As Humans Step Aside: Intellectual Property, Artificial Intelligence and Drug Development

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Research Handbook in Intellectual Property and Health (Ana Rutschman ed.) under contract with Elgar Publishing), forthcoming 2026/7

Draft of June 9, 2026: work in progress

I. Revolutionary Times

Pharmaceuticals as broadly defined[1] are integral to the promotion and protection of human health. Discussions of pharmaceuticals and intellectual property at the multilateral level for the past several decades have focused on the issue of access for individuals without sufficient financial resources or insurance/government coverage to obtain those products. A plethora of potential solutions have been proposed for making pharmaceuticals more accessible by addressing IP roadblocks.[2] The continuing difficulties raised by the exclusionary effects of IP do not result from the absence of credible solutions. This remains a political economy problem.[3]

We turn to the increasingly important question whether artificial intelligence (AI) may fulfill the dreams of its proponents and begin to solve the real problems of resource scarcity, particularly of affordable new drugs. Leaders in the AI community have floated the idea that artificial general intelligence (AGI) will change the world to one where individuals will contemplate what to do when freed from the demands of labor because resource utilization will be maximized.[4] We will live in an era of abundance. The same leaders have suggested that AI and/or AGI will tackle human biology and potentially find cures for all diseases.[5] To be clear-eyed, similar suggestions concerning the power of new technologies to transform the pharmaceutical space accompanied the mapping of the human genome

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[1] Including diagnostics, therapeutics and vaccines.

[2] See, e.g., Report of the United Nations Secretary-Generals High-Level Panel on Access to Medicines: Promoting innovation and access to health technologies, September 2016, access at https://www.unsgaccessmeds.org/final-report.

[3] Pharmaceuticals are but one of many areas where a large group of individuals would be better off with more access, whether that is to food, water, electricity, housing stock, education and other key components of day-to-day living.

[4] See, e.g., Scott Pelley, "Artificial intelligence could end disease, lead to 'radical abundance,' Google DeepMind CEO Demis Hassabis says, CBS News, Aug. 3, 2025, https://www.cbsnews.com/news/artificial-intelligence-google-deepmind-ceo-demis-hassabis-60-minutes-transcript/

[5] *Id*. See also note 7 infra.

at the turn-of-the-century and its promise that once we had identified the operative genetic components of human biology, we would be able to fix that biology.[6]

The Google spinoff, Isomorphic Labs,[7] as of mid-2026 the leader in applying AI to new drug development, has run into some early roadblocks in working to improve the success rate of novel drug development. Compounds that have predicted affinities *in silico* have confronted the reality of human biological systems. Recognizing the challenge, Nobel Prize winner and founder of DeepMind/Isomorphic, Demis Hassabis, has begun referring to a 10-year timeline for success in AI development of new drugs taking into account the need to model and predict delivery and processing within humans.[8] The challenge could be compared to the difficulties initially faced by mRNA vaccines before it was discovered that that a substitution for the uracil nucleotide base could create a vector capable of surviving entry into the cell.[9] Without that solution to the real-world complexity of the biological system, mRNA vaccines would not have worked. An AI-generated protein with an affinity for a particular chemical must reach its destination and not trigger a counterproductive reaction.

It seems more likely than not that the science teams at DeepMind and Isomorphic -- along with various industry partners that include the major originators -- can successfully task AI's to address the existing roadblocks. So far the teams have been moving rapidly to address challenges. But as with mapping the human genome, solving what appeared to be the fundamental problems that would unlock human biology was only a step in a longer process. Whether Isomorphic's ability to predict affinities will turn into effective therapies remains to be proven.

With those cautionary words, it seems almost certain that AI and/or AGI (hereinafter collectively referred to as "AI") will be successful in establishing a much better understanding of human biology and ways to modify it to promote health. Why the certainty? A comparison with humans.

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[6] See Michael J. Joyner1 and Nigel Paneth, *Promises, promises, and precision medicine*, J Clin Invest. 2019;129(3):946–948. https://doi.org/10.1172/JCI126119, referring inter alia to foundational paper by Francis Collins of 1999, FS Collins, Shattuck lecture--medical and societal consequences of the Human Genome Project, N Engl J Med,1999 Jul 1;341(1):28-37. doi: 10.1056/NEJM199907013410106.

[7] https://www.isomorphiclabs.com/. As of June 7, 2026, the main header on the Isomorphic website stated "Solve all disease".

[8] Demis Hassabis: Agents, AGI & The Next Big Scientific Breakthrough, April 29, 2026 https://youtu.be/JNyuX1zoOgU?si=OymNCbx4a5jofB_B.

[9] See Frederick M. Abbott, Intellectual Property and Technology Transfer for COVID-19 Vaccines: Assessment of the Record, at 52, World Intellectual Property Organization, 2023, Geneva, Switzerland.

The human species has evolved over several hundred thousand years,[10] with "modern" evolution measured in tens of thousands. The humans of biblical or vedantic times date back several thousand years. From that recent vantage point, human beings appear relatively unchanged from an evolutionary biology standpoint. Without venturing into a dissertation on that subject, and this line of reasoning has been developed before,[11] it seems doubtful that the human brain -- though better informed regarding its environment -- has changed much in several thousand years. And a limitation on the evolution of "knowledge processing" by the human brain is death. The effort that each human puts into educating itself is lost. The human DNA transposed in reproduction does not incorporate learned scientific knowledge. Of course, to the extent that an individual has made inventions or discoveries and they have become public (including on patent databases), thereby improving the earth's stock of knowledge, the great library evolves. But for another individual to make an important intellectual leap involves starting over, learning from the stock of knowledge, and applying that knowledge to create new knowledge.

AI is not bound by the same constraint. It does not sleep. It does not die. It stores information and continues evolving. And we know this includes neural networks that improve themselves. We understand that AI's can effectively talk to each other. In sum, human evolutionary biology cannot keep up with electromechanical -- and eventually quantum mechanical -- computational evolution.

We proceed further in two steps. The first is to consider the issues raised by introducing AI generated inventions into conventional IP systems, most prominently patent systems. The second is to contemplate the possibility of new paradigms that are developed on a fresh slate based on evolving requirements, and not looking back on the conventional modalities.

II. Conventional IP and Health

A. Patents

Intellectual property law is largely a construct of the late 1800s and 1900s.[12] Patent law evolved as a mechanism to grant and protect rights in new chemical compounds and mechanical equipment. These are physical products with characteristics definable by

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[10] Smithsonian National Museum of Natural History, "Homo sapiens", https://humanorigins.si.edu/evidence/human-fossils/species/homo-sapiensaccessed June 7, 2026.

[11] See, e.g., NICK BOSTROM, SUPERINTELLIGENCE: PATHS, DANGERS, STRATEGIES, OUP Oxford (2014); Ray Kurzweil. THE SINGULARITY IS NEAR: WHEN HUMANS TRANSCEND BIOLOGY (2006).

[12] For a general introduction to intellectual property rights from an international perspective, including historical background, see F. ABBOTT, ET AL., INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY, 5th ed., Aspen Publishing 2024.

drawings and text. In principle, in the pharmaceutical sector the commercialized end-products developed using AI should be definable in the same way as pharmaceutical products produced without AI involvement; that is by their chemical composition and structure, biological structure (e.g., DNA sequences), etc. It is therefore not the product "as such" that raises new issues, but rather the process by which the entitlement of the "inventor" to a patent will be determined.

1. Inventorship

My son, Ryan Abbott, some time ago identified the issue of AI inventorship as a key issue,[13] and pursued a series of patent applications and related legal contests seeking to name an AI as the sole inventor of the product (the so-called "DABUS" cases). Courts in Europe,[14] the United States, Australia[15] and other jurisdictions rejected assertions of sole AI inventorship, largely on grounds of statutory interpretation. Following resolution of the issue at the Court of Appeals for the Federal Circuit in the United States,[16] the USPTO issued guidance for the filing of AI invention affirming that an AI could not be named as an inventor (whether as a sole inventor or joint inventor), and further stating that humans who used AI as a tool for invention were not precluded from claiming inventorship.[17] This was in effect a practical solution to what might have been an insoluble problem for the PTO. Now the human inventor effectively becomes a fictitious proxy for the AI that did the inventing, and the PTO looks the other way. The PTO covers its tracks by indicating that the human must demonstrate participation in the inventive process sufficient to justify claiming inventorship.

In light of the most recent pronouncement by the USPTO, it is possible that the very obstacles that DeepMind and Isomorphic are confronting in developing new therapies will rescue them from unpatentability, at least temporarily. As discussed above, the fact that an AI generates a promising protein/chemical combination to address a disease does not assure that the candidate product will work in the complex human biological system. This necessitates further work by researchers in "classical" drug development. So, even though the "heart" of a new pharmaceutical product may have been conceived by an AI, the

[13] Ryan Abbott, *I Think Therefore I Invent: Creative Computers and the Future of Patent Law*, 57 BOST. COL. L. REV. 1079 (2016).
[14] E.g., In re Thaler, EPO Legal Board of Appeal, J 0008/20 - 3.1.01, 2021; Thaler v Comptroller-General of Patents, Designs and Trademarks ([2023] UKSC 49.
[15] Commissioner of Patents v Thaler [2022] FCAFC 62.
[16] Thaler v. Vidal, 43 F.4th 1207 (Fed. Cir. 2022).
[17] Revised Inventorship Guidance for AI-Assisted Inventions, 3510-16-P, Docket No. PTO-P-2025-0014, Nov. 26, 2025.

development of the surrounding technologies that make a new product work might well justify the grant of a patent to those who bring the new product to fruition.

How long this situation will last is "anybody's guess". What will bring it to an end? Improvements in AI capability that address the existing roadblocks in new drug development! As a broad generalization this would mean addressing "final delivery" in the human biological system including whatever human biological responses otherwise impede successful treatment (e.g., triggering immune response). How long will this take? Though of course there are more educated answers than my own, likely the answer for more knowledgeable observers would be, "we do not know, but it is just a matter of time". Whether one year, five years, 10 years, 20 years, or longer, the AIs will not be sleeping and will be hammering at the problems. While it may not be within the purview of the current staff of the USPTO, at some point the patent office and the courts will need to directly confront the situation of a patent application naming only an AI because no human could assert inventorship with even a remote claim to legitimacy.

This should not be an insoluble problem. The Paris Convention only requires that the inventor has the right to be named in the patent.[18] It does not specify "human", "individual" or "person" inventor. On its face it does not preclude naming an AI as an inventor. Countries can change their patent legislation to allow for the naming of AI's, and they can also create default rules for patent ownership on the assumption that an AI is not capable of owning a patent (i.e., property). The most likely default rule is that the owner of the AI will be the owner of its output. But ownership can be transferred such as through a contract from an AI service provider assigning the output to the user.

None of this would be particularly groundbreaking in terms of the general operation of a patent system and patent office. Functionally there is no difference between an AI being owned by a corporation and attributing its inventions to that corporation, and a typical scientist/employee assigning their patent rights to the employer, while being named as an inventor on the patent.

2. Subject matter

Pharmaceutical products created or modified by AI should not pose unique challenges from a subject matter standpoint since these will be combinations of chemicals or other physical materials contemplated by patent acts. The subject matter issues are more likely to revolve around the software embodied in an AI and the acts undertaken in AI processing

[18] Article 4ter, Patents: Mention of the Inventor in the Patent: "The inventor shall have the right to be mentioned as such in the patent." Paris Convention for the Protection of Industrial Property (as amended on September 28, 1979), https://www.wipo.int/wipolex/en/text/288514.

which are claimed to be inventions. The US Supreme Court presaged this emerging issue in evolving its *Alice-Mayo* framework.[19] That is, first inquire whether an invention is patentable subject matter. If yes, that settles it. If no, has the otherwise non-patentable subject matter been transformed such as to take it out of one of the exclusions (such as a law or property of nature). Regrettably the Supreme Court offered very little guidance as to what would constitute sufficient transformation, making the test less than helpful.

Because AI is a type of software involving a set of mathematical formulas or algorithms, there is effectively a presumption against patentability because it may be characterized as abstract idea.[20] Various tests have been used to assess whether a software program is sufficiently "non-abstract" to be patentable, including the machine or transformation test. For AI the question may likely be whether it performs functions with respect to inputted data that constitute a practical or tangible result, and this must be a sufficiently specific result. It would not be enough to say an AI could solve problems in the abstract, but rather to identify a specific problem that has been solved and has tangible or practical application.

3. Novelty

The conventional methodology for determining whether an invention is "new" or "novel" Involves searching the prior art to determine whether a previously invented technology "reads on" each and every claim of the putative invention. As a general matter this does not raise special issues for AI pharmaceutical inventions as the end products of the development process are the subject of the patent application, not the AI's themselves. However, if the issue is extended to the AI's, or the methodologies used to create the products with the AI's, the identification of prior art could become extraordinarily difficult. As but one illustration, academics publish papers which describe how AI's may work, and often involve highly complex mathematical algorithms, flowcharts, etc. Sifting through these papers and comparing them to AI models for which patents are sought may prove quite challenging. In addition, the level of abstraction at which the comparison should be made between existing programs or algorithms, and newly created ones needs to be identified. Should the comparisons be made at a metalevel (or high level of abstraction), or at the level of code or specific mathematical formula?

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[19] See discussion of Alice (*Alice CLS Bank*, 573 US 208 (2014))-Mayo (*Mayo v. Prometheus*, 566 US 66 (2012)) framework in Frederick M. Abbott, Advanced Introduction to Pharmaceutical Law, pgs. 25-26, Edward Elgar Publishing (2026).

[20] The long history of this abstract idea issue is recounted by the US Supreme Court in its *Mayo v. Prometheus,* id., decision, among others.

On the positive side, AI should make searching for prior art a faster and more thorough undertaking as AI programs are good at detecting similarities between different data sets. Patent offices already are using AI for this purpose.

4. Nonobviousness or inventive step

The third issue confronting patentability of AI generated drug discovery concerns the applicable standards for inventive step. Again, credit to my son Ryan for having identified this issue in a path-breaking work entitled Everything is Obvious.[21] A patent is granted only to an invention that would not be obvious to a person having reasonable skill in the art relevant to that invention. In the pharmaceutical space, that often means someone with a PhD in chemistry or biotechnology that can ascertain and appreciate the difference between a claimed invention that is an immaterial improvement to an existing product, or rather evidences sufficient innovation to be worthy of patenting. Effectively the inventiveness of the inventor is assessed against the ordinarily competent person of the same general background. But what happens when AI is used as a tool in the inventive process? And, more importantly perhaps, what happens when the AI is recognized as having actually created the invention? Is the inventiveness of the AI compared to that of an ordinarily skilled human being, or instead to an ordinarily skilled AI? If any reasonably competent AI with access to the same inputted data as the "inventor AI" would have come up with the same solution, does that involve an inventive step? Even if a human inventor might have spent years working to come up with the same solution, overcoming obstacles, etc.? And, as Ryan hypothesized, what happens when we achieve the level of AI inventiveness that the strong supporters of AI envisage, that is, capable of solving all the problems confronting the human race?

The issue of nonobviousness or inventive step is more difficult to solve from the standpoint of patent offices because it may effectively require an "observer" to assess which AI is the prototypical "AI having reasonable skill in the art" and another is the putative inventor. This would enable a determination of whether the AI invention is "inventive". But as easy as this may be to say, the practical challenges of assessing the inventive capabilities of advanced computer and software systems might be beyond human capability. We may need to change the relevant tests of whether a patent should be granted to something that humans can understand. Or we may need an entirely new mechanism for protecting investments in innovation.

5. Utility

[21] Ryan Abbott, *Everything Is Obvious*, 66 UCLA L. Rev. 2 (2019)

One of the most difficult challenges facing new drug developers using AI will be to identify the point where an AI-generated drug structure (broadly defined) has demonstrated that it will have a real-world utility. An AI may run a series of "experiments" that, for example, show a binding affinity between a chemical compound and a protein, and postulate that the combination will address a medical condition. But, without moving that digital experiment into physical chemicals and proteins, and without testing that combination on a living subject (in vivo), or at least in physical experimentation (in vitro) there may not be sufficient demonstration of utility to satisfy patent examiners. Should we allow an AI developer to secure a patent because its digital calculations suggest it will achieve a practical result? In all likelihood this will be an evolutionary question or issue. If an AI demonstrates that 90% of its postulated successful compounds perform in the manner it predicts, then a promising result might suffice as a reasonable demonstration of utility. For now, that level of predictive certainty has not been achieved. Drug developers appear to expect that they need to conduct some level of physical demonstration of the properties of their products, even if not necessarily through in vivo testing.

There is an important related question regarding the extent to which drug regulatory authorities will allow AI generated information to be used as a basis for approving a medicine for commercial sale, and at what stage in the process. There is a large body of ongoing work in this area, including by the US FDA[22] and the EU EMA,[23] but that is beyond the scope of this chapter.

6. Description and Enablement

Another challenge to the traditional patent system presented by AI involves the requirement that an invention be sufficiently described to allow it to be reproduced without undue experimentation, and to show sufficient enablement in the sense of being in the inventor's possession. AI's create their output using various methodologies, but typically accessing a set of data (or tokens) from a large language model (LLM), manipulating that data with a set of mathematical formula or algorithms (often characterized as neural networks), obtaining outputs from which some are selected as meeting preferred criteria (weighting), and reiterating or repeating that process until the output has achieved what appears to be a satisfactory result. It is by now well recognized that the internal mechanics of neural network processing may not be fully understood or capable of description by the

[22] See, e.g., US Food and Drug Administration, Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products, Discussion Paper and Request for Feedback, May 2023, Rev. Feb. 2025.
[23] See, e.g., European Medicines Agency, Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle Newton, EMA/CHMP/CVMP/83833/2023, 9 Sept. 2024 .

creator of the AI program, therefore described as having been achieved through a "black box".

If we assume that the invention itself is the AI and its method of extracting and processing data, presumably the underlying mathematical formulas and data extraction methodologies can be described in a patent application. This appears to create the same problem that was confronted by those considering the patentability of computer software in previous era, namely defining the level of abstraction at which a program can be described to allow it to be patented, but in a way that changes to the program will not place it outside its own claim and description parameters. This might be accomplished by describing the purpose of the program and some level of general architecture, but at that level it may either be non-inventive or anticipated by prior art. Or it may be considered nonpatentable abstract idea.

We are in somewhat early days in terms of judicial decisions regarding the patentability of AI software. There are decisions suggesting that merely describing a purpose and a defined set of input data is insufficient to constitute patentable subject matter.[24]

B. Trade Secret

Trade secrets are commercially valuable information not generally known in their configuration that a party has taken reasonable steps to protect.[25]

Trade secrets are commonly used in the pharmaceutical sector to protect information used in the manufacturing of products where internal corporate knowledge and expertise accumulate and help to give advantages over rivals. The typical technology transfer license involves provision of trade secret information such as the ways a company goes about testing its products during the manufacturing cycle.[26]

There are two principal areas where trade secrets might be considered in respect to pharmaceutical products developed using AI. The first is to protect the commercialization of the products themselves. Here originators would run into the same problem-set as those developing products using conventional human methods. Once physical products are introduced onto the market it may be relatively easy to reverse engineer and reproduce the product. This is why pharmaceutical product originators do not generally rely on trade secret protection. Will there be something different about AI-invented pharmaceutical products that will make them sufficiently different from conventional pharmaceutical

[24] See, e.g., Recentive Analytics, Inc. v. Fox Corp., No. 23-2437 (Fed. Cir. Apr. 18, 2025).
[25] F. Abbott, IP and Tech Transfer, supra n. 9, at 21.
[26] Id.

products that they cannot be reversed engineered? Or only with great difficulty? This is not inconceivable.

The products of synthetic organic chemistry have generally been susceptible to reverse engineering in part at least because the molecules themselves are not so complex, bearing in mind that the structure of these molecules may be difficult to replicate. Some such products are reverse engineered in a matter of weeks or months, some take years.

Biologics present different challenges. They are more complex than the products of synthetic organic chemistry. However, the path to reverse engineered reconstruction is facilitated by the fact that creating a biologic product involves starting with some piece of biological material, modifying the genetic instruction code, and reproducing the material in a suitable medium. In theory it might be quite difficult to determine the modifications that cause a particular biological therapeutic to function. However, modifications to genetic code can be ascertained by comparing wild type strains of biologic material with modified strains, allowing researchers to determine the difference. The challenge in creating a biosimilar involves developing a production process that effectively mimics the production process used by the originator. If an originator biological drug is patented, and the patent is not successfully challenged, the manufacturer of the biosimilar may attempt to undertake a "workaround" by varying the genetic code used to produce the biosimilar medicine, and such workarounds are possible. This will confront the biosimilar manufacturer with a new problem at the US FDA because a change in the genetic code of the starting material, according to FDA regulations, creates a new biologic that must be put through clinical testing.[27] But if the biosimilar manufacturer is willing to wait out the patent, trade secrets should not be a bar to putting a biosimilar on the market.

AI is likely to deepen the capacity of prospective biosimilar developers to understand the structure of originator biologics and to suggest ways of re-creating those biologics. Moreover, the AI is likely to be able to propose processes or methodologies of production that may well be different from those used by the originators, thereby avoiding the lack of access to internally maintained trade secrets. In other words, AI will reduce the value of trade secret protection by facilitating reverse engineering.

At the same time, trade secret is increasingly being used to protect existing AI drug development programs in comparison with patent protection because this avoids the need for public disclosure, as well as the risk of non-patentability. In this way it is inhibiting

[27] See, e.g., Kirchhoff CF, Wang XM, Conlon HD, Anderson S, Ryan AM, Bose A. Biosimilars: Key regulatory considerations and similarity assessment tools. Biotechnology and Bioengineering. 2017;114:2696–2705. https://doi.org/10.1002/bit.26438

follow-on science. Whether that is a good or bad thing likely depends on the interested person's perspective.

These developments do not at this early stage suggest the need for some type of modified trade secret law, though over time such a need may become more apparent. Debate will no doubt continue regarding the extent to which access to trade secrets might be mandated for particular circumstances – as such debate continues with respect to patents. I will not attempt to resolve those debates here.

III. New Paradigms

The underlying thesis of the existing international patent system is that by granting innovators exclusive rights to their creations for a limited period of time society encourages innovative activity, and financial investment in that innovative activity. If inventions can be replicated or copied upon their entry onto the market (i.e., becoming public), investment in innovation will be sharply curtailed because the funds expended on research and development are unlikely to be recovered.

One potential paradigm-shifting attribute of AI invention is that it is done by a machine (of one type or another), and the machine (presumably) is not interested in return on investment. If you assume that an AI exists and that its operating costs are marginal, then there may be no need to encourage investment in innovation since the AI does not require profit as motivation. The aspects that make this a contestable hypothesis is that first the AI must be constructed, so it is unlikely that the AI is available "for free". It takes capital to get to the starting line. But, perhaps more important, as Fritz Machup observed more than 75 years ago, the initial idea or conception of an invention is only part of the story. Turning that idea into a commercial product is where the larger scale investment is likely to take place. Even if the idea is "free" because it is conceived by a machine, somebody needs to provide the capital necessary to commercialize that idea, and that is where the property right or exclusionary right comes in.

With that said, taking the generic pharmaceutical industry as a model, companies might be willing to take "free" ideas and build out products in a purely competitive marketplace, electing to earn single-digit profits rather than multiples of that. But for the pharmaceutical industry bringing a product to the market is not a straightforward matter of being able to manufacture. Somebody needs to undertake the work necessary to see the product approved. That partially explains why patents are not the only form of exclusionary right available in the pharmaceutical sector. Exclusive marketing rights are separate from patent rights and perform the function of encouraging investment in the process of obtaining approval for new products.

As a threshold matter, whatever type of rights are needed to protect or encourage investments does not need to look like the patent as we know it, nor do the bases on which such rights are granted need to be the same as those currently used in the conventional patent system.

In contemplating the design of a new system to enable creators of innovative goods or services to protect their investments in their creations, we focus on the fundamentals. First, what is the subject matter we wish to protect. Second, what is the type and extent of protection we wish to confer. Should some forms of subject matter receive more extensive protection than others? Third, what should the duration of protection be? Fourth, what does the public gain from granting protection to the creator?

A. Should we protect?

Before embarking on potential alternatives, we should revisit the basic question whether any form of protection should be granted to inventions created by AI. We note that AI visionaries like Demis Hassabis envisioned that the output of their pathbreaking AI systems would be made available open source, and initially published output from DeepMind -- and in particular folded protein structures -- for all to use. But there came a time including the formation of Isomorphic when the output of AI controlled by Google would no longer be made freely available. It is important to ask what accounted for this fairly dramatic transition?

The answer seems fairly straightforward. Google is a commercial enterprise, investments in DeepMind and Isomorphic are very costly, and the company cannot afford to fund scientific research without securing a return on investment. And, to the point of AI and intellectual property, without some mechanism for establishing a moat (in the words of Warren Buffett) around innovation, how else will the investment yield a return? We immediately run into the classical problem. We could allow everyone to use the innovation and compete on the price of the product ultimately furnished, but as is demonstrated in the conventional pharmaceutical sector this drives prices down to the marginal cost of production where profits are minimal. You will not recover multibillion-dollar investments in AI technology with 5-7% returns on generic products.

And, this conundrum was identified by Fritz Machlup in the 1950s when he observed that the principal function of patents was not to encourage innovation as such, but rather to encourage investment in innovation. Putting this in the AI context, it may be that the AI can and will innovate without contemplation of financial reward, but companies will not invest in AI unless there is a sizable commercial-scale product that will result from that investment. And, that brings us back to the question of how we incentivize investment in

the development of new pharmaceutical products if the products cannot be sold at prices that justify the investment, taking into account the risks involved.

Market protection is not the only way to return investment. Nor is investment of risk capital the only way to promote innovation. AI development of pharmaceutical products could be funded by subsidies, with resulting products made available at cost-price pricing, for example. AI pharmaceutical inventions could be mandatorily made available on the basis of payment of royalties. This revives a classical discussion about alternative methodologies for aggregating capital and returning investment.

If it happens that AI develops to a sufficiently advanced place that a new drug or vaccine could be developed without downstream expenses such as clinical trials and refining delivery mechanisms, it could be that the requirement for return on investment would be substantially minimized. That may be the vision of some leaders in the AI field. Mainly it would be a matter of the funds needed to create production facilities and distribution networks, along with the expenses of labor, material components, etc. This latter vision may be in line with the idea of a "world of abundance" brought about by AI. In this world of abundance a new form of investment protection such as an alternative to the patent may not be needed, or the need might be modest. But we proceed on the assumption that the world of abundance is some decades in the future.

B. Subject matter

A new form of IP protection for AI inventions would presumably cover chemical and biotechnology-based compounds and living matter much like the existing patent system. The fact that an AI wholly or partly conceived of that subject matter would not make an obvious difference.

More difficult questions will arise regarding attempts to assert exclusivity over the processes used in conception. How will the abstract idea be distinguished from the commercial process? AI's typically work by accessing data accumulated in large language models(LLMs), subjecting that data to processing steps, assigning weights or values to results (i.e. proximity to desired targets), and reiterating the process until the optimal result is achieved. Can this set of steps or algorithm be the subject of some new form of intellectual property and market protection?

We are effectively asking whether there is a form of protection that can be conceived for a thinking or thought process. On first blush, this seems to be an idea that would be very difficult to implement without placing roadblocks in front of basic creative processes. If we take typical human thought as the process of a "neural network" we could not realistically envisage allowing any one party control over how humans think. Almost without doubt, the

developers of advanced AI thinking processes will use different modalities to achieve their ends. But would we want to give one or more of them the right to prevent others from using the same type of thought process?

The ultimate end of AI thinking is to solve technical problems. It would seem to be enough to protect the creative results of new thinking processes without protecting the thinking processes themselves. A company invested in AI will earn its way with new and useful products. We should not be paying the AI provider based on the thinking process it used.

Perhaps more to the point, given the fundamental mathematical nature of AI calculation or algorithmic process, it would be extraordinarily difficult for any administrator of a new AI protection system to determine whether a particular method of calculation is sufficiently different from or similar to an existing system.

This does not mean that the output of an AI in the form of a digital product would be off-limits for protection. For example, an AI might create a software tool that would allow architects to assess the structural integrity of new buildings. That software tool accessible online might be sufficiently different from previous architectural design tools to merit some form of temporary exclusivity for its creator. But this would not be the same as granting protection to the design of the AI itself -- the digital thinking process -- that developed the tool.

C. Type and duration of protection

The type of protection we afford AI-generated pharmaceutical products might depend on the degree of difficulty involved in creating those products. Assuming that AI becomes much more efficient at developing new pharmaceutical products there may be some grounds for allowing the AI developers to capture a greater than a purely competitive market price for their products for a time, but not the length of time typically accorded a patent (i.e., 20 to 25 years). We should also consider the period needed to amortize investment in the creation of the AI model, bearing in mind that AI thought leaders believe that once human biology is better understood by AI then drug development will be greatly facilitated. It is not inconceivable that a large number of innovative products will be brought to market in a relatively short span of time. If AI become successful in creating models that curtail the need for human clinical trials, the costliest part of drug development, the grounds for allowing greater than competitive market pricing diminish. The need to develop suitable manufacturing facilities and initiate distribution *might* merit some period of market protection. 3 to 5 years?

If AI developers believe that their new pharmaceutical products will be competing in the public health space on an essentially “generic” basis, what will this do to the amount of

capital being invested in AI for drug development? Recall that Google has shifted from the open-source model used to identify folded protein structures to a closed IP system for new drug development. What is it expecting in terms of return on its investment in AI platforms? Does it expect Isomorphic to secure 25-year terms of protection for AI-developed drug treatments and vaccines? Is that what will justify the huge capital outlays today being invested in AI development? And, if that is the plan, will it be politically palatable?

How do we define what deserves to be protected? Will we perhaps shift from a regime where drugs are protected based on their chemical formulation or DNA sequence to a regime where drugs are protected based on their capacity to address diseases? Could we formulate a set of assessments that would ask whether a treatment has in fact "cured" melanoma, for example, and accord that treatment a period of market protection? Can we shift from structurally-based to results-based awards of market protection?

D. The bargain with the public

The grant of patents is conventionally justified on, among other grounds, the fact that the public benefits from disclosure of the invention, even if public use is limited for the patent term. Presumably a pharmaceutical product created by an AI will have a composition and structure that can be disclosed in exchange for whatever period of market exclusivity is decided upon. What may not be capable of adequate disclosure is the process by which the product was developed because of the AI as black box phenomenon. But inventors have never been required to identify "how" they achieved their breakthroughs, only that they had adequately described them so that they could be replicated without undue experimentation. The actual production process for a medicine or vaccine is not the same as the process used in developing the medicine or vaccine. The production process is not a black box. So, in exchange for some period of market exclusivity the AI drug developer may be required to disclose how the product is made so that the process can be replicated by second-comers once the market exclusivity period is over.

IV. Concluding Thoughts

We are living in a period of accelerated evolution of science and technology without precedent in human history. It is difficult to view this without a mix of optimism and pessimism. Optimism that we are moving toward a world of abundance and better health. Pessimism that the same technologies that may make things better will instead make them worse. It is unlikely that intellectual property rules will play a material role in determining the path forward. AI's and their developers are not likely to pay much attention to IP rules. The tendency of companies involved in the AI space is to break things first, and clean them up after. Yet IP rules may help to determine the speed and scale at which the public has

access to the benefits of the new technologies, and as always with IP there are risks of under-protection and overprotection that need to be balanced. As has been the case in previous iterations of challenge to conventional IP rules, there will be choices between stepwise adaptation of existing rules and the adoption of sui generis rules to address the changed environment. We are in very early days and predicting what will happen is likely a foolish human errand.