### Counterplan text: the member nations of the WTO ought to increase intellectual property protections for CRISPR gene editing technology

**CRISPR gene editing patents control who can use the technology otherwise infinite actors have access. The question of who owns the technology is unresolved**

**Mischel 4/27** Fiona Mischel, April 27, 2021, Synbiobeta. Who owns CRISPR in 2021? It’s even more complicated than you think. Fiona Mischel is the Editor-in-Chief of SynBioBeta. She frequently covers sustainability, CRISPR research, food and agriculture technology, and biotech for space travel. <https://synbiobeta.com/who-owns-crispr-in-2021-its-even-more-complicated-than-you-think/> //AHS

The question of **who owns CRISPR**, the genetic editing tool expected to transform modern medicine, **is a confusing mess of legal battles**, obscure naming conventions, and subtle variations in molecular form and function. **The entities that eventually** **own the patent** rights to these tools **will** almost certainly **control who can use it, how it’s used, and how much it costs**. The original CRISPR patent battle between UC Berkeley and the MIT-Harvard Broad Institute has not been pretty. Patent fights rarely are, but the debate of who owns CRISPR-Cas9 has been especially heated. It’s not surprising. Since CRISPR is billed as the future of medicine, **the ability to own and license** some part of the tool **is critical** for a slew of companies founded on the original CRISPR-Cas9 technology. But who owns CRISPR in 2021 is significantly more complicated than it was just a few years ago. **As more companies, researchers, and academic institutions file patent applications** for subtly different CRISPR molecules, it’s no longer possible to narrow down the intellectual property rights to just two or three big players.

**It's a medicine** **Bergman 19** Mary Todd Bergman, Harvard University, January 9, 2019. Perspectives on Gene Editing. https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/

**Medicine is at a turning point**, on the cusp of major change as disruptive technologies such as gene, RNA, and cell therapies enable scientists to approach diseases in new ways. The swiftness of this change is being **driven by innovations such as CRISPR** **gene editing**, which makes it possible to correct errors in DNA with relative ease. Progress in this field has been so rapid that the dialogue around potential ethical, societal, and safety issues is scrambling to catch up. This disconnect was brought into stark relief at the Second International Summit on Human Genome Editing, held in Hong Kong in November, when exciting updates about emerging therapies were eclipsed by a disturbing announcement. He Jiankui, a Chinese researcher, claimed that he had edited the genes of two human embryos, and that they had been brought to term. There was immediate outcry from scientists across the world, and He was subjected to intense social pressure, including the removal of his affiliations, for having allegedly disregarded ethical norms and his patients’ safety. Yet as I. Glenn Cohen, faculty director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, has said, gene editing comes in many varieties, with many consequences. Any deep ethical discussion needs to take into account those distinctions. Human genome editing: somatic vs. germline The germline editing He claimed to have carried out is quite different from the somatic gene therapies that are currently changing the frontiers of medicine. While somatic gene editing affects only the patient being treated (and only some of his or her cells), germline editing affects all cells in an organism, including eggs and sperm, and so is passed on to future generations. The possible consequences of that are difficult to predict. Somatic gene therapies involve modifying a patient’s DNA to treat or cure a disease caused by a genetic mutation. In one clinical trial, for example, scientists take blood stem cells from a patient, use CRISPR techniques to correct the genetic mutation causing them to produce defective blood cells, then infuse the “corrected” cells back into the patient, where they produce healthy hemoglobin. The treatment changes the patient’s blood cells, but not his or her sperm or eggs. Germline human genome editing, on the other hand, alters the genome of a human embryo at its earliest stages. This may affect every cell, which means it has an impact not only on the person who may result, but possibly on his or her descendants. There are, therefore, substantial restrictions on its use. Germline editing in a dish can help researchers figure out what the health benefits could be, and how to reduce risks. Those include targeting the wrong gene; off-target impacts, in which editing a gene might fix one problem but cause another; and mosaicism, in which only some copies of the gene are altered. For these and other reasons, the scientific community approaches germline editing with caution, and the U.S. and many other countries have substantial policy and regulatory restrictions on using germline human genome editing in people. But many scientific leaders are asking: When the benefits are believed to outweigh the risks, and dangers can be avoided, should science consider moving forward with germline genome editing to improve human health? If the answer is yes, how can researchers do so responsibly? CRISPR pioneer Feng Zhang of the Broad Institute of Harvard and MIT responded immediately to He’s November announcement by calling for a moratorium on implanting edited embryos in humans. Later, at a public event on “Altering the Human Genome” at the Belfer Center at Harvard Kennedy School (HKS), he explained why he felt it was important to wait: “The moratorium is a pause. Society needs to figure out if we all want to do this, if this is good for society, and that takes time. If we do, we need to have guidelines first so that the people who do this work can proceed in a responsible way, with the right oversight and quality controls.” Aside from the safety risks, human genome editing poses some hefty ethical questions. For families who have watched their children suffer from devastating genetic diseases, the technology offers the hope of editing cruel mutations out of the gene pool. For those living in poverty, it is yet another way for the privileged to vault ahead. One open question is where to draw the line between disease treatment and enhancement, and how to enforce it, considering differing attitudes toward conditions such as deafness. Robert Truog, director of the Center for Bioethics at Harvard Medical School (HMS), provided context:“This question is not as new as it seems. Evolution progresses by random mutations in the genome, which dwarf what can be done artificially with CRISPR. These random mutations often cause serious problems, and people are born with serious defects. In addition, we have been manipulating our environment in so many ways and exposing ourselves to a lot of chemicals that cause unknown changes to our genome. If we are concerned about making precise interventions to cure disease, we should also be interested in that. “To me, the conversation around Dr. He is not about the fundamental merits of germline gene editing, which in the long run will almost certainly be highly beneficial. Instead, it’s about the oversight of science. The concern is that with technologies that are relatively easy to use, like CRISPR, how does the scientific community regulate itself? If there’s a silver lining to this cloud, I think it is that the scientific community did pull together to be critical of this work, and took the responsibility seriously to use the tools available to them to regulate themselves.”When asked what the implications of He’s announcement are for the emerging field of precision medicine, **Richard Hamermesh**, **faculty co-chair of** **the Harvard** Business School/Kraft **Precision Medicine Accelerator, said**: “Before we start working on embryos, we have a long way to go, and civilization has to think long and hard about it. **There’s no question that gene editing technologies** are potentially transformative and **are the ultimate precision medicine**. If you could precisely correct or delete genes that are causing problems — mutating or aberrant genes — that is the ultimate in precision. It would be so transformative for people with diseases caused by a single gene mutation, like sickle cell anemia and cystic fibrosis. Developing safe, effective ways to use gene editing to treat people with serious diseases with no known cures has so much potential to relieve suffering that it is hard to see how anyone could be against it.

**It's easy to misuse CRISPR to make bio WMDs that threaten humanity Cropper 20** Nicholas Cropper, April 29, 2020, American Security Project. Crispr is Making Bioweapons More Accessible. The American Security Project (ASP) is a nonpartisan organization created to educate the American public and the world about the changing nature of national security in the 21st Century. Accessed 9/1/2021 3:35 pm <https://www.americansecurityproject.org/crispr-is-making-bioweapons-more-accessible/> //AHS

Synthetic biology collectively refers to the concepts, tools, and approaches used to modify or create biological organisms. The most recent breakthrough in synthetic biology is a genetic engineering technique known as CRISPR-Cas9. The first genetic engineering experiments took months to complete and cost millions of dollars to produce results that were often unsatisfying. **CRISPR**-Cas9 **has** changed the landscape, offering **a relatively simple, low cost, speedy genetic modification tool**. CRISPR-Cas9 has become **so democratized that anyone can get everything they need to perform a simple genetic alteration** **delivered** to their door **for less than $300**. It may seem exciting to have cutting edge biological tools available to everyone, but **lack of oversight** of these tools **could be a danger to humanity**. Warfare has moved away from conventional weapons and towards asymmetric operations in the 21st century. The **U.S.’ adversaries, particularly non-state terror groups**, are looking for any opportunity to **use limited resources to inflict maximum damage** to the U.S. Advances in genetic engineering have offered them an opportunity to create **a low cost, low profile, potentially catastrophic weapon of mass destruction**; a bioweapon. Colonel Michael Ainscough highlighted the bioweapon threat in his paper for the USAF Air War College: “Biotechnology has made it possible **to inflict mass casualties** using only small-scale special operations that can evade detection in attempt to avoid retribution. In asymmetric warfare, biological weapons are seen as a ‘great equalizer.’” The National Academy of Sciences has put together a framework for assessing the threat posed by a synthetic bioweapon. **CRISPR**-Cas9 has dramatically improved the usability of genetic engineering, lowering the barrier to entry for the average person both financially and technically. Much of the science **is available for** free on the internet, giving **anyone with an internet connection and determination** access to all of the knowledge necessary to successfully perform a genetic edit. Additionally, because CRISPR-Cas9 can be done in your kitchen, the operational footprint is quite small.

**Kills tens of millions and outweighs nukes Markman 17** JD Markman, July 17, 2017, Yahoo! News. Jon Markman is an investment adviser, trader, columnist and author based in Seattle. <https://www.yahoo.com/news/bioterrorism-could-kill-30-million-people-143248192.html> //AHS

**Thirty million** people **dead in less than a year**. That’s the grisly **forecast for a successful bioterrorist attack**. And **it’s more likely than ever**, according to experts. Bill Gates made his fortune bringing personal computing to the world with Windows software. Lately he’s been consumed with closing the window on the next global epidemic. **Advances in biotechnology mean** it is now incredibly easy to re-create **fast-moving, airborne pathogens**, like smallpox or the Spanish flu. Patented in 2014, **CRISPR**-Cas9, **is** a gene-editing technique that uses molecular scissors to precisely snip genetic code. It’s a scientific marvel. With it, researchers have modified genes to help blind people see, cure sickle cell disease in some patients and expedite the development of numerous new drug treatments. They have also been able to create antibiotic-resistant forms of E. coli. CRISPR-Cas9 is unregulated, inexpensive and somewhat of a cottage industry. In 2016, the Nuffield Council of Bioethics warned that “garage scientists” **might unwittingly create a modified organism that could kill millions**. Gates is thinking more strategically. His foundation works in developing nations. He understands the perils of bad actors in unstable environments. He’s worried about biotechnology being weaponized. **A single infected person** strategically placed **in a busy airport could** ultimately **kill millions**. “The scariest thing is **something like the 1919** [Spanish] **flu**,” Gates warned at a gathering at the Royal United Services Institute in London. **Modern travel coupled with** the fact that people have **no immunity** to that strain **would be an unstoppable, deadly combination**. His concern is well founded. In the developed world, **we worry about bad actors getting** their hands on **nuclear materials**. **Though tragic, a** **nuclear bomb would not kill 10 million** people. Gates reckons that **an infected traveler could be the starting point for** a human-to-human respiratory infection. And it would all begin with simple aches and sniffles. The Spanish Flu of 1919 killed **50 million** people.

**The CP solves -- strong patents prevent rogue actors from using CRISPR as a weapon**

**Zettler et al 19** Zettler PJ, Guerrini CJ, Sherkow JS. Regulating genetic biohacking. Science. 2019 Jul 5;365(6448):34-36. doi: 10.1126/science.aax3248. PMID: 31273115; PMCID: PMC7004414. <https://pubmed.ncbi.nlm.nih.gov/31273115/> //AHS

Genetic biohacking is also potentially subject to U.S. **laws** that are **enforced by** private rather than government actors. These may fill some of the gaps in public regulators’ ambit ([9](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7004414/#R9)). **Patent owners**, for example, **can impose** **ethical restrictions on** licensees, such as the Broad Institute’s licenses for its **CRISPR** patents to Bayer (formerly Monsanto), with conditions that Bayer avoid research activities that are potentially harmful to public health, including tobacco research and germline editing ([10](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7004414/#R10)). **Such license restrictions can**—and should—**be used** **to police** commercial manufacturers of **genome-editing** kits **and** reagents popular in biohacking communities, just as they have previously been used to **prevent activities that pose national security, environmental, or public health risks (**[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7004414/#R11)). Even without a license in place, **patent owners can enforce restrictions** through threats of patent infringement litigation **against any recalcitrant biohackers or manufacturers** of biohacking products. A similar model was proposed as an attempt to restrict the use of “gene drive technology”—inheritable versions of CRISPR designed to drive a specific allele through generations of a population ([12](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7004414/#R12)). Beyond patents, people injured by genetic biohacking materials could potentially bring tort law claims against biohackers and component suppliers to seek compensation for their injuries. A person injured while using a DIY CRISPR kit, for example, would likely be able to sue the seller of the kit—**a potentially strong deterrent to marketers of unsafe biohacking materials.**

### 2NR Add-ons

**Without stronger patents current regulations can’t solve Mosby 18** Hannah M. Mosby, Biotechnology's Great Divide: Strengthening the Relationship Between Patent Law and Bioethics in the Age of CRISPR-Cas9, 19 MINN. J.L. SCI. & TECH. 565 (2018). Available at: https://scholarship.law.umn.edu/mjlst/vol19/iss2/8

**The time has come** for us, as a society, **to clarify the relationship between patent law and ethics**. The current state of passivity—a combination of the uncertain status of the Moral Utility Doctrine, congressional silence, and USPTO avoidance— has masked a unique opportunity for society to voice its opinion on new technologies **by using patent protection to support only those that provide a net benefit**. Further, **utilizing patent** prosecution as a means of ethical regulation **is superior to** any potential ex post facto **regulation** scheme, because it is both more timely and more flexible. 1. Patents as a Social Contract Patents are a contract between two entities: the inventor and the rest of society.105 This contract is implicit in the Patent Act—there are certain requirements that an invention must meet in order to qualify for patent protection, and certain benefits an inventor can receive if the invention meets those requirements. This ensures that an invention provides a true benefit to society, while the protection conferred—the exclusive right to make and use an invention for a period of 20 years— incentivizes inventors to invent.106 When a balance is appropriately struck, it creates a cycle that benefits both classes of participants—a feature responsible for much of the allure of a patent system. Necessarily implicit in this system is society’s approval of **those inventions that** receive patent protection. These inventions—in theory—**provide enough public benefit** to **warrant** bestowing legal **protection** thereon,107 and so society has inherently condoned both their existence and use.108 A problem arises, however, **when the potentially harmful implications** of a technology **are not adequately weighed against its potential benefits—or**, worse yet, aren’t even considered **in the bargaining process. In a system of patent law** with no opportunity to consider ethical implications, **it is impossible to ensure that the public is truly receiving a net benefit** in exchange for the inventor’s “limited monopoly.”109 Biotechnologies like the **CRISPR**-Cas9 system raise the stakes of the patent bargain, both negatively and positively. These technologies are incredibly attractive because of their potential for immense public health benefit,110 and therefore appear to more than justify their “congressionally mandated price.”111 However, the **negative implications** of these technologies—**and their potential for misuse**—**are also heightened because of their accessibility, and the presence of limited governmental oversight in many research processes**.112 To be sure, it is entirely possible that the benefits of technologies like CRISPR outweigh hypothetical notions of ethical offense, or that the public is willing to accept the associated risks. But if there is no opportunity for these implications to even be considered during patent law’s intrinsic “negotiation,” can it realistically be characterized it as a fair bargain? If we continue to sacrifice the opportunity to analyze these ethical issues during patent prosecution, we forego an opportunity for public input into a process where the public is a direct stakeholder. Although it is inarguably complicated by politics and attenuated by the U.S. democratic system,113 the legislative process provides at least some opportunity for public input.114 Since **Patent Act legislation articulates the parameters of the patent bargain and defines the terms of this social contract, refusing an opportunity to fully consider the ethical, legal, and societal implications** of emerging biotechnologies at this stage limits the opportunity for the public to weigh in innovations that will shape their future for years to come. 2. Existing Governance Is an Insufficient Ethical Regulatory Mechanism for Emerging Biotechnologies Emerging technologies are inherently challenging to regulate because they are both difficult for the non-scientific public to understand and rapidly evolving, particularly in the early stages of their development.115 **Existing restrictions** on controversial biotechnology **are inadequate** regulatory mechanisms **because of their limited reach** and temporally inappropriate relationship to research. Instead, an effective regulatory scheme must be both expansive and readily responsive. The **patent prosecution** process presents a unique opportunity for proactive ethical regulation that **would** **mitigate** many of **the issues** associated with playing a game of regulatory “catch-up” to these influential technologies. **Existing infrastructure is insufficient**—standing alone—to serve as an ethical regulatory scheme for developing biotechnology. Restricting access to funding undoubtedly discourages some prospective researchers, but does not alone provide a sufficient disincentive. Although a portion of healthcare research funding comes from federal sources, the largest portion comes from industry116—where grant restrictions are irrelevant. Therefore, **research into ethically questionable technologies can continue** unheeded in the majority of instances. For example, in 2017, researchers in Portland, Oregon announced that they had “successfully modified the genetic material of a human embryo” using CRISPR technology.117 **This** research occurred despite NIH and RAC disapproval—as well as public skepticism118—and **is** likely to become **more common as CRISPR** technology **matures**. Clearly, funding restriction has not proven to be an adequate mechanism for voicing governmental or societal opinions on the use of these technologies.119 Further, although FDA regulation does prevent products from entering mainstream clinical use—thereby somewhat mitigating their safety risk to consumers—FDA action occurs too late in a technology’s lifecycle to be an effective means of ethical regulation.120 By the time a technology has reached the FDA application stage, extensive research has already been conducted121 and, therefore, many ethically questionable events may have already occurred. In contrast, **patent prosecution occurs** at an ideal point in a technology’s life cycle for regulation: **early enough to mitigate the risk of unethical use**, but late enough to allow future applications of a technology to be somewhat apparent.122 This temporal relationship is unique to patent law, and resolves many issues inherent in an exclusively retroactive system like FDA regulation. Incorporating ethical regulation into patent prosecution is also superior to industry self-governance in many ways. Although proponents often assert that self-regulation is a desirable mechanism because an inventor—or, in a broader sense, the industry in which the inventor operates—is the most familiar with the ethical risks associated with a technology, often the direct effect of this “regulation” is a simple “warding off more direct government intervention.”123 Although inventor discretion in the licensing process does provide some means of self-regulation—including in the case of CRISPR itself124—it would be unwise for the public to rely exclusively on individual restraint in the face of technologies with such potentially large public health effects. Further, in addition to the potential for case-by-case variance in the restraint actually exercised by individual patent holders and industries,125 enormous monetary incentives are often at play for the owners of these influential technologies.126 Undeniably, profits of this size could cloud a selfregulator’s judgment. Therefore, self-regulation—though a desirable component of or complement to an ethical regulatory scheme127—is an insufficient regulatory mechanism when standing alone. As a whole, addressing ethical concerns during the patent process is a far more consistent, tailored, and efficient manner in which to regulate biotechnology. Funding restrictions only affect the subset of technologies that utilize the particular funding mechanism, whereas **patent law reaches** a much larger number of **potentially threatening technologies**.128 Additionally, because inventions are evaluated by a USPTO examiner on a case-by-case basis,129 ethical regulation during the patent prosecution process would be highly individualized. **This is enormously beneficial** because the ethical issues presented by a biotechnology can vary widely based on its unique implications, rates of accuracy, **and** potential for misuse. Finally, consideration of the ethical implications would occur soon after the development of the technology,130 which would allow an external assessment of the ethical risks to be made clear to the inventor early in the research process. Together, these features **make patent law an** incredibly **advantageous** ethical regulatory mechanism.

**CP solves bioweapons**

**Mosby 18** Hannah M. Mosby, Biotechnology's Great Divide: Strengthening the Relationship Between Patent Law and Bioethics in the Age of CRISPR-Cas9, 19 MINN. J.L. SCI. & TECH. 565 (2018). Available at: https://scholarship.law.umn.edu/mjlst/vol19/iss2/8

Proposing an ideal regulatory scheme is significantly easier than employing it in practice. The CRISPR system is an exemplary biotechnology around which to debate patentability because it highlights many of the ethical dilemmas associated with gene editing technology. However, **CRISPR** also illustrates the complexity of attempting to apply patentability restrictions to technologies that have a wide array of applications. For example, is possible to use CRISPR-Cas9 to edit human embryos,184 but it can just as easily be used to enhance crop yield185 or alter flower color.186 Some of these uses are clearly more contentious than others. Should we deny **patent protection** to the entire technology because of a handful of its applications? The answer is not simple. Some technologies **would** almost certainly **be barred** by the proposed regulatory framework: **for** example, those **encompassing biological weapons.**187 In this case, the patent “balancing act” would tip plainly in favor of societal disapprobation—**whatever benefit** these technologies provide **is unlikely to warrant the risk of their misuse.** A more borderline instance might involve a claim encompassing human neural material,188 wherein the potential medical benefits may or may not outweigh concerns about autonomy and morality. To be sure, this kind of marginal technology presents some opportunity for judicial overstep or abuse189—a variance in human conviction that no regulatory system can entirely preclude. In the case of CRISPR-Cas9, **however, it is unlikely that** professional consensus,190 international approaches,191 or current public opinion192 would instruct barring patentability entirely. Instead, subjecting **CRISPR** to the recommended framework is still likely to indicate that it **merits patent protection**—the technology has too many **ethically permissible applications** to warrant total denunciation in the name of a select few, which **could be addressed individually**.193 Therefore, this Note does not purport to recommend total condemnation of any technology that implicates ethical concerns. Instead, it simply attempts to encourage discourse—involving all participants in the patent bargain—about the ethical risks we are willing to accept in exchange for technological progress. Despite other approaches taken internationally, the current U.S. patent system provides no opportunity to consider the ethical implications of a technology during the patent process. There has never been a statutory basis for doing so,194 and the common law doctrine that once allowed such considerations to be the basis of patent invalidation—the Moral Utility Doctrine— has been dormant for at least a decade.195 To date, its status remains uncertain. Current biotechnological developments have brought once-dystopian ethical concerns to the forefront of public discourse, providing a renewed opportunity to establish a relationship between ethics and patent law in the U.S. The ramifications of a technology are necessary considerations in patent law because patent issuance is a bargaining process— the public must receive a true net benefit in exchange its recognition of a patentee’s limited monopoly right. Further, **evaluating** an emerging **technology’s** ethical **implications during the patent process**—rather than after they have achieved mainstream commercial use—**is a uniquely proactive way to regulate** rapidly-evolving **technologies before they impact the** general **public.** However, effective evaluation of the ethical considerations inherent to new biotechnologies cannot be adequately accomplished by preventative legislation or common law supervision alone. Instead, a blended approach involving a legislative provision that mimics international approaches and accommodates discretion in agency policy, combined with a limited revival of a modernized Moral Utility Doctrine, strikes the appropriate balance between incentivizing innovation and protecting the public interest. Whether **patent protection** for CRISPR-Cas9 and its progeny would ultimately be disallowed by this schema is speculative, but it **creates a regulatory environment equipped** **to handle the** complex ethical implications of 21st Century biotechnology—making it **an ideal approach** to U.S. patent law for the years to come.