models already placed on market)

RISK-BASED APPROACH

Classification system according to the level of risk that AI technology could pose to the health and safety or fundamental rights of a person (i.e., minimal, limited, high, unacceptable risk).

**Distributors*, *importers*, *deployers* or *other third parties* considered *providers* if they (i) put their name/trademark on high-risk system already on market or put into service, (ii) make substantial modifications to high-risk AI system, or (iii) modify the intended purpose of an AI system, inc. GPAI systems, so it becomes high-risk.

2 The EU AI Act – "High-Risk" AI Systems

WHAT IS A "HIGH-RISK" AI SYSTEM? (*Article 6*)

- AI system is **"high-risk"** where:
  - (i) it is intended to be used as a **safety component** of a product, or the AI system is **itself a product**, that is considered high-risk under relevant Union harmonization legislation (e.g., Regulation (EU) 2017/745 on Medical Devices); or
  - (ii) in light of its intended purpose, poses a **high risk of harm** to the health and safety or the fundamental rights of persons (as listed in Annex III of the EU AI Act).
- An AI system shall always be considered **high-risk** if it performs **profiling of natural persons**

Providers (and other members of the AI value chain) that develop or use high-risk AI systems, will be **subject to certain obligations** under the EU AI Act e.g., quality management systems, conformity assessments, registration obligations, maintenance of technical documentation. *Deployers* (if not considered providers) of high-risk AI systems also have certain obligations, including assigning human oversight to use of such systems.

EXCEPTIONS (*Article 6(2a)*)

AI systems will **not be considered high-risk** if they **do not pose a significant risk of harm** to the health, safety or fundamental rights of natural persons, including by **not materially influencing the outcome of decision making**. This will be the case if one or more of the following criteria are fulfilled:

NARROW PROCEDURAL TASK
e.g., an AI system that transforms clinical trial data into a graphic, or structured database

IMPROVE RESULTS OF HUMAN ACTIVITY
e.g., AI is used to improve the tone of communications with patients

DETECT DECISION-MAKING PATTERNS
e.g., an AI tool provides insights on product uptake and patient journeys

PREPARATORY ASSESSMENT
e.g., using an AI system to identify gaps in applications for public health benefits/services

Human-centric approach: *In general, EU regulators (such as the European Medicines Agency) are advocating for a "human-centric" approach, requiring the* ***inclusion of human agency and oversight*** *within the development of AI/ML tools. The EU AI Act also states that high-risk AI systems shall be designed and developed in a way that can be effectively overseen by humans.*

2 The EU AI Act – "General Purpose" AI

Pharma/Biotech companies incorporating GPAI models into their products or services should consider (i) additional obligations imposed on providers of such models, and (ii) appropriate allocation of responsibility with third party providers.

"GENERAL PURPOSE"

AI model, that displays **significant generality** and is capable to competently perform a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of **downstream systems or applications**.

AI system, which is **based on a general-purpose AI model**, that has the capability to serve a **variety of purposes**, both for direct use as well as for integration in other AI systems.

OBLIGATIONS ON PROVIDERS OF GPAI MODELS*

TECHNICAL DOCUMENTS
inc. training and testing process and evaluation results

DISCLOSURE
of info & documents to downstream providers who integrate GPAI model

COPYRIGHT POLICY*
to respect EU copyright law, inc. TDM opt-outs

TRAINING SUMMARY*
to be drawn up and made available publicly

**Providers* of AI models made accessible under free and open licence still need to comply with these obligations, plus applicable obligations if model poses systemic risk.

"HIGH IMPACT" CAPABILITIES

GPAI models classified as having systemic risk:

- if high impact capabilities; or
- based on a decision of the Commission, ex officio.

Presumption of high impact capabilities: amount of compute used for training measured in **floating point operations > 10^25**

OBLIGATIONS FOR "HIGH IMPACT" GPAI MODELS

- **Model evaluation**, inc. adversarial testing
- Assess and **mitigate** possible systemic risks
- Document and report **serious incidents** and corrective measures
- Ensure adequate level of **cybersecurity** protection for model and physical infrastructure

REBUTTABLE PRESUMPTION

Provider of "high impact" GPAI model may argue model does not present systemic risk

2 The EU AI Act – R&D Exclusions

To support innovation, the EU AI Act acknowledges the importance of research and development activities and therefore excludes certain of such R&D activities from its scope. **Article 2 expressly excludes:**

a) AI systems and models (including their output) specifically developed and put into service for the sole purpose of **scientific R&D**.
b) Research, testing and development activities regarding AI systems/models **prior** to being placed on the market or put into service.

Note - Testing in real world conditions is not exempted.

2 Product Liability and AI Liability Directives

In September 2022, the European Commission published two proposals to address liability in respect of digital technologies (including AI).

A *Revisions to Product Liability Directive ("PLD")*

- Clarification that the **product liability regime extends to digital technologies,** including AI-enabled goods and services, and that providers of digital services and software can be held liable under such regime.
- **Extension of "products" beyond tangible goods**. Products comprising software (other than free and open-source software) or integrated in, or interconnected with, digital services are **likely to fall within the broad definition of "product"** under the revised PLD, irrespective of the mode of supply or usage.
- The revised PLD introduces **claimant-friendly (rebuttable) presumptions** in respect of product defectiveness.

B *New AI Liability Directive ("AILD")*

- AILD seeks to introduce certain **uniform requirements in respect of non-contractual fault-based civil law claims for damages caused by an AI system**, including in relation to disclosure of evidence relating to high-risk AI systems, and the burden of proof in such cases.
- Both **"providers" and "users" of AI systems can be held liable** in respect of fault-based liability claims.
- AILD adds a **claimant-friendly (rebuttable) presumption** that an AI system was defective where it was used in the process that resulted in the harm (**even if establishing causation is very difficult**).

Pharma/Biotech companies using AI tools in their business should consider these directives when developing/licensing tools that could cause harm to patients e.g., a chatbot delivering medical advice based on patient inputs.

3 IP Protection for AI-Generated Outputs

Copyright / Database Rights *e.g., AI used to generate R&D materials/reports and molecular simulation data*	— a work of authorship must be the "**author's own intellectual creation**", which is excluded where the content of the work is dictated by technical considerations which leave no room for creative freedom *(Infopaq, CJEU)* BUT consider: — **EU database rights *might* be available** for the substantial investment in obtaining, verifying or presenting the contents of the database – such rights <u>do not</u> require a human author (though there may be challenges to showing "substantial investment" threshold has been met for AI-generated databases)	— the concept of "**originality**" or "**human creativity**" applies to AI-created works — a work of authorship must be the "**author's own intellectual creation**", which is excluded where the content of the work is dictated by technical considerations which leave no room for creative freedom *(Infopaq, CJEU)* BUT under Section 9(3) CDPA: — **original computer-generated works with no human creator may be copyrightable** – the author is the person by whom the arrangements necessary for the creation of the work are undertaken — See also *Nova Productions v. Mazooma Games (EWHC 24, 2006); THJ Systems v. Sheridon (EWCA Civ 1354, 2023)* IN ADDITION: — **UK database rights *might* be available** for the substantial investment in obtaining, verifying or presenting the contents of the database – such rights <u>do not</u> require a human author (though similar challenges as in the "EU" column)	— a work of authorship must be **created by a human being** *(Thaler v. Perlmutter (D.D.C. Aug. 18, 2023); Naruto v. Slater (9th Cir. 2018))* — a database might in certain circumstances be protectible as a compilation under U.S. copyright law, but human authorship is still required
Patent *e.g., AI used to generate new compounds / production methods*	— **inventor must be a natural person** *(Thaler v. EPO (EPO Board of Appeal, J0008/20)*	— **inventor must be a natural person** *(Thaler v. Comptroller (UKSC 49, 2023))*	— **inventor must be a natural person** *(Thaler v. Vidal (Fed. Cir. 2022))*

Pharma/Biotech companies should take these limitations into account when developing AI-generated works and consider alternative forms of protection (e.g., via contract, internal policies or other areas of IP law).

4 Practical Considerations – *AI Collaborations*

To mitigate some of the uncertainty surrounding IP ownership and allocation of rights in any AI-generated outputs, Pharma and Biotech companies should consider the following:

A ***Contracts with Third-Party AI Vendors***

e.g., Pharma/Biotech company in-licensing AI tools, or partnering with AI developers for drug discovery expansion.

- Expand vendor's *confidentiality obligations* to include customer data, prompts and output data provided to and by the AI tool
- *Allocation of IP rights* i.e., ownership of outputs (and improvements and derivative works)
- Terms governing *retention, storage, deletion and use* of prompt/output data by third party vendor
- Consider requiring hosting of the AI tool (or customised instance of it) in customer's environment (whenever possible)
- In the case of breach of confidentiality obligations, consider provisions covering available remedies i.e., uncapped indemnification, right to audit, right to obtain injunction etc.

B ***Internal Measures and Strategy***

- As IP ownership under existing patent and copyright laws is uncertain, Pharma/Biotech companies should consider:
  - Alternative forms of protection for AI-generated output, such as **trade secrets** or **database rights**, and
  - Implementing robust procedures and policies to prevent breach of confidentiality or loss of trade secret protection e.g., *internal policies covering employee usage of third-party AI tools (e.g., ChatGPT), and including restrictions on including confidential information (such as trade secrets) in prompts*

4 Practical Considerations – *M&A*

Buyers of AI-centric target companies should consider some unique risks and opportunities posed by AI:

A *AI-Specific Issues for Due Diligence*

- **Consider territories** in which AI products/services were developed and physical location of AI/data assets, given current substantial divergence in AI/data regulations across jurisdictions.
- **Ensure disclosure of core technical documents** needed for diligence of seller's product development and buyer's intended future uses of the relevant AI products or systems (e.g., results of third-party cybersecurity and adversarial testing of a target's AI systems).
- **Review data curation and governance processes**, particularly for R&D, health, clinical trial or medicinal product data if a core deal objective is to acquire "clean" proprietary data for future data mining and AI analysis.
- **Scrutinise claims of ownership** of AI-enabled and AI-generated assets.
- **Assess hidden litigation risks** – e.g., large-scale data scraping without regard to whether third-party permissions are required.

B *AI-Specific Protections for Transaction Documents*

- **Supplement customary compliance with law, litigation and IP reps and warranties with AI-specific provisions.** Conventional litigation and IP infringement reps may fail to elicit disclosure and allocate risk for major legal grey areas such as whether large-scale data gathering is "fair use" under U.S. copyright law. Consider specific indemnities.
- In asset deals, data and database transfers for AI training may require **specific data protection clauses**.
- In AI-centric carve-outs, ensure access to **books and records relating to AI product development** coupled with **transitional knowledge-sharing services** if seller retains key personnel.