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Monopolies on Addiction: Should Recreational Drugs be Patentable?

Marsha J. Ferzigert†

Science without conscience is the death of the soul.

François Rabelais

Pot will probably be legal in ten years. Why? Because in this audience probably every other one of you knows a law student, who will become a senator, who will legalize it to protect himself. But then no one will smoke it anymore. You'll see.

Lenny Bruce (1967)

With the passage of the Harrison Narcotics Act in 1914, America began the “War on Drugs.”¹ The war appeared to falter in the 1970s under the Ford and Carter administrations,² but the Reagan administration renewed it with full force, pledging to “do what is necessary to end the drug menace.”³ Despite Reagan’s vow, drug abuse in the United States has continued to escalate, and the War on Drugs has accelerated in kind.⁴

As with any war, there are dissenters. Some believe that the solution to the drug problem lies not in enforcement or interdiction, but in the legalization of recreational drugs. These “legalizationists” began to publish articles advocating legalization as early as 1969,⁵ they were soon joined by distinguished individuals such as economist Milton Friedman, who first publicly

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¹ Steven Wisotsky, Beyond the War on Drugs: Overcoming a Failed Public Policy xvii (Prometheus Books, 1990).
² Id at xvii-xviii.
³ President Ronald W. Reagan, October 14, 1982, quoted in Wisotsky, Beyond the War on Drugs at xviii (cited in note 1).
⁴ Id at xviii-xix.
⁵ Rod L. Evans and Irwin M. Berent, Drug Legalization: For and Against 2-3 (Open Court, 1992), citing New Guard (April 1969) (statement of David D. Friedman). For a detailed history of the legalization debate, see generally The Background to the Debate, in Evans & Berent, For and Against at 1-9.
advocated legalization in 1972.\(^6\) The publicity surrounding the legalization debate peaked in 1988 following Baltimore Mayor Kurt Schmoke's pro-legalization remarks,\(^7\) and the debate recently made headlines again when Surgeon General Joycelyn Elders suggested studying the legalization alternative.\(^8\)

Although numerous symposia\(^9\) and statistical studies\(^10\) have addressed this issue, the legalization question remains unresolved. Some legalizationists argue that legalization would promote individual liberty\(^11\) and decrease the drug problem.\(^12\) Others believe that the War on Drugs is "unwinnable"\(^13\) and that it should be fought not as a law enforcement war but rather as a public health problem.\(^14\) Those opposing legalization claim that drug legalization would transform the United States into a

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\(^{6}\) Evans & Berent, *For and Against* at 3 (cited in note 5).

\(^{7}\) US Conference of Mayors (April 25, 1988), Nightline (May 10, 1988), and The Washington Post (May 15, 1988), cited in Evans & Berent, *For and Against* at 3 (cited in note 5) (noting that Schmoke's remarks called for Congress to hold hearings on legalization). Schmoke has continued to advocate the "medicalization" of drugs. Despite the apparent unpopularity of this position, Schmoke was reelected Mayor of Baltimore in 1991, winning 72 percent of the vote. See Dennis Cauchon, *Drug War's Popular Voice, Unpopular Plan*, USA Today 3A (Feb 22, 1994).


\(^{11}\) See, for example, Todd Austin Brenner, *The Legalization of Drugs: Why Prolong the Inevitable?*, 18 Cap U L Rev 237 (1989), as printed in Evans & Berent, *For and Against* at 157 (cited in note 5).

\(^{12}\) See, for example, Ethan A. Nadelmann, *The Case for Legalization*, as printed in Evans & Berent, *For and Against* at 20 (cited in note 5).

\(^{13}\) David Boaz, *Let's Quit the Drug War*, NY Times A31 (March 17, 1988).

"society of zombies." The debate continues, yet few scholars have examined the practicalities of a society with legalized drugs.

If recreational drugs were legalized, a legitimate market would naturally develop for these drugs. As with any new market, competitors would fight for market share. Pharmaceutical companies would most likely become the biggest players in the new market because they possess the necessary equipment and expertise to enter the industry. These companies would likely create new recreational substances in hopes of realizing large profits.

Ordinarily, such behavior would indicate the existence of a healthy market. However, the recreational drug market would be disconcertingly unique: because consumers of recreational drugs often become addicted to these substances, the market would be, in a sense, a permanent one. Traditional concepts of supply and demand would not fully apply to this market because addicts would be willing to purchase their "fix" at almost any price.

Current patent law would exacerbate this problem. If the federal government were to grant a patent on an addictive recreational drug, the patent holder would essentially possess a seventeen-year monopoly on a substance that an addicted consumer must purchase. Such monopolies would not comport with the generally recognized goals of legalization programs, such as making drugs available at lower prices and thereby eliminating the need for a black market. In a post-legalization world, Congress would need to pay careful attention to the effect that patent policy would have on the legalization regime.

This Comment argues that recreational drugs, if legal-
ized, should not be patentable. Allowing patents for recreational drugs would provide economic incentives for drug producers to devote too many resources to developing new classes of recreational drugs. Allowing patents would also seriously undermine any potential benefits of the legalization of recreational drugs.

Part I of this Comment examines the relevant areas of intellectual property law that might serve to protect an inventor's property rights in legalized drugs: patents and trade secrets. Part II argues that while trade secret protection would not be available to manufacturers of legalized drugs in most circumstances, patent protection would be both available and useful to these parties. Part III shows that while patent protection would be available, Congress could act to deny such protection to legalized recreational drugs. Finally, Part IV argues that Congress should deny patent protection to legalized drugs.

I. BACKGROUND IN PATENT AND TRADE SECRET LAW

A. American and European Patent Law

This Part first explains relevant basic concepts of United States and international patent law, including the problem of "copycat" patents, an issue especially relevant to the problem of "designer drugs" under a legalization regime. This Part then discusses the law of trade secrets, another area of intellectual property law that manufacturers might use to protect legalized drugs.

Congress created the United States patent system pursuant to its constitutional authority to "promote the Progress of Science and useful Arts . . .". In the United States, inventors may obtain patents for processes, machines, manufactures or compositions of matter, or any "new and useful improvement thereof."
The holder of a patent has the right to exclude all others from making, using, or selling the patented invention for seventeen years. The patent system thus promotes scientific research and artistic creativity by granting a seventeen-year monopoly in exchange for disclosure of the invention. This limited monopoly provides strong economic incentives to develop new inventions. Indeed, without patent protection, there would be no way to eliminate "free riders" and hence little economic incentive to research and create. Additionally, without patent protection, an inventor has the incentive to keep new inventions secret, because secrecy is the only way to maintain exclusive control over the invention.

Any new and useful invention enjoys a presumption of patentability unless it encounters certain statutory problems. 35 USC § 101. See also 35 USC § 102 (1984) ("A person shall be entitled to a patent unless" the invention is known or used in this country, or patented or described in a publication in another country prior to invention by the applicant; the invention is patented or described in a publication in any country or is in public use or on sale in the United States more than one year before the application; the applicant has abandoned the invention; the invention was patented in another country before the United States application was filed; the invention was described in another application by another invention before the instant application; the applicant did not invent the applied-for invention; or the invention was made by another in the United States before the applicant invented the invention.). For a helpful discussion of the requirements of patentability, see Graham v John Deere Co., 383 US at 6.

See 35 USC § 154 (1993) ("Every patent shall contain . . . a grant to the patentee, his heirs or assigns, for the term of seventeen years . . . of the right to exclude others from making, using or selling the invention throughout the United States and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.").

See US Const, Art I, § 8, cl 8.

See 35 USC § 154.


See Yehuda Kotowitz, Issues in Patent Policy With Respect to the Pharmaceutical Industry 1 (Minister of Supply and Services Canada, 1986) ("While new information is costly to create it is relatively cheap to disseminate or imitate. Thus unless inventors are at least partly protected from imitation their incentive to invest in R&D may be severely curtailed."). Certain types of inventions have a "public goods" aspect, thereby causing this free rider problem. Many people may simultaneously use public goods, such as information, once they are made available. Thus, the owner of a public good cannot easily prevent unauthorized third parties from using the good. Alden F. Abbott, Developing a Framework for Intellectual Property Protection to Advance Innovation, as printed in Francis W. Rushing and Carole Ganz Brown, Intellectual Property Rights in Science, Technology and Economic Performance 311, 317 (Westview Press, 1990). People who do not pay for their use or consumption of a public good are "free riders." "The fact that excluding free riders is difficult or impossible for purely public goods disrupts the workings of the markets for these goods." Robert Cooter and Thomas Ulen, Law and Economics at 109 (HarperCollins Publishers, 1988).

See Erich Kaufer, The Economics of the Patent System 19, 41 (Harwood Academic
Under United States patent law, to be patentable an invention must meet three basic requirements: novelty, utility, and non-obviousness. The novelty requirement provides that the invention must be "new": it must not have been in public use nor patented or described in a publication before its invention. Utility requires that the invention be useful. The non-obviousness requirement bars patentability of any invention that "would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." In addition, United States patent law provides many other prerequisites to the granting of a patent.

While similar in many ways to United States patent law, European patent law imposes on an inventor an additional patentability requirement—morality. European patent law is controlled by the European Patent Convention ("EPC"); held in 1973, it attempted to simplify the process of applying for patents in multiple European nations. EPC Article 53(a), an interesting but little-used clause, disallows patents on inventions against the public morality. Other foreign patent systems have incorporated similar provisions into their own laws.

While not embodied in our statutory system, these ethical considerations have surfaced in American patent law. In 1817, Publisher, 1989).

28 35 USC §§ 101, 102.
29 35 USC § 101.
31 35 USC § 102 (a), (b).
32 35 USC § 101.
33 35 USC § 103.
34 For example, only the inventor may apply for a patent on a given invention. 35 USC § 101. Additionally, a written description of the invention must be contained in every application. 35 USC §§ 111, 112 (1984).
36 Article 53(a), European Patent Convention of October 5, 1973 ("Article 53, Exceptions to Patentability: European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to public order or morality, provided that the exploitation not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States. . . . ").
37 See generally Sinnott, World Patent Law and Practice (cited in note 35) (setting forth the patent laws of many countries). See, for example, the patent law of the Republic of South Korea ("[I]nventions that contravene public order, morality or public health . . . continue to be unpatentable."). J. W. Baxter, 2 World Patent Law and Practice §§ 16-54 (Matthew Bender & Co., 1989). Many countries, however, have not enacted such a provision. See, for example, Israel, Sri Lanka, Syria, and Turkey in volumes 2E, 2H, 2I, and 21 of Sinnott, World Patent Law and Practice respectively (cited in note 35).
Judge Story declared that the definition of utility was in "contra-distinction to [the] mischievous or immoral," thereby inextricably linking patentability with morality. Subsequent courts, however, have expressed disdain for the notion that judges should decide questions of morality, suggesting instead that these questions should be left to elected officials.

One problem in modern patent law that would likely surface in a world of legalized drugs is the "copycat" patents problem. Critics of the current United States patent system often claim that the present system encourages too many "copycat" inventions; that is, inventors "invent around" patents by building upon existing patents through similar but non-obvious relatives of a recently patented invention. This system allows different inventors to obtain patent protection on inventions that may appear to be identical to all but those highly skilled in the field.

In the current world of recreational drugs, a type of "inventing around" occurs with "designer drugs." These drugs are variants of existing drugs, acting in a manner similar to the existing illegal drug but different enough to fall outside of the illegal drug statutes. Designer drugs are relatively easy to make and potentially limitless in number and scope. Thus, upon legaliza-
tion, manufacturers could conceivably "invent around" currently illicit drugs and receive patents on a large number of similar chemical analogs.

B. Background in Trade Secret Law

Although it is the most straightforward method, patent law is not the only way to gain protection for an invention. In most states, trade secret law protects "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it."45

Manufacturers of newly legalized drugs may seek trade protection for these substances. The definition of a trade secret explicitly includes chemical compounds,46 and the patentability of a compound does not affect its status as a trade secret.47

II. WHY LEGALIZED DRUGS QUALIFY FOR PATENT PROTECTION

Due to the ease of "reverse engineering" chemical compounds, however, trade secret protection would be either unavailable or useless for most new recreational drug compounds. On the other hand, newly legalized drugs would satisfy all the requirements for patent protection, and patent protection would be both available and useful for new drug compounds.

A. Legalized Recreational Drugs Would Not Qualify For Trade Secret Protection

Trade secret protection would not be useful to producers of legalized recreational drugs. Because the law of trade secrets only prohibits discovery and/or misappropriation of trade secrets through improper means (such as a breach of confidence),48 a
competitor may lawfully obtain a sample of the compound and "through inspection and analysis, create a duplicate, unless of course, the item is patented." This process is called "reverse engineering"—working backward from a known substance to determine the process of creation and the starting materials. Chemical compounds are unlike Coca-Cola or specific colors of paint, heterogeneous mixtures whose content is difficult to determine through chemical analysis. A competent and well-equipped chemist can readily ascertain the structure of a homogeneous molecular compound, such as a drug. Thus, even if one considered a certain formula for a recreational drug a trade

to do so, is liable to the other if (a) he discovered the secret by improper means, or (b) his disclosure or use constitutes a breach of confidence reposed in him by the other in disclosing the secret to him, or (c) he learned the secret from a third person with notice of the facts that it was a secret and that the third person discovered it by improper means or that the third person's disclosure of it was otherwise a breach of his duty to the other, or (d) he learned the secret with notice of the facts that it was a secret and that its disclosure was made to him by mistake.

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K & G Oil Tool & Service Co. v G & G Fishing Tool Service, 314 SW2d 782, 788, 158 Tex 594, 603 (S Ct Tex 1958).

Chicago Lock Co. v Fanberg, 676 F2d 400, 404, 216 USPQ 289, 292 (9th Cir 1982), quoting Sinclair v Aquarius Electronics, Inc., 42 Cal App 3d 216, 226, 116 Cal Rptr 654, 661 (1974) ("It is well recognized that a trade secret does not offer protection against discovery by fair and honest means such as by independent invention, accidental disclosure or by so-called reverse engineering, that is, starting with the known product and working backward to divine the process."). California, like most states, has adopted the Restatement law governing trade secrets. Chicago Lock, 676 F2d at 404.

See Douglas A. Skoog and Donald M. West, Fundamentals of Analytical Chemistry 687, 689 (Holt, Rinehart and Winston, 1963) ("The difficulties encountered in the analysis of real substances arise, of course, from the complexity and variability of their composition. . . . Each new component creates several new variables. . . . With each new step, additional variables arise; and with this increase, a theoretical treatment of the problem becomes difficult or even impossible."). See also James T. O'Reilly, Right to Know: Cincinnati's More Righteous, Less Knowing Experiment, 52 U Cin L Rev 337, 339-40 n 14 (1983) ("But the trade name used for a mixture substance, such as the hypothetical 'Chemslurry'—an aqueous solution of (2,2-bis)dimethyl alkyl diphosphonate, colorant dye and chromium [sic] disulfide, permits the manufacturer of Chemslurry to market the product without duplication of the product by competing firms . . . . In a number of common applications, processes are used that mask the identity of key starting ingredients to eliminate the threat of reverse engineering by a competitor's customary detection efforts.").

See Skoog & West, Fundamentals of Analytical Chemistry at 687 (cited in note 51) ("Thus, if every chemical analysis consisted simply of determining the concentration of a single element or compound in a simple and readily soluble homogenous mixture, analytical chemistry could profitably be entrusted to the hands of a skilled mechanic; certainly a well-trained chemist could find more useful and challenging work for his mind and his hands."). See also Note, The Foreign Use of U.S. Patents: Damming the Flow of Downstream Products, 30 Colum J Transnatl L 145, 158 (1992) ("Specialty chemical, pharmaceutical, and biotechnology products . . . can readily [be copied] through reverse engineering.").
secret, the protection afforded by state trade secret law would not be useful. Rival pharmaceutical companies certainly possess the resources, equipment, and knowledge to procure and analyze the drug, thereby discovering its composition by lawful means. Because reverse engineering is not a defense to patent infringement, patent protection remains the only effective method of protecting such chemical compounds.

B. Legalized Recreational Drugs Would Qualify for Patent Protection

Legal recreational chemical substances, other than those that have been in the public use for more than one year, are patentable under current law, as are tobacco- and alcohol-related paraphernalia. Given that these relatives of once-illegal recreational substances, such as ethanol, are now patentable subject matter, the current law does not prevent inventors from patenting newly legalized, novel recreational drugs. The only reason that such drugs are not presently the subject of frequent patent applications is that producers have no incentive to develop and patent products that they cannot legally market.

See notes 51-52 and accompanying text.


35 USC § 102(b).

See, for example, Wooden stein with responsive emblem, Patent Number 5,156,283 (Oct 20, 1992); Tricyclic ether substituted acetic acid, tobacco flavoring use thereof and process for preparing the same, Patent Number 5,188,129 (Feb 23, 1993); Cigarette with cellulosic substrate, Patent Number 5,203,355 (Apr 20, 1993); Processes for producing flavor substances from tobacco and smoking articles made therewith, Patent Number 5,235,992 (Aug 17, 1993). It is unclear whether Congress would grant a patent for recreational drug paraphernalia. But see Embroidering tool, Patent Number 4,886,003 (Dec 12, 1989) ("Unfortunately, the use of such needle assemblies has been found objectionable by certain governmental bodies and agencies because the tools can be disassembled and the cannulation needle assemblies thereafter used as illegal drug paraphernalia by unauthorized drug users.").

See US Const, Amend XVIII (banning alcohol); US Const, Amend XXI (repealing prohibition).

There is some evidence supporting the idea that illegal inventions cannot be patented. See Whistler Corp. v Autotronics Inc., 14 USPQ 2d 1885, 1886 (N D Tex 1988) (addressing an application for a patent on radar detectors: "Unless and until detectors are banned outright, or Congress acts to withdraw patent protection for them, radar detector patentees are entitled to the protection of the patent laws.").
The effect of patentability would be especially notable for designer drugs. Companies discovering new recreational drugs would not only patent the particular compounds they discover, but they would also seek to patent broad classes of compounds, encompassing all conceivable variations of their compound with the same active component. These broad patents would comprise an entirely new class of drugs and prevent other companies from inventing around these drug patents without infringing.

The "doctrine of equivalents" would further frustrate efforts by competitors to invent substances that do not infringe such broad patents. This doctrine states that an item that does not literally infringe a patent may still be found to infringe "if it performs substantially the same function in substantially the same way to obtain the same result." Additionally, under the doctrine of equivalents, infringement of a pioneer patent—"a patent concerning a function never before performed, a wholly novel device, or one of such novelty and importance as to make a distinct step in the progress of the art"—would occur even when the infringing product's characteristics "lie considerably outside the boundaries of the literal claims."

Moreover, even if a rival company could develop a literally non-infringing substitute for a new class of recreational drugs, the company probably would not expend the resources to develop such drugs. The return on the investment for such a substitute would likely be small, given the high probability that the holder of the "original" would claim infringement. Thus the available substitutes for the compound would be few or none, thereby in-

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59 Such patents often include what are known as "Markush groups," named for Ex parte Markush, 1925 D C 126, 340 O G 839 (1924). Markush groups claim a genus, and then provide a list from which the substituent groups may be chosen. These Markush claims can encompass thousands or even hundreds of thousands of compounds, covering very broad classes. Robert Patrick Merges, Patent Law and Policy: Cases and Materials 499 (The Michie Company, 1992).

60 This reason explains why this Comment presumes that new recreational drug research will focus on developing new classes of compounds rather than new compounds in a known class, such as opiates. The patents on classes of compounds will be much more financially valuable.


64 Id at 705 ("[T]he history of many industries . . . shows that outsiders with promising approaches have been held back. . . . These episodes testify to the blocking power of broad patents . . . .").
creasing the ability of the patent holder to extract monopoly-inflated prices from newly addicted consumers.

III. CONGRESSIONAL AUTHORITY AND PRECEDENT FOR DENYING PATENT PROTECTION

The Constitution empowers, but does not require, Congress to grant patents. Thus, Congress maintains plenary control over the patent laws and may restrict the patentability of a class of substances, such as recreational drugs.

Indeed, Congress has restricted patentability in the past. The Atomic Energy Act of 1964 (the “AEA”), Title 42, Section 2181 of the United States Code (“Section 2181”) states 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.” Additionally, the AEA revoked any existing patents on such matter.

Congress passed the AEA to “assure that atomic energy makes the maximum contribution to the general welfare of the Nation, subject to the paramount objective of having it make the maximum contribution to the common defense and security.” Congress cited as its authority for this pronouncement the clause of the Constitution allowing Congress to “provide for the common defense,” declaring that there was “no doubt of the authority of the Congress to exercise its powers to provide for any manner of regulation needed to protect the national interests, and the interests of the public.”

Section 2181 provides precedent for disallowing patents on recreational drugs. Section 2181 acknowledges that while the Constitution provides for a patent system, it does not dictate the scope of that system. Public concerns may override the interest in

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66 Mast, Fos & Co. v Stover Mfg. Co., 177 US 485, 494 (1900); McClurg v Kingsland, 42 US 202, 206 (1843). See also Boyden v Commissioner of Patents, 441 F2d 1041, 1043, 168 USPQ 680, 681 (DC Cir 1970); Giuliani, 8 USPQ 2d at 1095.
67 42 USC § 2181(a) (1973).
68 42 USC § 2181(b). The patent holders whose patents were revoked under this section received subsequent compensation. Id.
70 Id at 3466.
71 Id.
promoting certain inventions. Just as Congress used Section 2181 to further defense policy, it could deny patents to recreational drugs to further legalization policy.

The non-patentability debate has encompassed other classes of inventions as well. The members of the European Patent Convention seriously considered disallowing patents on living matter after the United States Patent and Trademark Office ("PTO"), in 1988, granted a patent to the inventors of the "Harvard Onco-mouse," the first transgenic animal to gain such approval. The Onco-mouse was, however, finally granted a European patent.

The debate over the ethical issues and public policy concerns inherent in granting patents on living organisms has direct applicability to the issue at hand. Commentators examining the patentability of biotechnological advances have recognized that Congress has the authority to limit patent rights in order to advance the general welfare. Robert Merges states that historically, the inventions declared unpatentable for moral reasons are those that have "posed a direct threat to a readily identifiable [moral] norm . . . ." Merges advocates a "sort of moral balancing test" in which benefits and detriments to the public welfare would be weighed to determine patentability.

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73 "The Onco-mouse is a mouse that is genetically engineered to be susceptible to human cancer." Cynthia M. Ho, Building a Better Mousetrap: Patenting Biotechnology in the European Community, 3 Duke J Comp & Intl L 173 (1993). The mouse is useful because smaller amounts of compounds suspected to be carcinogens can be introduced into the system of the Onco-mouse, with a much higher probability that the mouse will develop cancer.
74 "A transgenic animal is one whose DNA . . . has been changed by adding DNA . . . usually from different animals or from humans." Margaret J. Lane, Patenting Life: Responses of Patent Offices in the U.S. and Abroad, 32 Jurimetrics Journal 89 n 1 (1991).
77 Merges, 47 Md L Rev at 1065 (cited in note 77). Merges cites gambling devices as an example of such inventions, even when such devices were legal.
78 Id at 1066.
In comparing biotechnology policy to the AEA, Merges states that the AEA was meant to "keep [information about nuclear weapons] out of the hands of those who would misuse [it]." Legislation by Congress disallowing the patentability of recreational drugs would accomplish a similar goal—keeping recreational drug patent monopolies out of the hands of pharmaceutical companies who could or would misuse them, or use them in a manner contrary to the public interest.

Merges additionally argues that even if one concedes that the non-patentability portion of the AEA is based on morality, "these weapons would still constitute a rare limiting case—a technology we do not want to encourage." Because society might choose to discourage use of this technology, the AEA's non-patentability clause would provide precedent for declaring recreational drugs unpatentable.

In summary, Congress has authority to include a non-patentability clause in legislation legalizing currently illicit drugs. Its task, however, is to determine whether such a clause is appropriate. Scholars continue to debate the economics of legalization without examining a major factor in that debate—the economic incentives that would cause big business to become involved or uninvolved in the recreational drug industry. Congress must examine this factor as part of any scheme legalizing recreational drugs.

IV. WHY CONGRESS SHOULD DENY PATENT PROTECTION TO LEGALIZED DRUGS

This Part argues that once Congress legalizes recreational drugs, it should make these drugs unpatentable. First, this Part sets forth the goals of a legalization regime and posits that patent policy should further these goals. Second, this Part shows that Congress, not the courts, should disallow patents on legal recreational drugs. Third, this Part differentiates between newly legalized drugs and substances such as alcohol and nicotine, which do enjoy some patent protection. Finally, this Part examines the pharmaceutical industry, likely the largest player in the legalized drug market, and shows how denying patent protection to these potential patentees would best serve the goals of legalization.

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80 Id at 1067.
81 Id.
A. The Goals of Legalization

The underlying goals of a legalization regime are critical to analyzing the patentability issue because the patent laws should help effectuate these goals. Current legalizationists differ in their views of what legalization can or should accomplish. However, a number of common arguments supporting the legalization of recreational drugs have surfaced.

Legalizationists first argue that legalizing recreational drugs would eliminate, or at least severely cripple, the "black market" in currently illicit substances. The black market thrives for two reasons. First, because consumers cannot acquire illegal drugs in a legal marketplace, the black market holds a monopoly on the sale of these drugs. Second, the profit realized from selling illicit drugs outweighs the risk of criminal sanctions faced by dealers. Legalizationists suggest that if recreational drugs were legalized, then drug companies would engage in the competition for consumers as well; the result would be an increase in drug quality and a decrease in price. Street dealers would no longer earn exorbitant profits from illegal drug sales. As Kurt Schmoke stated: "Elimination of black market profits will effectively eliminate the market itself, and all of its atten-

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63 Among other things, different legalizationists claim that legalization will help U.S. foreign policy; prevent the hypocrisy of distinguishing between tobacco, alcohol, and drugs; protect individual freedom from drug searches and drug testing; eliminate the black market; and stop drug-related crime. Church, Time at 15 (cited in note 15). Many legalizationists want to drop criminal sanctions in favor of public health solutions. Cohen, March 10, 1988, quoted in Wisotsky, Beyond the War on Drugs at xxiii (cited in note 1). See note 5. For a general summary of pro-legalization arguments, see Ethan A. Nadelmann, The Case For Legalization, as printed in Evans & Berent, For and Against at 19 (cited in note 5).
66 Id.
67 "It is a simple matter of supply and demand: as long as demand exists on the scale of the U.S. craving for, say, cocaine, someone is going to supply it, legally or illegally." Church, Time at 14 (cited in note 15).
68 Wisotsky estimates that in the 1980s, the street price of cocaine was approximately $60-100 per gram at 25-35 percent purity. In 1982, by contrast, pharmaceutical cocaine cost about $1.80 per pure gram. Wisotsky, Beyond the War on Drugs at 31-32 (cited in note 1).
Legalizationists also believe that legalization would help current addicts in several ways. First, it would remove the fear of legal sanctions that prevents many addicts from seeking help. Legalization would also help remove the social stigma attached to drug use or abuse, enabling those users or addicts who fear losing jobs or embarrassing their families to seek help. In addition, legalization would help addicts acquire drugs at lower prices, reducing their incentive to steal. Moreover, government regulation would result in safer, higher quality drugs, perhaps preventing numerous deaths now caused by bad drugs. Finally, after legalization, recreational drugs would provide a large source of revenue through both taxes and savings on law enforcement. These funds could then be earmarked for much-needed addiction treatment programs.

Legalizationists also believe that America's youth would benefit from legalization. Recreational drug use would likely decrease after legalization by removing curiosity about drugs, especially among young people. Illicit drugs are "forbidden fruit,"

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89 Schmoke, 18 Hofstra L Rev at 518, 519 (cited in note 85).
90 Three main types of drug-related crimes exist: psychopharmacological, or crimes committed because of the influence of the drug; systemic, or crimes committed by traffickers and dealers to resolve disputes; and economic compulsive, or crimes committed by users to finance their drug use. David Elkins, Drug Legalization: Cost Effective and Morally Permissible, 32 BC L Rev 575, 581 (1991).
91 The President's Commission on Organized Crime estimates that more than seventy drug market murders take place each year in Miami alone. James Ostrowski, The Moral and Practical Case for Drug Legalization, 18 Hofstra L Rev 607, 650 (1990). A nationwide estimate based on extrapolation of this data would suggest that there are more than 825 drug market murders per year. Id. Without a drug market to spark these murders, this number could decrease significantly.
92 A tragic example is the death of former University of Maryland basketball star Len Bias of a cocaine overdose. His friends waited until after his third seizure to call an ambulance, most likely because they feared criminal repercussions. Ostrowski, The Moral and Practical Case at 669 (cited in note 91).
94 See note 90 and accompanying text.
96 Church, Time at 14-15 (cited in note 15).
97 "As long as the mystique surrounds the drug [LSD], the curious will want to try it,
and many people, especially children and young adults, try them simply for that reason. Additionally, if drugs were legal, children might confide in parents or other adults about their drug use. Finally, the illicit drug industry would no longer provide a lucrative and dangerous place for children to work as drug runners. Legalization would eliminate both the thrill of illegal activity and the need for drug runners, removing two strong incentives for children to become involved with drugs. Legalizationists hope that decreasing use of drugs in young people would help break the cycle of addiction in American society.

Overall, any drug legalization policy would attempt to decrease drug abuse and the harmful effects of drug use. While this Comment does not express an opinion on the value or feasibility of either these general goals or the more specific ones outlined above, it does assume that if Congress were to legalize recreational drugs, its actions would be motivated by the above reasons. Therefore, any policy—including patent policy—relating to recreational drugs following legalization should conform to the above goals.

B. Congress, Not the Courts, Should Proscribe Patents on Legalized Drugs

Legalization implies acceptance and legitimacy. Regardless of the government’s actual purpose in legalizing recreational drugs, legislation legalizing recreational drugs would remove the social stigma that such drugs have carried since their criminalization. People would thus be more likely to try these
drugs, and the recreational drug industry could become difficult to control.

The patent system provides a method for imposing a check on this industry. Congress could limit the destigmatizing effect of legalization by permitting the manufacture and sale of currently existing recreational drugs but not encouraging the production of new ones. To this end, Congress could pass legislation legalizing only "drugs in existence before" a certain date. However, Congress would also desire to encourage the manufacture and sale of safer recreational drugs. Thus, a date-restricted policy would contradict Congress's goal of encouraging the creation of safer recreational drugs.\textsuperscript{104}

Instead, Congress could simply discourage purely mercenary research into recreational drugs by eliminating the economic incentives that the patent system provides. Pharmaceutical companies would be able to develop safer recreational drugs; the companies simply could not gain monopoly control over these newly discovered substances.

Alternatively, Congress could avoid the debate over patentability of recreational drugs by instituting a morality clause in the patent laws, as many other countries have done,\textsuperscript{105} thereby shifting the issue to the courts.\textsuperscript{106} Congress should not, however, use this option. Courts are generally reluctant to determine what is moral.\textsuperscript{107} In fact, the Patent and Trademark Office

\textsuperscript{104} Additionally, the Food and Drug Administration could treat recreational drugs like other drugs by regulating their quality and sales. For an explanation of the FDA's drug approval process, see Beth E. Meyers, The Food and Drug Administration's Experimental Drug Approval System: Is It Good For Your Health?, 28 Houston L Rev 309 (1991). The question of what the FDA will do when recreational drugs are legalized will not be addressed in this Comment, but it deserves mention as a consequence of legalization.

\textsuperscript{105} See note 37 and accompanying text.

\textsuperscript{106} The federal trademark system does include a morality clause. "No trademark . . . shall be refused registration on the principal register on account of its nature unless it—(a) Consists of or comprises immoral, deceptive, or scandalous matter; . . . ." 15 USC § 1052(a) (1974). The inclusion of such a morality clause in the trademark statute, but not the patent statute, suggests that the drafters of the patent statute wished to avoid large-scale morality decisions by the patent courts. See U.S. v Azeem, 946 F2d 13, 17 (2d Cir 1991) ("In general, congressional consideration of an issue in one context, but not another, in the same or similar statutes implies that Congress intends to include that issue only where it has so indicated.").

\textsuperscript{107} Ex parte Murphy, 200 USPQ at 803 ("[W]e think this Office should not be the agency which seeks to enforce a standard of morality with respect to gambling, by refusing, on the ground of lack of patentable utility, to grant a patent on a game of chance if the requirements of the Patent Act otherwise have been met."). Judge Story's definition of utility, currently used by numerous courts, includes morality considerations. Lowell v Lewis, 15 F Cas at 1019. Morality concerns, however, should not preclude the patenting of recreational drugs. See note 58 and accompanying text. This definition forces the courts to
Board of Patent Appeals has expressed concern that the Patent and Trademark Office might need to make morality judgments about drugs. Including a general morality clause in the patent laws would introduce morality as a fourth court-determined requirement for patentability, thus forcing the courts to make these morality decisions. Therefore, a general morality clause would not significantly contribute to solving the recreational drug patentability problem.

Instead, Congress should make these morality decisions by taking affirmative legislative action to disallow patents on recreational drugs. The morality clause of the EPC refers to "public morality," implying that public opinion is the relevant standard. The public, through the electoral process, has already made its opinion known—in elections. The public elects people who represent them in expressing their moral and ethical concerns. The public does not elect regulatory agencies or the federal judiciary; thus these bodies are not clearly responsible to any one constituency. Neither can these other bodies provide the same opportunity for public debate. Therefore, Congress should determine whether moral considerations preclude the patentability of recreational drugs.

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engage in an examination of morality, but patents are never denied on these grounds because the courts refuse to make morality decisions.

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108 *Ex parte Murphy*, 200 USPQ at 802 ("Or is utility negatived by the mere fact that the thing in question is sometimes injurious to morals, or to health, or to good order? [This] hypothesis cannot stand, because if it could, it would be fatal to patents for steam engines, dynamos, electric railroads, and indeed many of the noblest inventions of the nineteenth century. (And what of such things as automobiles, airplanes, power tools, explosives, lawn mowers, and drugs in the twentieth century?)").

109 EPC, Article 53(a) (cited in note 36).

110 See, for example, G. Liedl, H. Noth and G. Zeitler, *Draft Guidelines for Examination in the European Patent Office* 222 (1977) ("A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.").

111 See Debates at 22 (cited in note 72) (remarks of Mr. Bangemann).

112 Federalist 49 (Madison), in Clinton Rossiter, ed, *The Federalist Papers* 313, 316 (NAL Penguin, 1961) ("The nature of [the legislature's] public trust implies a personal influence among the people, and that they are more immediately the confidential guardians of the rights and liberties of the people.").

113 Id ("The [judiciary]; by mode of their appointment, as well as by the nature and permanency of it are far too removed from the people to share much in their prepossession. The . . . administration [of the executive] is always liable to be discolored and unpopular.").
C. Distinguishing Ethanol and Nicotine from Currently Illicit Drugs

Some may argue that once legalization legitimizes recreational drugs, the patent laws should treat alcohol, tobacco, and recreational drugs equally. It then follows that because alcohol and tobacco products are freely patentable, legal recreational drug products should be as well. On its face, this argument makes sense. Alcohol was once illegal in the United States and was legalized, just as currently illicit drugs would be upon legalization. Additionally, both ethanol and nicotine are physically and psychologically addictive chemical substances.

Nonetheless, two principal reasons explain why the patent laws should treat nicotine and alcohol differently than currently illegal recreational drugs. First, the designer-drug problem highlights a significant difference between ethanol and nicotine, and other recreational drugs: ethyl alcohol and nicotine are unique in the effects they produce. No non-toxic analogue of either compound will produce identical or even similar effects. Currently illegal recreational drugs, however, belong to large “families” of drugs: a simple shift of a carbon or hydrogen atom or a simple reaction can create an entirely new substance with similar physiological effects.

114 Although novel alcohol and tobacco products would be patentable, ethanol and nicotine themselves are not patentable because they are not novel under 35 USC § 102. See discussion at notes 55-56 and accompanying text.

115 Ethanol, or ethyl alcohol, has psychic dependence effects ranging from “missing the presence of alcohol at social functions” to being “so obsessed with obtaining alcohol that [the addict] will go to any lengths to do so and will drink whatever is available, even poisonous mixtures.” Physical dependence is evidenced by the statistic that 10 percent of all alcohol users are alcoholics. Withdrawal symptoms include common hangovers, convulsions, and hallucinations. Lingeman, Drugs from A to Z at 74 (cited in note 97).

116 Psychologically speaking, nicotine is very addictive. “One hallmark of an addicting substance is the fact that users seek it continuously, day after day[…] The typical pattern of nicotine use […] is not only daily, but hourly.” Edward M. Brecher, Licit and Illicit Drugs 223 (Little, Brown and Company, 1972) (emphasis in original). Although it was once commonly thought that nicotine was not physically addictive, symptoms such as nervousness, drowsiness, anxiety, cramps, insomnia, and palpitations occur upon withdrawal from nicotine use. Id at 225.

117 Alcoholics, when desperate for alcohol, will occasionally ingest methanol, isopropanol, and ethylene glycol if they cannot obtain ethanol. When ingested, or even applied to the skin, these substances can cause poisoning. Moreover, ingesting such substitutes is a popular method of committing suicide. Keith K. Burkhart and Kenneth W. Kulig, The Other Alcohols: Methanol, Ethylene Glycol, and Isopropanol, 8 Emergency Medicine Clinics of N Am Number 4 913, 913-14 (Nov 1990).

118 The very structure of drug statutes suggests the ease with which certain drugs can be “invented around.” See notes 42-44 and accompanying text. For example, crack, or rock cocaine, is produced by combining cocaine hydrochloride (powder cocaine) with water and
Because existing drugs and drug families are easily modifiable, the patentability of recreational drugs is particularly disturbing. Ease of modification, combined with the economic incentive to effect these modifications, would likely result in a flood of new products available to consumers. Nicotine and ethanol products do not present this concern because they cannot be modified in the same way. Therefore, nicotine and ethanol differ from recreational drugs due to the difference in public policy concerns.

Second, the psychological and physiological effects of these drugs are wildly different. Ethanol, in its myriad recreational forms, may be consumed occasionally and in moderation with few undesirable effects. In fact, ethanol use may yield some beneficial effects. While nicotine has "unpleasant side effects" to which a user must become accustomed before experiencing pleasurable effects, these effects are minimal. Both substances may act as tranquilizers, stimulants, or depressants.

On the other hand, neither drug is a narcotic or hallucinogen. Neither drug impairs mental acuity when taken in moderation. Neither one causes the "pseudo-hallucinations" of mescaline or peyote; the "stimulant-induced psychosis" of cocaine and amphetamines; the hallucinations of psilocybin, LSD, and other hallucinogens; or the psychotic episodes of sodium bicarbonate, thereby removing the hydrogen chloride group from the cocaine molecule and precipitating out the rock cocaine. See United States v Shaw, 936 F2d 412, 414 (9th Cir 1991). The resultant "crack" has a lower melting point and is therefore smokeable, allowing absorption of the narcotic into the bloodstream much faster than powder cocaine, which is generally snorted. Id.

Of course, to be patentable these compounds must pass the non-obviousness test of 35 USC § 103. See note 33 and accompanying text.

Brecher, Licit and Illicit Drugs at 245 (cited in note 116).

See, for example, Alcohol and Cold Risk, NY Times C14 (Oct 20, 1993) (reporting a study which shows that "alcohol may foster resistance to the common cold"); Dolores Kong, Study Cites Alcohol's Role in Lowering Heart Attack Risk, Boston Globe 3 (Dec 16, 1993) (reporting a study showing that drinking one to two drinks per day lowers the incidence of heart disease); Sharon Loh, Reconsider Age Limit, Straits Times 4 (Aug 4, 1993) (reporting a study showing that one to two drinks per day may benefit learning and reasoning skills in later life).

Brecher, Licit and Illicit Drugs at 224 (cited in note 116).

Id at 207, 245.

Gabriel G. Nahas, The Decline of Drugged Nations, as printed in Evans & Berent, For and Against at 247-48 (cited in note 5).

National Clearinghouse for Drug Abuse Information Report Series, Ser 15, No 1, Mescaline 7 (1973). Pseudo-hallucinations are alterations in a person's perception that the person realizes have no basis in reality. Id.

Redda, Cocaine, Marijuana, Designer Drugs at 76 (cited in note 42).

National Clearinghouse for Drug Abuse Information Report Series, Ser 16, No 1,
Neither is generally as instantly dangerous as cocaine, which is physically addictive on the first dose, or LSD, which can cause recurrence of the effects of a “trip,” or “flashbacks,” even after use is discontinued.

D. The Pharmaceutical Industry

1. The economics of the pharmaceutical industry.

In the United States, private industry produces most pharmaceutical innovations. Studies have shown that a company will undertake research and development (“R & D”) in the areas that it deems either most profitable or most likely to provide the highest return with the least investment. The pharmaceutical industry heavily depends upon patent protection to maintain its R & D incentives and profits. A 1986 study by Edwin Mansfield showed that in the early 1980s, 60 percent of pharmaceuticals developed and 65 percent of pharmaceuticals introduced in the United States would not have been developed or introduced in the absence of patent protection. Because disallowing patent protection for recreational drugs would significantly lower the profit margin from the development of new recreational drugs, denying this protection could decrease the number of new recreational drugs introduced into the marketplace.


129 Lingeman, Drugs from A to Z at 130 (cited in note 97).

130 From 1960 to 1969, 91 percent of all new drugs introduced in the United States were discovered and developed by private industry. Office of Technology Assessment, Patent-Term Extension and the Pharmaceutical Industry 16 (1981). The other 9 percent were the product of universities, non-profit enterprises, and governmental research.

131 Id at 18. The emphasis on profit is evidenced by the current lack of production of "orphan drugs"—those drugs that are medically important but financially unprofitable. See Carolyn H. Asbury, Orphan Drugs: Medical versus Market Value 2 (D.C. Heath and Co., 1985).


134 Office of Technology Assessment, Patent-Term Extension at 49 (cited in note 130) (“[R]esearch-intensive pharmaceutical firms consider patent protection as a prerequisite to innovation.”).
Upon legalization of recreational drugs, pharmaceutical companies would have great incentive to take the first step and enter the market, selling their own varieties of non-novel, and therefore unpatentable, currently available illicit substances. Because the two prerequisites of a good R & D prospect—high prospective demand and ability to create an innovative product—would be present in a legal recreational drug market, the second step would likely follow: assuming the availability of patent protection, the companies would develop their own new kinds of novel recreational drugs, thereby increasing the number of recreational drugs available.

If pharmaceutical companies were to create new addictive recreational drugs and people were to experiment with them, these companies would have an addicted group of consumers. The demand for these products would become "inelastic" because the consumer's desire for the item would not vary with the price of the good. While elastic demand causes demand to decrease as price increases, consumers of goods with an inelastic demand, such as addictive recreational drugs, would purchase the goods at almost any price.

Furthermore, patent protection creates an artificial monopoly that allows patentees to increase their price beyond marginal cost. Monopoly-inflated prices, combined with the addictive nature of recreational drugs, would possibly lead to the rebirth of a black market. Addicted consumers would seek the cheapest drugs possible, and they would purchase these drugs from illicit sellers if necessary. Because the black market can supply

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135 See generally Asbury, Orphan Drugs at 1-5 (cited in note 131).
136 See Nogués, Patents and Pharmaceutical Drugs at 11-14 (cited in note 132).
137 An example of this phenomenon was the explosion of Rubik's Cube variations and other hand-held puzzles developed after the original Rubik's Cube hit the market. See Mark Roman, Rubik's Cube: Ideal Toy Takes on the Knock-Offs, NY Times 3-21 (Oct 4, 1981); Andrew and Janet Gallant, Diversions; Perplexing Puzzles, Washington Post B5 (Dec 1, 1988).
138 Elkins, 32 BC L Rev at 578 (cited in note 90). But see Gary S. Becker and Kevin M. Murphy, A Theory of Rational Addiction, 96 J Pol Econ 675 (1988) (arguing that higher prices will prevent some people from starting to use drugs, so not all drug demand is inelastic).
139 Elkins, 32 BC L Rev at 578 (cited in note 90). See also Steven Wisotsky, Exposing the War on Cocaine: The Futility and Destructiveness of Prohibition, 1983 Wis L Rev 1305, 1395 (noting that demand for cocaine is likely to be inelastic).
140 Abbott, Developing a Framework at 318 (cited in note 26). Marginal cost is the cost of developing an additional unit of a good. Cooter and Ulen, Law and Economics at 32 (cited in note 26).
141 The black market would be different in this post-legalization world—the laws that the black market would violate would not be criminal drug laws but civil patent laws.
poorer quality products at lower prices, the black market could find a viable place in a world where recreational drugs are patentable.\textsuperscript{142}

Inelasticity of demand for recreational drugs concerns commentators who study patent policies for various countries. For example, in examining Canadian patent policy, Yehuda Kotowitz states:

The nature of demand in the [pharmaceutical] industry is different than in most industries... First, demand for many drugs may be highly inelastic allowing very high mark-ups over cost. The monopoly awarded by patent rights is therefore more valuable to the innovator and may lead to lower social benefits relative to the innovator's profits under certain circumstances. Patent policy must take account of this possibility.\textsuperscript{143}

In summary, if pharmaceutical companies could gain patents on recreational drugs in a post-legalization world, then they would have great incentive to develop highly addictive compounds in order to take advantage of the inelastic demand created by addicted consumers. Because the pharmaceutical industry depends on patent protection to justify large R & D expenditures, disallowing patents on recreational drugs would likely dampen pharmaceutical companies' enthusiasm for developing new substances.

2. Denying patent protection would further the goals of legalization.

Opening a new area of potentially lucrative research could increase the number of new drugs in the marketplace—a prospect we may not desire. Some legalizationists argue that if market forces were allowed to shape the recreational drug industry, then the new drugs developed would be safer than those available today; therefore, the incentive that patents provide would

\textsuperscript{142} Interestingly enough, the character of the black market would change drastically. Because it would be legal to purchase the drugs in stores, black market dealers would compete based on low prices, altering the drugs available in stores in order to make a profit. This possible universe radically differs from today's world, where chemical companies can produce illicit drugs for pennies, but where the black market sells them for exorbitant prices. Additionally, if the government were to place limits on who may purchase drugs, those individuals unable to obtain drugs legally, such as children, would purchase them on the black market.

\textsuperscript{143} Kotowitz, \textit{Issue in Patent Policy} at 18 (cited in note 26).
function as a public service.144 “Safer” drugs, however, are not necessarily better. The availability of a cleaner, faster, and higher “high” could transform America into the “nation of zombies” forecast by Senator D’Amato and the anti-legalizationists.145

The question becomes one of line drawing: for every research trail that leads to a safer drug, others might lead to more dangerous drugs. Patent incentives for recreational drugs would not distinguish between these two categories, nor would a researcher know beforehand whether the resulting drug would be more or less dangerous. Thus, the patent system inherently cannot promote “safer” drugs without also promoting more dangerous ones.146

Moreover, companies would be less inclined to develop physically non-addictive drugs than addictive drugs. In large part, a company’s incentive in the recreational drug market would be to create a permanent, necessity-based consumer demand for the product.147 Under a system in which recreational drugs were patentable, pharmaceutical companies would possess the only product in the market satisfying the particular need. Significantly, a monopoly in addictive drugs is far more useful than an ordinary patent monopoly: consumers, once addicted, cannot truly decide not to purchase the product. Pharmaceutical companies would have the incentive to create the most addictive drugs possible to gain the most financial benefit from their patents.

If recreational drugs were patentable in a post-legalization world, a new area of innovation would open in which chemists could experiment without fear of criminal sanction.148 The likely chain of events following legalization is clear: first, each pharma-

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144 See Bandow, 3 Stan L & Policy Rev at 247 (cited in note 14).
145 See note 15 and accompanying text.
146 Although the Food and Drug Administration could regulate dangerous recreational drugs, previous experience teaches that regulation based solely on FDA approval is usually expensive and time-consuming. See note 104.
147 Not all drugs currently available through the black market are physically addictive, although most are psychologically addictive, or habituating. For example, physically addictive drugs include sedatives (including barbiturates), narcotics (including heroin, morphine, and opium), select tranquilizers, and stimulants in large doses. Habituating drugs include marijuana, hashish, amphetamines, hallucinogens (including LSD, mescaline, psilocybin, and peyote), and cocaine. See Lingeman, Drugs From A to Z (cited in note 97).
148 This argument has been made in the context of anti-interdiction: if we completely eliminate foreign drug imports, “[s]ynthetic drugs would take over within two months.” In other words, creation of a market for synthetic drugs would certainly breed new synthetic drugs. See Bandow, 3 Stan L & Policy Rev at 247 (cited in note 14), quoting Report from the Field on an Endless War, NY Times E9 (Mar 12, 1989).
A pharmaceutical company would rush to market its own brand-name versions of the newly legalized drugs. Next, each company would funnel large amounts of time and money into its new "Recreational Drug Division," attempting to find a new class of compounds with better, faster, and cleaner highs and fewer side effects. Finally, as such drugs were discovered, they would be patented, tested, and marketed, finding their way into the mouths, noses, and veins of consumers everywhere.

Although pharmaceutical companies would not deserve blame simply for trying to make money, the question remains whether a world in which legalized recreational drugs are patentable is desirable. As companies began to spend money and time on recreational drug research, they would spend less time and money on more complicated, more time- and money-consuming, and less potentially lucrative research in areas such as cures for AIDS, Alzheimer's disease, and cancer. While it is unlikely that pharmaceutical companies would abandon such efforts entirely, it is likely that they would cut the riskiest, least-lucrative areas of their research budgets first in order to move more money to the profitable recreational drugs area. Pharmaceutical companies would not have the same incentive to spend great amounts of time and money to develop new drugs, however, if they could not gain patent protection for these products.

Thus, a world in which legalized drugs are patentable would not further the goals of legalization. Indeed, the result would be a world where drugs would be more addictive and less safe, where research on more socially beneficial drugs would suffer,

\[^{149}\text{The pharmaceutical industry is currently struggling with rising costs and decreasing profits resulting from the ever-increasing cost of developing a patentable drug and winning FDA approval. See John Carey, A Bitter Tonic For Drugmakers?, Business Week 84 (Mar 8, 1993). In 1991, to develop a new drug, test it, and market it in the United States cost approximately $245 million and took ten years. Jane H. Cutaia, 1992 Will Be Easy to Swallow, Business Week 102 (Jan 13, 1992). Given this exorbitant expense, it is logical that pharmaceutical companies could seek projects that give the greatest return on investment, such as recreational drugs.}\]

\[^{150}\text{In 1985, the FDA approved the drug isoprinosine for use on AIDS patients. The cost of compliance with FDA regulations was more than $2,000 per patient. This cost prevented the manufacturer from introducing the drug into the marketplace. Lisa C. Will, Accelerated FDA Approval of Investigational New Drugs: Hope for Seriously Ill Patients, 94 Dick L Rev 1037, 1046 (1990).}\]

\[^{151}\text{Such a phenomenon already exists in the area of "orphan drugs"—drugs with valid (and often very important) medical uses, but with little or no financial value to a drug company. See note 131 and accompanying text.}\]

\[^{152}\text{Stanley M. Besen, New Technologies and Intellectual Property: An Economic Analysis 7 (National Science Foundation, 1987). See notes 132-34 and accompanying text.}\]
and where a black market would still thrive. This Comment has asserted, however, that these ills are not the result of a legalization regime itself, but of patentability accompanying legalization. Thus, if Congress chooses to legalize recreational drugs, it should make them unpatentable.

CONCLUSION

Although legalization of purely recreational drugs may never become a reality in the United States, legalization legislation could be proposed in the near future. The speculative nature of the legalization debate, however, does not give the advocates and enemies of legalization license to ignore a serious question of the post-legalization world. The proponents of all sides in the recreational drug legalization debate have argued the issues for years; they should now examine the issue of patentability as a further obstacle to a legalization regime.

When deciding whether to legalize recreational drugs, Congress must consider the ramifications of patentability. If Congress, through legalization, truly wishes to strive for elimination of black markets, drug-related crime, and extremely high rates of addiction, especially among young people, then it must not provide the pharmaceutical industry with a powerful incentive to undermine these goals. Therefore, legalized recreational drugs should not be patentable.