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Of Mice and 'Manimal': The Patent & Trademark Office's Latest Stance Against Patent Protection for Human-Based Inventions

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I. INTRODUCTION

The twentieth century has witnessed incredible technological advances in such fields as transportation, medicine, and everyday consumer goods. Historically, these technological advances have challenged judges and legislators alike because they greatly affect the legal system. In order to appreciate legal changes spurred by technology, one need only consider the impact on tort law of the railroad and the automobile, or the shift toward strict products liability accompanying the increase in mass-produced goods. However, no area of the law has been as directly impacted by technological advances as patent law.

The United States patent system awards limited protection to inventors who expend considerable time and effort in perfecting their creations. Nonetheless, at least one group of inventors on the cutting edge of technology is currently denied this protection. These inventors are biotechnologists involved in creating human-based inventions. Biotechnology has been defined as the science of molecular biology implemented in an effort to utilize naturally-occurring processes in new and useful ways.¹

During the last quarter century, terrific strides have been made in the area of biotechnology. The United States Patent and Trademark Office (PTO)

INTELL. PROP. L. has awarded, albeit reluctantly, patents for genetically-engineered products and processes, including multicellular animals. However, the PTO has made it quite clear that it will not grant a patent for a "human multicellular living organism." In a 1987 announcement, the PTO lifted the ban on multicellular animal patents, but it simultaneously stated that "[a] claim directed to or including within its scope a human being will not be considered a patentable subject." While the statement does lift the ban on multicellular animals, it creates a barrier to human-based patents by stating that claims directed toward a nonplant, multicellular organism must be "non-human." The PTO's initial reasoning for precluding the issuance of patents for "human-based bioproducts" rested on two prongs: (1) its interpretation of the Patent Act and (2) its reliance on the Thirteenth Amendment as prohibiting the issuance of human-based patents. More recently, the PTO has released a statement indicating that it might deny a patent application involving humans based on public policy and morality aspects of the utility requirement of the Patent Act. This statement was allegedly issued by the PTO in response to a joint patent application filed by New York cellular biologist Stuart Newman and Jeremy Rifkin, president of the Foundation on Economic Trends. The

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4 Donald J. Quigg, Policy Announcement by Assistant Secretary and Commissioner of Patents and Trademarks, in 69 J. PAT. & TRADEMARK OFF. SOC'Y 328 (1987) (announcing that the PTO would thereafter consider "non-naturally occurring, non-human, multicellular organisms" to be patentable subject matter).

5 Id.

6 Id.

7 Id.


10 Incidentally, neither man truly wants the patent application to be granted. Instead, they support the PTO's guidelines regarding human-based inventions and would prefer to strengthen the bar to such patent protection by having their application denied. In fact, Jeremy Rifkin has battled against genetic patents for years, stating that "these patents are the greatest legal scam of the 20th century." Joan O. Hamilton, Get a Life, CAL. LAW., Feb. 1996, 39, 79. The fact that the two applicants support a denial of the patent raises the interesting issue of whether they would appeal a denial in order to get a decision from...
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application claims a technique for combining human and animal embryo cells to produce a single human/non-human chimera. "A chimera is a type of being or organism, organ or part thereof, consisting of tissues of diverse genetic constitution." The genetic composite is created by combining portions of embryos from two closely-related species or varieties within a species. The resulting organism contains DNA from both species.

This Note will attempt to address the PTO's former and current stance against the patentability of human-based inventions. It will examine the rationale behind the PTO's positions and determine whether the latest statement is a retreat from the former announcement or a mere refinement.

Part II will provide a brief overview of United States patent law. Part III will provide a chronological history of "living patents" including plant, single cell, and multicellular animal patents. Part IV will consider the changes in the status of the patentability of human-based inventions, if any, which have resulted from the PTO's latest statement as well as examine the arguments for and against the recognition of patents for human-based inventions.

II. THE MECHANICS OF THE PATENT PROCESS

Patents for "living inventions" have come slowly and with great reluctance from the PTO. The PTO's current reaction to the Newman/Rifkin patent application is yet another example of an inventor pushing the envelope of biotechnology only to be slowed by the apprehension of the PTO to recognize certain forms of "living inventions." The PTO's former and current stance against these inventions can only be understood after a brief overview of the origins and the requirements of United States patent law.

the courts. An appeal would be quite risky because, as this Note will point out, the PTO guidelines in this area seem to contradict the strong and unambiguous language of the United States Supreme Court in Diamond v. Chakrabarty, 447 U.S. 303, 206 U.S.P.Q. (BNA) 193 (1980).


Quigg, supra note 9, at 17. "The word chimera is derived from a monster in Greek mythology having a lion's head, a goat's body, and a serpent's tail." Id.


Id.
A. THE ORIGINS OF UNITED STATES PATENT LAW

The Constitution gives Congress legislative authority "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." One of the purposes of this constitutional provision is to provide incentive for a potential inventor to put forth the capital and time needed to advance his field of expertise. Thomas Jefferson, the author of the first Patent Act, noted that "ingenuity should receive a liberal encouragement," which could be accomplished by granting inventors a temporary monopoly over their inventions.

Under current patent law, an inventor may exclude others from making, using, or selling the invention for twenty years from the date of filing. During this period, the owner of the patent is able to exploit the invention, reaping a return on his intellectual and financial investment. In return for this limited monopoly, the inventor must completely disclose his invention, thus allowing the public to improve upon or augment it.

B. THE UNITED STATES PATENT ACT

The current Patent Act states that "[w]hoever 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." The requirements for patentability are novelty, nonobviousness, and utility.

16 Letter from Thomas Jefferson to Oliver Evans (May 2, 1807) in 11 WRITINGS OF THOMAS JEFFERSON 200, 201-02 (Andrew A. Lipscomb et al. eds., The Thomas Jefferson Memorial Ass’n 1904) (1853).
18 See 35 U.S.C. § 112 (1994) (providing the enabling disclosure requirement); see also 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.01 (1994) (comparing the disclosure requirement to a quid pro quo between the inventor and the government). This statutory provision is known as the enabling disclosure requirement because the disclosure enables other would-be inventors to produce the invention and to change the process enough to obtain their own patent, thus leading to scientific advancement.
20 Id. § 102.
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The novelty provision of the Patent Act requires that a patentable invention be new at the time of its discovery and that its inventor was the one who actually conceived of the invention and reduced it to practice.\(^{23}\) It does not matter if someone creates something in good faith, believing that it has not been invented before; if the invention is already patented, the subsequent "inventor" has no rights under the Patent Act.\(^{24}\)

The nonobviousness provision of the Act requires that a patentable invention must not have been obvious to a person having ordinary skill in the art or field to which the invention pertains.\(^{25}\) The test for nonobviousness requires two determinations: (1) the scope of "prior art" and the level of ordinary skill in the inventor's field and (2) whether the invention would have been obvious to someone with ordinary skill in light of the prior art.\(^{26}\) Due to the inherent difficulty of this test, courts have formulated alternative methods through which an inventor may satisfy the nonobviousness requirement.\(^{27}\)

In order for an invention to satisfy the utility requirement of 35 U.S.C. § 101, it must have a significant use.\(^{28}\) In order for an invention to be useful, it must be operative for a purpose set forth in the patent application.\(^{29}\) Commercial success is not a requirement to prove operability or the broader concept of utility.\(^{30}\)

For the purposes of this Note, the most important aspect of the utility requirement is the so-called "morality" standard. In its April 1998 press release concerning Newman's patent application, the PTO relied on this morality standard in asserting its reluctance to grant the patent. A more in-

\(^{23}\) Id. § 102.
\(^{24}\) Id.
\(^{26}\) See E. KITCH & H. PERLMAN, LEGAL REGULATION OF THE COMPETITIVE PROCESS: CASES, MATERIALS AND NOTES ON UNFAIR BUSINESS PRACTICES, TRADEMARKS, COPYRIGHTS AND PATENTS 862 (4th ed. 1989) (labeling "prior art" as a term of art including both actual knowledge of one skilled in the field as well as constructive knowledge of particular documents and events).
depth analysis of the morality standard of the utility requirement will therefore be provided in Part III along with a discussion of the present status of the patentability of human-based inventions.

C. THE UNITED STATES PATENT SYSTEM

In order to appreciate the importance (or lack thereof) of the PTO's stance against "human inventions," one must understand an inventor's procedural rights following the denial of a patent application.

Initially, a patent application is filed with the PTO; there the decision whether to grant the patent rests with one of the PTO's examiners. If the inventor is dissatisfied with the denial of his patent, he may appeal the decision to an administrative review board and the Board of Patent Appeals (the Board). Denials by the Board may subsequently be reviewed by a federal district court, whose decision may be reviewed all the way to the United States Supreme Court. "[P]rior to the organization of the Federal Circuit, patent decisions were appealed to the Court of Customs and Patent Appeals (C.C.P.A.)."

A denial by the PTO is certainly not a death sentence for an inventor. Time and time again, the PTO has denied a patent application only to have the Board or a federal court reverse the denial. One area in which courts have repeatedly reversed PTO decisions has been that of "living patents."

III. THE HISTORY OF "LIVING PATENTS"

The first "living patent" is widely considered to be that granted in the landmark 1980 Supreme Court case of Diamond v. Chakrabarty. However, a patent was issued to Louis Pasteur in 1873 claiming a yeast, free from organic germs of disease, as an article of manufacture. This suggests that Chakrabarty's 1980 patent was not the first granted for a living organism.

33 Burk, supra note 1, at 26 n.156.
35 U.S. Pat. No. 141,072 (May 9, 1873).
36 See Chakrabarty, 447 U.S. at 314 n.9, 206 U.S.P.Q. (BNA) at 201 n.9 (indicating that the Court's grant of a patent for a living organism was nothing new).
Pasteur's yeast patent, however, was a rare example of the PTO granting a patent for a living organism. Prior to the *Chakrabarty* decision, the PTO refused to issue patents for living organisms, independent of their use, but would issue patents for compositions containing living things, such as waste-disposal systems containing bacteria.³⁷ Many patent application denials have been predicated on the grounds that “products of nature” are not patentable.

A. PRODUCTS OF NATURE

It is well established in patent law that products of nature are not patentable; rather, patentable inventions are those devised only by humans.³⁸ The policy underlying this doctrine seems to be that a product of nature does not satisfy the novelty requirement of the Patent Act because it existed before its “discovery” by the patentee.³⁹ The key distinction is between the act of invention and the act of discovery. A patent rewards an inventor for the fruits of his labor, not for a mere discovery of something that already existed in nature.

An often-cited opinion regarding the product of nature doctrine is the 1948 United States Supreme Court decision in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*⁴⁰ In *Funk Bros. Seed Co.*, the patentee claimed a patent for a mixture of bacterial strains which were used to infect plant roots, thereby aiding the plant in the fixing of nitrogen.⁴¹ The Court denied the application

³⁷ See, e.g., Cameron Septic Tank Co. v. Village of Saratoga Springs, 159 F. 453 (2d Cir. 1908) (holding valid a patent for a septic tank utilizing bacteria); Union Solvents Corp. v. Guaranty Trust Co., 61 F.2d 1041 (3d Cir. 1932) (recognizing infringement of patent for a bacterial process utilized in the synthesis of alcohol); City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577 (7th Cir. 1934) (recognizing patent for septic tank utilizing bacteria). These cases demonstrate that the PTO has not had qualms with granting patents for processes that utilize a living organism. However, these patents did not grant a property right in the organism itself, but merely in the process which utilized it.

³⁸ See General Elec. Co. v. De Forest Radio Co., 28 F.2d 641, 642 (3d Cir. 1928) (“If it is a natural thing then clearly, even if [the patentee] was the first to uncover it and bring it into view, he cannot have a patent for it because a patent cannot be awarded for a discovery or for a product of nature . . .”); see also Anheuser-Busch Brewing Ass’n v. United States, 207 U.S. 556, 562 (1908) (denying a patent for cork); cf. Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887) (denying patent for seashells that have not been changed).


⁴¹ Id. at 129-30.
because the effect of the mixture was merely the combined effect that the individual strains of bacteria would have had on their own. 42

It is difficult to determine why the Court denied the patent other than simply by finding that the strains were products of nature and the combination did not substantially change their character. Was the decision based on the determination that these products of nature lacked novelty? Or, was the patent denied because the strains, being merely products of nature, were obvious? 43

However unclear the basis for the Court's decision, it is clear that a product of nature is not patentable subject matter absent some degree of refinement or improvement by the patentee. This requirement is relevant in the field of biotechnology because "[b]iotechnicians alter, modify, assist, or manipulate nature. Biotechnicians are not inventors of organisms or genes . . ." 44

B. PLANT PATENTS

Throughout the early twentieth century, the PTO commonly rejected the patent applications of horticulturists for their botanical inventions. 45 In response, Congress enacted the Plant Patent Protection Act of 1952. 46 The Act guarantees patent protection for anyone who "invents or discovers and asexually reproduces any distinct and new variety of plant." 47 Although the Act protected plant breeders, it did not help the creators of flowers, seeds, or fruit. 48

In order to protect creators' rights in sexually-reproducing plants, Congress enacted the Plant Variety Protection Act of 1970. 49 This Act

42 Id.
43 IVER P. COOPER, BIOTECHNOLOGY AND LAW § 3.01, at 3-4 (1987).
48 Czarnetsky, supra note 45, at 1350.

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extended patent protection to sexually-reproduced plants, thus protecting creators of flowers, seeds, and fruits.  

C. IN RE MERAT

Following the adoption of the Plant Patent Protection Act and of the Plant Variety Protection Act, it appeared that the patent system was poised to provide protection for inventions that benefited society, regardless of the form of the invention. However, there still existed a barrier against inventors and engineers of single-celled and multicellular animal life forms.

In *Merat*, an inventor applied for a patent on a dwarf chicken. The chicken was not the product of genetic engineering but rather was the result of controlled breeding. The patent examiner rejected the application because the chicken was a product of nature produced by controlled propagation, and not a "manufacture"; it was, therefore, not patentable under section 101 of the Patent Act. The Board agreed. The C.C.P.A. affirmed the Board's decision but on other grounds. Thus, the question of whether the dwarf chicken was patentable subject matter under section 101 remained unanswered.

D. IN RE BERGY

While in *Merat* the C.C.P.A. left the question of the patentability of the dwarf chicken a mystery, two years later it expressed an opinion on whether microorganisms which were not products of nature were patentable subject matter under section 101 of the Patent Act.

In *Bergy*, an inventor developed an original method for cultivating the previously-known antibiotic *lincomycin B*. In the process of this development, Bergy discovered a previously-unknown microorganism which proved useful in the production of the antibiotic, namely a pure culture of *streptomyces vellosus*.  

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50 Id.
52 Id. at 1391.
53 Id.
54 Id. at 1396 (rejecting patent because it failed to distinctly claim the subject matter of the patent).
56 Id. at 967.
The PTO's patent examiner allowed all of Bergy's process claims for the production of the new microorganism. However, the patent examiner rejected Bergy's claim to the microorganism itself on the ground that patentable subject matter under section 101 of the Patent Act did not include products of nature. The patent applicants had relied on the premise that a pure product may be patentable even when it is found in nature in an impure form. The PTO disagreed, relying on Funk Bros. Seed Co. to distinguish between pure chemicals and pure microorganisms.

The applicants appealed to the Board, which held that living organisms did not fall within patentable subject matter under the patent statute. Upon further appeal, the C.C.P.A. decided that non-naturally occurring microorganisms were patentable subject matter. This is of great importance, as the court had previously found that Bergy's claim for a living organism was without legal significance.

E. DIAMOND V. CHAKRABARTY

A similar question to that in Bergy was presented in In re Chakrabarty. Ananda M. Chakrabarty, a microbiologist, sought to patent a non-naturally occurring single-celled microorganism which had been genetically engineered to biologically decompose and control oil spills. The bacterium was created through the introduction of new genetic material into a living organism.

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57 Id.
58 Id.
61 Ex parte Bergy, 197 U.S.P.Q. (BNA) at 82.
62 Id. at 79.
63 See In re Bergy, 596 F.2d 952, 975, 201 U.S.P.Q. (BNA) 352, 373 (C.C.P.A. 1979) (reasoning that the microorganism was not found in nature but rather was man-made in a laboratory).
66 Id. at 41.
The PTO’s patent examiner allowed the claims for products and processes involving the bacteria but rejected the claim for the bacterium itself. The rejection was based on the grounds that (1) the invention was a living organism and (2) the invention was a product of nature. The Board upheld the application denial, but in doing so it rejected the examiner’s “product of nature” rationale. The applicants appealed the denial to the C.C.P.A., which reversed the Board’s decision. In doing so, the C.C.P.A. relied primarily on its Bergy decision.

Following the C.C.P.A. decision in Chakrabarty, its previous Bergy decision was vacated and remanded for reconsideration by the United States Supreme Court in light of its decision in Parker v. Flook. The Flook decision involved a patent application for a computer algorithm which was held to fall outside patentable subject matter because it embodied “a formula or law of nature.” Therefore, the C.C.P.A. was again required to decide both cases (Bergy and Chakrabarty), this time consolidating them into one dispute. Just as it had done before, the C.C.P.A. decided in favor of both Bergy and Chakrabarty. In doing so, it disregarded Flook because neither of the cases at bar involved an algorithm, formula, or law of nature.

Finally, in 1980 the United States Supreme Court granted Chakrabarty certiorari. The Supreme Court held for Chakrabarty, finding that a live,
man-made microorganism is patentable subject matter. The Court focused its inquiry on whether Chakrabarty's microorganism was a nonpatentable, naturally-occurring phenomenon or a patentable "manufacture" or "composition of matter."

The Court determined that "Congress plainly contemplated that the patent laws would be given wide scope," and that patentable subject matter was to "include anything under the sun that is made by man." However, the Court qualified this statement by opining that Congress did not intend section 101 to cover every discovery and that "laws of nature, physical phenomena, and abstract ideas" are not patentable. The Court proceeded to distinguish the Chakrabarty bacterium from the aforementioned unpatentable categories by labeling it as "markedly different" from any microorganism found in nature and as having "significant utility." Thus, Chakrabarty's "discovery was not nature's handiwork, but his own; accordingly it was patentable subject matter under section 101." The Court distinguished this situation from that in Funk Bros. Seed Co., where the bacterial mixture claimed was made up of bacteria found in nature, used for their natural characteristics.

A majority of the Court rejected the PTO's argument that Congress had impliedly excluded living organisms from patentability by enacting both the Plant Patent Act and the Plant Variety Protection Act. These statutes provided patent protection only for specific living organisms. The PTO argued that these Acts would not have been enacted if such exceptions for living organisms under the Patent Act were unnecessary. The Court

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79 Id. at 318. It is ironic that the first microorganism to be granted a patent was Chakrabarty's oil-eating bacterium. Ecological groups were among the fiercest critics against the granting of patents for living organisms. The fear was that these "new" scientifically-altered organisms would disrupt the fragile ecological chain. Clearly, however, these same ecological groups loved the idea of a better aid in the fight against oil spills. Rachel E. Fishman, Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?, 15 AM. J.L. & MED. 461, 463 (1989).
81 Id. at 308.
82 Id. at 309 (quoting S. REP. NO. 82-1979, at 5 (1952) and H.R. REP. NO. 82-1923, at 6 (1952)).
84 Id. at 310.
85 Id.
86 Id.
87 Id. at 310-11.
examined the appropriate legislative history and determined that Congress intended to distinguish products of nature, both living and non-living, from man-made inventions. Thus, neither the Plant Patent Act nor the Plant Variety Protection Act precluded the patenting of Chakrabarty's microorganism as the result of "human ingenuity and research."

The Supreme Court also rejected the PTO's argument that microorganisms are not patentable until Congress expressly authorizes such protection. The Court held that a "rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability." Further, "Congress employed broad general language in drafting [section] 101 precisely because inventions are often unforeseeable." This liberal statutory interpretation is extremely favorable to inventors who wish to patent multicellular organisms.

The granting of Chakrabarty's patent was a crucial event in the evolution of patent law. The Supreme Court's "anything under the sun" language seemed to expressly include human-based inventions. The next step toward the patenting of a human based-invention, namely the PTO's acceptance of the validity of a patent on a multicellular animal, seemed inevitable.

F. EX PARTE ALLEN

Although the Chakrabarty decision did not expressly give an open invitation to patent any type of life form, the case opened the door for animal patenting. The decision immediately spurred the growth of the biotechnology industry in the 1980s because it provided prospective inventors with hope that their work could be protected by the patent system. However, the PTO was slow to follow the rationale of Chakrabarty

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88 Diamond v. Chakrabarty, 447 U.S. 303, 313, 206 U.S.P.Q. (BNA) 193, 198-99 (1980). The Court went on to state that bacteria were excluded from the Plant Variety Protection Act because Congress approved of either an earlier case which held that bacteria are not plants under the Plant Patent Act or prior patents issued for bacteria. Id. at 313-14.

89 Id. at 313; see also Ex parte Hibberd, 227 U.S.P.Q. (BNA) 443 (Bd. Pat App. & Int. 1985) (expanding the Chakrabarty decision to allow the patenting of a maize seed, plant, and tissue culture). In Hibberd, the patent examiner contended that the passages of the Plant Protection Act and the Plant Variety Protection Act "implicitly excluded protection of these plants under Section 101." Id. at 445. The Board rejected the contention, relying heavily on Chakrabarty. Id.


91 Id. at 316.

92 Id.
and failed to grant patents for genetically-engineered, multicellular products. The persistent denial of patents for multicellular life forms, like the earlier denials for plants, deprived many researchers of the fruits of their labor.

In 1987, *Ex parte Allen* tested the limits of the “anything under the sun” language of the *Chakrabarty* decision. The patent application was for Allen’s method of inducing polyploidy in oysters and, more importantly, for the resulting oyster produced by the process. The PTO rejected the patent on the basis that “the animal produced by the method claimed is ‘controlled by laws of nature and not a manufacture of man that is patentable.’”

Allen appealed the PTO’s decision to the Board, which ultimately rejected the application, but on different grounds than the PTO examiner. The Board disagreed with the patent examiner’s conclusion that the oysters were not patentable solely because they were living organisms. Instead, the Board rationalized its upholding of the PTO’s denial by noting that polyploidy had been produced previously in another oyster species. The patent therefore failed the nonobviousness requirement of section 103 of the Patent Act.

While the decision was not good for Allen personally, it was a good sign for his industry. In the course of affirming the denial of the application, the Board restated the *Chakrabarty* reasoning that the patent laws should be given a wide scope, which again would seem to include human-based inventions. Although the patent was not granted, the Board clearly endorsed the Supreme Court’s view that section 101 allowed patents to be issued for “anything under the sun that is made by man.”

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94 The inventor employed a procedure which created an alteration in the number of chromosomes in oyster eggs by exposing fertilized eggs to pressure for a given period of time. *Id.* at 1426. Polyploidy refers to an organism with more than two sets of chromosomes. Robert B. Kambic, Note, *Hindering the Progress of Science: The Use of the Patent System to Regulate Research on Genetically Altered Animals*, 16 FORDHAM URB. L.J. 441, 453 n.115 (1988). The utility of the method of creating polyploidy in oysters is that it makes them sterile, which both increases their size and makes them edible all year long. *Id.* at 453 n.116.
96 *Id.* at 1426 (quoting the patent examiner).
97 *Id.* at 1426-27 (“The issue, in our view, in determining whether the claimed subject matter is patentable under section 101 is simply whether that subject matter is made by man. If the claimed subject matter occurs naturally, it is not patentable subject matter under section 101.”).
98 *Id.* at 1427.
99 *Id.*
G. THE 1987 ANNOUNCEMENT & ANIMAL LEGAL DEFENSE FUND V. QUIGG

On April 7, 1987, a mere four days after the Board’s decision in Allen, the PTO announced that it would begin to accept patents on “nonnaturally occurring, nonhuman multicellular living organisms, including animals.” The announcement specified that, in order to be patentable, an animal must be “given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law.” The announcement, apparently discounting the Supreme Court’s language in Chakrabarty, explicitly stated that any organism including human genetic material should be identified as non-human in order to be accepted because human beings are still not patentable subject matter.

Immediately following the 1987 announcement, various animal rights groups, farmers, and animal husbanders sued the PTO in the Federal District Court for the Northern District of California. Because the PTO’s statement was neither made with the aid of any public comment nor published in the Federal Register, the plaintiffs claimed that the rule announced in the statement was promulgated in violation of the Administrative Procedure Act and exceeded the PTO’s statutory authority.

The PTO moved to dismiss the suit on the grounds that (1) the plaintiffs lacked standing and (2) the cause of action failed to state a claim upon which relief could be granted. The district court assumed without deciding that the plaintiffs had the requisite standing, but it dismissed the suit on the grounds that the PTO’s “new” rule was not really new at all, but merely synthesized prior decisions without undue expansion.

On appeal to the United States Court of Appeals for the Federal Circuit, the district court’s decision was affirmed on the alternative ground that the

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101 Quigg, supra note 4, at 328.
102 Id.
103 Id.
105 Id. at 729.
106 Id.
107 Id.
108 Id. at 732.
plaintiffs lacked standing. The court held that the plaintiffs had not satisfied the constitutional requirement that the party seeking review must have suffered personal injury in fact.

The plaintiffs claimed that the injury in fact was increased cruelty to animals due to the PTO announcement. Although relying on the lack of a valid injury in fact in its decision, the court also reached the issue of whether there was causation between the actions of the PTO and the claimed injury to the plaintiffs. The court noted that the action of an independent third party would have to occur before there could be increased cruelty to animals. In essence, the court refused to equate the issuance of animal patents with the violation of animal cruelty laws.

H. THE HARVARD MOUSE

In April 1988, the PTO granted the first patent for a multicellular organism. The patent was issued to Harvard University, whose faculty had genetically engineered a mouse which was particularly susceptible to cancer.

Nearly 200 years after the United States Constitution purported to promote science and the useful arts by offering limited protection for inventions, biotechnologists engaged in the genetic engineering of animals were finally allowed to benefit from the patent system. It took not only the ingenuity of these biotechnologists but also the intervention of the United States Supreme Court to overcome the conservative stance of the PTO regarding the patenting of living organisms. The PTO was forced, by both the Supreme Court and the Board, to recognize the patentability of a bacteria


Id. at 936.

Id. at 936-37.

Id. at 937.


The "Harvard Mouse" patent covered a mouse which had been genetically altered so that it would be born with cancer in its cells. As a result, its progeny are exceptionally susceptible to the development of tumors when exposed to cancer-causing agents.

and eventually a multicellular animal. However, on two separate occasions, the PTO has publicly limited the language of the United States Supreme Court which would otherwise appear to support the patentability of human-based inventions.

IV. THE PTO'S TWO ANNOUNCEMENTS

On April 7, 1987 the PTO released the following statement regarding *Ex parte Allen*:

The Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101. The Board's decision does not affect the principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article. . . A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a . . . property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim . . . which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection.\(^\text{115}\)

The 1987 statement erects a bar to the patenting of human-based inventions because of (1) the PTO's interpretation of patent law and (2) its reliance on the Thirteenth Amendment.\(^\text{116}\)

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\(^\text{116}\) *See id.* (discussing the patentability of human-based inventions).
A. THE PTO'S INTERPRETATION OF THE PATENT ACT

The PTO's statement does not provide any explanation as to why human-based inventions do not meet the "patentability" requirement. The PTO at one point distinguished an unpatentable "product of nature" from an article of manufacture or composition of matter occurring in nature that is patentable—the key distinction being that the matter must be "given a new form, quality, properties or combination not present in the original article." At the same time, the PTO announced that a claim directed to or including a human being will not be considered patentable.

These two positions, taken together, seem inconsistent. What about a human embryo that is given a new form, quality, properties or combination not present in any embryo ever produced in nature? Certainly the ability to create a chimera consisting of two different or closely-related species constitutes a combination not present in the original article existing in nature. A chimera would plainly fall within the requirements of both the 1987 PTO statement and the Patent Act. Under current patent laws, a genetically-engineered chimera should be treated no differently than a genetically-engineered plant or mouse. It would be a man-made composition of matter not existing in nature before the invention. The PTO's statement regarding human creations concerns a subject that can and should only be pronounced by Congress.

Furthermore, the Supreme Court's definition of the patentability of living creatures in *Chakrabarty* contains no qualification concerning human-based inventions; it simply states that anything "under the sun" that is man-made is patentable (presuming that it is novel, nonobvious, and has some utility). Although the Court was considering the patentability of bacteria, there is nothing in the opinion to indicate that human-based inventions are to be excluded from patent protection. Therefore, the PTO's glib announcement that inventions involving humans do not meet the standards for patentability under section 101 is not supported by the Patent Act and is simply a unilateral reinterpretation of the law.

117 Id.
118 Id.
119 Ironically, the PTO cites, as one of its reasons for denying patent protection for human-based inventions, constitutional concerns via the Thirteenth Amendment while at the same time doing an end run around separation of powers, bicameralism, and the Presentment Clause of Article I, Section 7.
B. CONSTITUTIONAL CONCERNS

It is widely presumed that the PTO's reference to a constitutional prohibition against owning a property right in a human being is grounded in the Thirteenth Amendment, preventing the involuntary servitude of men and women.\footnote{U.S. CONST. amend. XIII, § 1. An initial issue presented by providing a chimera with constitutional protection is whether such a creature is a "person" under the Constitution.}

Even assuming that a human-based invention is considered to be "sufficiently human" to fall within the Thirteenth Amendment, in order for there to be a violation of the amendment, there must also be some degree of involuntary servitude involved. Simply because a patentee owns a patent does not necessarily mean that he owns the invention. The grant of a patent gives him property rights in the patent, not in the invention itself.\footnote{See Kevin D. DeBre, Note, Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Science?, 16 HASTINGS CONST. L.Q. 221, 224 nn.15 & 16 (1989) (citing congressional testimony of Jeremy Rifkin).} Unlike slavery, where a person is the property of an owner, a patentee of a human-based invention does not own the product. A biotechnologist who holds a patent in a human-based invention can do as he pleases with the patent rights without controlling the resulting invention itself, in no way violating the Thirteenth Amendment.

An additional problem created by the PTO's reliance on the Thirteenth Amendment is the fact that the PTO is an administrative agency of the executive branch of the federal government, which lacks the authority to make decisions regarding fundamental constitutional rights.\footnote{See, e.g., Kent v. Dulles, 357 U.S. 116, 129 (1958) (holding that the refusal of an administrative agency to issue a passport to a communist was an unconstitutional exercise of administrative power).} Certainly freedom from slavery is such a fundamental constitutional right. Therefore, regardless of its statement, it is quite unlikely that the federal courts would uphold a patent examiner's denial of patent protection for a human-based invention based solely on the Thirteenth Amendment.

The PTO's 1987 announcement that it would not grant patents for human-based inventions carelessly relied on its interpretation of both the Patent Act and the Thirteenth Amendment. The PTO's reliance on the Constitution is dubious at best and an unconstitutional exercise of administrative power at worst. As for its interpretation (or lack thereof) of
the Patent Act, the PTO provides no justifications for its presumption that human-based inventions are not patentable subject matter.

C. THE PTO'S 1998 ANNOUNCEMENT

This part will discuss whether the PTO’s 1998 announcement has shifted its stance against the patentability of human-based inventions from an assertion apparently drafted quickly and carelessly\(^{124}\) to a statement more grounded in the law.

On April 2, 1998 the PTO issued a media advisory allegedly concerning a joint patent application for a human-based invention by Stewart Newman and Jeremy Rifkin.\(^{125}\) The announcement stated that “[i]t is the position of the PTO that inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.”\(^{126}\)

The PTO also stated that it “will not, [therefore], issue a patent for an invention of incredible or specious utility or for inventions whose utilization is not adequately disclosed in the application.”\(^{127}\) Additionally, the PTO pointed out that courts have interpreted the patent law’s utility requirements to exclude inventions deemed to be “injurious to the well being, good policy, or good morals of society.”\(^{128}\)

The PTO’s 1998 statement can be viewed as both a retreat from and an expansion of its 1987 statement. It seems as though the PTO has wisely backed away from its reliance on the Thirteenth Amendment, which was a shaky legal basis for the denial of patents for human-based inventions. Instead of citing the public policy and morality aspects of the utility requirement, the PTO could have simply declared that granting a patent for the Newman/Rifkin chimera would constitute involuntary and unconstitutional servitude under the Thirteenth Amendment. However, the

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124 The 1987 announcement was made only four days after the Board’s decision in Ex parte Allen.
125 Quigg, supra note 9.
126 Id. at 17.
127 Id.
PTO shifted the focus of its stance away from a constitutional basis and toward an expansion of its statutory reading. 129

In its 1987 statement the PTO offered no explanation as to why it considered unpatentable any invention directed to or including humans. 130 However, the latest statement provides a basis for the policy that at least certain human-based inventions 131 are not patentable subject matter under section 101. In what could be viewed as an effort to legitimize its 1987 pronouncement against claims directed to, or including within their scope, a human being, the PTO quoted the language of Justice Story in the 1817 case of Lowell v. Lewis. 132

In Lowell, Story made the following statement in the course of explaining the utility requirement:

All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word "useful," therefore is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention. But if the invention steers wide of these objections, whether it be more or less useful is a circumstance very material

129 Quigg, supra note 9, at 17.
130 Quigg, supra note 115, at 24.
131 The PTO's 1998 announcement is presumably specifically directed at a single patent application. Quigg, supra note 9. The announcement does not necessarily declare that the patent will not be granted. It merely states that such an application may not satisfy the morality and public policy aspects of the utility requirement. However, this Note addresses the statement as if it will be applied "across-the-board" to all human-based inventions just as the 1987 statement applied. This approach will be taken because (1) the 1998 statement provides a useful explanation of the unspecified statutory basis underlying the 1987 statement, (2) such a basis could presumably be used to deny patents to all human-based inventions, and (3) as this Note demonstrates, the PTO has shown such a desire to deny patents for all human-based inventions.

132 Lowell v. Lewis, 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8,568) (involving alleged patent infringement of a water pump). See also Bedford v. Hunt, 3 F. Cas. 37, 37 (C.C.D. Mass. 1817) (No. 1,217) (defining a useful invention as "one as may be applied to some beneficial use in society, in contradistinction to an invention, which is injurious to the morals, the health, or the good order of society").
to the interests of the patentee, but of no importance to the public.\textsuperscript{33}

Story's comments raise a few questions with respect to human-based inventions: (1) is his recognition of a morality/public policy aspect of the utility requirement a proper judicial interpretation of the patent laws, (2) how often has this theory been asserted to deny patents, and (3) even assuming \textit{arguendo} that Story's insertion of a morality standard into the utility requirement of section 101 is a proper "interpretation" of the Act, should it be used to deny patent protection for human-based inventions, including the Newman/Rifkin chimera?\textsuperscript{34}

1. \textit{Story's Interpretation of the Utility Requirement}. The three commonly recited requirements for patentability are novelty, utility, and nonobviousness.\textsuperscript{35} However, the Constitution only specifically mentions utility in the form of the promotion of the "useful Arts."\textsuperscript{36} Despite its obvious importance, no congressional statute has gone very far in defining either the term "utility" or what is "useful."\textsuperscript{37} Therefore, it has been left predominantly to the judicial branch to fashion the standard for utility.

Story's comments in \textit{Lowell} were not his first regarding the utility standard. In 1817, Story made a pronouncement that became widely known as the "Story view of utility."\textsuperscript{38} The Story view was that "[t]he law ... does not look to the degree of utility; it simply requires, that it shall be capable of use, and that the use is such as sound morals and policy do not discountenance or prohibit."\textsuperscript{39} While the "Story view of utility" had its time in the spotlight, the United States Supreme Court rejected its logic in 1966.\textsuperscript{40}


\textsuperscript{35} U.S. CONST. art. I, § 8, cl. 8.

\textsuperscript{36} See 35 U.S.C. § 101 (1994) ("Whoever invents or discovers any new and useful ... "); \textit{see also} 35 U.S.C. § 112 (1994) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it ... ").

\textsuperscript{37} Bedford v. Hunt, 3 F. Cas. 37, 37 (C.C.D. Mass 1817) (No. 1,217).

\textsuperscript{38} \textit{Id}.

In *Brenner v. Manson*, the Court specifically looked to the degree of utility of the patent application and determined that utility was lacking.\(^{140}\) In the course of its opinion, the Court stated that there could be no patent protection for processes "which either [have] no known use or [are] useful only in the sense that [they] may be an object of scientific research."\(^{141}\) While *Brenner* was an instant and obvious departure from Story's view of the necessary degree of utility, the departure from the morality/public policy aspect of the utility requirement has been more of a gradual process.

2. Prior Use of the Morality/Public Policy Standard. Story's comments regarding inventions which are "injurious to the well-being, good policy, or sound morals of society"\(^{142}\) were used sparingly in the nineteenth century. For example, this doctrine of "social utility" was occasionally invoked in order to deny patents on gambling devices and products or processes useful only for perpetrating frauds.\(^{143}\) The initial nineteenth century cases which invoked the doctrine of social utility denied the patentable utility of inventions that could be used for gambling or fraud along with other less morally repulsive purposes.\(^{144}\) However, the use of the doctrine was quickly narrowed to inventions with no use other than gambling.\(^{145}\)

While the doctrine may have had some support soon after Story's comments, courts have not invoked the doctrine in decades. As a matter of fact, the PTO has since upheld an invention even though it was used solely for gambling purposes.\(^{146}\) In modern times, it seems issues of morality and

\(^{140}\) *Id.* at 534-35.  
\(^{141}\) *Id.* at 535.  
\(^{142}\) Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568).  
\(^{143}\) 1 DONALD S. CHISUM, CHISUM ON PATENTS, § 4.03[1] (1999); see generally Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1062 (1988) (arguing that the morality standard has proven to be a difficult test and that the PTO should not address such concerns).  
\(^{144}\) See, e.g., Schultze v. Holtz, 82 F. 448, 449 (C.C.N.D. Cal. 1897) (denying a patent for a coin return device simply because it was widely used on slot machines); National Automatic Device Co. v. Lloyd, 40 F. 89, 90 (C.C.N.D. Ill. 1889) (denying a patent for a miniature race horse course because it was used solely for the purposes of gambling). For cases involving fraudulent inventions, see, for example, Klein v. Russell, 86 U.S. 433, 445 (1873) (holding that patents should be denied for any processes that cannot be made useful for any honest purpose and which result in perpetrating a fraud upon the public); Rickard v. Du Bon, 103 F. 868, 872-73 (2d Cir. 1900) (denying patent for a process which artificially produced spots on tobacco leaves, making them resemble a higher grade of tobacco without substantively improving the tobacco).  
\(^{145}\) See Fuller v. Berger, 120 F. 274, 275 (7th Cir. 1903) (stating that an invention lacks patentable utility only if it is incapable of serving any beneficial end).  
of public policy are irrelevant in the determination of whether or not an invention has patentable utility. A patent covering a police radar detector has been held not lacking in patentable utility even though its sole purpose is the circumvention of law enforcement.\textsuperscript{147} Today few question whether patent grants for inventions as lethal as the Gatling gun,\textsuperscript{148} as environmentally unsound as polystyrene-foam fast food packaging,\textsuperscript{149} or as unhealthy as a cigarette-making device\textsuperscript{150} are beneficial to society or in keeping with sound patent policy.

The determination of what constitutes an immoral invention is a subjective one and thus changes from generation to generation. Therefore, it should be no surprise that the use of the doctrine of social utility in denying patents has, over the years, fallen out of favor with the federal courts, if not with the PTO. It appears that today’s conservative Supreme Court would be hesitant to invoke a subjective doctrine which has not seen much use over the last century. In an effort to legitimize its stance against granting patent protection to biotechnologists for human-based inventions, the PTO, in its 1998 announcement, has relied upon a dying doctrine. The 1987 statement lacked constitutional logic while devoid of any statutory analysis. After eleven years and one more announcement, the PTO has gone no further toward offering a rational basis for its wholesale denial of human-based patents in the face of Supreme Court language arguably holding otherwise.

3. Application to Human-Based Inventions. Even assuming arguendo that Story’s insertion of a morality standard into the utility requirement of section 101 is a proper interpretation of the Patent Act, it remains to be decided whether human-based inventions, including the Newman/Rifkin chimera, are “injurious to the well-being, good policy, or good morals of society.”\textsuperscript{151} The recent granting of a patent for the Harvard Mouse sparked a debate among commentators as to whether these patents should be issued at all.\textsuperscript{152} As science steadily marches toward more advanced technology

\textsuperscript{148} U.S. Pat. No. 36,836 (Nov. 4, 1862).
\textsuperscript{149} U.S. Pat. No. 4,132,344 (Jan. 2, 1979).
\textsuperscript{150} U.S. Pat. No. 5,012,823 (May 7, 1991).
\textsuperscript{151} Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568).
\textsuperscript{152} See generally Rebecca Dresser, Ethical and Legal Issues in Patenting New Animal Life, 28 JURIMETRICSJ. 399, 410-24 (1988) (recognizing concerns such as increased animal suffering); Merges, supra note 143, at 1057-58 (noting the possibility of immediate direct or indirect ecological disasters and a
involving humans, e.g., cloning, the debate has spread into the arena of human-based inventions.

One of the major arguments in support of animal patents has traditionally been their significant role in the field of medical research. Rightly or wrongly, society seems to have accepted the fact that animals are bred, tested, and now actually genetically engineered for the sole purpose of saving human lives. Most people place human life on a level above that of the animal world, but what about a creature that is part human? Any argument in favor of patent protection for human-based inventions must be supported by the utility of the invention. It is difficult to envision many other uses of such inventions other than those involving medical research. A strong argument can be made that subjecting human hybrids to the pain and suffering of medical research would be "injurious to the well-being, good policy, or good morals of society." Another argument that the patenting of human-based inventions would violate Story's morality requirement stems from the view that such creatures should be afforded all of the constitutional rights of United States citizens. Assuming that human-based inventions are "persons born or naturalized in the United States," they would be entitled to the protections provided by the Constitution. The denial of a person's fundamental rights is against the public policy of our nation. For this reason, the framers of the Constitution included the Bill of Rights, which was later augmented by, most notably, the Thirteenth and Fourteenth Amendments. Assuming for the purpose of argument that the granting of a patent by the government constitutes state action, the use of a person, in the form of a hybrid human, for medical research or any other use not voluntarily chosen by the person could violate that person's rights under substantive due process and the Equal Protection clause of the Constitution. Any violation of the Constitution which would necessarily flow from the utility of an invention must certainly render

153 But see DeBre, supra note 122, at 222 n.8 (citing J.B.S. Haldane, Biological Possibilities for Human Species in the Next Ten Thousand Years, in MAN AND HIS FUTURE 337, 354 (G. Wolstenholme ed. 1963)). Dr. Haldane has suggested that genetic engineering could lead to humans with prehensile feet and no heels who would be ideal astronauts.
154 Keep in mind that Story's test does not ask whether granting the patent itself would violate public policy but rather whether the intended use of the invention/process would violate public policy.
155 U.S. CONST. amend. XIV, § 1. See generally Rivard, supra note 13 (discussing whether transgenic humanoid species would be considered "persons" under the Constitution).
156 Rivard, supra note 13, at 1441.
that utility “injurious to the well-being, good policy, or good morals of society.”

The patenting of a human-based invention may well violate Justice Story’s public policy/morality aspect of the utility requirement. However, this fact alone cannot justify a ban on the patenting of these inventions because Story’s requirement is a doctrine which is no longer embraced.

V. CONCLUSION

The PTO has a long history of reluctance in granting patent protection for inventions and processes involving living organisms. In 1980 the United States Supreme Court directed the PTO to grant a patent for the Chakrabarty bacterium. The Court pronounced that patentable subject matter was to “include anything under the sun that is made by man.” By 1987 the Board had recognized that a multicellular animal made by man was patentable subject matter. Finally, in 1988, the PTO for the first time granted a patent for a genetically-engineered multicellular animal: the Harvard Mouse.

Despite its recent acceptance of patent protection for animals and the strong language of Chakrabarty, the PTO in 1987 declared that patent claims directed to or including in their scope a human being would be denied. This proscription was based on a vague reference to the Patent Act coupled with a dubious reliance on the Thirteenth Amendment. In 1998 the PTO issued another statement in which it retreated from its constitutional rationale while explaining its statutory basis for denying patent protection for human-based inventions.

The PTO’s recent reliance on Justice Story’s view of a morality/public policy aspect of the utility requirement is flawed in two respects. First, it assumes that any utility inherent in such an invention would necessarily violate public policy. While the most readily apparent uses would seem to violate the Constitution, thereby violating public policy, the PTO, as an administrative agency, is in no position to make such decisions regarding fundamental constitutional rights. Second, even assuming that any utility derived from a human-based invention would violate public policy, Story’s
utility standard is a dead doctrine which had its time in the nineteenth century. This century has seen the grant of patents for inventions and processes whose only utility could be deemed injurious to the well-being of society.

While the PTO may have valid concerns about the consequences of granting patents for human-based inventions, none of its past or present reasons for a wholesale denial are persuasive. Although there may be strong arguments, both legal and ethical, against the patenting of a parallel humanoid species, the PTO is not the organization to make such determinations. Instead of relying on the PTO and ultimately the United States Supreme Court to make ad hoc decisions concerning the constitutionality of human-based inventions, Congress should step forward to provide for or proscribe patent protection for these inventions. Such legislative action would preclude any constitutional challenge to a patent based on substantive due process or equal protection. Furthermore, it would not be unprecedented for Congress to statutorily deny patent protection in a certain field of technology. For example, the Atomic Energy Act provides that "[n]o patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon." But until Congress takes such affirmative action or publicly refuses to do so, human-based inventions will remain subject to the PTO's wholesale prohibition, no matter how misdirected it may be.

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