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Patents Fettering Reproductive Rights

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Supreme Court decisions over the last half century have established important fundamental rights to reproductive choice: the right to procreate as well as the right to terminate a pregnancy. The Court has rooted these decisions in the Due Process and Equal Protection clauses of the Fourteenth Amendment, using those clauses to affirm the applicability of “liberty” and “privacy” to reproductive choice. Despite the Court’s articulation of a constitutional footing, disagreement exists as to the scope of those rights. Many believe that constitutional protection of reproductive choice should not exist. Whatever the source of contention, be it religious, scientific, moral, or political, this persistent and steadfast hostility is exacerbated by the scientific community’s relentless stretch to push the boundaries of reproductive science. Industry continually develops new technologies that provide reproductive options as it tries to address the market’s demand for safety, availability, and access to further procreative and reproductive choice, even amidst vocal opposition.

Often neglected in the public debate is the fact that the technologies that facilitate reproductive choice are frequently owned as intellectual property. Traditionally, patent protection has been seen as one requisite for commercial viability and market success. Whether society is ready or not, emerging “new, useful, and non-obvious” reproductive technologies will be ripe for patent
protection and their inventors will be eligible to secure the robust exclusionary rights that patent protection affords.

Because these patentable reproductive inventions have enabled reproductive choice and are often catalysts for reproductive rights, opposition to reproductive autonomy has translated into opposition to specific technologies. In turn, opposition has slowly begun to find its way into the patent laws that provide limited monopolies on reproductive inventions. Unlike inventions of antiquity, the advanced technology that now constitutes patent-eligible subject matter has the potential to tread on deeply moral, religious, and political ideologies. One commentator has noted that “[a]s human existence becomes increasingly embedded in technology, the impact of traditionally patentable subject matter upon the exercise of individual liberties grows.”

There is no area more fundamental to human existence than that of reproduction—an area that has recently experienced extraordinary technological advances. For example, in the last several decades, patents have been issued on technologies ranging from abortive methods, pharmaceuticals, and instruments, to in vitro fertilization (IVF), cloning (e.g., Dolly), and in vitro pre-implantation genetic diagnostic (PGD) procedures. Reproductive knowledge and capabilities have expanded in exponential ways, promising that the future holds even more technological advancements. Much of that practical knowledge is owned, or has the potential to be owned, as intellectual property.

These “twenty-first century” technological developments, and the new perceived reproductive liberties that may accompany their growth, pose new challenges to a

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14. See Telomerizing Nuclear Donor Cells and Improving the Efficiency on Nuclear Transfer, U.S. Patent No. 7,265,262 B2 (filed Mar. 21, 2002) (issued Sep. 4, 2007) (This patent is the first of several U.S. patents issued to the Roslin Institute for the work surrounding “Dolly,” the sheep. The patent claims “a system for creating cloned cells and embryos.” However, some variations of the Dolly method patents claim the products of the cloning, raising the possibility of ownership of cloned life.).
16. For example: “Reproductive rights could refer either to women’s ability to control their reproductive lives or to the ability to choose when and how to have offspring. In the former case, reproductive rights would help secure equality with men and avoid the
constitutionally empowered system of “promot[ing] the Progress of Science and useful Arts” with eighteenth-century origins. Whether or not the Framers contemplated the vast universe of procreative and reproductive developments as within the scope of traditionally patentable subject matter, the fact remains that as section 101 of the Patent Act currently stands, inventions related to human reproduction will routinely fall within its broad scope. It is likely, however, that the Framers did contemplate a patent system that would continue to provide broad and robust incentives to invent—a set of incentives that has helped establish the United States as a technological superpower and that many feel may be best left untouched.

As currently configured, the patent system is susceptible to use by those opposed to reproductive rights—those who desire to prohibit access to reproductive and procreative technologies that directly bear on reproductive rights. Taken to its extreme, those who want to limit individuals’ ability to exercise their currently constitutionally protected rights or future constitutional rights, or desire to deny access to technologies on other moral bases, could obtain patent rights (by application, assignment, or license) on reproductive technologies and then enforce those governmentally granted property rights against any infringer. In other words, the same government that affords the rights to reproductive choices as found in the Constitution could be forced to grant limitations on the access to a private patentee’s reproductive technologies or inventions—regardless of societal value. Because a private patentee is a private actor, as opposed to a state actor, the

subordination that comes from forced motherhood. In the latter case, reproductive rights might include the right to have a child engineered to lack a particular disease or disability, or more fancifully, the right to have a child with blonde hair and blue eyes, or even a clone of one’s self.” Jack M. Balkin, How New Genetic Technologies Will Transform Roe v. Wade, 56 EMORY L.J. 843, 858 (2007); see generally Yvonne Cripps, The Art and Science of Genetic Modification: Re-Engineering Patent Law and Constitutional Orthodoxy, 11 IND. J. GLOBAL LEGAL STUD. 1 (2004). While the 1943 case of “Skinner v. Oklahoma became the Supreme Court precedent for our belief that the right to procreate is so basic, so fundamental, that government should not interfere with its exercise,” today “fundamental rights remains the basis for protecting . . . reproductive pioneers who are expanding the social and medical definitions of who can have babies.” LYnda Beck Fenwick, Private Choices, Public Consequences: Reproductive Technology and the New Ethics of Conception, Pregnancy, and Family 16–17 (1998) (citation omitted).

17. U.S. CONST. art. I, § 8, cl. 8. This phrase, which is commonly referred to as the Patent Clause or the Intellectual Property Clause, was unanimously approved at the ratification convention without any objections. “[T]he uniqueness of the Intellectual Property Clause flows from its status as the only enumerated power granted to Congress that explicitly defines the mechanism for exercising this power.” Edward C. Walterscheid, To Promote the Progress of Science and Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution, 2 J. INTELL. PROP. L. 1, 54 (1994).

18. Thomas, supra note 9, at 610. See also Fenwick, supra note 16, at 20 (“Applying the concept of fundamental rights to reproductive technologies . . . could not have been imagined by our forefathers . . . .”).

application of the Bill of Rights and the Fourteenth Amendment has traditionally been thought to be inapplicable in this context.\textsuperscript{20}

Admittedly, only the most rare inventions or pioneer inventions with broad, upstream, genus claims would offer alternativeless\textsuperscript{21} or nearly alternativeless solutions to such serious reproductive and procreative concerns. It is reasonable, however, to believe that those technologies will be developed\textsuperscript{22} and that the opportunity for abuse is real.\textsuperscript{23} While counter to the typical economic incentives for obtaining patent rights, some undoubtedly see value in denying the market access to reproductive options that are against their moral or religious beliefs. Alternatively, companies may see an economic advantage to not marketing products that will be the target of a very active and vocal opposition. Such acts of suppressing patented technologies would be the private equivalent of state legislation banning the manufacture, use, or sale of a product—raising serious concerns of monopolization of reproductive rights. Moreover, the result of denying access to reproductive technology and choice may be to push individuals, mostly women, to seek those technologies in foreign jurisdictions. By forcing the market outside of the supervision and safety of U.S. regulations, the dangers of “reproductive tourism”\textsuperscript{24} or “fertility tourism” may escalate at an unknown cost to Americans, especially to American women.\textsuperscript{25}

In Part I, this Note will outline the fundamental reproductive rights afforded to all United States citizens. It will show why some individuals, organizations, and corporations might oppose certain reproductive technologies and, in fact, have an extensive history of doing so. Part II of this Note will provide an historical example, using the controversy surrounding the abortifacient RU-486, to show how patents have previously had implications on access to reproductive choice. Part II also demonstrates why one might suspect that, in the future, individuals, organizations, or corporations with private agendas might again manipulate the property rights afforded by the United States patent system in a way that could

\textsuperscript{20} See Thomas, supra note 9, at 571.

\textsuperscript{21} Expanding on the idea that in patent law an “applicant is entitled to be his or her own lexicographer,” the term “alternativeless” is used throughout this Note to succinctly describe broad, upstream, or pioneer inventions that are not easily designed around. MPEP § 2111.01(IV) (8th ed. Rev. 8, July 2010).

\textsuperscript{22} Only alternativeless or nearly alternativeless solutions to reproductive and procreative concerns would be at issue. In other words, if a patented technology has generic substitutes or equivalents, a patient would not be denied access to the reproductive choice by only prohibiting access to the one patented technology. However, such alternativeless, upstream technologies are likely to be developed, even if currently unknowable. After all, people once thought that it would be impossible to divide the atom.

\textsuperscript{23} Technology suppression has a disturbingly robust history in the U.S. patent system. See Kurt M. Saunders, Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression, 15 HARV. J.L. & TECH. 389, 402–17 (2002) (recounting the history of patent suppression and discussing several examples).

\textsuperscript{24} See infra text accompanying note 207.

\textsuperscript{25} Artificial reproductive technologies place a greater burden on the female body than the male body. The chemicals used to increase the rate of ovulation as well as the implantation procedures themselves uniquely tax the female body, without risk to the male body. See infra text accompanying notes 212–13.
deny citizens access to technologies that they perceive as critical to their constitutional reproductive rights. Part III will survey the possible legislative or judicial options for addressing such a conundrum, identifying some of the advantages and disadvantages of fashioning an institutional level change to allow patent law to remain in accord with perceived constitutional reproductive freedoms. For, without a solution, unanticipated limitations to freedoms may result. As some have already recognized, “due to the quickly evolving nature of medical science, the debate regarding procreative freedom must expand to encompass these [possibilities].”

I. REPRODUCTIVE RIGHTS, REPRODUCTIVE TECHNOLOGY, AND PATENTS THEREON

The Supreme Court has established fundamental rights to reproductive choice: the right to procreate as well as the right to terminate a pregnancy. While Supreme Court decisions ensure that the government cannot interfere with those rights, they do not protect individuals from private actors who deny those rights. In light of a long history of vigorous opposition to reproductive rights, the robust property rights afforded by patent protection may provide fertile opportunity for private actors to promote a private agenda for reproductive choice. Conceivably, private actors could use patents to circumvent important fundamental reproductive rights by withholding patented reproductive technology from the public.

A. Reproductive Rights and Their Opponents

The constitutional right not to have a child was established by the Supreme Court in the seminal case of Roe v. Wade. It was solidified and reaffirmed in Planned Parenthood v. Casey. Although instructive, even without exploring the details and intricacies of those cases, without detailing the strands of cases preceding or following those decisions, and without doing justice to the tremendous struggle associated with the development of the right to terminate a pregnancy, suffice it to say the “right to choose” is now rooted in this country’s supreme governing document:

Constitutional protection of the woman’s decision to terminate her pregnancy derives from the Due Process Clause of the Fourteenth Amendment. It declares that no State shall “deprive any person of life, liberty, or property, without due process of law.” The controlling word in the cases before us is “liberty.”

27. See infra note 64.
30. Id. at 846.
Predating the cases that established “the right to choose” as we currently know it, the “liberty” associated with the procreative right to have a child was articulated in the 1942 case of *Skinner v. Oklahoma*.

In *Skinner*, the Supreme Court struck down a forced sterilization law that allowed criminals convicted of certain crimes to be subjected to sexually sterilizing medical procedures. In his opening paragraph, Justice Douglas wrote: “Oklahoma deprives certain individuals of a right which is basic to the perpetuation of a race—the right to have offspring.” In determining that such sterilization programs were unconstitutional, the Court stated that “marriage and procreation are fundamental to the very existence and survival of the race.”

The Court noted that it was dealing with “one of the basic civil rights of man,” a “basic liberty.”

In *Stanley v. Illinois*, the Court noted that *Skinner* set forth a right to “conceive and to raise one’s children,” which is a right “far more precious . . . than property rights.” The justices who decided *Skinner* were “moved to recognize . . . a right to reproductive autonomy in part because of fear about the invidious and potentially genocidal way in which government control over reproductive matters might be exercised if the choice of whether or when to beget a child were to be transferred from the individual to the state.”

In summarizing these rights on paper, it is easy to overlook the immense moral, political, and religious implications that accompany them. The underlying moral issues that flow from these rights deeply divide people throughout this nation; the implications they invoke gives this sphere of rights a delicate dynamic and shades them with strong emotional color. In *Gonzales v. Carhart*, for example, the Court dealt with a previability, but late-term, abortion technique framed by some members of Congress as “a gruesome and inhumane procedure.” The startling testimony, submitted as evidence, described the “dilation and extraction” abortion procedure at issue in the following manner:

The doctor opened up the scissors, stuck a high-powered suction tube into the opening, and sucked the baby’s brains out . . . . He cut the

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31. 316 U.S. 535 (1942); see also Fenwick, supra note 16, at 16.
33. *Id.* at 536.
34. *Id.* at 541.
35. *Id.*; see also Kenneth L. Karst, *The Supreme Court 1976 Term: Foreword: Equal Citizenship Under the Fourteenth Amendment*, 91 Harv. L. Rev. 1, 32 (1977) (“For the state to deny such a choice is for the organized society to deny the individual [the] presumptive right to be treated as a person, one of equal worth among citizens.”).
40. *Id.* at 141.
umbilical cord and delivered the placenta. He threw the baby in a pan, along with the placenta and the instruments he had just used.\footnote{Id. at 139 (citation omitted).}

In addition to enormous opposition from fundamental religious groups, led prominently by the Catholic Church and its membership,\footnote{The Catholic Church, claiming over one billion members, has long opposed contraceptives and prophylactics and now opposes almost all other modern reproductive technologies, methods, and procedures that are not a part of “natural” family planning. \textit{See Pope Paul VI, \textit{Humanae Vitae: Encyclical Letter of Pope Paul VI} (July 25, 1968), reprinted in \textit{Humanae Vitae and the Bishops: The Encyclical and the Statements of the National Hierarchies} 33 (John Horgan ed., 1972); \textit{see also Pope John Paul II, \textit{Evangelium Vitae} (Mar. 25, 1995), reprinted in \textit{The Encyclicals of John Paul II} 792 (J. Michael Miller ed., 1996). The Catholic Church and its membership are said to be responsible for the birth of the “right to life” movement. \textit{See Ziad W. Munson, The Making of Pro-Life Activists: How Social Movement Mobilization Works 85 (2008). In a more recent example, the Catholic Church had a large influence on keeping abortions out of the Health Reform Act of 2010. Letter from United States Conference of Catholic Bishops to U.S. Senate on Healthcare (Sept. 30, 2009), \textit{available at www.usccb.org/issues-and-action/human-life-and-dignity/health-care}.}} it is not difficult to see how others could be otherwise morally or viscerally opposed to the exercise of these rights. If a five-member majority of the Supreme Court can let their partially subjective perspective on the “humanity” of a seemingly constitutionally protected abortive medical procedure affect the scope of that right, then it is not surprising that many others, possibly less open minded and less knowledgeable about the ramifications of such a decision, could feel similarly.

In fact, many highly motivated and politically active individuals and organizations have a history of forceful opposition to reproductive technologies much less “gruesome” and much more frequently required than the extremely rarely used dilation and extraction procedure in \textit{Carhart}.\footnote{Dilation and extraction procedures are rarely, if ever, a justifiable means of abortion. \textit{See, e.g., Janet E. Gans Epner, Harry S. Jonas & Daniel L. Seckinger, \textit{Late-term Abortions}, 280(8) JAMA 724, 729 (1998) (“[T]he AMA recommended that the intact D\&X procedure not be used unless alternative procedure pose materially greater risk to the woman.”). This type of technology may not be the type of technology that a majority of the public would demand, but it is illustrative of the intense controversies that exist in this sphere of reproductive rights.} History illustrates that almost any invention or technology used in connection with creating or ending human life has encountered at least some, if not forceful, opposition.

For instance, opposition to the use of contraceptives, which resulted in the well-known contraception cases and was squarely addressed by the Court in \textit{Griswold v. Connecticut},\footnote{381 U.S. 479 (1965) (holding that states may not criminalize the use of contraceptives).} is still healthfully alive today. Individuals and organizations opposed to contraceptives have simply found new battlefronts to oppose that reproductive choice, even as birth control and contraceptives have become mainstream. Recently, pro-life pharmacists, with support from large, pro-life, anti-abortion
groups, have begun to refuse to fill prescriptions for contraceptives. In some instances, pharmacists have refused to return the unfilled prescriptions to customers after refusing to provide birth control, effectively denying any route for that customer to purchase her prescribed contraceptive, even from another pharmacy.

In the late 1970s and 1980s, large opposition was mounted against the development of “test-tube baby” procedures as in vitro fertilization became publicly marketed. Like contraceptives, in vitro fertilization still engenders opposition even as the procedure has become medically accepted. Activists opposing IVF procedures have lobbied so strenuously over the years that governments throughout the world have, to varying extents and degrees, banned embryonic research, surrogate motherhood, PGD procedures, and a cornucopia of other embryonic transfers and treatments. Germany, for example, issued its version of embryo protection legislation, called the Embryo Protection Act of 1990, partly out of fear of being stigmatized as advocating potentially eugenic technology reminiscent of the horrors that still emanate from its not-so-distant past.

History provides several examples of boycotts of companies affiliated with reproductive pharmaceuticals. Notably, the Upjohn Company was the victim of a nationwide boycott after the company decided to market FDA-approved Prostaglandins, a drug used to induce abortions. Pro-life groups staged a nationwide boycott of all Upjohn products, such as Nuprin, Motrin, and Unicap, for over two years. After rallies at the Upjohn Company’s national headquarters and significant pressure from company shareholders who sympathized with the boycotters, Upjohn stopped all research and production of such drugs. The pro-

45. Examples of such pro-life pharmacies are those registered through Pharmacists for Life International (PFLI). See PHARMACISTS FOR LIFE INT’L, www.pfli.org. Doctors and pharmacists have refused for other reasons as well. See Caroline Bollinger, Access Denied: Find Out Why Growing Numbers of Doctors and Pharmacists Across the US Are Refusing to Prescribe or Dispense Birth Control Pills, PREVENTION MAG., Aug. 2004 at 150. These pharmacies chose to exclude medicines from the inventories even though it would be economically beneficial to provide those prescriptions.

46. See Noesen v. State Dep’t Regulation & Licensing, Pharm. Examining Bd., 751 N.W.2d 385 (Wis. Ct. App. 2008). In such an instance, a patient would have to seek a doctor to write another prescription—conceivably allowing too much time to elapse for certain prescriptions to be effective.

47. For example, Robert Edwards was awarded the 2010 Nobel Prize in Physiology or Medicine “for the development of human in vitro fertilization.” Press Release, The Nobel Assembly, The Nobel Prize in Physiology or Medicine 2010 to Robert G. Edwards (Oct. 4, 2010). The press release estimated that 10% of the world’s couples are affected by infertility and would therefore potentially benefit from IVF.


50. Id. at 1122–23.

51. Id. at 1123.
life movement continues to be one of the most politically mobilized and vocal lobbying groups in the nation. The National Right to Life Committee is the largest pro-life organization in the United States, and it has historically organized Catholic and non-Catholic activists into one unified group.

From this small sample of the opposition to reproductive rights, it is easy to imagine the myriad ways that technologies engender actions and emotions of individuals and organizations. Those opposed to reproductive choice spend significant time and money to uphold and advocate their beliefs. Additionally, it sometimes makes more economic sense for corporations to withhold controversial technology than to market it and face damage to their image and consumer boycotts. It is clear that not only “gruesome” methods, like the rarely used technology in Carhart, but almost any technology under the sun that treads on human reproduction will provoke and enrage someone.

B. Patents and Reproductive Technologies

The equipment and instrumentation for medical procedures, like the seldom-used dilation and extraction procedure in Gonzales v. Carhart as well as the other more common reproductive technologies that have garnered opposition, are clearly patent eligible under the broad umbrella of current 35 U.S.C. § 101. Not surprisingly, the medical device industry, a particularly profitable market, is one of the most highly patented fields of technology.

If the Carhart Court had been composed of a different political and ideological membership, the “gruesome,” but patentable, dilation and extraction procedure, which was banned by the Partial-Birth Abortion Ban Act of 2003, could have been found to be definitively within the scope of the governmentally enforced “right to choose.” From a reading of the dissenting opinions, it is apparent how close and controversial this Supreme Court decision was: “Justice Ginsburg’s dissenting opinion essentially accuses the majority—five politically and religiously conservative males—of writing their morality into the Constitution.”

The procedure and associated instrumentation remain potentially patentable. The

52. Id.
54. “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101 (1952).
55. The medical instrument field is notoriously patent active. There were over 4500 patents issued in the year of 2009 alone in the technology of just 600 Class “surgery” inventions. See USPTO, Patent Counts by Class by Year Report, available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cbchy.pdf.
56. The decision in Gonzales v. Carhart was a five-to-four split. Some commentators have suggested that Justice Ginsburg’s dissent was meant to imply that “a Court that once included two women would not have ruled this way.” William N. Eskridge, Jr. & Nan D. Hunter, Sexuality, Gender, and the Law 24–25 (2d ed. Supp. 2009).
procedure remains “the safest procedure for late term (previability) abortions” and, although rarely used, it could easily come back within the scope of the rights afforded by Roe and Casey with a change of Court composition and mind set.

Posit the case of a woman who inadvertently ingested a drug that caused permanent malformations of her late-term unborn child. What if, as with the patent eligible procedure and instrumentation in Carhart, the procedure she needed was the best, safest, and alternativeless procedure? Obviously, as raised in the Carhart litigation, there would be an argument that depriving her of that particular procedure would be equivalent to depriving her of her constitutional rights. As a rational person, she might necessarily and, perhaps desperately, oppose a decision such as Carhart, despite how “gruesome” morally biased individuals (as we all are) may perceive the procedure.

Now imagine that the Supreme Court had made a different decision and the hypothetical women’s right to choose to use the safest procedure to abort the child is grounded in the Due Process Clause of the Fourteenth Amendment. But instead of a Court-imposed ban, groups or individuals with beliefs similar to those of the five-member Carhart majority, or religious groups simply opposed to all abortions, own or buy the patent rights to the abortion procedure and the associated instrumentation and refuse to license their use. Would the federal government’s enforcement of the private patentee’s property rights interfere with the constitutional rights to reproductive choice? Would a private patentee be denying a U.S. citizen her constitutional right to use the safest procedure to abort the child?

Stated differently, “[i]f Congress unduly restricted a fundamental liberty interest” in reproductive technologies or inventions, “a facial challenge would prove fatal to the statute.” But, “if the U.S. Patent Office . . . issued identically worded patent claims to a private actor, the patent could be freely enforced without regard to constitutional limitations.” This is because a private patentee is not a state actor and is, therefore, currently unrestricted by the Bill of Rights and the Fourteenth Amendment’s Due Process Clause.

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60. Id. at 25.
61. It is not difficult to imagine this scenario, especially since pharmacological mix ups occur at an uncomfortably high frequency. See, e.g., Associated Press, Pregnant Woman Waits to See if Pill Harmed Embryo, MSNBC.COM (Feb. 10, 2011, 10:43 AM), http://www.msnbc.msn.com/id/41481554/ns/health-womens_health (reporting a case of a pregnant women who was accidently administered a chemotherapy pharmaceutical instead of an antibiotic).
62. Thomas, supra note 9, at 571.
63. Id. (citation omitted).
64. The state action doctrine is generally considered to be a limitation on the operation of the Fourteenth Amendment. It has been described as a “tool with which the courts attempt to balance at least three competing interests: (1) individual autonomy—the individual’s interest in preserving broad areas of life in which he or she can develop and act without being subjected to the restraints placed by the Constitution on governmental action, (2) federalism—the nation’s interest in preserving the proper balance between state and national power, especially the power of states to determine, within generous limits, the extent to which regulatory power should be applied to private action, and (3) constitutional rights—the interest in protecting constitutional rights against invasion by government or by action fairly attributable to government.” G. Sidney Buchanan, A Conceptual History of the State
A valid patent affords its owner a broad, but limited, twenty-year term of negative rights:

Although the twenty-year patent term is short in comparison to other intellectual property rights, few restraining doctrines allay a patent’s scope of exclusivity. Liability rests solely upon a comparison of the text of the patent instrument with an accused infringement, whether or not the defendant derived the invention from the patentee. The patent law also lacks an effective defense . . . of . . . fair use privilege. 65

Using the facts of Gonzales v. Carhart as illustration, one can see how, in light of a patentee’s traditionally robust rights, the act of withholding technologies that provide the safest, best, or alternativeless routes to enable the desired reproductive outcome could be seen as bearing on constitutional rights.

In fact, this scenario, a variation on “patent blocking,” is not as far-fetched as it may seem. By substituting the rarely used dilation and extraction technology at issue in Carhart with a technology that more Americans would demand access to, but that would still engender opposition, the scenario quickly becomes frighteningly realistic. For example, a morning-after-style pill that could repetitively be taken without adverse medical effects could be used after each act of unprotected sex. 66 Such a pill might be seen as promoting pre-marital sex and promoting abortion by, for example, the National Right to Life Committee and its immense membership. 67 From another perspective, it could be seen as a revolutionary way to eliminate the pitfalls of daily birth control pills 68 and mitigate the social stigma and health consequences of abortifacients and abortion procedures. Under such a hypothetical, the patent system might easily become a

\[\text{Action Doctrine: The Search for Governmental Responsibility,}\ 34\ \text{Hous. L. Rev.}\ 333,\ 339–40\ (1997).\ \text{Unfortunately, it also has been described as “a conceptual disaster area” and as “a torchless search for a way out of a damp echoing cave.” Charles L. Black, Jr., Foreword: “State Action,” Equal Protection, and California’s Proposition 14,}\ 81\ \text{Harv. L. Rev.}\ 69,\ 95\ (1967).\]


66. While “[d]ata are not available on the safety of current regimens of ECPs [“emergency contraceptive pills”] if used frequently over a long period of time,” there is at least some concern about frequent repeated use in additional to a slew of common side effects. James Trussell & Elizabeth G. Raymond, Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy, EMERGENCY CONTRACEPTION WEBSITE (June 2011), available at http://ec.princeton.edu/questions/EC-review.pdf.

67. The National Right to Life Committee is a federation with affiliate organizations in all fifty states, some 3000 local chapters, and a membership, by some estimates, of nearly seven million people. See NAT’L RIGHT TO LIFE COMMITTEE AFFILIATE INDEX, http://www.nrlc.org/states/index.html.

68. For example, Planned Parenthood has identified that “[a]lmost all women on the pill forget to take it at some time. The pill works best when taken on time, every day—but knowing what to do when you forget could save you from having an unplanned pregnancy.” Birth Control Pills, PLANNED PARENTHOOD, http://www.plannedparenthood.org/health-topics/birth-control/birth-control-pill-4228.htm. Eliminating concerns such as these would allow for a more consequence-free sexual environment.
useful tool in restricting access to reproductive technologies. With the potential universe of technologies of the future, history illustrates that reproductive technologies, such as the morning-after pill described above, are certainly fertile grounds for exploitation and controversy.

II. A HISTORY OF WITHHELD TECHNOLOGY AND A POTENTIAL FUTURE

A. RU-486

In 1982, “[a] revolutionary new development . . . emerged in the drug industry. A new drug, RU-486, ha[d] the ability to induce abortions without the need for surgery and, thus, ha[d] the potential to radically alter current abortion procedures.”69 The drug was one that, at the time, seemed so revolutionary that the drug’s developer, endocrinologist Dr. Etienne-Emile Baulieu, received “one of America’s most prestigious medical awards for [the invention].”70 Yet, not surprisingly, at the same time the drug was described by forceful and vocal opponents as “chemical warfare against the unborn”71 and as the “death pill.”72

The French-made drug, RU-486, is a pill that allows for an abortion by chemical inducement up to eight weeks after conception.73 RU-486 interferes with the hormone progesterone, which is secreted during a woman’s natural reproductive cycle:

[Progesterone] caus[es] the uterine wall to thicken, allowing a fertilized ovum to implant and mature in the womb. Progesterone must be produced continually until the placenta is in the place . . . . Without progesterone, the uterine lining deteriorates in a process similar to the menstrual cycle.74

Ironically, the pill with so much promise, a pill so groundbreaking that French Health Minister Claude Évin pronounced that, once produced, RU-486 “became the moral property of women, not just the property of a drug company,”75 was

69. Lees, supra note 49, at 1113.
70. Id. (citing Associated Press, Developer of Disputed Abortion Pill Receives Prestigious Award, L.A. TIMES, Sept. 28, 1989, pt. I, at 37) (announcing that the Albert Lasker Medical Research Award was presented to Dr. Baulieu on September 17, 1989).
73. There are varying statistics on the point of how long after conception the RU-486 pill will effectively terminate a pregnancy. Early research suggested that the success rate approached nearly 100% effectiveness when RU-486 was taken within the first five weeks of pregnancy. See Lees, supra note 49, at 1118; Gwendolyn Protho, RU 486 Examined: Impact of a New Technology on an Old Controversy, 30 U. MICH. J.L. REFORM 715, 725–26 (1997).
75. Steven Greenhouse, France Ordering Company to Sell Its Abortion Drug, N.Y. TIMES, Oct. 29, 1988 (emphasis added); see also LINDA GORDON, THE MORAL PROPERTY OF
effectively banned from U.S. citizens. This was due in part to the hostile political climate under the administration of conservatively rooted U.S. President, George H.W. Bush. But other factors also led to RU-486’s demise: mobilized anti-abortion groups targeted Roussel-Uclaf, the French-based manufacturer of RU-486, pressuring the company to discontinue the pill; and, pivotally, Roussel-Uclaf was unwilling to license its U.S. patent out of fear that the company would be affiliated with the image of RU-486 as a genocidal “death pill.” Roussel-Uclaf used its U.S. patent rights to effectively prohibit any use of the pill within the United States, even though it was said that the pill could directly serve “health benefits . . . for millions of women worldwide.”

The patent was withheld even though it may have provided an alternativeless abortive means to certain U.S. women, who have reproductive rights guaranteed by the Fourteenth Amendment under Roe and Casey.

In May 1994, after careful negotiation and an executive order by President Clinton, the RU-486 pill was eventually licensed to the Population Council, a not-for-profit organization, the mission of which is to “improve the well-being and reproductive health of current and future generations.”

Professor John Thomas postulated that RU-486 “might not be available in the United States had more politically conservative individuals controlled Roussel-Uclaf.” Further, Thomas suggested that had RU-486 “been assigned to say, the National Right to Life Committee,” the marketing scheme for RU-486, or lack thereof, would have been dramatically altered, to say the least. In the midst of such controversy and


76. Wyser-Pratte, supra note 26, at 1125 (The George H.W. Bush Administration prohibited importation based on “political considerations rather than concerns for public health . . . .”).

77. Nene, supra note 74, at 115. “Roussel-Uclaf . . . is controlled by the giant international firm, Hoechst. As a descendent of the German company that produced cyanide for the Nazi death camps, Hoechst has been lobbied hard by pro-life leaders and has been frightened by rhetoric about ‘chemical warfare against the unborn’ and by threats of boycotts of other products.” Lees, supra note 49, at 1113 n.3 (quoting Ellen Goodman, Abortion: By Pill . . ., WASH. POST, July 29, 1989, at A17).

78. Sharon Bernstein, Secret Deals, Big Money and Abortion Politics - to Bring RU-486 to This Country, Wealthy and Influential Private Citizens Put Up Money—and Lots of It, ORLANDO SENT., Nov. 26, 2000, at G1.


80. RU-486 also, and importantly, had the potential to allow women to obtain abortions without the stigmatizing and socially unacceptable experience of obtaining a surgical procedure at abortion clinics.

81. One of President Clinton’s first official acts as president was to issue a memorandum directing the FDA to analyze RU-486. See Memorandum on Importation of RU-486, 29 WEEKLY COMP. PRESENCE 57, 89 (Jan. 22, 1993); see also JUDICIAL WATCH, INC., A JUDICIAL WATCH SPECIAL REPORT: THE CLINTON RU-486 FILES (2006), available at http://www.judicialwatch.org/archive/2006/jw-ru486-report.pdf.


83. Thomas, supra note 9, at 582.

84. Id.
political posturing, the RU-486 pill remains extremely inaccessible, even following the pill’s September 2000 FDA approval (eighteen years after its discovery).85

B. A Potential Future

With historical evidence of how a very important technology with the ability to dramatically change the landscape of reproductive rights was withheld by a company (under anti-abortion pressure, for example), it is not too difficult to imagine future technologies invoking a similar response. Since “[t]he early stewards of our patent system never envisioned the prospect of public advocates anticipating objectionable activities, prosecuting patent applications, and being granted a proprietary interest in prohibitive regulation,”86 such future technologies now pose opportunities to manipulate the patent system to further private agendas. From that perspective, with the rapid pace of new inventions, and with the increased intermingling of technology with reproduction, not only will the constitutional right not to have a child be increasingly implicated, but the constitutional right to reproduce may also be brought back into the limelight.87

Since 2002, when Professor Thomas commented on abortion rights in relation to RU-486, technology has continued its ever-expanding course. In particular, technologies like IVF88—the process by which human egg cells are fertilized by sperm outside the body—in combination with the strides in understanding human gene sequences,89 have opened the door for scientists to develop many so-called PGD procedures.90 PGD procedures are currently used to test the embryos used in

85. The pill is not prescribed as a pharmaceutical prescription, but rather must be given from a specially licensed doctor, creating additional hurdles and rendering the drug relatively inaccessible. See Tania Khan & Megan Arvad McCoy, Access to Contraception, 6 GEO. J. GENDER & L. 785, 790–91 (2005).

86. Thomas, supra note 9, at 576. By way of counter example, universities across the nation currently prosecute patents simply to ensure that technologies can be freely used instead of exploited by corporations.

87. See Balkin, supra note 16 (postulating a future of reproductive rights that includes the right to have a child genetically engineered to be free of certain genetic traits); see also Fenwick, supra note 16, at 23 (“Mothers and fathers today are exercising their fundamental rights of procreation and privacy in unorthodox ways . . . .”).

88. “The first ‘test tube’ baby, Louise Brown, was born in 1978, and thereafter IVF followed by transfer of pre-embryos to a woman’s uterus allowed those who were aware of their risk, as well as single parents, homosexual couples, and couples with fertility problems, to select both the ova and sperm that would be brought together in fertilization attempts in vitro.” Roberta M. Berry, Can Bioethics Speak to Politics About the Prospect of Inheritable Genetic Modification? If So, What Might it Say?, in THE ETHICS OF INHERITABLE GENETIC MODIFICATION: A DIVIDING LINE? 243, 253 (John E.J. Rasko, Gabrielle M. O’Sullivan & Rachel A. Ankeny eds. 2006). IVF technologies open the door to innumerable reproductive possibilities.


90. “By the 1990s, pre-implantation genetic diagnosis (PGD) became available for use in conjunction with an IVF procedure. This allowed future parents to test for certain conditions in the pre-embryos created in vitro and selectively transfer to the women’s uterus
IVF for genetic defects, such as deafness, cystic fibrosis, and gender, but PGD also have the potential to be used for an increasingly diverse array of possible indicators with unknown ramifications on moral, religious, and socially acceptable behavior. As understanding of how human characteristics, like obesity, are linked to particular gene sequences increases, parents may be able to preselect growing numbers of characteristics of their offspring, raising the specter of “designer babies.” The “[US]PTO inevitably will grant patents on biological discoveries with such eugenic potential,” similar to the eugenic potential that was of concern in 

In that vein, “the same umbrella of rights that the Supreme Court has extended toward procreation and contraception could also be used to cover PGD and to protect a parent’s right to engage in genetic, as well as reproductive, choice.”

In particular, and related to an issue on the minds of many American citizens given the media attention surrounding “Don’t Ask, Don’t Tell” and gay marriage, the possibility of linking homosexual orientation to a gene sequence is a real possibility. It would afford parents-to-be the ability to screen out embryos that show the indicators for homosexuality or, conversely, same-sex couples may select offspring with the indicators for homosexual orientation. In that regard, the idea of anticipatory patent blocking has already become an issue looming on the horizon. For example, Dr. Dean Hamer, a leading geneticist in the field of inheritable homosexuality, has published works indicating his desire to patent the “gay gene,” if discovered, and use patent rights to prohibit its use. Dr. Hamer has stated:

I could try to use the law to withhold the “testing” technology, should it ever become available. Genetic testing as practiced in the United States only those that were not affected by a detected condition.” Berry, supra note 88, at 253.

91. See id. at 254–59; see also Zachary P. Demko, Matthew Rabinowitz & David Johnson, Current Methods for Preimplantation Genetic Diagnosis, 13 J. CLINICAL EMBRYOLOGY 6, 10 (2010) (“Over the last 20 years, the scope of PGD has expanded to include screening for a wide range of disease-linked genes, as well as screening for aneuploidy at all chromosomes.”); Alan H. Handyside, John G. Lesko, Juan J. Tarín, Robert M.L. Winston & Mark R. Hughes, Birth of a Normal Girl After In Vitro Fertilization and Preimplantation Diagnosis Testing for Cystic Fibrosis, 327 NEW ENG. J. MED. 905 (1992) (announcing the first successful attempt at the procedure).


94. See Tribe, supra note 38, at 1339.

95. Spar, supra note 92, at 125.


97. Dr. Dean Hamer is a prolific writer and, in particular, the author of a 1993 paper suggesting that certain genes were responsible for predisposing men toward homosexuality. See Dean H. Hamer, Stella Hu, Victoria L. Magnuson, Nan Hu & Angela M.L. Pattatucci, A Linkage Between DNA Markers on the X Chromosome and Male Sexual Orientation, 261 SCI. 321 (1993).
requires commercialization, and commercialization generally requires protection of intellectual property through patents. If a lab does discover a “gay gene,” it might be able to control the licensing of the technology.98

Others have written that “[Hamer] also vowed to patent his genetic testing techniques to insure that they could not be used in a discriminatory way.”99

The relative dearth or abundance of potential outrage from individuals, organizations, or corporations opposing the withholding of this patented “gay gene” technology on moral, social, religious, or other grounds is not pivotal to this discussion. Rather, Dr. Hamer’s views are simply illustrative of the fact that people are aware of how to manipulate the rights that a patent affords to advance a private moral, social, or religious agenda. Whether or not the agenda is categorically for good or bad, it is a private, not public, social agenda nonetheless. Furthermore, the future of what people perceive as “fundamental” rights, “personal liberties,” or within their “right to choose” is entirely predictable, but only to the extent that those perceptions will change over time.100 In the future “reproductive rights might include the right to have a child engineered to lack a particular disease or disability, or more fancifully, the right to have a child with blonde hair and blue eyes, or even a clone of one’s self.”101

With that being said, the future of technologies or inventions with the capacity to influence the sphere of reproductive choice is doubly difficult to fathom. The technological future may have reproductive “miracles” in store that our current society can only begin to conceptualize. For example, if we currently have the ability to regenerate full fingers from certain cellular matrices102 and to grow completely new livers from a combination of fetal cells and cadaver organs,103 it is not totally outside the realm of possibility to regenerate or grow a new uterus or ovaries for women. Such a development might provide alternatives for those who

100. See supra note 16 and accompanying text.
102. See Wyatt Andrews, Medicine’s Cutting Edge: Re-Growing Organs, CBS NEWS (Feb. 11, 2009, 3:13 PM), http://www.cbsnews.com/stories/2008/03/22/sunday/main3960219.shtml (“[The powder used in this technology] is a substance made from pig bladders called extracellular matrix. It is a mix of protein and connective tissue surgeons often use to repair tendons and it holds some of the secrets behind the emerging new science of regenerative medicine.”). The potential application for regeneration of body parts is limitless—businesses, such as the Tengion Company, have already bought licenses to the patented technology. Id.
103. See Daniel J. DeNoon, First Human Liver Grown in Lab, WebMD HEALTH NEWS (Oct. 29, 2010), http://www.webmd.com/news/20101029/first-human-liver-grown-in-lab (“The organs are grown on ‘scaffolds’ created from cadaver organs . . . . When fetal cells from the appropriate organ are pumped into the scaffold, they hone in on the appropriate location and begin to grow.”).
are infertile, for whatever reason, or could benefit stem cell research generally. Would such a procedure or organ transplant, one that arguably represents an advancement in reproductive research, be hindered by new moral or religious concerns surrounding stem cell research? Would the government’s interference with access to a procedure or enforcement of patent rights of someone withholding or overpricing this technology implicate the rights espoused in Skinner? In the future there may be a drug or a series of hormone injections that could restore sexual fertility, but only by harvesting the chemicals or hormones from developing in vitro embryos. Or, while possibly only marginally less “shocking” than a dilation and extraction abortion procedure, what if a chemical injection could be used to safely dissolve and breakdown a fetus in utero, including late in pregnancy? Would the Court extend the window on the right to choose in that instance? Would society eventually demand such a freedom of choice?

While such technologies seem far-fetched to some, they are as likely to occur in some fashion as splitting the atom was to occur for the societies of the pre-atomic era. These technologies may implicate the much less explored realm of the fundamental right to procreate as well as the oft-discussed right not have a child. Serious thought must be invested into designing a preemptive system to deal with the inevitable technologies of the future and how they will align with the inevitable changes in the perception of (or actual changes in) fundamental reproductive rights in future societies.

In the context of genetic engineering, one commentator has noted that medical technology in the United States is likely “to proceed along different channels, channels that may keep the most far reaching innovations out of public consciousness until they have become impossible to eliminate.” Expanding on that reasoning, in the realm of reproductive rights, as reproductive technology develops and “proceed[s] along different channels” (namely, the back laboratories of large, private corporations), important, maybe revolutionary, technologies that would be opposed by certain groups will be developed, similarly to RU-486. And, just like the RU-486 scenario, due to vocal opposition groups and generous patent procurement, the technology may never be marketed out of fear of boycotts and negative press. Thus, those technologies will become not “impossible to eliminate” but, rather, impossible to integrate.

III. SOLUTIONS TO MITIGATE THE CIRCUMVENTION OF REPRODUCTIVE RIGHTS

Changes to the patent system have been carefully implemented over time to preserve its delicate balance of incentives. While exploring solutions in

105. June Carbone, Roadblocks or Bypasses?: Religion, Science, and the Future of Genetic Engineering, 18 KAN. J.L. & PUB. POL’Y 188, 189 (2009); see also Cripps, supra note 16, at 11 (noting that cloning was developed outside of the public consciousness before Dolly).
106. “The fertility industry . . . has developed largely outside federal funding or oversight.” Carbone, supra note 105, at 199. Because of religious opposition, there has been little or no federal funding for many fertility and reproductive technologies. Id. at 200.
107. See generally, e.g., Edmund W. Kitch, The Nature and Function of the Patent
anticipation of possible manipulation of the system (a manipulation that arguably
cuts against the constitutional goal of “promot[ing] the Progress of Science and
useful Arts”108), it must be remembered that more than 200 years of discourse and
case law have buttressed this system. Every change will affect the incentives the
patent system provides. One such incentive is the incentive to invent, which
requires the patent system to provide a broad scope of patent-eligible subject matter
as an initial entryway towards patentability.109 If inventors have little hope that
their new, useful, and nonobvious products will even be considered for
patentability, then those inventors and their financial backers will have little
motivation to invest time and money into the technology. Moreover, there should
be incentives to invest in all technologies, as development in one arena often leads
to unanticipated but important developments in tangential fields.110

The U.S. patent system is a fundamental aspect of the successful U.S. economy,
which has, over time, helped the United States remain a technological superpower.
As our human existence becomes further “embedded”111 with technology, and as
those technologies impact new and important individual liberties,112 it is important
to realize that the incentives that the patent system provides are partially
responsible for the realization of those liberties: new technologies encourage new
fundamental expectations from society.

In order to maintain the strength of the patent system and balance the need to
guard reproductive choice, several courses of action can be considered. While all
seem to have merit, upon deeper scrutiny many are unworkable or may create more
problems than they resolve. The most promising of these courses of action may be
the most unlikely: subjecting private patentees to the rigors of the Bill of Rights
and the Fourteenth Amendment.

A. Legislative Options

1. Narrowing the Scope of 35 U.S.C. § 101

In the most recent of the cases involving the patentability of human gene
sequences, the district court in Association for Molecular Pathology v. U.S. Patent


108. U.S. CONST. art I, § 8, cl. 8 (emphasis added).


“According to the Supreme Court, patents serve three purposes: to promote invention, to
encourage inventions, and to encourage inventors to disclose their inventions.” Saunders,
supra note 23, at 426 (citing Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974)).

110. In a simplistic example:

Since the introduction of Post-it® Notes in 1980, the sticky yellow notes have
become one of the best known of all 3M products. In a twist to the tradition of
innovation, the product had its root as a solution looking for a problem. 3M
research scientist, Dr. Spence Silver, first developed the technology in 1968
while looking for ways to improve the acrylate adhesives that 3M uses in many
of its tapes—but he found something remarkably different.

Post-it® Notes . . . Little Sticky Notes that Revolutionized Messages, 3M CANADA,
http://www.3m.com/cms/CA/en/1-30/rFzeEA/view.html.

111. See Thomas, supra note 9, at 610.

112. See supra note 16 and accompanying text.
& Trademark Office ("Myriad") held that patent claims to isolating and extracting gene sequences for the identification of breast cancer were invalid. Judge Sweet, in deciding the case in favor of the plaintiff, took a step toward narrowing the scope of patent-eligible material—arguably, a step away from long-standing precedent. Myriad is illuminating with regard to managing the scope of technologies that are perceived to directly bear on the sanctity of the human body. On appeal from this decision, the appellants argued that 35 U.S.C. § 101 should remain untouched and that there are other ways of limiting patent scope. As the appellants argued, drawing from the history of patent eligibility may best demonstrate what the appellants perceive as a dramatic change by the lower court and may best support the broad language of the case law precedent.

The Patent Act of 1793 first introduced the idea of patent-eligible subject matter, stating that "any . . . art, machine, manufacture or composition of matter" was to be considered for letters patent. The early case law worked to narrow, but only slightly, the immense breadth of that original language. For example, after first allowing patents such as Louis Pasteur’s patent for an “[improvement in the manufacture of beer and yeast],” which contained claims to living organisms and would likely not be considered eligible today, the United States Patent and Trademark Office (USPTO) began to announce some limitation on patentable subject matter starting with Ex Parte Latimer. In Latimer, the Commissioner of Patents ruled that a patent could not be obtained for a fiber identified in needles of


114. Myriad, 702 F. Supp. 2d at 235–37 (holding several of Myriad’s patent claims invalid).


116. Myriad involved arguments regarding implications for "women facing the threat of breast cancer or who are in the midst of their struggle with the illness.” Myriad, 669 F. Supp. 2d 365 (S.D.N.Y. 2009). The case involved patent claims for gene sequences and mutations that “impact the body’s ability to create proteins necessary for sound health.” Id. at 377. When ruling on summary judgment the court stated that “[t]he resolution of the issues presented to this Court deeply concerns breast cancer patients, medical professionals, researchers, caregivers, advocacy groups, existing gene patent holders and their investors, and those seeking to advance public health.” Myriad, 702 F. Supp. 2d at 185.


118. Id. at 30–34.


120. Manufacture of Beer and Yeast, U.S. Patent No. 141,072, at 1 (filed May 9, 1873).

121. 1889 Dec. Comm’r Pat. 123.
pine trees,\textsuperscript{122} and in \textit{Funk Bros. Seed Co. v. Kalo Inoculant Co.}, the Court further narrowed that decision by stating that “patents cannot issue for the discovery of the phenomena of nature.”\textsuperscript{123} However, since \textit{Funk Bros.}, only in the landmark case of \textit{Diamond v. Chakrabarty}\textsuperscript{124} has the Supreme Court enunciated an overriding test for patentability, stating: “Congress intended statutory subject matter to ‘include anything under the sun that is made by man’” and that only “[t]he laws of nature, physical phenomena, and abstract ideas have been held not patentable.”\textsuperscript{125} The broad threshold for patent eligibility is to “ensure that ‘ingenuity should receive a liberal encouragement.’”\textsuperscript{126} These decisions fundamentally stand for the proposition that inventive, novel, and useful technologies, in whatever form, should be ripe for at least patent consideration.

From a historical perspective, in order to achieve a society that “encourage[d] the sharing, the creation, and the dissemination of ideas . . . the proper . . . system had to be implemented.”\textsuperscript{127} Significantly, “nowhere within this implementation was there a provision taking into account the ethical or moral repercussions of the ideas seeking protection.”\textsuperscript{128} After several attempts to introduce morality, ethics, and consumer protection into the patent examination procedure, the Court of Appeals for the Federal Circuit in \textit{Juicy Whip, Inc. v. Orange Bang, Inc.} effectively ended any such inquiry.\textsuperscript{129} The Federal Circuit pronounced that “[o]ther agencies, such as the Federal Trade Commission and the Food and Drug Administration, are assigned the task of protecting consumers from fraud and deception in the sale of food products.”\textsuperscript{130} Put differently, the patent system was created to operate as an objective system designed to analyze inventiveness—not to analyze moral, ethical, societal, or constitutional implications of the subject matter sought to be patented.\textsuperscript{131}

\begin{enumerate}
\item[\textsuperscript{122}]} \textit{Id.} at 123.
\item[\textsuperscript{123}]} 333 U.S. 127, 130 (1948) (holding that the properties of inhibition or of non-inhibition in bacteria were “the work of nature” and therefore not patent eligible).
\item[\textsuperscript{124}]} 447 U.S. 303 (1980) (finding the first genetically engineered single-cell organism to be patent eligible). “In choosing such expansive terms . . . modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws should be given wide scope.” \textit{Id.} at 308.
\item[\textsuperscript{125}]} \textit{Id.} at 309 (emphasis added) (citation omitted).
\item[\textsuperscript{128}]} \textit{Id.}
\item[\textsuperscript{129}]} 185 F.3d 1364, 1367 (Fed. Cir. 1999) (“The fact that customers may believe they are receiving fluid directly from the display tank does not deprive the invention of utility.”).
\item[\textsuperscript{130}]} \textit{Id.} at 1368.
\item[\textsuperscript{131}]} Congress never granted the USPTO rulemaking authority under 35 U.S.C. § 2(b)(2). \textit{See} Merck & Co., Inc. v. Kessler, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996). And, as discussed, in \textit{Juicy Whip} the Federal Circuit removed moral inquiry from the scope of the USPTO’s review.
\end{enumerate}
In light of a large body of history and case precedent, legislative changes to the scope of 35 U.S.C. § 101 to preemptively institute a system that could avoid issues of reproductive rights colliding with the property rights of patents may be a rash measure. By selectively excising technologies from patent consideration, Congress would be ignoring precedent that has matured over time and has been infused with decades of thought, insight, and deliberation.\textsuperscript{132} Congress would flirt with a slippery slope. Perhaps wisely, each time Congress has had opportunities to redefine the scope of 35 U.S.C. § 101, it has declined.\textsuperscript{133} Presumably Congress does not want to uproot a patent system that has been a fundamental incentive for technological development in America’s capitalistic society. Since no one can predict all of the various paths that technology will take, Congress is well advised not to attempt to enumerate or carve out all exceptions. The current quasi-exception that limits patent infringement damages for certain medical activities\textsuperscript{134} should not be followed as common practice; Congress cannot legislate at the pace that technology will be introduced. Congress must create an anticipatory escape hatch instead of reactively introducing legislation.

2. Statutory Patent Misuse

One approach to ensuring that reproductive technologies that may bear on constitutional rights are not withheld by private actors is to leave the scope of 35 U.S.C. § 101 untouched and fashion a statute similar to a patent misuse doctrine used in other countries.\textsuperscript{135} A common law patent misuse doctrine was once a part of the U.S. patent system but has since been effectively abandoned with the implementation of 35 U.S.C. § 271(d).\textsuperscript{136} The patent misuse doctrine was an equitable defense that permitted “defendants in an infringement . . . action . . . [to] claim that the patentee plaintiff has ‘misused’ its patent grant.”\textsuperscript{137} The patent misuse doctrine was typically invoked in response to a patentee trying to extend or assert his or her patent rights beyond the scope of the exclusionary rights in his or her particular invention (e.g., patent-tying arrangements, antitrust violations, price fixing, and illegal use)—not when a patent was withheld from use. In fact, when codifying the patent misuse doctrine, Congress clearly refused accused infringers relief from infringement liability when a patentee “refused to license or use any


\textsuperscript{133.} Congress has not altered 35 U.S.C. § 101 but rather has carved out exceptions from the statute’s scope. See 42 U.S.C. § 2181(a) (2000) (addressing areas on nonpatentable subject matter for reasons such as national security).

\textsuperscript{134.} 35 U.S.C. § 287(c) (2006) (exempting certain medical activities that do not require a patented machine, manufacture, or composition of matter).


rights to the patent. Refusing to provide accused infringers with relief from liability in such circumstances was said to be codifying the existing common law.

As such, while the patent misuse concept has had some success in its various forms in foreign jurisdictions, it will not likely be revived in this country. First, legislatively creating a new statute to implement this doctrine would likely lead to increased litigation in an area of law that is already among the most expensive and time consuming. The difficulties in trying to limit its use as a defense and define what constitutes misuse would likely restrict the practical application of the doctrine. More importantly, it would appear that the version of patent misuse doctrine necessary here would be a reactionary remedy that would only enable application of the defense after a pattern of misuse had been established. This reactionary remedy is not the type of escape hatch necessary for thoughtful constraints on the “dizzying ambitions of the contemporary intellectual property community.” Furthermore, technologies particularly prone to misuse in the realm of reproductive rights might be those that are time sensitive. As such, the remedy might fail in that access to technologies would be delayed while a potential defendant (infringer) collected evidence to substantiate a defense for the infringement.

3. USPTO Authority

Alternatively, Congress could bestow authority on the USPTO to evaluate patents based on moral, ethical, or constitutional considerations. The USPTO does not have its own substantial rule-making power, and all of its promulgations are essentially nonbinding. However, with congressional delegation of authority, the USPTO could be used to screen technologies that have the potential to restrict reproductive rights. Aside from the fact that authorizing the USPTO to use subjective authority would be effectively rewriting 35 U.S.C. § 101 to add an explicit morality-type requirement, the USPTO and its examiners lack the competence and experience to act as a moral or constitutional authority for America. Given that the USPTO currently has a conservatively estimated eighteen-month backlog of patents to examine and is already overburdened in its role as a technical assessor of invention, this is an impractical solution. Also, as noted

141. Thomas, supra note 9, at 619.
143. Dennis Crouch & Jason Rantanen, Unreasonable Patent Applicant Delay and the USPTO Backlog, PatentlyO L. Blog (July 9, 2010, 3:11 PM), http://www.patentlyo.com/patent/2010/07/unreasonable-patent-applicant-delay-and-the-uspto-backlog.html (“Over 1.2 million non-provisional patent applications are pending examination at the USPTO. Of those, more than 700,000 have not received even a
above, the courts have already addressed the use of moral considerations and consumer protection in granting patents, holding there is no proper place for that analysis within the USPTO. Finally, and more practically, there would be no way for the USPTO to know what type of inventions would impinge upon reproductive rights as of the time of filing—the Patent Office would need a crystal ball to evaluate patent applications under such criteria.

B. Judicial Options

The solution to this institutional-level reform, therefore, does not seem to be best put in the hands of Congress alone. In addition to problems outlined above, the difficulties in implementing legislation and the extremely bipartisan, politically polarized environment in which the elected officials of Congress currently operate do not furnish fertile grounds for change. The judiciary remains a key regulating body in handling any effective, practical institutional-level change, as it has in many patent law issues over time.

Three types of judicial changes could be implemented to create a feasible and robust system of regulating the withholding of patents that directly bear on the constitutional reproductive rights of citizens: (1) a compulsory licensing scheme similar to regulations under the Clean Air Act and Atomic Energy Act; (2) antitrust schemes; and (3) subjecting private patentees to the constitutional constraints of the Bill of Rights and Fourteenth Amendment by fashioning a logical way to connect private patentees to state action.

1. Compulsory Licensing

A compulsory licensing system could serve as a solution to reconciling the patent system with reproductive rights. For example, the language of Skinner, such as the right to “conceive and to raise one’s children,” a right “far more precious . . . than property rights,” could enable courts to justify a compulsory license. The courts could analogize to the Atomic Energy Act and the Clean Air Act, which

preliminary examination.”).

144. See Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999). The government used to consider morality and consumer protection when reviewing technology for patentability (especially in the case of gambling), but that approach has since been deemed, in certain contexts, not to be in accord with the Patent Act of 1952. But see Holbrook, supra note 93, at 594 (“Currently, the patent system is viewed as morally agnostic, making no judgments about the value of individual patents. This perspective may need reconsideration in light of the biotechnology revolution.”).

145. It might be practical to give the USPTO authority to have applicants of inventions with reproductive implications sign a declaration at the time of filing stating that they will not withhold the technology, but this could also result in prohibitory pricing schemes. See infra Part III.C; see also Saunders, supra note 23, at 429–30.

146. 42 U.S.C. § 7608 (2006) (certain inventions to control air pollution are subject to compulsory licenses).


148. Lesko & Buckley, supra note 37, at 29 (citing Stanley v. Illinois, 405 U.S. 645, 651 (1972)).

149. 42 U.S.C. § 2183(g).
provide clauses with semblance to compulsory licensing,\textsuperscript{151} and reasonably conclude that Congress desired that technologies which constitute public goods should not be susceptible to private decisions to withhold them from use. In one outlier case, the Ninth Circuit, in \textit{Vitamin Technologists, Inc. v. Wisconsin Alumni Research Foundation},\textsuperscript{152} may have been attempting to do exactly that. In dicta, the court noted that the suppressive licensing practices of the plaintiff were against the “public interest” and constituted a “public offense,” which likely contributed to the ultimate decision to invalidate the patent-in-suit.\textsuperscript{153}

Compulsory licensing seems attractive in that it does not totally destroy the property rights of the patent holder and could be narrowed, relatively speaking, to the cases of patent suppression by a private patentee. Compulsory licensing in the United States could be tailored parallel to other countries’ patent regimes that entail a responsibility to work the patent rather than let it stagnate.\textsuperscript{154} This measure, however, would constitute a significant departure from the expectation of robust property rights traditional of the United States—thus, it may be difficult to enact. The analogy between policies that favor all citizens nationwide (e.g., provide cheap, clean energy to citizens) and a policy that favors only those who do not oppose the idea of reproductive choice is tenuous. Also, the Supreme Court has already deferred to Congress in this regard. For example, in \textit{Diamond v. Chakrabarty}, the Court, dealing with the patentability of a modified living organism, stated that “[t]he choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide.”\textsuperscript{155}

Moreover, this would require reversing Supreme Court precedent. In the specific context of companies refusing to license technology, the Supreme Court in \textit{Continental Paper Bag Co. v. Eastern Paper Bag Co.}\textsuperscript{156} rejected the argument that a patent should be unenforceable because the patentee was not using the patented [technology] and was continuing to exclude competitors from using the [technology].\textsuperscript{157} The Court held that “such exclusion may be said to have been of

\begin{itemize}
  \item \textsuperscript{150} 42 U.S.C. § 7608.
  \item \textsuperscript{151} See, e.g., 42 U.S.C. § 7608 (“[A] district court of the United States . . . may issue an order requiring the person who owns such a patent to license it on such reasonable terms and conditions as the court, after hearing, may determine.”).
  \item \textsuperscript{152} 146 F.2d 941 (9th Cir. 1945).
  \item \textsuperscript{153} Id. at 945–46.
  \item \textsuperscript{154} For example, China’s patent laws include such a regime. See Xiaohai Liu, \textit{A Study on Patent Compulsory License System in China – with Particular Reference to the Drafted 3rd Amendment to the Patent Law of the P.R. of China, in 6 PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALIZED WORLD}\textsuperscript{115} 115–19 (Wolrad Prinz zu Waldeck und Pyrmont et al. eds., 2009). Various international agreements have provided templates for such doctrines. \textit{Id.; see also Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), including Trade in Counterfeit Goods of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), art. 31(a), reprinted in 47 Patent, Copyright & Trademark Rep. (BNA) 230 (Jan. 13, 1994).}
  \item \textsuperscript{155} 447 U.S. 303, 317 (1980) (“Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.” (emphasis added)).
  \item \textsuperscript{156} 210 U.S. 405 (1908).
  \item \textsuperscript{157} ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY:
the very essence of the right conferred by the patent” and that “it is the privilege of any owner of property to use or not to use it, without question of motive.”158 Even in the face of various dissenting opinions criticizing the rule in Continental Paper Bag Co.,159 Congress eventually codified the case holding by enacting 35 U.S.C. § 271(d)(4), protecting a patentee who refuses to license his or her patented works.160

Thus, while at first blush this option may seem feasible and would be similar to having a patent applicant sign a declaration requiring him or her to market the invention, it would constitute a major deviation from both legislative and judicial authority. Moreover, it would amount to a major derogation of expected property rights. Likely, a compulsory licensing scheme would lead back to the pitfalls of Congress having to implement a slow, reactionary, technology-by-technology approach toward a solution while facing evidence of clearly contradictory legislative history in analogous areas of law.161

2. Antitrust

In the context of RU-486, it has been postulated that “[a]lthough there are no reported cases that required a pharmaceutical company to market a drug, there are analogous cases in other areas [of law] which support the constitutionality of such an action.”162 In that regard, one commentator noted that “significantly, in antitrust cases, courts can order parties to take affirmative actions.”163 There are several examples of courts ordering companies to sell their products on the open market and ordering companies to permit competitors to use patents, trademarks, and trade secrets.164

It is not within the scope of this Note to outline the vast contours of antitrust law, but, as with compulsory licensing, finding a solution with an antitrust scheme

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160. See supra note 136 and accompanying text.
161. While likely not a completely satisfactory solution, some saving grace is found in the Supreme Court’s recent pullback from the general rule that courts would issue permanent injunctions absent exceptional circumstances. In eBay, Inc. v. MercExchange, L.L.C., the Court suggested that it would be willing to grant permanent injunctions only where “the public interest would not be disserved.” 547 U.S. 388, 391 (2006). Operating under this premise, a group willing to pay the damages resulting from an infringement suit brought by a patentee withholding reproductive technology would quite possibly not be enjoined from continuing the infringing activity going forward. This result would be a less satisfactory, back-door way to compulsory licensing, but certainly a type of forced “licensing” nonetheless.
163. Id.
only at first appears to be workable. The act of withholding a patent on the type of technology at issue in this discussion, which would necessarily be technology that could not be designed around or easily disregarded in turn for other solutions, is analogous to an antitrust situation—it conjures images of true monopolies, which this country’s founders opposed. During the drafting of the first Patent Act, the founders debated whether patents were too much like anti-competitive monopolies. However, aside from the fact that patents by their very nature afford their owners a quasi-monopoly, a major problem is that there is no competition or market share domination to speak of: if a private patentee never markets the invention and gains no economic value, many of the basic elements of antitrust law are never violated.

Specifically, the historical foundation of antitrust litigation is in the realm of competition law under the Sherman Antitrust Act. Antitrust law was developed for the purpose of exposing concealed business negotiations that allowed price fixing and market domination, which would not be present when a product was never used to establish a market in the first place. Because of this fact, the case law surrounding patents in antitrust lawsuits would be largely unhelpful as precedent. In fact, the Federal Circuit has expressly held that patentees refusing to deal or market patent technology are free from antitrust liability regardless of their subjective intent, such as an anti-abortion agenda:

We see no more reason to inquire into the subjective motivation of [patent holders] in refusing to sell or license [their] patented works than we found in evaluating the subjective motivation of a patentee in bringing suit to enforce that same right. In the absence of any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws.


166. Id.

167. “Standing alone, a refusal to use or license a patent is neither misuse nor an antitrust violation.” Saunders, supra note 23, at 431. Rather, only where other economic factors are implicated do antitrust considerations come into play. Id. (“The possibility for resort to antitrust law may arise . . . when there is horizontal collusion involving patents or when the patentee holds monopoly power in the relevant market . . . .”).


170. CSU, L.L.C. v. Xerox Corp. (In re Indep. Serv. Orgs. Antitrust Litig.), 203 F.3d 1322, 1327–28 (Fed. Cir. 2000) (“We answer the threshold question of whether Xerox’s refusal to sell its patented parts exceeds the scope of the patent grant in the negative. Therefore, our inquiry is at an end. Xerox was under no obligation to sell or license its
Antitrust solutions in this manner violate the quid pro quo that the patent system purports to establish and fly in the face of the enormously strong exclusionary property rights that a U.S. patent affords.

3. Subjecting Private Patentees to the Rigors of the Bill of Rights

Commentators have opined that with the “application of the state action doctrine and Intellectual Property Clause” being uncertain, a solution other than arguing for allowing constitutional defenses in cases of reproductive technology infringement should be advocated. As a leading authority on the topic, Professor Thomas explains that while typically “[c]onstitutional defenses apply only against government entities,” private patentees could fall under the state action doctrine, in which constitutional defenses can be applied against these nominally private parties because they enjoy sufficient governmental connections. Evaluating the state action doctrine within the sphere of patent law, Professor Thomas concludes that “patent law seems most unlikely to serve as the rudder for lending order to a state action doctrine that has so far avoided a coherent explanation” and that “constitutional protections such as substantive due process, equal protection, and freedom of speech are unlikely to be of direct application.”

However, more recent scholarship and litigation strategies demonstrate that the nexus between the applicability of the Bill of Rights and the Fourteenth Amendment to private patentees may be less “unclear” than once imagined. Professor Holbrook has recently argued that the government conferring a patent on technologies could be seen as approving that technology: “Unlike other forms of property, therefore, the signal from a patent is necessarily intermingled with expressions of the government’s approval.” In discussing technology that bears on morality and potentially future constitutional rights, such as the “gay gene” and behavioral sciences, Holbrook notes that “[m]any of these discoveries are patentable, and the government grant of a patent on these technologies could signal approbation of such technologies.” Thus, “[t]he patent system is . . . directly patented parts and did not violate the antitrust laws by refusing to do so.” (citation omitted)); see also Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1071 (Fed. Cir. 1998).

171. The patent system has traditionally been seen as giving limited-term monopolies in exchange for an enabling public disclosure of invention. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc., 534 U.S. 124, 142 (2001) (“The disclosure required by the Patent Act is ‘the quid pro quo of the right to exclude.’” (emphasis in original)).

172. Thomas, supra note 9, at 619.

173. Id. at 584. See supra note 64 and accompanying text (discussing the state action doctrine).

174. Id. at 594.

175. Id. at 571.

176. Contra id. at 588.

177. Holbrook, supra note 93, at 577 (emphasis added).

178. See supra text accompanying note 16 (discussing the possible future of reproductive rights).

179. Holbrook, supra note 93, at 578.
implicated in these technologies and is fostering an incentive to create eugenic
technologies that will be in the hands of private parties.”

Holbrook’s reasoning presents a new concept of the patent system that lends
support for Thomas’s initial proposition “that patentees [should] accept
constitutional responsibility for an elevation in status.” Under this reasoning, the
protection that a private patentee receives from the government could be justifiably
withdrawn where rights are violated. As Professor Holbrook points out, “[t]he
courts have found laws unconstitutional under the Equal Protection Clause even
absent any actual, non-psychoharm: the expression of these views alone is
sufficient.” This lends credibility to the argument that the issuance of a patent
alone might be enough to show government interference. Harkening to the
Supreme Court’s ruling in *Palmore v. Sidoti*, while “[p]rivate biases may be outside
the reach of the law . . . the law cannot, directly or indirectly, give them effect.”
Some momentum has built behind the insinuations that the U. S. government can
no longer let patent rights, which can be “conceived as a sort of private
legislation,” exist in a world separate from constitutional protections. New
constitutional challenges using the Intellectual Property Clause and First
Amendment arguments have already been percolating and gathering strength under
these theories.

For example, this reasoning has gained some support in that new litigation
strategies have started to include constitutional arguments that assert what used to
be irrelevant considerations. The complaint filed by the ACLU in the *Myriad*
case contains a series of such arguments along with several amicus briefs that present
these “novel” positions. The plaintiffs asserted that *Myriad’s* patent hindered the
“promotion of the useful arts” under Article I of the U.S. Constitution and inhibited
scientific research in the area of breast cancer diagnosis.

New theories that frame the scope of patent protection as not singularly private
action could reinvigorate and buttress Justice Douglas’s several dissents in
response to the holding in *Continental Paper Bag Co*. Douglas’s remarks in 1945
that patent suppression “preclude[s] experimentation which might result in further
invention by competitors,” which is “a clog to our economic machine and a barrier

180. *Id.* at 590–91.
181. Thomas, *supra* note 9, at 596.
(2005) (Stevens, J., dissenting)).
184. Thomas, *supra* note 9, at 582.
185. *See Complaint, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office,*
(Fed. Cir. July 29, 2011); *see also,* e.g., Brief for Universities Allied for Essential Medicines
as Amicus Curiae in Support of Plaintiffs-Appellees, Supporting Affirmance, Ass’n for
186. *See Plaintiffs’ Memorandum of Law in Support of Motion for Summary Judgment*
29, 2011); *see also* Brief for Appellees at 60–63, Ass’n for Molecular Pathology v. U.S.
to an economy of abundance,” ring even more true today.\textsuperscript{187} New views of the patent system, such as Holbrook’s, add fresh persuasive force to Douglas’s half-century-old conclusion that “[i]t is difficult to see how that [suppression] of patents can be reconciled with the purpose of the Constitution ‘to promote the progress of science and the useful arts.’”\textsuperscript{188}

While Holbrook’s “expressive impact of patents” theory and other lines of argument, such as those found, tangentially, in Professor Burk’s recent scholarship in \textit{Do Patents Have Gender}?\textsuperscript{189} may provide new ways to connect private patentees directly with the Constitution in a way that could allow parties to traverse the state action doctrine, there still may be some pitfalls to such a solution. Namely, in a case where an individual needs access to a reproductive technology in a way that affects her Fourteenth Amendment rights, should such an important technology be invented, the appeal could take years. As explored above, individuals demanding access to reproductive technologies may be in time-sensitive plights (especially in the case of abortion) and cannot be slowly dragged through the appeal process, or maybe not even the initial litigation process.\textsuperscript{190}

Finally, issues of standing may arise as well as issues of whether such a decision would violate the rule against advisory opinions if a party were to seek a declaratory judgment. For example, in the \textit{Myriad} case, amicus briefs have correctly pointed out that Judge Sweet’s opinion, in essence, was the equivalent to a prohibited advisory opinion:

\textit{In its attempt to be sensitive to the social implications of this case, the District Court impermissibly expanded its declaratory judgment jurisdiction to cover an “advisory opinion” for anyone merely expressing the desire to purchase a patented product or utilize a patent method, including non-existent products and services. However, this decision, if affirmed, presents a very real concern for other federal courts and patent holders. The dramatic expansion of federal declaratory judgment jurisdiction to those without a real and immediate...}

This is exactly the same scenario that would be present if plaintiffs seeking declaratory judgment were to assert constitutional violations in the context of reproductive rights.

\section*{C. A Hybrid Alternative}

Even with a more substantial nexus between private patentees, state action, and the Fourteenth Amendment, as can be inferred from recent scholarship and trends mentioned in Part III.B.3 above,\footnote{See, e.g., Holbrook, supra note 93, at 597 (“The main reason patents can serve such varied functions is because they are grants of exclusive rights from the federal government. The patent has gone through a review by the government that vests the patent with some level of certainty regarding the credibility of the disclosure. The government also ensures that the patent will have some bite—it is a right enforceable against the world at large. While not technically legislation, the patent grant can be viewed as akin to private legislation.”).} the applicability of the Fourteenth Amendment likely remains too muddled and unpredictable to be immediately useful. None of the traditional remedies enumerated above, used by themselves, provides an efficiently administrable remedy—each having its own significant pitfalls.

One remedy that may be all-at-once easy to administer, cost effective, and anticipatory of exploitation of the patent system is to legislatively require an additional “statement of intended use” declaration by the named patent inventors.\footnote{A similar concept has been advocated by Kurt Saunders. See Saunders, supra note 23, at 429. Saunders suggests that patentee be required “to file an annual statement with the [USPTO] in which the patentee would indicate whether the invention was being used internally or was licensed for use to another.” \textit{Id.} The concept suggested in this Note is different in implementation and narrowly tailored to the realm of reproductive rights, but likely similar in its potential to “deter[ ] patent suppression.” \textit{Id.} at 426.} Such a declaration or oath would be akin to the “oath or declaration” already prescribed by the USPTO.\footnote{37 C.F.R. § 1.54(b) (2010).} The current MPEP § 1.63 oath requires the declarant to certify the “named . . . inventors to be the original and first . . . inventors of the subject matter which is claimed and for which a patent is sought,” among other things.\footnote{MPEP § 1.63 (8th ed. Rev. 8, July 2010); 37 C.F.R. § 1.53 (2010).} While the MPEP § 1.63 oath is submitted along with an original patent filing, the proposed additional oath or declaration would be required after a filed patent received its “official filing receipt” and “preliminary classification.”\footnote{MPEP § 1.63(a)(4) (8th ed. Rev. 8, July 2010). Only if the preliminary classification placed the patent in a classification field corresponding with reproductive technologies would the declarant be required to file the additional oath or declaration. The oath would then attach to the patent and be carried along with it through any subsequent licenses or assignments if the patent were to issue.} Only if the preliminary classification placed the patent in a classification field corresponding with reproductive technologies would the declarant be required to file the additional oath or declaration. The oath would then attach to the patent and be carried along with it through any subsequent licenses or assignments if the patent were to issue.
The proposed additional oath would be configured to require the declarant to further certify that the technology at issue would not be withheld from commercialization in bad faith. In the vast majority of cases the inventor seeking to patent a reproductive technology will not be doing so with the intention to withhold but rather to commercialize the invention. With only the very minimal expense of exchanging of documentations between the USPTO and the inventors, reproductive technologies with the potential to be used in a manner that would violate existing or future reproductive rights\(^{197}\) will have a prenegotiated disposition towards commercialization. This would all be done with minimal cost or intrusion to the prosecution process of the typical patentee.

This additional oath would create a disfavored subsection of technology similar to the disfavored medical procedure class of inventions.\(^{198}\) However, instead of having a slow-moving Congress not in touch with the state-of-the-art, attempt to statutorily predetermine what technologies would be disfavored, that determination would be left to the technologically savvy USPTO. In this way the additional oath would be a hybrid preventive measure that would call on (1) Congress to enable the USPTO to issue the additional oath; (2) the USPTO to determine if the technology at issue in a patent application has inventive aspects which tread on human reproduction and thus require the additional oath from the patent filer; and (3) the courts, only in the rare instance of bad faith, “private legislation”-type\(^{199}\) uses of a patent, to interpret the oath and any evidence of violation thereof to determine whether the quid pro quo\(^{200}\) of the patent exchange was violated.

The oath would only affect a very limited class of inventors and inventions and would preemptively mitigate attempts at using the patent system as a means of “private legislation.” But it would nevertheless be seen as a derogation of the robust patent rights promulgated by our founders. Likely, it would be seen by some as an extreme derogation in light of the traditional interface of antitrust laws and compulsory licensing schemes with withheld patents.\(^{201}\) While many issues would need to be resolved and harmonized if an additional “statement of intended use” oath were to be implemented, some of those issues may be more easily traversed by the fact that the oath would be administered before the patent issued.\(^{202}\) In other words, since the oath would come before issuance, the granted patent would never carry with it the right to withhold the technology in bad faith. In other words, there would be no right to eviscerate because it was never created.

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197. See supra note 16 and accompanying text.
198. See 35 U.S.C. § 287(c) (limiting infringement liability for a class of patent inventions).
199. See Holbrook, supra note 93, at 597 (“[T]he patent grant can be viewed as akin to private legislation.”).
200. See supra note 171 and accompanying text (the oath and certification therein would be part of the patentee’s bargained-for exchange).
201. See supra Part III.B.
202. See, e.g., ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY 183 (2011) (“Governments may change the parameters of property rights before they are granted, at the ex ante stage. But woe unto any governmental official who tries to seize property or even rejigger property rights after they have been granted.”).
CONCLUSION

While the addition of a “statement of intended use” declaration for reproductive technologies appears to be a viable option to mitigate the risk of having reproductive technologies with potential constitutional implication withheld from use, there are of course always alternatives. In fact, there are likely alternatives or modifications that may more easily mesh with the historical precedent of patent withholding. As such, this Note should not be viewed as trying to prescribe one particular remedy. Rather, it is a call to action and a compilation of possible ways to think about solutions that recognizes that “[d]iscussing and crafting the patent system’s vision of technology within the public sphere will raise awareness among legislators, judges, scholars, and the public of [this] inquiry’s critical role within the patent system, and its critical impact on society.”\(^{203}\) By narrowly focusing on the reproductive set of fundamental rights, more can be gained about finding solutions to technologies that directly bear on other fundamental rights. For example, if the state action doctrine could be traversed in the courts, Congress could also enact statutes under the Commerce Clause which would prohibit further private expression of private biases via the patent system.

Moreover, it is hoped that the message is clear: without addressing this issue in a timely fashion and finding a workable solution, undesirable solutions or consequences may result. If there is not a solution to the “pervasive creep of technology into formerly sacrosanct areas of life”\(^{204}\) that provides for people’s perceived reproductive rights, they will find reproductive choice elsewhere. The phenomenon of “reproductive tourism”\(^{205}\) will continue to grow. As was true with RU-486, “if the [technology] is obtained through the black market rather than through normal means, it will lose some of its safety value.”\(^{206}\) For example, like the Italian ban on IVF, a patentee withholding a technology related to reproduction would spur fertility tourism.\(^{207}\) And, just like the result from the Italian legislation, the procedures would become more expensive and less effective.\(^{208}\) Patents that take the shape of private legislation make the United States an unwelcoming jurisdiction for those who need the reproductive options the most: “When a jurisdictions [sic] limits treatment to married couples, gays and lesbians—who may already feel excluded from parts of mainstream society . . . [they] may be among

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203. Irwin, supra note 132, at 822.
204. Id. at 815.
205. “The willingness to travel for [assisted reproductive technology (ART)] and the practices that facilitate fertility travel are known as ‘reproductive tourism.’” Lisa C. Ikemoto, Reproductive Tourism: Equality Concerns in the Global Market for Fertility Services, 27 LAW & INEQ. 277, 277 (2009). “In the past few years, reproductive tourism has expanded rapidly, and has acquired a public profile . . . . [The media stories] illustrate, even if they do not directly address, that the underlying global inequalities between geographic regions and their residents—and local inequalities among residents based on gender, class, race, and ethnic hierarchies—enable reproductive tourism.” Id.
207. Carbone, supra note 105, at 189 (“Italian regulation has spurred fertility tourism to friendlier locales such as Romania and Spain.”).
208. Id. at 204.
the first groups to seek alternative treatments abroad.” 209 In other words, groups of people who are in already burdened classes of society would be affected the greatest. By allowing private patentees to “block development of new technology,” a jurisdiction would “simply lose any ability to contribute to the terms on which [that technology] develops.” 210

For example, “to the extent that reproductive tourism relies on the use of others’ bodies, it relies primarily on women’s bodies.” 211 Even in the case of male infertility, most of the treatments for infertility are administered to women. 212 In that sense, “ART is a gendered technology”: it is women who bear most of the health risk, as well as the social stigmas, while men, at most, bear the financial burden. 213 Thus, encouraging “reproductive tourism” is encouraging the unequal protection of women. 214

If a technology that is capable of truly revolutionizing reproductive choice is withheld, the fact will be as such: “It’s coming. The question is whether it will come unsupervised and unsafe or supervised and safe.” 215 Where constitutional values are at stake, a solution must be found.

209. Id. at 206.
210. Id.
211. Ikemoto, supra note 205, at 294.
212. Id.
213. Id. (citing Marcia C. Inhorn & Daphna Birenbaum-Carmeli, Assisted Reproductive Technology and Culture Change, 37 ANN. REV. ANTHROPOLOGY 177, 182–83 (2008) (addressing the health risks faced by women patients and also noting other stigmatizing effects of participation in ART by patients, donors, and surrogates and how these effects threaten western notions of motherhood)).
214. See id.; see also Jody Lynée Madeira, Common Misconceptions: Reconciling Legal Constructions of Women in the Infertility and Abortion Contexts (unpublished manuscript) (on file with author).