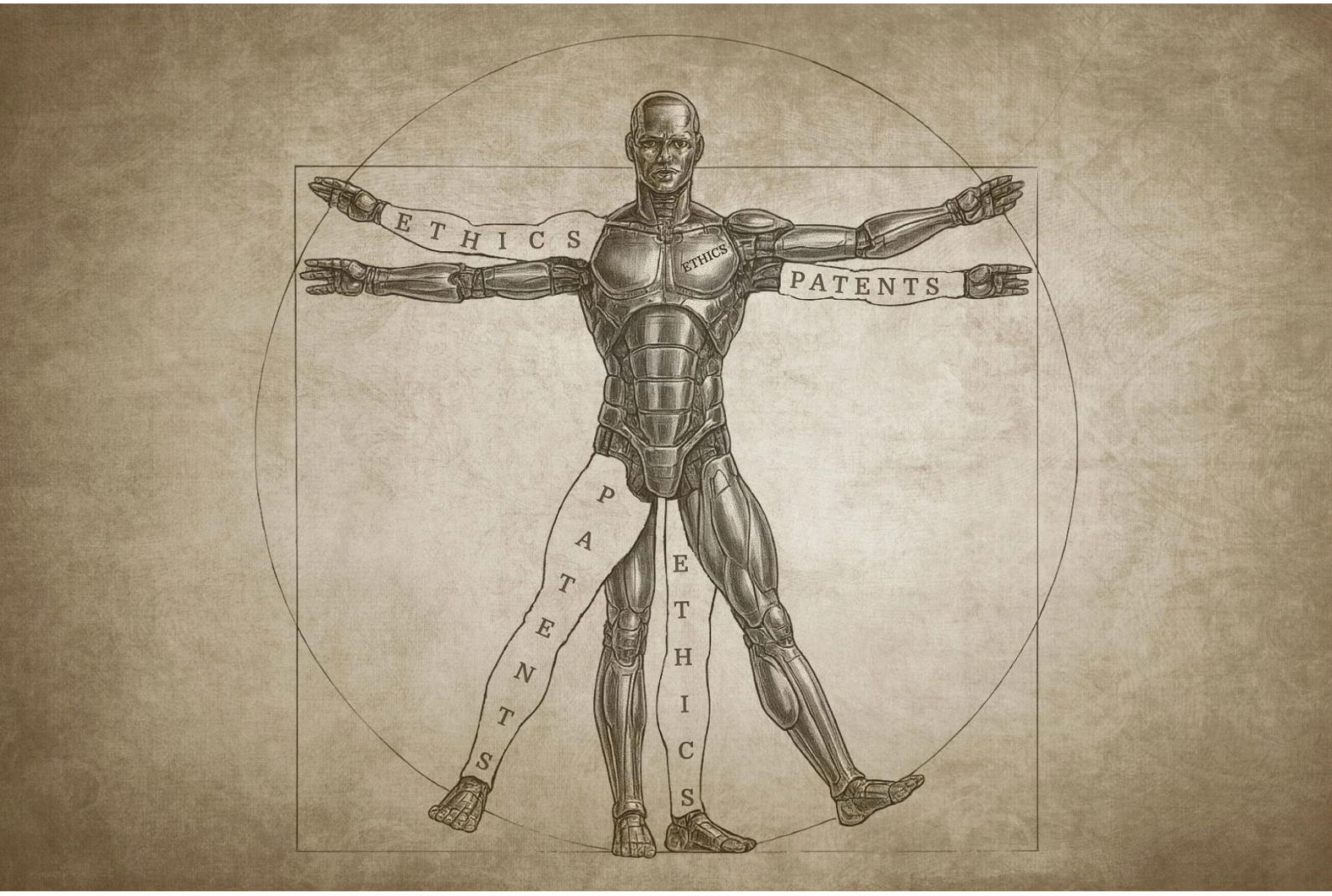
DOS AGOS

ETHICS & PATENTS



TO PATENT OR NOT?

The clash of law, innovation and values

The new technological developments are moving at a breathtaking speed. Artificial intelligence (AI), synthetic biology, genetic engineering and regenerative medicine are no longer the stuff of the future, but today's routine tools. Yet, as science surges exponentially, the legal frameworks entrusted with regulating it, remain static and anchored in another age. For example, patent law, once built for cogs and pistons, now finds itself wrestling with questions of human dignity, morality and cultural values.

Patents are grounded in a simple bargain: an inventor is given a temporary monopoly, a reward for one's ingenuity in exchange for disclosing one's work to the public. In theory, everyone benefits.

In practice, however, this trade-off is anything but. It grows complicated when new inventions touch on life itself, material of human origin, genetic identity, sentient code, etc. Such a bargain becomes unsteady and this results in a collision between economic incentive, public good and ethical restraint.

Without clear guidance on how to address the moral and social implications of these new technologies, innovation reliant on patent protection risks turmoil, uncertainty and confusion.

The first contact

Before laws are (re)written or policies are drafted, new technologies almost always arrive first at the patent office.

Patent offices remain the first legal stop for new technologies, serving as a test of whether law can keep pace with science.

This puts patents on the frontline in assessing whether law can keep in line with science. In a way, patents are the first real-world ethics filter for socially controversial innovation. But, as breakthroughs in AI and biotechnology advance, the central question has begun to change. It is no longer just about what we can invent, but what rights we should grant over those inventions. That makes ethics and above all, the principle of human dignity, central to the future of innovation.

Human dignity and patents

Human dignity is a universal idea. The idea that every person deserves respect.

Human dignity isn't an abstract idea. It's the line that decides where innovation ends and commodification begins.

This concept is frequently invoked in bioethical debates, from cloning and stem cell research to genetic engineering and the use of human material in inventions. At the heart of all these debates is a concern that life itself could be commercialised.

In Europe, this principle is enshrined in the Biotech Directive which makes it an obligation under patent law that it be applied to "respect the fundamental principles safeguarding the dignity and integrity of the person".

Yet, while human dignity is a universal norm, patent systems around the world differ in how

they apply it and sometimes struggle to draw the line.

Europe's morality clause

Europe translates ethics directly into its patent law. Under Article 53(a) of the European Patent Convention (EPC), no patent can be granted if its commercial exploitation would be contrary to ordre public or morality. Europe's legal framework, including the EU Biotech Directive, requires that patent law is applied in a way that safeguards human dignity, as well as other values such as public safety, individual integrity and the environment.

The Biotech Directive even lists specific exclusions which include:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

This list is not exhaustive but it sets a strong signal.

Article 53(a) EPC (EPO guidelines) aims to "deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour". This indicates a proactive attempt to integrate ethical safeguards directly at the patent examination stage.

In practice, Article 53(a) is used sparingly. It featured in the landmark WARF stem cells case, where the indirect destruction of human embryos meant a patent being refused.

More recently, in a case T 1553/22 concerning the production of human-pig chimeras aimed at generating humanised blood vessels for transplantation, the EPO Board of Appeal rejected claims illustrating how dignity concerns can override inventive claims. Although the inventors used pluripotent (not totipotent) human cells, the claims were seen as sufficiently wide that human cells could become incorporated in a chimera's brain or germ-line. Thus, in turn creating a potential to confer upon an animal human-like cognitive or reproductive abilities. As a result, the patent was considered an affront to human dignity pursuant to Article 53(a).

One other case that dealt with Article 53(a) is T 2510/18 which addressed traditional knowledge and what the morality clause is not. In this case, a patent on a malaria drug derived from indigenous traditional knowledge was opposed as "immoral" biopiracy.

The opponents argued that the research involved deception and a breach of trust. They claimed that this equated to "biopiracy" and violated Article 53(a) EPC. The Board drew a distinction, clarifying that the morality clause applies to how an invention is used commercially, not how the invention was derived. Furthermore, given the dire need for antimalarial medication, the commercial exploitation was deemed beneficial, not immoral.

The European Commission is now in process revising this framework. As part of its 2024-2029 guidelines, it announced plans for a European Biotech Act. Draft legislation, now in preparation, aims to "enhance the single market for biotech" and accelerate the path "from lab to market" without undermining ethical safeguards.

Europe writes morality into its patents, the US leaves it to politics. Both approaches reveal their blind spots.

The WARF decision

The morality clause was put to the test in the landmark WARF case at the EPO. The application involved stem cells and while the patent application did not explicitly claim it, it required the destruction of human embryos to actually work. That implication alone was enough for rejection.

The ruling highlighted a key challenge for Europe's patent system: the difficulty of consistently applying morality.

Despite the morality clause in the EPC, the EPO has been criticised for a "lack of substantive definition of morality" and inconsistent application of tests like the "public abhorrence test" or the "balancing test" (which weighs animal suffering against human usefulness). This results in uncertainty which can discourage research in Europe.

Different national attitudes add another layer of complexity. For instance, what is unpatentable in Germany might be granted in the UK, as definitions of when life begins or what counts as an embryo vary across countries. By contrast, in the US, WARF successfully secured patents on embryonic stem cells, underscoring a stark transatlantic divide.

The US

Patents in the US are generally available to any person who "invents or discovers any new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof". Patents typically expire after 20 years from the original patent application date.

Unlike Europe, US patent law has no morality clause. Historically, there was a doctrine called the moral utility doctrine, which authorised the refusal to grant inventions that were detrimental to the well-being, good policy, or sound morals of society. For example, gambling devices or fraudulent inventions.

However, the test vanished over time. The Federal Circuit decision of Juicy Whipp v Orange Bang brought down the morality doctrine to its knees ending future applications of it. It rejected moral utility as a basis for patentability: an invention that is operable and meets technical criteria cannot be denied a patent simply because the inventions serve immoral or illegal purposes. The court pointed out that it was not the patent system's role to serve as a general guardian of public morality, rather if Congress wants to exclude certain inventions on ethical grounds it must say so explicitly.

The result is a system with very few ethical safeguards. This ethical deficit has allowed for patents to issue related to human cloning methods and transgenic animals with human genetic material, often without generally following through on moral debates in the pre-grant phase. This could potentially lead to "legal and social mayhem" with "ghoulish" patents.

It is feared by critics that this approach is producing "ethical blind spots" and might grant too broad rights. These threaten to substantially undermine research and lead to costly legal fights, such as for example, the WARF human embryonic stem cell patents or Myriad Genetics' breast cancer gene patents.

Where ethical concerns do exist, they usually surface only after the patent has already been issued, or as one may put it, after "the horse has bolted". The US Congress did try to rectify this with the 2004 Weldon Amendment (now enacted in the Leahy-Smith America Invents Act §33(a)) against patenting human organisms, showing a political will that no one should be able to own rights on a human life. However the Amendment has left loopholes, especially in the case of human-animal chimeras. Patents on human cells, tissues, genes, or stem cells remain patent-eligible.

At present, Congress is engaged in considering the boundaries of patentable subject matter (Patent Eligibility Restoration Act or PERA), not to rely on morality exception per se, but to redefine or undo what some perceive as overreach by the courts (for e.g., Mayo 2012, Myriad 2013, Alice 2014).

The Road Ahead

Do we need to sacrifice our moral compass in order to jump-start a biotech boom? How should patent systems adapt to meet new technologies and norms in society? Biotechnology stretches our concept of ownership and life. But, even in the most challenging cases, ethics and morality can act as a compass. If fairness and dignity are their values, patents can drive innovation that benefits society. Without them, the system could be exploitable.

Overall, there is a growing pressure for clearer legislation and international frameworks to address the ethical and moral dimensions of patent law. The old, "one size fits all" approach model is no longer enough for technologies that blend human biology, advanced materials and machine intelligence. Patents remain the first legal stop for emerging science, and they must benefit not just markets, but humanity as a whole.

Where
ethics guide patents
innovation serves humanity

Without
ethical guidance,
it EXPLOITS.

References

35 U.S.C. §§ 101, 131.

Amina Agovic, Patents, Ethics and Stem Cell Research: The Case of hESC Innovation in Anglo-America and Europe (PhD thesis, University of Helsinki 2010).

Bently, Lionel; Sherman, Brad; Gangjee, Dev and Johnson, Phillip. Intellectual Property Law. Oxford University Press, 2022.

Christopher H. Smith, 'America Invents Act' in Congressional Record, House of Representatives, vol 157, no 91 (23 June 2011) E1177.

Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 OJ Special Edition 1/2007.

David B. Resnik, Embryonic Stem Cell Patents and Human Dignity, 15(3) Health Care Analysis (2007).

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L213/13.

Dr Rose Hughes, 'The morality (and patentability) of inventions derived by immoral means (T 2510/18)' (IPKat, 31 October 2024) https://ipkitten.blogspot.com/2024/10/the-morality-and-patentability-of.html accessed [22 Aug 2025].

EPO, Enlarged Board of Appeal, G 2/06 (Use of embryos/WARF) (25 November 2008) OJ EPO 2009, 306.

EPO, Technical Board of Appeal, T 1553/22 (Human-pig chimeras/University of Minnesota) (4 September 2024) ECLI:EP:BA:2024:T155322.20240904.

EPO, Technical Board of Appeal, T 2510/18 (31 May 2024) ECLI:EP:BA:2024:T251018.20240531.

Eric L Abada, 'Bipartisan Law Introduced to Clarify Patent Eligibility' Knobbe Martens (3 June 2025) https://www.knobbe.com/blog/bipartisan-law-introduced-to-clarify-patent-eligibility/ accessed 6 October 2025.

Juicy Whip, Inc v Orange Bang, Inc 185 F 3d 1364 (Fed Cir 1999).

USPTO, Manual of Patent Examining Procedure § 2105 (10 October 2024, last modified), 'Patent Eligible Subject Matter — Living Subject Matter' (US Patent and Trademark Office).