IS PATENTING A THREAT TO REPRODUCTIVE RIGHTS?

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Abstract
Technology is the way to progress for the human race. Technology has changed the life of human beings from ancient times to the modern era. Law and society are interdependent on each other. Today’s modern society is standing on the crossroads of law, science, and technology. Technology, on the one hand, brings with it a vulnerability that cannot be neglected in the society like Invasion of privacy. On other hand there are technology that are introduced in modern times which helps one to procreate. With the extensive advances in medicine and medical technologies and to open a way to this manifestation of human mind, the medical sciences made an acute beginning by way of medically assisted human reproduction.

Innovation in these technologies open a gateway for the innovator to apply for patent of these ideas to encourage economic and technological development and encourage competition by creating a financial incentive. But Patenting of ART can have an effect on reproductive rights in a number of ways. One of the main concerns is that it can make these technologies less accessible to people. It also raises ethical, social and legal issues. This study critically warrants the examination of current patent system with relation to the reproductive rights available under different legislations.

Keywords: Patent, IVF, Reproductive Rights, Technology, Hampering.

Introduction
Over the last 50 years, Supreme Court decisions have established fundamental rights to reproductive freedom, such as the right to reproduce and the right to terminate a pregnancy (Gur-Arie, 2016). The Fourteenth Amendment has served as the foundation for court rulings (Rehnquist, 1975). It can assess the significance of "liberty" and "privacy" to reproductive choice by using both parts of the due Process and Equal Protection clauses (Pillard, 2006). Even if the Court acknowledged a constitutional basis, there remains debate on the extent of those rights. Many people argue that the constitution shouldn't guarantee freedom of choice regarding reproduction. Regardless of the origin of the conflict, religious, scientific, moral, or political, the scientific community's unwavering determination to advance reproductive science only serves to intensify this enduring and tenacious hostility. In spite of harsh criticism, the industry keeps creating new reproductive technologies to satisfy consumer demands for safety, accessibility, and additional reproductive and procreative options.

In public discourse, it is frequently forgotten that technologies that allow for reproductive choice are typically owned as intellectual property. Traditional views of patent protection as a prerequisite for commercial viability and market success (Devlin, 2009). Emerging technologies that are "novel, beneficial, and non-obvious" may not be ready for society" (Boni, 2013) when reproductive technologies can be protected, their inventors will be able to benefit from the considerable exclusionary rights granted by patent protection.

Patentable reproductive innovations have made it easier to make reproductive choices and are frequently the driving force behind reproductive rights, hence opposition to reproductive autonomy has often taken the form of opposition to certain technology. Since limited monopolies on reproductive inventions are granted by patent laws, opposition has gradually started to seep in. Contrary to historical notions, contemporary patent-eligible subject matter may go against deeply held moral, religious, and political principles. One critic said, "As human existence gets more and more enmeshed in technology, the impact of conventionally patentable subject matter on the exercise of individual liberty increases” (Choi, 2018).

The most crucial aspect of human existence is reproduction, a field that has recently seen significant technical advancements. As an illustration, over the previous few decades, patents for technologies ranging from abortive techniques to (Karst, 1975), medications, and instruments used in in vitro pre-
implantation genetic diagnosis (PGD), and in vitro fertilisation (IVF) procedures. Further technical developments are likely to be produced in the future, as evidenced by the exponential rise of reproductive knowledge and capacities. Most of the practical knowledge is either already protected as intellectual property or will be in the future.

An eighteenth-century antecedent system of "supporting the Progress of Science and useful Arts," which is permitted by the Constitution, faces new challenges in light of these "twentieth-century" technological advancements and the newly perceived reproductive freedom that may go along with their expansion (Allen, 2012). Right now, people who oppose reproductive rights can take use of the patent system to limit access to reproductive and procreative technologies that have a direct influence on such rights. It follows logically that those who want to limit people's access to technologies or their ability to exercise currently or future constitutional rights could apply for, assign, or licence patent rights on reproductive technologies and then use those legally granted property rights to hold those who violate them accountable. To put it another way, despite cultural norms, the same government that defends reproductive rights under the Constitution may be forced to prohibit use of a private patentee's reproductive technology or inventions. Previously, it was thought that the Bill of Rights and the Fourteenth Amendment did not apply in this case since a private patentee is a private actor rather than a state actor (Thomas, 2002).

It is realistic, however, to foresee the development of such technology, as well as the danger of abuse (Saunders, 2001). Even though it may appear counterintuitive given the traditional commercial motivations for obtaining patent rights, restricting market access to reproductive options that violate their moral or religious convictions may seem beneficial to some people.

Businesses may also profit financially by refraining from marketing goods that may be the target of particularly vocal and harsh criticism. The restriction of copyrighted technology raises serious concerns about the monopolisation of reproductive rights since it would be the private equivalent of a state that forbade the creation, use, or distribution of a good. Denying individuals, particularly women, access to reproductive technology and freedom (Faircloth & Gürtin, 2018), to seek those technologies in foreign jurisdictions. By leaving the business unregulated and unprotected by laws, "reproductive tourism" or "fertility tourism" risks are heightened.

An Overview of Reproductive Rights, Technology and their Patents related to them

Fundamental reproductive rights, such as the freedom to reproduce and the right to terminate a pregnancy, have been established by the Supreme Court. Although Supreme Court rulings guarantee that the government cannot violate certain rights, they do not shield people from private parties who do the same. The enormous property rights granted by patent protection may offer fertile ground for private actors to push a private agenda for reproductive choice given the long history of passionate opposition to reproductive rights. Theoretically, private parties might use patents to evade fundamental reproductive rights by keeping patented reproductive technology hidden from the general public (Kreimer, 1984).

Reproductive Rights: Supporters and Critics

The Supreme Court recognised the constitutional right to an abortion in the precedent-setting case of Roe v. Wade. It was reaffirmed and enhanced by the Planned Parenthood v. Casey case. It is sufficient to state that the "right to choose" is now enshrined in documents, without delving into the specifics and complexities of those cases, or outlining the threads of cases that preceded or followed those decisions, or doing justice to the enormous struggle involved in the development of that right.

The Skinner v. Oklahoma ruling from 1942 defined the "liberty" associated with the procreative freedom to bear children (Daar, 2008). It came before the decisions that made "the freedom to choose" what it is today. In Skinner, the Supreme Court overturned a law that permitted criminal defendants to have sexually sterilising medical operations performed on them while they were in prison (Lombardo, 1996). "Oklahoma deprives certain individuals of a right which is fundamental to the preservation of a race of the freedom to bear offspring," said Justice Douglas in his opening line. The Court found that "Marriage and procreation are essential to the race's survival and very existence" in deciding that such
sterilisation plans were unconstitutional. In its ruling, the Supreme Court stated that it was addressing "one of man's fundamental civil rights" and a "basic liberty" (Karst, 1977).

Skinner established a right to "conceive and nurture one's offspring," which is "far more precious than property rights," according to the Supreme Court in Stanley v. Illinois. The Skinner justices were "moved to recognise a right to reproductive autonomy in part because of fear about the inhumane and potentially genocidal manner in which government control over reproductive matters might be exercised if the decision of whether or not to have children were transferred from the individual to the state," according to the Skinner justices” (Laurence, 1988).

It is simple to overlook these rights' enormous moral, political, and theological significance when they are written out. The underlying moral questions that these rights raise sharply divide individuals in the nation, and the repercussions that they cause give this area of rights a delicate dynamic and give it a lot of emotional colours. In Gonzales v. Carhart The Court, for instance, looked at a late-term abortion method that some government authorities called "a harsh and inhumane process” (Garrow, 2007).

In fact, many politically active and highly motivated individuals and groups have a long history of vocally opposing reproductive techniques that are both much more common and much less "gruesome" than the very intrusive therapies. In Carhart, the dilation and extraction procedure are rarely utilised (Epner, et.al., 1998). Throughout history, almost every discovery or piece of technology that has been utilised to begin or end human existence has come in for considerable, if not vehement, criticism.

For instance, the Court expressly addressed opposition to the use of contraception in Griswold v. Connecticut, which resulted in the well-known contraception cases (Roraback, 1989), is still alive and well today. Despite the fact that birth control and other forms of contraception are now widely accepted, those who oppose them have recently sought for new fronts in their battle. Pro-life pharmacists have recently started declining to fill prescriptions for contraceptives, supported by major pro-life, anti-abortion organisations. Rarely, following a customer's request for birth control, a pharmacist has declined to fill the prescription, essentially preventing the consumer from using any other method to obtain the contraception they were prescribed, even from another pharmacy (Walker, 2009).

When in vitro fertilisation became more widely available in the late 1970s and early 1980s, there was a significant backlash against the growth of "test-tube baby" firms. Even while in vitro fertilisation is legal from a medical standpoint, it is criticised, much like contraception. As a result of years of relentless campaigning by anti-JVF campaigners, governments all over the world have outlawed PGD procedures, embryonic research, surrogacy, a variety of additional embryonic transfers, and therapies, to varying degrees. For instance, Germany passed its own version of an embryo preservation law, known as the Embryo Protection Act ,1990 (Bernat, 1993) primarily to avoid being accused of promoting potentially eugenic technologies that are reminiscent of the catastrophes that continue to plague the nation's recent past.

It is easy to envisage the myriad ways that technology influences people's and organisations' behaviours and attitudes based on this small sample of opposition to reproductive rights. Opponents of reproductive choice invest a lot of time and resources in presenting and defending their arguments. Additionally, firms may find it more profitable to withhold contentious technology than to promote it and run the risk of negative publicity and consumer backlash. It is obvious that not simply "gruesome" techniques like the infrequently employed technology in Carhart, but almost any technology that has anything to do with human reproduction will infuriate and irritate someone.

**B. Patents and Reproductive Technologies**

The Gonzales v. Carhart dilatation and extraction procedure. Additionally, other contested more widespread reproductive technologies are categorically eligible for patent protection under 35 U.S.C. 101.54 for use in medical operations (Squires & Biemer, 2005). Unsurprisingly, one of the technological areas with the most patents is the highly valuable medical device market (Chatterji, 2009).

If the members of the Carhart Court had a different political and ideological stance (Eskridge, et.al., 1997), the "gruesome" (Hill, 2010) but patentable dilation and extraction procedure, which was
prohibited by the Partial-Birth Abortion Ban Act of 2003 (Haddad, et.al., 2009), could have been declared to be clearly within the purview of the imposed "right to choose" by the government. The dissenting opinions indicate how difficult and close this Supreme Court judgement was: "In essence, the majority of five politically and religiously conservative men are accused in Justice Ginsburg's dissenting opinion of incorporating their morality into the Constitution" (Tatalovich, et.al., 2014). Imagine a mother who mistakenly consumed a drug that resulted in irreversible defects in her late-term unborn child (Kaczor, 2022). What if the treatment she needed was the best, safest, and only option, similar to the patent-eligible technique and equipment in Carhart? There would undoubtedly be a defence that depriving her of that particular procedure implied depriving her of her constitutional rights, as was indicated in the Carhart case. She would have to resist a decision like Carhart if she were acting rationally, regardless of how "gruesome" ethically skewed people would find the approach to be.

The Due Process Clause of the Fourteenth Amendment would serve as the legal foundation for the hypothetical woman's ability to choose the safest method of abortion, if the Supreme Court had reached a different conclusion. The five-member Carhart majority or religious organisations that are solely opposed to all abortions are the owners or purchasers of the patent rights to the abortion process and related tools. They do not offer licences for its use as a result. If the government upheld the private patentee's property rights, would it be a violation of the Constitutional freedom to choose one's own reproductive life? A citizen's capacity to utilise their constitutional right to the most secure form of transportation would a private patentee be preventing?

Given the Gonzales v. Carhart facts as an illustration, it is simple to understand how withholding technology that offers the safest, best, or alternate routes to allow the desired reproductive outcome could be viewed as a violation of constitutional rights given a patentee's typically robust rights. This instance of "patent blockage" is more common than it might first appear to be. The situation becomes unsettlingly realistic by substituting the infrequently used dilatation and extraction technique at issue in Carhart with a device that more patients would want access to but would still encounter opposition.

Another way to look at it is as a novel way to get around the drawbacks of taking daily birth control pills (Clarke & Clarke, 1998), meanwhile reducing the detrimental social stigma and health consequences connected to abortion practises and contraceptives. In order to limit access to reproductive technology, the patent system may soon prove to be helpful. Given the potential universe of future technologies, history shows that reproductive technologies are definitely fertile ground for exploitation and conflict.

C. Law Governing Patents in Reproduction
The laws governing the patenting of assisted reproductive technologies in India are governed by the Indian Patents Act of 1970 (Ganguli, 2004) and the Manual of Patent Office Practice and Procedure (India, I. P. 2019).

The Indian Patents Act states that certain inventions, such as those that violate moral or legal principles and those associated with the discovery of a living being or non-living substance found in nature, are ineligible for patent protection. The Act further states that, save from micro-organisms, neither plants nor animals, in whole or in any part, are patentable.

This means that in the context of assisted reproductive technologies, natural processes like fertilisation and embryonic development cannot be trademarked. However, if they are innovative, non-obvious, and useful, new processes or techniques for assisted reproduction, as well as new technology or equipment used in these techniques, may be eligible for patent protection.

Despite this, India has a long history of being a developing country, and in some cases, it may not have enough money for a well-funded patent office in addition to a lack of specialists in the field of assisted reproduction, which could make it difficult to understand the technology and assess patent applications.

Biotechnology has recently played a key role in the growth of the Indian economy. In light of the swift advancements in biotechnology occurring all over the world, while emphasising that the advantages
for Indian farmers continue to be its top concern, the Indian Patent Office has loosened its regulations for the patenting of genes in India. With the introduction of strict guidelines through The Manual of Patent Office Practice and Procedure, 2005 and Indian Biotechnology Guidelines, 2013, the Indian Patent Office has successfully achieved the delicate balancing act of allowing new technologies to develop without having an adverse effect on established market competitors.

The technique of patenting a method of modifying DNA and the chemicals connected to it, as well as gene sequences and fragments of genes, is known as gene patenting and is not present in nature in its natural state.

Section 3(C) of the Patent Act of 1970 in India prohibits the "discovery of any living organism or non-living substance existing in nature" as patentable subject matter. Furthermore, section 3 (j) of the Indian Patent Act, 1970 prohibits the patentability of any plant or animal, in whole or in part, other than microorganisms, but including seeds, varieties, and species. It also effectively forbids the patenting of biological processes used in the production or propagation of plants and animals.

The Manual of Patent Office Practice and Procedure, 2005 focuses on the fact that recombinant DNA, plasmids, and methods for producing them can all be patented if they were invented with significant human involvement. The following conditions must be met in order to award a patent for any gene, according to the Manual:

1. The genetically modified gene or amino acid sequence needs to be new, inventive, and useable in industry.
2. A unique way of expressing the genetically modified gene sequence/amino acid sequence;
3. A genetically engineered antibody against that protein/sequence can be claimed to be protected; or
4. It is possible to assert that a kit made using the antibody or sequence is secure.

According to the Manual, "novelty attributable to substantial human intervention" is a prerequisite for patenting recombinant DNA.

In Association for Molecular Pathology v. U.S. Patent & Trademark Office ("Myriad"), the current case challenging the patentability of human gene sequences, the district court determined that patent claims on isolating and extracting gene sequences for breast cancer screening were invalid (Cook-Deegan & Chandrasekharan, 2014). Judge Sweet's decision to rule in the plaintiff's favor arguably narrowed the range of items that qualify as patentable subject matter (Jacobs, 2004), departing from long-standing practice (Klein, 2011). Myriad offers guidance for controlling the influence of technology that is thought to directly affect the sanctity of the human body. The appellants contended that 35 U.S.C. 101 should stand and that there are alternative means to restrict the scope of patents in their appeal (McHugh, 2010).

The idea of "patent-eligible subject matter" was introduced by the Patent Act of 1793, saying that "any art, machine, manufacture, or composition of matter" was eligible for letters patent (Conlin, et al., 2015). Early case law made a feeble attempt to limit the vast scope of that original term. Following the initial acceptance of patents such as Louis Pasteur's patent for an "improvement in the manufacturing of beer and yeast," which included claims to living creatures and would almost certainly not be declared eligible today. With the announcement of Ex Parte Latimer, the United States Patent and Trademark Office (USPTO) started to publish some limitations on patentable subject matter.

In Latimer, the Commissioner of Patents determined that a patent could not be issued for a fibre discovered in pine tree needles, and in Funk Bros. Seed Co. v. Kalo Inoculant Co., the Court narrowed that ruling even further by ruling that "patents cannot issue for the discovery of natural phenomena" (Kip Jr, 1951). In the seminal case of Diamond v. Chakrabarty (Robinson & Medlock, 2005) has The Supreme Court has established a broad bar for patentability since Funk Bros., stating that "The government intended for statutory subject matter to embrace everything created by man, with the exception of abstract ideas, physical events, and laws of nature.” The objective of the broad patent eligibility standard is to “make sure that inventiveness receives ample support” (Abraham, 2011).

Conclusion
There are always other options, even though including a "Description of the intended use" declaration for reproductive technologies appears to be a practical strategy to reduce the likelihood that they will be prohibited from use due to their important constitutional consequences. Undoubtedly, there are substitutes or modifications that are more in line with the historical pattern of patent withholding. As a result, this study should not be interpreted as providing a single solution. Instead, it is a declaration of intent and list of prospective remedies that admits that "Legislators, judges, academics, and the general public will become more aware of the importance of inquiry to the patent system and its importance to society as a whole through discussion and the creation of the patent system's vision of technology in the public realm" (Irwin, 2008). By concentrating on the collection of rights connected to reproduction, it is feasible to learn more about establishing solutions to technologies that directly affect other fundamental rights. For instance, if the state action thesis is upheld in court, the government may enact rules that prohibit future private expression of private biases through the patent system.

The message should also be clear: if this problem is not resolved quickly and a workable solution cannot be found, undesirable outcomes or consequences could result. If a remedy to the "pervasive intrusion of technology into formerly sacrosanct elements of life" that supports people's perceived reproductive rights is not found, people will look for reproductive choice elsewhere. "Reproductive tourism" (Ikemoto, 2009) will continue to rise in popularity. For example, a patent holder withholding reproductive technologies can encourage fertility tourism, akin to Italy's IVF ban. Furthermore, due to Italian legislation, the procedures would become more expensive and ineffective. People who need reproductive options the most are made to feel unwelcome by patents in the form of private legislation: "When a state only allows married couples to receive treatment, homosexuals and lesbians, who may already feel isolated from some areas of mainstream society, may be among the first populations to look for alternative therapies abroad. Those already burdened by society will therefore suffer the most. A jurisdiction would "simply lose any capacity to contribute to the terms under which develops new technology" if it allowed private patentees to "prevent development of new technology."

For instance, "Reproductive tourism focuses primarily on the use of women's bodies to the extent that it relies on the use of other people's bodies." The bulk of infertility treatments are given to women, even in cases of male infertility. As a result, "ART is a gendered technology" since women are more likely to experience health problems and social stigma than men, who just have to worry about the financial costs. As a result, encouraging "reproductive tourism" encourages unequal protection for women.

Reproductive rights are impacted in a number of different ways by the patenting of ART. One of the main concerns is that it would reduce access to these technologies for people who cannot afford to licence patented methods or tools. Additionally, ART patents may restrict access by limiting the accessibility of specific treatments to only those clinics that can afford to licence the patented technology.

Another problem is that patenting ART can create a society where profit comes before patient welfare. This could lead to the creation and usage of techniques or tools that are not always in the patients' best interests but are lucrative for patent holders. In the area of in vitro fertilisation, patenting could have benefits including financial incentives for R&D and intellectual property rights protection. However, it can raise ethical and access to care issues by raising the cost of procedures and reducing the availability of particular treatments. IVF-related technology patenting should be carefully evaluated in light of these advantages and risks.

References


