Agricultural Biotechnology and the Law: Patents, Plant Patents, Plant Variety Certificates, and the Rise of Intellectual Property Rights in Biological Subject Matter

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> Man, as two handed manipulator. . . has projected himself outward upon his surroundings in a way impossible to other creatures... since the first ... man-ape hefted a stone in his hand ... [His] creations. . . ride in the skies and the sea's depths; he has hurled a great fragment of metal at the moon. . . he once feared. He holds the heat of suns within his hands. . . .
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> "Natural" is a magician's word. . .. Perbaps there may come to us in some . . . moment, a ghostly sense that an invisible doorway has opened. . . which, widening out, will take man beyond the nature he knows.
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> Loren Eisley, How natural is "natural,"11u! *Star Thrower,* pp. 282-283, 296,1977.
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> The atmosphere of the "Front": it was . . . from having plunged into that atmosphere. . . that I ceased to notice any break (if not any difference) between. . . "natural" and "artificial." . . . It was not merely that I [saw] the organic unity of the living membrane [that] is stretched like a film over the . . . surface of the star which holds us . . . [A)n ultimate envelope was. . . becom[ing] apparent to me. . . . This envelope was not only conscious but thinking. . . .
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> Pierre Teilhard de Chardin, The heart of matter, *The Heart of Matter,* pp. 31-32 (Rene Hague trans., 1978).

I. INTRODUCTION

When TeiIhard and Loren Eisley penned these words, humans stood at the threshold of a new era of biotechnology that bas taken him or her "beyond the nature that he knows" in a way perbaps no other technology has. Indeed, this most recent voyage-into the vast inner space of the cell's depths-epitomizes the ironic conception of our essential nature as artifice: A power to reshape the "natural" world. which itself is the product of nature.

In a broader sense, biotechnology bas been with us ever since farmers first began "artificially" selecting and breeding plants and animals, and bakers and brewers harnessed a microorganisms-yeast-in their craft [1]. Only in the last two decades. however. bas it been possible to operate directly on the heart of biological matter, transcending the reproductive barrier between species. and creating entirely new life forms that either would be impossible to bring about through breeding 01'would take many generations, and much trial and error, to develop [2].

As the other chapters in this book vividly detail. this development bas bad particular significance for agriculture. Indeed. the advent of recombinant DNA technology heralded a second. more radical Green Revolution of Plants. animals, and microorganisms engineered to defeat disease, pests,. and harsh conditions. or to yield more and better produce with reduced inputs. without the adverse effect on health and the environment associated with the rise of mechanization in the 1930s and agricultural chemistry in the 1950s [3].

Because of the enormous effort so often required to advance "science and the useful arts:' it is essential, if such advances are to be made, that inventors have some way of preventing others from unjustly reaping the fiuit of their labor. Intellectual property [4] law provides that mechanism by allowing those who can demonstrate true invention a temporary legal monopoly on its commercial exploitation (if not its very use) [5]. Not surprisingly, biotechnology companies, many of which have little capital beyond their know-how, consider intellectual property protection as the very "lifeblood" of their industry [6].

The patent law, however, was cast in the crucible of the Industrial Revolution. Biological matter did not fit comfortably into its categories. Substantial change was required to accommodate the major biotechnical advances that span this century-whether by legislative or judicial fiat or some combination of the two [7]. The recently completed process of adaptation was not easy. Legal change generally lagged years behind the major technical advances. It also was not without controversy. There bas been considerable political opposition. for example, to the most recent move to allow patents on genetically engineered animals [8]. In addition, extending full patent protection to living things, by some lights, poses a danger of overprotection by denying subsequent innovators the use of genetic material to make further advances, thereby robbing the storehouse of knowledge of "some of the basic tools of scientific and technological work" [9]. This concern contributed to the development of two rival approaches to protecting new plant varieties intemationally-patents and the somewhat less protective plant variety certificates [10].

The rest of this chapter describes in greater detail the evolution and current state of the three different forms of intellectual property rights that can be acquired in biological subject matter. with primary reference to U.S. law to illustrate the basic concepts. The United States is one of the only countries that offers all three, yet otherwise, it is fairly typical of the regimen that obtains in the 100-odd countries that have signed the long-awaited Uruguay Round Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) [11].

II. THE U.S. LEGAL REGIMEN

Under current law, it is possible to obtain a U.S. Patent on any sort of "artificial" life-from cells and plant parts to microorganisms. plants. and animals (except human beings) [12]. Indeed, the developer of a new plant variety may obtain either a patent, or a specialized plant patent. or a patent-like. "plant variety certificate." This scheme comports with the TRIPS Agreement, which allows, but does not require. member states to "exclude from patentability . . . plants and animals other than micro-organisms." as long as they "provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination

thereof" [13]. Before delving into the details of the three modes of protection, it is necessary to explain how this unusual complex of three overlapping statutes came to be. For to quote Oliver Wendell Holmes, "[u]pon this point, a page of history is worth a volume of logic" [14].

The basic patent statute is the Patent Act [15]. It was promptly enacted by the First Congress in 1790 pursuant to the provision of the U.S. Constitution that had included among the limited powers of the Federal Government the power "[t]o Promote the Progress of Science and the useful Arts, by securing for limited times to . . . Inventors the exclusive Right to their . . . Discoveries" [16]. The first section of the Patent Act—virtually unchanged since then—currently provides: "Whoever invents or discovers *any new* and *useful process, machine, manufacture, or composition of matter*, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title [17].

To qualify as an "invention," then, the subject matter claimed in a patent application must meet three basic requirements: Novelty ("new"), utility ("useful"), and subject matter eligibility ("process, machine, manufacture, or composition of matter"). For most applicants, the first requirement—establishing true invention—has always presented the biggest challenge in obtaining a patent. Applicants claiming biological subject matter, however, faced an insurmountable obstacle in establishing the very eligibility of their discoveries for patent protection. Until quite recently, the Patent and Trademark Office (PTO) [18] rejected out of hand any application that claimed a living thing—no matter how much human ingenuity might have been involved in causing it to occur.

This rule apparently originated in the 1889 decision of the Commissioner of Patents in the case of *Ex Parte Latimer* [19]. In that case, the patent applicant had claimed the fiber of the needle of the *Pinus australis* tree, whose uniquely desirable properties he claimed to have been first to "discover." The Commissioner approved the rejection of the Claim on the ground that the fiber was a "product of nature," not man, and thus was not a "discovery" in the patent law sense [20]. To hold otherwise, reasoned the Commissioner would mean "that patents might be obtained on the trees of the forest and the plants of the earth, which of course would be unreasonable and impossible" [21].

Because Mr. Latimer had claimed a naturally occurring plant part, the Commissioner in fact never addressed the difficult legal question whether "artificial" life might qualify as a "manufacture" or "composition of matter" and thus constitute eligible subject matter. Be that as it may, the *Latimer* decision came to stand for the broad proposition that one cannot patent a living thing.

The Supreme Court's landmark decision in *Diamond v. Chakrabarty* [22] finally changed all that in 1980. *Chakrabarty* involved an application claiming a genetically engineered microorganism with a unique ability to completely break down crude oil into compounds edible to aquatic life [23]. Such an organism was thought to be quite useful in cleaning up oil spills.

The Supreme Court noted the *Latimer* decision and its association with "the belief that plants, even those artificially bred, were products of nature for purposes of the patent law" [24]. The Court concluded, however, that the proper distinction was not "between living and inanimate things, but between products of nature, whether living or not, and human-made inventions" [25].

Chakrabarty thus cleared the way for patenting biological matter under the Patent Act. In its wake, the PTO extended its rule first to plants in *Ex Parte Hibberd*, [26] a 1985 case involving claims to new variety of maize genetically engineered for elevated tryptophan levels, and then to animals 2 years later [27].

Some 80 years before *Chakrabarty*, however, horticulturalists armed with the newly uncovered work of Gregor Mendel [28] had refined the technique of cross-pollinating selected plants

to produce offspring with distinctive characteristics and multiplying them asexually (i.e., by growing genetically identical individuals from cuttings) [29]. To obtain protection for such creations seemed to be foreclosed not only by the "product of nature" doctrine [30], but also by the inherent difficulty of verbally describing a new plant and how to produce it with the precision required by the Patent Act [31].

Horticultural interests appealed to Congress as early as 1906 for legislative change [32], but their efforts did not succeed until a quarter century later with the enactment of the Plant Patent Act of 1930 (PPA) [33]. The object of the PPA was to place agriculture on an equal footing with industry by giving plant inventors the *full* measure of protection that industrial inventors had always enjoyed [34]. Accordingly, Congress did not enact a free-standing statute, but rather, "[e]ngrafted" three short sections "onto the basic patent law," the provisions of which otherwise were to apply equally to plants [35]. The first section established the subject matter eligibility of "any distinct and new variety of plant" that was successfully reproduced asexually [36]. The second relaxed the "written description" requirement for such subject matter (and limited applicants to one claim per patent) [37]. The third defined infringement as the "asexual [ ] reproduc[tion]" of a patented plant or the "selling or using the plant so reproduced" [38]. Conspicuously absent was any modification of the scope of the patent monopoly to accommodate what we now call "breeders' rights." Again, the idea was to treat agricultural and industrial innovators equally.

The reason for the exclusion of sexually reproducible new plant varieties from the PPA's coverage is historical. In 1930, it was not yet practicable to sexually reproduce a new and distinct plant derived by breeding without losing its distinctive characteristics in subsequent generations [39]. The limited protection afforded under the PPA became inadequate by the 1950s when it became practicable to "stabilize" new and distinct varieties and reproduce them sexually [40].

At about the same time, momentum was building in Europe to establish an international convention to govern plant variety protection [41]. States who joined the convention would modify their national law as necessary to conform to its rules, in exchange for the reciprocal benefit of guaranteeing to their nationals in other member states [42]. This movement culminated in the creation of the Union for the Protection of New Varieties of Plants (known by its French acronym "UPOV") in 1957 [43], and the promulgation of the International Convention for the Protection of New Varieties of Plants (the UPOV Convention) in 1961 [44].

The authors of the UPOV Convention confronted an extremely uneven international landscape that proved quite difficult to smooth out politically [45]. In the end, it reflected a basic compromise between countries that had extended patent protection to plants [46] and those that had adopted so-called "breeders' rights" statutes [47]. These statutes created an exclusive and entirely separate system of plant variety protection that was administered by agricultural ministries and, more importantly, permitted a range of activities that would be considered infringing under a patent. To compound the problem, some countries had adopted breeders' rights statutes *and* allowed general, "utility" patents on plants [48].

In 1960, the Group of Legal Experts tasked with recommending a model convention reflected the prevailing European view, which favored the more limited degree of protection afforded by the breeders' rights statutes. But faced with the political reality of competing systems, the experts fell short of insisting that patents no longer be available for plants. They allowed that the idea of patenting plants was "not absolutely impossible" because the patent laws could be revised to guarantee breeders' rights [49].

The final wording of the UPOV Convention, however, did not clearly require such revisions. It allowed signatory states to offer both patents and variety certificates on plants, provided only that they did not allow both for the same botanical genus or species [50].

Nevertheless, even this relatively modest intrusion into national patent systems proved too much for countries such as Japan and the United States. They would not join the UPOV until the convention was revised *mutatis mutandis* [51] in 1978 to allow their accession [52].

Although the United States did not join the UPOV Convention until 1981 [53], it did not wait until then to cover the gap in U.S. intellectual property law that had developed by the 1950s with the advent of sexually reproducible varieties. Indeed, as early as 1966, an independent commission convened by the president to consider possible reforms to the patent laws actually recommended repealing the PPA in favor of an exclusive plant variety protection system modeled on the UPOV breeders' rights paradigm [54]. The bill introduced in Congress the next year to implement these recommendations, however, dropped the idea of repealing the PPA in order to enhance its prospects for passage—and even that half-measure failed [55]. The American Seed Trade Association subsequently drafted a similar measure, which 3 years later was enacted as the Plant Variety Protection Act of 1970 (PVPA) [56].

The United States thus replicated internally the conflict between patent and breeders' rights that confounded the UPOV Conference. One could patent an asexually reproducible new variety under the PPA—and after 1985, any sort of variety under the Patent Act—and thus bar virtually any use of the variety or its genetic material even though the PVPA purported to provide breeders and farmers with a safe harbor to carry on their traditional practices [57]. As a practical matter, however, the conflict between patent and breeders' rights is not as extensive as it seems, for as the following discussion suggests, it is rather difficult to claim a new plant variety successfully under the Patent Act because of its "inventive step" and "written description" requirements [58]. It is to these requirements that this chapter now turns.

A. The Requirements of Novelty, Utility, and Disclosure Under the Patent Act

An applicant for utility patent protection must, above all, prove that the subject matter claimed is worthy of the name "inventive" or "discovery" [59]. In a word, that means that the thing or process claimed must be "new" [60]. Newness, however, has come to have two distinct aspects—novelty" and "nonobviousness" ("inventive step" in European parlance). These concepts, which are defined in the second and third sections of the Patent Act [61], respectively, are also reflected in the TRIPS Agreement [62].

Generally speaking, a claimed invention is said to lack novelty if the exact same thing or process already exists in the public domain (although if the inventor himself put it there, he has a year to file a patent application) [63]. This is determined by comparing the language of the claims by which the applicant has described his or her invention [64] with the "prior art" in the field, which includes everything from earlier patents to papers published in scientific or technical journals [65]. If the claim language more or less perfectly describes a single piece of prior art, the claimed invention is said to have been "anticipated" and thus lack novelty under the second section of the Patent Act [66].

The term *novelty* is somewhat misleading, however, because a claimed invention also must be new in the sense that it does not represent an "obvious" combination of elements from several prior inventions [67]. The test is whether all of the significant elements of the invention can be found in the prior art [68] and, if so, whether the hypothetical "person of ordinary skill in the art" would have some "reason, suggestion, or motivation" to combine them [69].

The "nonobviousness" requirement is probably the most common stumbling block for patent applicants [70], and it poses unique challenges to applicants claiming biotechnology [71]. Indeed, because the development of new plant varieties through conventional-breeding techniques does not really involve an inventive step, as a practical matter, protection for such

creations may be available only under the PVPA, which eliminate the nonobviousness concept and require only novelty for this reason.

The last of the three basic requirements of patentability—in addition to subject matter eligibility and novelty or nonobviousness—is that the claimed invention must be "useful" [72]. Similar to the eligible subject matter requirement, most inventors have little difficulty in satisfying the utility requirement. It is not particularly strict, mainly because applicants can be expected not to claim useless things. It is enough that a claimed invention has some apparent, lawful use—however slight—in the "useful arts" [73] (as opposed to the liberal arts, fine arts, or pure science) [74].

Again, however, biotechnology has been somewhat of an exception to the rule. Applications that assert no use beyond laboratory research, for example, may be rejected on the ground that the invention falls within the ambit of pure science (or lacks "substantial" utility [75], whereas those who assert a utility in curing a putatively "incurable" disease (such as cancer or AIDS) may be deemed inherently incredible absent proof to the contrary. Recent judicial decisions finally have adopted a more relaxed stance, however [76].

In addition to the three requirements of patentability, the Patent Act also places on the applicant the burden of making a full disclosure of the claimed invention and how to make it in exchange for a legal monopoly on its exploitation [77]. This serves two purposes. First, it assures that the *de jure* monopoly will not be extended *de facto* beyond its term (which is now 20 years from the date the application is filed) [78] by assuring that commercial rivals will be "enabled" to enter the marketplace immediately and drive prices down to competitive levels. Second, it assures that the knowledge and insights embodied in the invention become part of the public domain as soon as the patent issues, thus facilitating further invention as well.

To these ends, the Patent Act provides that each application must "contain a *written description* of the invention, and the manner and process of making and using it, in such *clear and full, clear, concise, and exact* terms as to *enable* any person skilled in the art . . . to make and use" it. In addition to enabling others to "practice" the invention, the written description requirement also assures that the claims are sufficiently "definite" to fairly apprise the world of the boundaries of the intellectual property [79].

The "definiteness" and especially the "enablement" aspects of the "written description" requirement, if literally enforced, would impose a nearly insurmountable obstacle to biological inventors because of the inherent difficulty of verbally describing a new plant variety and how to make it. The PTO and the courts, however, have construed the Patent Act to require only a reasonable description of the new plant variety and to allow an alternative procedure by which applicants may deposit the biological material necessary to make the invention in a public repository [80].

8. The Nature and Scope of Rights Conferred By a Patent

A patent gives its owner a "right to exclude" others from the intellectual property staked out by the claims [81]. Specifically, a patent entitles its owner to sue in federal court [82] to stop anyone who, without permission, "make[s], use[s], or sell[s]" a thing or process that "infringes" the patent monopoly or be compensated monetarily [83].

A thing or process can infringe a patent in two ways: either "literally" or under the "doctrine of equivalents." Literal infringement means that a thing or process is more or less perfectly described by the words of the patent claims, properly interpreted [84]. The doctrine of equivalents, by contrast, is rooted in the ancient legal principle, traceable through the civil law tradition back to Aristotle, that a thing may be within the ambit of a legal text if it is within its spirit, even if it is not within its letter (and vice versa). The test for infringement by equiva-

lence is whether the accused thing or process performs substantially the same function in substantially the same way to achieve substantially the same result as the thing or process described by the claims [85]. Pointing to an insignificant difference between the claimed invention and the accused thing or process will not do. To avoid infringement, then, one must steer clear of not only the literal terms of the claims, but also the fuzzy zone of equivalents that lies at the periphery of the claims.

There is one final thing worth noting about the nature and scope of patent protection. Some patents are "invalid" (meaning the applicant did not in fact meet all the statutory requirements), and even valid patents may be "unenforceable" in court. The validity of a patent under the statutory criteria is subject to challenge either by asking the PTO to reconsider its decision to issue the patent [86] or as a defense in the context of an infringement suit [87]. In other words, an accused infringer can escape liability either by denying infringement [88], or by establishing, say, that the claimed invention lacks novelty or that the written description is inadequate [89]. And even if a patent is valid, an accused infringer still may be able to escape liability by offering evidence that some "inequitable conduct" has tainted the patent, as when the applicant withheld important prior art from the PTO and thus cannot "in equity" enforce his "legal" rights under the patent [90].

C. The PVPA Compared and Contrasted with the PPPA and the Patent Act

The nature and scope of protection available under the three statutes and the requirements for securing such protection are similar, but significant differences exist on both scores.

1. Nature and Scope of Protection

The PVPA contains four provisions that exempt activities generally considered infringing under the patent statutes. First, in the *breeders' exemption*, the PVPA permits unlicensed use and reproduction of protected varieties "for plant breeding or other bona fide research," including the development of other new varieties [91]. Second, the PVPA exempts any otherwise infringing activity from its prohibition as long as it is "done privately and for noncommercial purposes" [92]. Neither the Patent Act nor the PPA, by contrast, contain any express, general exemption for research or private use. And although the courts have recognized an implied exception for such uses, it is relatively narrow, allowing at most a *purely* "experimental" or *de minimis* use of a patented invention. Research conducted with a view toward eventual commercial development is not allowed [93]. The remaining exemptions in the PVPA—the *farmers' exemption* [94] and the *crop* exemption [95]—are a bit more complicated.

The farmers' exemption allows farmers (if they are not in the seed business themselves), to replant their fields with seed produced by plants grown in earlier years from protected seed [96]. It even used to allow such farmers to sell this "saved seed" to other farmers in lieu of replanting their own fields (as long as the other farmers were not in the seed business either).

In a 1995 decision, *Asgrow Seed Co. v. Winterboer* [97], the Supreme Court resolved an ambiguity concerning what limit, if any, the PVPA placed on the quantity of saved seed one farmer might sell to another under the farmers' exemption. The court ruled that the farmers' exemption impliedly limits the quantity a farmer may sell to no more than what he could have planted on his own land. This closed what otherwise could have become a rather large loophole—particularly for plants, such as the soybeans involved in *Asgrow Seed*, that produce

vast quantities of seed. Shortly before the court rendered is decision in *Asgrow Seed*, Congress amended the PVPA to bring it into line with the revised, 1991 UPOV Convention. These amendments narrowed the farmers' exemption even further, requiring farmers to secure the permission of the certificate holder before making any "brown bag" sales [98].

Under the crop exemption, a farmer may sell saved seed to anyone, in any quantity, as long as it is used for "nonreproductive purposes" such as food, animal feed, or producing industrial products, such as oil or ethanol [99].

The second major difference in the protective scope of the three statutes lies in the definition of infringement. Although the two patent statutes both define infringement in general terms as the "mak[ing], us[ing], or sell[ing]" of an infringing article [100], the PVPA is much more specific.

Relative to making, the PVPA's prohibition is limited to reproduction by seed or tuber [101]. On the other hand, it is deemed an infringement to commit any of the other acts listed—such as selling—even if the plants involved were "made" by asexual reproduction [102]. For using, the PVPA narrowed the definition to include only the use of a protected variety "in producing (as distinguished from developing) a hybrid or different variety therefrom" [103]. The PVPA also expressly expanded the concept of "sell[ing]" to include any sort of transaction—i.e., "market[ing]," "buy[ing]," and "exchang[ing]" [104]. The PVPA also added "import[ation]" and "exportation" [105], as well as the "condition[ing]" and "stock[ing]" of protected varieties, to the trilogy of infringing acts [106].

As for the temporal scope of the monopoly, the term of both patents and plant variety certificates is the same 20 years), except that trees and vines receive an extra 5 years worth of protection under the latter [107]. However, the clock starts running on a patent the day the application is filed, whereas the term of a plant variety certificate is still measured from the date of issue. Because that could be some time after filing, the effective term of a given plant variety certificate may be more than 20 (or 25) years.

2. *Requirements for Securing Protection*

The plant-specific statutes relax the basic requirements for securing protection under the Patent Act in four principal ways. For "newness," as indicated in the foregoing, Congress eliminated the nonobviousness requirement. Congress also eliminated the utility requirement in the plant-specific statutes.

Under the PPA, an applicant need demonstrate that its asexually reproduced variety is "new and distinct" [108]. The PVPA further requires, for the sexually reproducible varieties that are the subject of its protection, that applicants to show that the claimed variety is "stable" and "uniform" [109]. The PVPA also defines these terms with great precision [110].

For "novelty" or "anticipation," inventors under both patent statutes are held to the same standard [111]. The problem of self-anticipation by the inventor has less of a bite, however, when applied to plant patents. This is because only *enabling* disclosures count for such purposes, and it is often quite difficult, if not impossible, to recreate a plant invention without seeds or cuttings, no matter how detailed the written or pictographic description of the plant and breeding procedure might be [112].

The PVPA is both specific and more relaxed than the PPA. It expressly provides that the presence of a variety in a printed publication makes it an anticipating "public variety" [113]. And in the 1994 amendments, Congress eliminated the concept of self-anticipation by deleting the second part of the "public variety" bar which, similar to the second part of the analogous provision of the patent law [114], had required applicants who publicly disclosed a new variety in a printed publication to file for protection within a year or be barred [115].

For "written description," the PPA requires only that "the description [be] as complete as is reasonably possible" [116]. The Court of Customs and Patent Appeals [117] interpreted this to mean "that there is no requirement for a how-to-make [i.e., enabling] disclosure in a plant patent application" [118]. At the same time, the court underscored that the applicant must make a reasonable effort to describe the new variety, affirming the PTO's rejection of an application claiming a new variety of Bermuda Grass where "the characteristics chosen to define the new plant [were] meaningless unless compared with predecessor plant varieties" [119]. In such cases, "it is incumbent upon the applicant to provide information of such a character that a meaningful comparison can be made" [120].

Similar to the PPA, the PVPA provides only that an application must contain a "description of the variety setting forth its distinctness, uniformity, and stability and a description of the genealogy and breeding procedure, when known" [121]. It then expressly recognizes what was insinuated into the patent law by judicial decision—that "photographs or drawings or plant specimens" may be used to address any definiteness concerns. Indeed, unlike the PPA, but like the Patent Act, the PVPA requires an enabling disclosure. The applicant must deposit "a viable sample of basic seed, including any propagating material, necessary for propagation . . . in a public repository" [122].

3. *Claiming Agricultural Biotechnology Under the Patent Act*

To show how the rules discussed in the foregoing are applied in particular cases, the balance of this chapter surveys the few recent published decisions involving efforts to patent agricultural biotechnology under the most challenging and protective of the three statutes—the Patent Act.

The first is a 1992 decision involving an application claiming "a method of combatting plant insect pests" by "applying to the plant environment or plant seed plant-colonizing bacteria" containing DNA that encodes for a protein toxic to insects, but harmless to humans [123]. This and inventions like it promise to reduce reliance on chemical insecticides and the attendant risks to health and the environment.

The patent examiner rejected the application on the ground that it was obvious in view of the prior art. The Board of Patent Appeals and Interferences (which reviews initial decisions made by examiners) disagreed. After "carefully review[ing] all the references cited by the examiner in their entirety," the Board was "unable to find a suggestion therein to do what [the applicants had] done, namely incorporate the gene into the chromosome of bacteria capable of proliferating in the plant environment and applying that bacteria to the environment or seed of the plant" [124].

A year later, in 1993, the board had occasion to address an application claiming a "recombinant DNA molecule" with a "DNA sequence encoding a polypeptide displaying the biological activity of swine growth hormone" and a method for producing this polypeptide [125]. Identifying the gene for swine growth hormone allowed the manufacture of a synthetic hormone that could be used to make larger pigs—a use that had been "limited since extracting swine growth hormone from pituitary glands of swine [had not been] adequate to provide the needed commercial quantities."

This time the board agreed with the examiner that in view of what was known about human, bovine, and rat growth hormones—including the high degree of similarity between them—it would have been obvious to a person of ordinary skill in the art to identify the swine growth hormone gene. Although the application was thus rejected, a recent court decision in a similar case disagreed that the state of the biotechnological art generally was advanced enough at that time to permit a person of ordinary skill to find a gene if given a partial or even an entire DNA sequence [126].

Despite the availability of specialized protection under the PPA and the PVPA, the list of agriculture-related inventions patented under the Patent Act includes plants too, for as the board has noted, some plant inventors view the various exemptions in the PVPA, as well as the PPA's limitation to asexual reproduction, as "loopholes" [127]. However, although the utility requirement is easily satisfied, and even definiteness and enablement problems may be avoided with little difficulty, the nonobviousness requirement remains a formidable obstacle to obtaining a patent on plants developed through conventional breeding.

This can be seen in another recent case involving an application claiming a new variety of soybean with greater yield and resistance to root rot than existing varieties. The patent examiner rejected the application on enablement grounds because its description of how to make the invention—by crossing two varieties—omitted "significant information about the breeding process, the selection pressures for disease resistance," and so forth. The "language used ... was so indefinite that one skilled in the art [would be] unable to identify that plant variety and distinguish it from other varieties."

On appeal, the board disagreed on both points. First, the board noted that the applicant had offered to make the seeds of his new variety publicly available by placing them in the depository of the American Type Culture Collection. This cured what otherwise might have been a failure to satisfy the enablement requirement. Second, the board seemed to be relaxing the written description requirement along the lines of the PPA and the PVPA. It was enough that an application "sets forth a reasonable description of the characteristics of the seed and plant including, flower color, plant type, maturity group, bacterial resistance, nematode resistance," and the like.

The board concluded from evidence put forward by the applicant that such a description "is accepted by the art as descriptive of the characteristics of a soybean variety." Nevertheless, the board ultimately upheld the examiner's rejection on the ground that it would have been obvious in view of the prior art to achieve rot resistance by crossing a certain prior art plant with rot-resistant varieties and the degree of resistance that the applicant had achieved was not so unexpected that there was no motivation or suggestion to combine. In another case decided about the same time, an applicant unsuccessfully sought protection for a cotton cultivar the applicant claimed "possesse[d] the okra leaf character in combination with a high yield, high ginning out turn, good quality fiber and with resistance to 19 common races of the wide spread disease, bacterial blight" [128]. Once again, the nonobviousness requirement proved to be the rub. New plant varieties developed through genetic engineering, rather than conventional breeding, however, would seem to be less somewhat likely to run afoul the nonobviousness requirement because a true inventive step may well be involved in the engineering.

III. CONCLUSION

The differences between the three modes of protection outlined in this brief survey are significant and must be carefully considered by plant variety developers. For although one may protect a new variety under either the Patent Act or one of the plant-specific statutes (depending on whether the variety is sexually reproducible or not), that is not to say that one may protect the *same* variety under both a utility patent and a plant-specific title of protection. There is a judge-made rule against "double patenting"—that is, obtaining two patents on the same invention or an additional patent on an obvious variation first (unless the additional patent is limited to the term of the first patent) [129]. Under this rule, one cannot obtain both a utility patent and a plant patent on the same variety. The courts have yet to decide whether this rule applies equally to plant variety certificates. It is also not entirely clear how they would.

because the difference in the scope of protection patents and variety certificates is sufficiently different to be considered as distinguishing from double-patenting [130].

NOTES

1. See Note, Elizabeth Joy Hecht, *Beyond Animal Legal Defense Fund v. Quigg: The Controversy Over Transgenic Animal Patents Continues*, 41 Am. U. L. Rev. 1023, 1026–27 (1992); Reid G. Adler, *Controlling the Applications of Biotechnology: A Critical Analysis of the Proposed Moratorium on Animal Patenting*, 1 Harv. J. L. & Tech. 1, 2, and n. 3, 20 and nn.122–25 (1988).

   Biotechnology has its origins in the mid-19 century, when Charles Darwin identified natural selection as the evolutionary mechanism in his seminal work *On the Origin of Species* (1850). Gregor Mendel independently discovered the role of genetics in such selection with his pea experiments in 1865 (although that knowledge did not come to light until 1900). Adler, *supra*, at 22 and n.142. In 1869, Miescher discovered deoxyribonucleic acid (DNA) which, in 1944, was identified as the medium of genetic communication. The stage was finally set for the biotechnological revolution when, in 1953, Crick and Watson discovered the structure of DNA. *Id.* at 22 & n.146. The secrets of the genetic code were thus unlocked.
2. Reid G. Adler, *Can Patents Coexist with Breeders' Rights? Developments in U.S. and International Biotechnology Law*, 1986 Int. Rev. Ind. Propr. Copyright L. 195, 207 and n.80 (reprinted with permission from the Max-Planck Inst., Munich, Germany). The terms *biotechnology*, *genetic engineering*, and *recombinant DNA technology* denote the process of identifying the gene sequence thought to cause the expression of a particular trait in an organism, splicing together that sequence (perhaps using material from other species), and microinjecting or otherwise introducing the composite gene into an embryonic organism then develops the trait as it matures and contributes the gene in the creation of offspring. *See* Adler, *supra* note 1, at 2 n.3, 5 n.19; *see also* Hecht, *supra* note 1, at 1024–28 and nn.4, 13–17. This technique was first practiced successfully in microorganisms in 1974, and in plants and animals in 1982. Adler, *supra* note 1, at 3–4.
3. *See* Adler, *supra* note 1, at 19–20 and nn.113–18; *see also* U.S. House Report No. 699, 103d Cong., 2d Sess. 9 (1994) (accompanying the 1994 amendments to the Plant Variety Protection Act (PVPA)), *reprinted in* 1994 U.S. Code, Cong. Admin. News 2423 [hereinafter] "House Report"] (emphasizing the genetic security and environmental benefits of stimulating plant variety development through intellectual property protection).
4. "Industrial property" in European parlance.
5. For a more detailed statement of the rationale behind intellectual property protection, see, e.g., *In re* LeGrice, 301 F. 2d 929, 934–35 (C. C. P. A. 1962); Adler, *supra* note 1, at 220–22.
6. Steven Holtzman, CEO of Embryogen Corporation, *quoted in* Gladwell, *Mouse Patent May Bolster Research Efforts*, The Washington Post, Apr. 13, 1988, at F1.
7. *See, e.g.*, Thomas Zeleny, *Property Rights in Living Things: Difficulties with Reproduction and Infringement*, 2 San Diego Justice J. 209 (1994); Margaret J. Lane, *Patenting Life: Responses of Patent Offices in the U.S. and Abroad*, 32 Jurimetrics J. 89 (1991) (discussing the inherent difficulties of meeting traditional patent criteria with claims to organisms); Marsha L. Montgomery, Note, *Building a Better Mouse—And Patenting It: Altering the Patent Law to Accommodate Multicellular Organisms*, 41 Case W. Res. L. Rev. 231 (1990); JoAnne E. Seibold, *Can Chakrabarty Survive the Harvard Mouse?*, 2 U. Fla. J. L. Public Policy 81, 90–93 (1989) (same).
8. *See Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991) (dismissing suit by animal rights activists challenging policy allowing animal patenting invalid on procedural grounds). *See generally* Hecht, *supra* note 1; Adler, *supra* note 1; *id.* at 5–8 (summarizing the arguments of the animal rights movement relative to animal patenting).
9. *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (citing *Funk Bros. Seed Co. v. Kalo Innoculant Co.*, 333 U.S. 127 (1948)) (discussed *infra* note 24).
10. *See generally* Adler, *supra* note 2; Thomas E. Jurgensen, *Of Plants, Patents, and Breeder's Rights: Some Proposals for International Unification of Proprietary Protection of Plant Biotechnology*, 12 J. Agric. Tax. L. 291 (1991).
11. *Done* Apr. 15, 1994, ch. 5 (patents), *reprinted in* 1 Law & Practice of the World Trade Organization annex 1C (Joseph F. Dennin ed., 1995).

12. This one remaining prohibition is technically based on the Thirteenth Amendment to the U.S Constitution, which outlawed slavery in the wake of the Civil War.
13. TRAIP Agreement, *supra* note 11, art. 27(3)(b).
14. *New York Trust Co. v. Eisner*, 256 U.S. 345, 349 (1921).
15. 35 U.S.C. §§ 101 *et seq.* (1994).
16. U.S. Const. art. I, § 8, cl. 8.
17. 35 U.S.C. § 101 (emphasis added); *accord* TRIPS Agreement, *supra* note 11, art. 27 and n.5 ("patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application"; "inventive step" and "capable of industrial application" are synonymous with the terms "nonobvious" and "useful").
18. The PTO is the agency Congress established to administer the patent law, subject to judicial review. Congress created a specialized court, the Court of Customs and Patent Appeals (CCPA), in 1929 to conduct review in these technically complex cases. *See generally* The Honorable Giles S. Rich, A Brief History of the Court of Customs and Patent Appeals (1980).

    In 1982, Congress merged the CCPA and another specialized tribunal, the Court of Claims, into a single court—the U.S. Court of Appeals for the Federal Circuit. Congress also expanded the patent jurisdiction of the new court to include appeals from all U.S. District Courts in patent infringement suits. That jurisdiction had been committed to the various regional courts of appeals. It was hoped that creating a single court to hear all patent-based cases would cure the serious conflict of law that had developed between the regional circuits. *See* Federal Courts Improvement Act of 1982, Pub. L. No. 97–164, § 402, 96 Stat. 37; S. Rep. No. 275, 97th Cong., 2d Sess. 3–6, *reprinted in* 1982 U.S. Code, Cong. & Admin. News 11, 13–16, Titanium Metals Corp. v. Banner, 778 F.2d 775, 779 (Fed. Cir. 1985).
19. 1889 Dec. Comm'r Pat. 123, *quoted in Diamond v. Chakrabarty*, 447 U.S. 303, 311 (1980).
20. *See id.* at 125.
21. *Id.*
22. 447 U. S. 303 (1980), *aff'g* 596 F. 2d 952 (C. C. P. A. 1979).
23. *See* 596 F. 2d at 968–69.
24. 447 U. S. at 311. An earlier Supreme Court itself had contributed to this belief in a case involving agricultural biotechnology. The applicant in *Funk Bros. Seed Co. v. Kalo Innoculant Co.*, 333 U. S. 127 (1948), had discovered a way of making an innoculant of nitrogen-fixing bacteria from the genus *Rhizobium* that was effective on a multiplicity of different plant types. This had not been possible before, because the presence of different species of the bacteria—each of which was effective on only one type of plant—generally inhibited nitrogen-fixing activity. The applicant overcame this obstacle by identifying certain strains of each species that could be successfully mixed together.

    The Court concluded that the PTO had properly rejected the application after observing that the inhibitory qualities of the bacteria "are the work of nature," and "the discovery of [such] phenomena" is not patentable. *Id.* at 130. The Court's conclusion seems to be a *Latimer*-esque nonsequitur, however, because the applicant had claimed an artificial agglomeration of natural phenomena that clearly could be considered, as a matter of ordinary English, a biological "composition of matter."
25. 447 U.S. at 313.
26. 227 USPQ (BNA) 443 (Bd. Pat. App. & Interf. 1985).
27. *Ex Parte* Allen, 2 USPQ2d (BNA) 1425 (Bd. Pat. App. & Interf. 1987) (allowing claim to a genetically-engineered polyploid oyster), *aff'd without published op.*, 846 F.2d 77 (Fed. Cir. 1988). The first patent actually granted on a multicellular animal was the famed "Harvard Mouse" Patent, U.S. Patent No. 4, 736,866 (1988), which claimed any nonhuman mammal, such as a mouse, genetically engineered in the prescribed manner to increase its susceptibility to cancer).

    For a discussion of the moral, legal, and political issues that extending patent protection to animals has raised, see Adler, *supra* note 1; Hecht, *supra* note 1. For more on the "product of nature" doctrine, *Chakrabarty*, *Hibberd*, and *Allen*, see 1 Donald S. Chisum, Patents: A Treatise on the Law of Patentability, Validity and Infringement § 1.02[7] (1985 & Supp. 1994), and the writings collected therein.
28. *See supra* note 1.

29. *See* Adler, *supra* note 2, at 197; *see also In re* LeGrice, 301 F. 2d 929, 937–38 (C. C. P. A. 1962) (describing the use of this technique in breeding roses).
30. *See Chakrabarty*, 447 U.S. at 311 & n.8.
31. *See id.* at 312.
32. *See Chakrabarty*, 596 F.2d at 982–83 & n.18.
33. 35 U.S.C. §§ 161–164 (1994).
34. *See In re* LeGrice, 301 F.2d 929, 932–33 (C.C.P.A. 1962) (citing the legislative history of the PPA in a case involving a rose plant patent).
35. *Id.* at 944.
36. 35 U.S.C. § 161.
37. *Id.* § 162.
38. *Id.* § 163.
39. *See Chakrabarty*, 447 U.S. at 312; *see also LeGrice*, 301 F.2d at 937–38 ("because of the infinite number of possible combinations between genes and chromosomes," "the actual creation of a new plant . . . is not subject to controlled reproduction"); 35 U.S.C. § 161 (defining "new variety of plant" as a legion of clones—"whoever invents or discovers *and asexually reproduces*" a "distinct and new" individual gets "variety" protection).
40. *See* Adler, *supra* note 2, at 198.
41. *See id.* at 198, 210.
42. *See generally id.* at 211–12 (explaining the difference between reciprocal rights and "national" treatment); 7 U.S.C. § 2403 (1994) ("nationals of a foreign state in which they are domiciled shall be entitled to so much of the protection here afforded as is afforded by said foreign state to nationals of the United States for the same genus and species. House Report, *supra* note 3, at 9.
43. *See id.* at 198 & nn. 22–23.
44. *See id.* The treaty entered into force in 1968, and its original signatories were France, The Federal Republic of Germany, Belgium, and Holland. It has been amended three times—in 1972, 1978, and 1991, and currently has 25 members. Thirteen of them (including the United States) have signed the revised 1991 version.
45. *See generally id.* at 212.
46. *See id.* at 210 (Italy and Sweden under general patent statutes; the United States and South Africa under plant patent statutes).
47. *See id.* (Czechoslovakia, Austria, and Holland).
48. *Id.* (France and the Federal Republic).
49. *See id.* at 211; *see also id.* at 213 & n.106 (quoting UPOV Article 5[3] [breeders "shall" be allowed to use protected material in developing other varieties and marketing them, but cannot repeatedly use protected material to produce a new variety commercially]).
50. *See id.* at 208 n. 83 and 210–12 (quoting UPOV Article 2).
51. "The necessary changes having been made."
52. *See* Adler, *supra* note 2, at 209 & n.90. In 1994, Congress amended the PVPA "to make such Act consistent" with the 1991 revisions to the UPOV Convention. The PVPA Amendments Act of 1994, Pub. L. No. 103–349, 108 Stat. 3136; *see* House Report, *supra* note 3, at 7–8.
53. *See* House Report, *supra* note 3, at 9.
54. *See id.*
55. *See* Adler, *supra* note 2, at 198–99.
56. 7 U.S.C. §§ 2401–2582 (1994).
57. For a more expansive analysis of this tension, see Adler, *supra* note 2, at 196, 201–15.
58. *See id.* at 207.
59. 35 U.S.C. §§ 101.
60. *Id.*
61. *Id.* §§ 102–103.
62. *Supra* note 11, art. 27 (quoted above in the text accompanying note 13).
63. *See id.* § 102(a) (patent not available if "the invention was known or used *by others* in this country, or patented or described in a printed publication in this or a foreign country, *before* the invention thereof *by the applicant* for patent") (emphasis added); *see also id.* § 102 (b) (patent not available if "the invention was patented or described in a printed publication in this or a foreign country or

in public use or on sale in this country, *more than 1 year prior* to the date of the application for patent") (emphasis added).

Note that § 102(a) deals with anticipation by others, whereas § 102(b) deals with self-anticipation and is essentially a promptness requirement, allowing an inventor only a year after placing the invention in the public domain to file for a patent. *See generally* 1 Chisum, *supra* note 27, ch. 3.

64. A patent has two basic parts, the "claims" and the "specification." *See* 35 U.S.C. § 112 paras. 1–2 (technically, the claims are part of the specification, but they appear in a separate section at the end and are usually referred to as if they were separate). The claims alone define the "metes and bounds" of the patented invention and thus the scope of the monopoly. *See Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336 (1961). The rest of the specification by contrast, is discursive and contains all of the information that the inventor is required to disclose as well as any other information he thinks might be worth including, such as background information describing the need for the invention, the state of the prior art, and so forth.
65. *See* 1 Chisum, *supra* note 27, § 3.02[1], at 3–12 (collecting cases); Donald S. Chisum, *Prior Invention and Patentability*, 63 J. Pat. and Trademark Off. Soc. J. 397 (1981); Donald S. Chisum, *Anticipation, Enablement and Obviousness: An Eternal Golden Braid*, 15 Am. Int. Prop. L. Assoc. O. J. 57, 58 (1987).
66. *See* 1 Chisum, *supra* note 27, § 3.02[1], at 3–6 (collecting cases).
67. *See* 35 U.S.C. § 103; *Graham v. John Deere Co.*, 383 U.S. 1 (1966). *See generally* 1 Chisum, *supra* note 27, ch. 5.
68. *See* e.g., *In re* Oetiker, 977 F.2d 1443, 1447 (Fed. Cir. 1992) (note, however, that relative to obviousness, "the reference must either be in the field of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned") (citations omitted). *See generally* 2 Chisum, *supra* note 27, § 5.03[1]–[3].
69. *Oetiker*, 977 F.2d at 1447. *See generally* 2 Chisum, *supra* note 27, § 5.04[1]; Kenneth R. Adamo, *The Power of Suggestion: Teaching, Reason or Motivation and Combined-Reference Obviousness*, 76 J. Patent Trademark Off. Soc. 177 (1994); James W. Badie, *"Motivation" or "Obvious to Try": Is There a Difference?*, 75 J. Patent Trademark Off. Soc. 54 (1993) (pointing out differences in the "motivation," "obvious to try," and "suggestion" tests and arguing that the PTO should return to the suggestion test because the motivation test is unclear); Robert W. Harris, *Critique of the Federal Circuit's Suggestion Test for Obviousness*, 72 J. Patent Trademark Off. Soc. 990 (1990).
70. *See generally* Nonobviousness: The Ultimate Condition of Patentability (J. Witherspoon ed., 1980).
71. *See generally* Jeremy Cubert, *U.S. Patent Policy and Biotechnology: Growing Pains on the Cutting Edge*, 77 J. Pat. & Trademark Office Soc'y 151 (1995); Karl Bozicevic, *Patenting DNA—Obviousness Rejections*, 74 J. Patent Trademark Office Soc. 750 (1992); Brian C. Cannon, *Toward A Clear Standard of Obviousness for Biotechnology Patents*, 79 Cornell L. Rev. 735 (1994); *see also infra* text accompanying notes 126–27.
72. 35 U.S.C. § 101. *See generally* 1 Chisum, *supra* note 27, ch.4.
73. U.S. Const. art. I, § 8, cl. 8.
74. *See Bedford v. Hunt*, 3 Fed. Cas. 37 (No. 1217) (C.C.D. Mass. 1817) (Story, J.) ("It is sufficient, that it has no obnoxious or mischievous tendency[ ] [and] that it may be applied to practical uses.... If its practical utility be very limited, it will follow, that it will be of little or no profit to the inventor.... The law, however, does not look to the degree of utility...."); *see also Ex Parte* Murphy, 200 USPQ (BNA) 801 (Bd. Pat. App. and Interf. 1977) (reversing examiner's rejection of claim to new slot machine on the ground that such machines were legal in some places and morality, as such, is not the proper concern of the patent law). Note that the argument the examiner made in *Murphy* resembles the moral argument that the animal rights movement has leveled against animal patenting. *See generally* 1 Chisum, *supra* note 27, § 4.03.
75. *See* 1 Chisum, *supra* note 27, § 4.02[2] [c] (discussing *Brenner v. Manson*, 383 U.S. 519 (1966), which suggested this possibility, but did not have to reach the question because the applicant had not expressly asserted the utility of his claimed mouse-tumor-inhibiting compound in cancer research). *See generally* 1 Chisum, *supra* note 27, § 4.02[2] [g] (the utility requirement in the biotechnology field); Christopher A. Michaels, *Biotechnology and the Requirement of Utility in Patent Law*, J. Patent Trademark Off. Soc. 247 (1994); Maebius, *Novel DNA Sequences and the Utility Requirement: The Human Genome Initiative*, 74 J. Patent Trademark Off. Soc. 651 (1992).

76. *See In re* Brana, 1995 U.S. App. LEXIS 6362, at *21 (Fed. Cir. 1995) ("Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans.").
77. *See generally* 2 Chisum, *supra* note 27, ch. 7.
78. *See* TRIPS Agreement, *supra* note 11, art. 33. Previously, the term of U.S. patents—unlike that of most European patents—had been 17 years from the date of *issue*. This was considered less desirable than the European practice, because it allowed an applicant who could drag out the application process through dilatory procedural tactics to emerge from it many years later, after all sorts of infringing technology had grown up within the scope of the claims, like a hostile submarine in the middle of a slow-moving convoy (hence, the name "submarine patents"). And while most patent applications are prosecuted within 3 years, so that the effective, term remains at least 17 years, pioneering technologies—of which DNA-related inventions are a prime example—may take longer. Proponents of a date-of-issue system point out that these are precisely the inventions that ought not to be discouraged by the effective truncation of the patent term.
79. 35 U.S.C. § 112 para. 1 (emphasis added). The application also must "set forth the *best mode*" of the invention (e.g., the best materials to use) "*contemplated* by the inventor." *Id.*
80. *See Ex Parte* ***, 27 USPQ2d (BNA) 1492 (Bd. Pat. App. & Interf. 1992) (discussed *infra*); *see also In re* Argoudelis, 434 F. 2d 1390 (C.C.P.A. 1970) (claim to antibiotic compound derived by process employing live microorganism enabled by deposit of microorganism in public repository). The rule of *Argoudelis* has been codified in regulations the PTO has promulgated to govern the examination of patent applications. *See* Manual of Patent Examination Procedure § 608.01(p). This subject is discussed in Adler, *supra* note 2, at 215–19; Adler, *supra* not 1, at 13 & nn. 70–74; *see also* Lance Leonard Barry, *A Picture is Worth A Thousand Words: Vas-Cath, Inc. v. Mahurkar*, 76 J. Patent, Trademark Off. Soc. 5 (1994); William E. Player, *Does Ex Parte Humphreys Suggest A Double Standard?*, 75 J. Patent Trademark Off. Soc. 853 (1993) (noting that commercial availability is considered enough for chemical compounds, but not for genetic probes); Richard Warburg, *Enablement of Biotechnological Inventions: The Deposit Requirement*, 24 Suff. U.L. Rev. 951 (1990); Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. Patent Trademark Off. Soc. 569 (1985).
81. *See* Adler, *supra* note 1, at 11–12. *See generally* 4 Chisum, *supra* note 27, § 16.02.
82. *See* 28 U.S.C. § 1338 (1994). The loser has a right to appeal to the U.S. Court of Appeals for the Federal Circuit, *see id.* § 1295(a)(1) (1994); *supra* note 18.
83. *See* 35 U.S.C. § 281 (1994). *See generally* 5 Chisum, *supra* note 27, ch. 20. This does not mean, however, that a patent owner necessarily has an absolute right to make, use, or sell the claimed invention, since the patent holder is still subject to the rest of the law. Thus, a patent holder claiming a drug cannot market the drug without first gaining approval of the Food and Drug Administration (FDA). Nor can a patent holder practice an invention that entails the release genetically engineered pesticidal or herbicidal microorganism into the environment without the approval of the Environmental Protection Agency (EPA) or the Department of Agriculture (USDA), or that would involve transgenic experimentation on nonfarm animals without the approval of peer reviewers mandated by federal guidelines. *See* Adler, *supra* note 1, at 11–12 and nn.59–63.
84. *See, e.g., Builders Concrete, Inc. v. Bremerton Concrete Prods.*, 757 F.2d 255, 257 (Fed. Cir. 1985). *See generally* 4 Chisum, *supra* note 27, § 16.01.
85. *See, e.g., Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605 (1950). *See generally* 4 Chisum, *supra* note 27, § 18.04.
86. This is called a "reexamination" proceeding. *See* 35 U.S.C. §§ 301–307 (1994) (any person may bring prior art to the attention of the PTO and request that they reconsider their decision to issue a patent in view of that art); *see also Patlex Corp. v. Mossinghoff*, 758 F.2d 594 (Fed. Cir. 1985) (holding that this administrative procedure does violate the right of trial by jury in civil cases guaranteed by the Seventh Amendment, even where an accused infringer seeks reexamination in the midst of a lawsuit).
87. *See* 35 U.S.C. § 282 (1994). *See generally* 5 Chisum, *supra* note 27, § 19.02.
88. *Id.* § 282(1).
89. *Id.* § 282(2)–(3).

90. *See* 5 Chisum, *supra* note 27, § 19.03–.04.
91. *See* 7 U.S.C. § 2544 (1994); *see also id.* § 2541(3) distinguishing between "use" of the new variety in "producing" a new variety and "developing" a new variety).
92. *Id.* § 2541(e).
93. *See* 4 Chisum, *supra* note 27, § 16.03[1].
94. *See* 7 U.S.C. § 2543.
95. *See id.*
96. *Id.*
97. 115 S. Ct. 788.
98. *See* Pub. L. No. 103–349, § 10, 108 Stat. 3136, (deleting exemption); House Report, *supra* note 11, at 14–15.
99. *See id.*
100. *See* 35 U.S.C. §§ 161, 271 (1994).
101. *See* 7 U.S.C. § 2541(a)(3).
102. *See id.*
103. *Id.* § 2541(a)(4).
104. *See* § 2541(a)(1).
105. *Id.* § 2541(a)(2).
106. Note also that under the Patent Act, there is no limitation on the number of distinct inventions that an applicant may claim in one patent. *See* 35 U.S.C. § 112 (employing the plural word "claims"). Under the PPA, by contrast, an applicant may claim only one new plant. *See id.* § 162 para. 2 (1994).
107. *See* House Report, *supra* note 3, at 8; 7 U.S.C. § 2483(b).
108. 35 U.S.C. § 161.
109. 7 U.S.C. §§ 2402(a)(3)–(4) (1994).
110. *See id.*; *see also id.* § 2401(b)(5) (further defining "distinctness"); *id.* § (a)(1)–(a) (defining other terms, such as "variety," "breeder," and "sexually reproduced").
111. *See* 35 U.S.C. § 102(b) (set out *supra* note 61); *id.* § 161 para. 2 ("The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided."); *In re* LeGrice, 301 F.2d 929, 933, 944 (C.C.P.A. 1962) (Section 102 applies to plant patents as well as utility patents).
112. *See LeGrice*, 301 F.2d at 937–38, 944–45.
113. *See* 7 U.S.C. § 2401(b)(6).
114. 35 U.S.C. § 102 (b).
115. *See* House Report, *supra* note 3, at 11 (discussing changes to Section 42 (a) (2) of the PVPA, 7 U.S.C. § 2402 (a)(2)).
116. 35 U.S.C. § 162. Also unlike the Patent Act, the PPA allows only one claim per patent. Since each independent claim is a free-standing monopoly, many related inventions may be claimed in a single utility patent application.
117. *See supra* note 18.
118. *In re* Greer, 484 F.2d 488, 490–91 (C.C.P.A. 1973) (citing *In re* LeGrice, 301 F.2d 929, 944 (C.C.P.A. 1962)).
119. *Id.* at 491.
120. *Id.*
121. 7 U.S.C. § 2422 (2).
122. *Id.* § 2422 (3). For further discussion of the differences between the patent statutes and the PVPA, see Adler, *supra* note 2, at 199, 205–07.
123. *Ex Parte* Obukowicz, 27 USPQ2d (BNA) 1063 (Bd. Pat. App and Interf. 1992).
124. *Ex Parte* Movva, 31 USPQ2d (BNA) 1027 (Bd. Pat. App. and Interf. 1993).
125. *In re* Deuel, 34 USPQ2d (BNA) 1210 (Fed. Cir. 1995).
126. *In re* Deuel, 34 USPQ2d (BNA) 1210 (Fed. Cir. 1995).
127. *Ex Parte* ***, 27 USPQ2d (BNA) 1492 (Bd. Pat. App. & Interf. 1992).
128. *Ex Parte* Thomson, 24 USPQ2d (BNA) 1618 (Bd. Pat. App. & Interf. 1992).
129. *See generally* 3 Chisum, *supra* note 27, ch. 9.
130. For a discussion of whether double protection should be allowed, see Straus, *Patent Protection for New Varieties of Plants Produced By Genetic Engineering—Should "Double Protection" Be Prohibited?*, 15 Int. Rev. Ind. Prop. Copyright L. 426 (1984).