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SUBSTANTIVE VERSUS INTERPRETATIVE RULEMAKING IN THE UNITED STATES PATENT AND TRADEMARK OFFICE: THE FEDERAL CIRCUIT ANIMAL LEGAL DEFENSE FUND DECISION

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I. INTRODUCTION

The United States Patent and Trademark Office (PTO), like many other administrative agencies, functions pursuant to a statutory grant of delegated power to issue rules that have the force and effect of law (quasi-legislative power), and a grant of authority to decide cases (quasi-judicial power). This Congressional delegation is expressed in the agency's organic legislation creating the office of Commissioner and the Board of Patent Appeals and Interferences (Board), and has respectively defined their limited authorities. [n.1]

The PTO, like other agencies, must comply with the procedures in the Administrative Procedure Act (APA). The APA requires all agencies to give notice of proposed substantive rules in the Federal Register, to give a minimum of 30 days for public comment, to consider the comments presented, and when adopted, to publish them with a concise statement of their bases and purposes. [n.2] The notice and comment requirement serves as a safeguard to ensure that unelected officials, who are not directly accountable to the public, are forced to justify their exercise of legislative authority.

However, "interpretative" rules are exempt from notice and comment procedures. The PTO Board has the authority to interpret statutes and *236 regulations via adjudicative decisions. The Commissioner has the authority to issue notices interpreting the current state of law, and to incorporate these interpretations into PTO practice. The reviewing courts instead provide legal safeguards by extending interpretative rules less deference. In contrast, courts are bound by the legislative effects of validly promulgated substantive rules.

As a practical matter, whether rules or rulings issued by the agency carry any legal effect, and if so, what degree of legal effect, depends on the scale of deference given by the reviewing courts. Whether a rule is characterized as substantive or interpretative does not by itself resolve the deference question. While a substantive rule has the force and effect of law, it is but one factor, although an overwhelming one, which influences deference.

The Federal Court Improvement Act of 1982 (FCIA) established the Court of Appeals for the Federal Circuit. [n.3] The goal of the FCIA was to establish consistency and uniformity in patent law by conferring on the Federal Circuit exclusive jurisdiction over all patent matters from district courts [n.4] and the PTO. [n.5] Thus, the decisions from the Federal Circuit are precedent for the PTO.

The Federal Circuit's dominion over the PTO necessitates the Court to establish a standard of review in which the agency can follow in its daily rulemaking and adjudicatory tasks. Federal Circuit cases have held that rules and rulings issued pursuant to the rulemaking power of the Commissioner and the adjudicatory power of the Board are entitled to deference. However, the issue of the extent of the Commissioner's rulemaking power has never been directly resolved.

The Federal Circuit recently held in Animal Legal Defense Fund v. Quigg [n.6], a Notice issued by the Commissioner of the PTO in the Official Gazette, [n.7] which stated, inter alia, that the PTO "now considers non- naturally occurring, non-human multicellular organisms, including animals, to be patentable subject matter within the scope of *23735 U.S.C. § 101," [n.8] to be an interpretative rule exempt from notice and comment requirements.

According to the Federal Circuit, the Notice, which outlines the genesis of the "new" section 101 interpretation, "clearly corresponds with the interpretations of section 101 set out by the PTO Board of Patent Appeals and Interferences" in previous administrative adjudications. Thus, the Notice, as concluded by the Court, was merely interpretative of previously valid administrative actions, and therefore, represents no change in the law by the Commissioner. Furthermore, the Federal Circuit also concluded that the delegated legislative power of the Commissioner is only directed to the "conduct of proceedings" before the PTO, and does not extend to the interpretation of substantive criteria under which a patent may be granted. As a result, the Notice also fails as legislation since it was not promulgated pursuant to delegated authority.

Animal is the threshold opinion from the Federal Circuit to address the subject of substantive versus interpretative rule-making in the PTO. [n.9] In its opinion, the Court clarifies the respective quasi-legislative and quasi- judiciary roles of the Commissioner and the Board in resolution of substantive law. [n.10]

*238 II. SUBSTANTIVE v. INTERPRETATIVE RULES

Three elements must be satisfied before a rule can be deemed substantive and have the force and effect of law: [n.11] (1) The rule "effects a change in existing law or policy" which "affect s individual rights and obligations;" [n.12] (2) the agency has been delegated statutory legislative authority, and that the rule was promulgated pursuant to that authority; [n.13] and lastly, (3) the agency must have given notice by publishing the proposed rule in the Federal Register for comment pursuant to section 553 of the APA.

[n.14] By negative inference, a rule is interpretative if it does not effect a change in existing law or policy, nor it affects individual rights and obligations. Instead, interpretative rules are rules which merely clarify or explain existing laws. [n.15]

For example, a rule which satisfies element (1) in that it changes existing law does not become "interpretative" simple because the agency overextended its delegated authority (or lack of), or failed to provide notice and comment procedures; such a rule is invalid and thus without effect. In the converse, a rule which does not satisfy element (1) is ipso facto interpretative.

That an agency has delegated authority does not necessarily mean that any rule it promulgates is automatically substantive. There is no automatic presumption that legislative authority is necessarily exercised each and every time the agency promulgates a rule. An agency with broad rulemaking power can also make interpretative rules, versus an *239 agency with no delegated rule making power that can only make interpretative rules. If "every action taken by an agency pursuant to statutory authority would be subjected to public notice and comment under section 553," then "[s]uch a result would vitiate the statutory exceptions in section 553(b) itself, here the exception for 'interpretative rules'. We cannot so interpret section 553." [n.16]

Section 553 of the APA requires agencies to provide public notice and opportunity for comment prior to the promulgation of "substantive" or "legislative" rules. [n.17] Notice and comment, however, is not required for "interpretative" rules. [n.18] The courts generally have interpreted section 553 to mean that any substantive rulemaking by the agency must meet the notice and comment requirements, whereas interpretative rules do not. [n.19]

The notice and comment procedure is to democratize the agency's legislative process, "to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies." [n.20] The notice and comment procedure also assures the widest input of information from the most informed so "that the agency will have before it the facts and information relevant to a particular administration problem, as well as suggestions for alternative solutions." [n.21]

But most importantly, "[t]he APA notice and comment procedures exist ... to ensure that unelected administrators, who are not directly *240 accountable to the populace, are forced to justify their quasi-legislative rule-making before an informed and skeptical public." [n.22] In contrast, an interpretative rule is a rule which does not change existing law or policy, thus does not require legislative authority to promulgate (since nothing is being legislated), and therefore does not require any of the procedural safeguards of section 533.

III. FACTORS WHICH INFLUENCE DEFERENCE

Professor Davis identified three factors which influence the amount of deference reviewing courts give to agency resolution of questions of substantive law: The extent of power conveyed to the agency, the generality or specificity of the statutory term, and the comparative qualifications of courts and agencies. [n.23] The first two factors go to the expressive and implicit delegations of power, respectively. The third goes to whether the rule reflects the agency's expertise; i.e. whether the rule resolves a technical question pursuant to the function of the agency. If the validity of the rule merely rests on statutory interpretation, then the courts and not the agencies, are logically the experts to decide on a question of law. Each of these three factors may not necessarily accord equal weight.

The scope of power intended by Congress to be conveyed to the agency for the implementation of statutory policies can be deduced from the legislative history. The amount of power actually conveyed to the agency are plainly expressed in its organic or enabling statute. An organic statute is the statute that created the agency: it names officers and expresses the extent of their discretion. For example, section 6 of the patent act grants the Commissioner the power to make rules. The enabling statute enables or empowers the agency to act accordingly. The sections 101 and beyond would be the enabling section of the patent act.

The power of the agency is deducible in its organic statute. For example, section 6(b)(5) of the Occupational Safety and Health Act of 1970 gives the Secretary of Labor power to issue rules "to the extent feasible." This delegation is open ended and relies much on the Secretary's discretion of what is "feasible." Congress recognizes that some agencies, due to the nature of the social problems that they are charged with administering, require flexibility in implementing policy in an environment where the future is not always foreseeable while its organic statute is being drafted on the floor.

*241 In Chevron, U.S.A., Inc. v. Natural Resources Defense Council, [n.24] the Supreme Court unanimously established an analytical framework for judicial review of agency interpretations of statutory provisions. The Chevron doctrine applies to policy-making agencies, and limits the court's discretion to substitute its own policy in place of the agency's interpretation. Chevron directs the courts to refrain from policy making noting that "policy arguments are more properly addressed to legislators or administrators, not to judges." [n.25]

The Supreme Court in Chevron established a two-step method of analysis. The first step requires the reviewing court, "employing traditional tools of statutory interpretation," [n.26] to first determine "whether Congress has directly spoken to the precise question at issue," [n.27] in which case "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." [n.28] If the court concludes, however, that "Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute." [n.29] Instead, "the question for the court is whether the agency's answer is based on a permissible construction of the statute." [n.30]

The first step of Chevron determines whether or not the agency is a policy making agency. The generality of the statutory term enabled the agency flexibility in its interpretation to implement policy. If the agency is a policy-making agency, the second step examines whether the agency interpretation was reasonable in light of Congressional intent.

The PTO is not a policy-making agency, and thus not entitled to deference merely because its interpretation of a statutory term is "reasonable." The statutory grant of legislative power conferred to the Commissioner does not employ broad "to the extent feasible" language. Nothing in the patent act suggests that the Commissioner can enact rules having the force and effect of law on matters of patentability. Rather, section 6 precisely outlines the duties of the Commissioner, and *242 stipulates his authority to be directed to the "conduct of proceedings" before the PTO. [n.31]

In Glaxo, [n.32] the Federal Circuit considered whether deference was due to the Commissioner's interpretation of 35 U.S.C. § 156. The Commissioner citing Chevron, argued that the Court must defer to his statutory interpretation provided it was "reasonable," and not contrary to Congressional intent. The Court in response, stated: "The rule of deference to when the statutory language has 'left a gap' or is ambiguous. (Citations omitted). Here ... section 156(f)(2)'s operable terms, individually and as combined in the full definition, have a common and unambiguous meaning, which leaves no gap to be filled in by the administering agency. Accordingly, we need not defer to any reasonable interpretation of the Commissioner." [n.33]

It would not be surprising if the Federal Circuit finds all of the statutes to be unambiguous. Congress enacted the original patent statute in 1790. [n.34] Since then, there is no evidence that Congress has delegated policymaking responsibilities to the Commissioner to exercise the views of the political branch where the courts are not the experts in the matter. The relative expertise of theFederal Circuit on patent law relative to the PTO makes deference unnecessary. "Significant deference is due to an agency's technical expertise when Congress has explicitly or implicitly delegated to the agency the making of scientific determinations. (Citation omitted). But when 'the interpretation rests not on policy considerations but on a narrow dissection of statutory language, the courts are equally skilled in making such an interpretation, and reduced deference is owed." [n.35] Statutory interpretation is a question of law. And the PTO's conclusion of law is reviewed de novo for correctness or error as a matter of law. [n.36]

*243 IV. ANIMAL LEGAL DEFENSE FUND

a. Background

On April 7, 1987, the Commissioner of the PTO issued the following Notice in the Official Gazette:

A decision by the Board of Patent Appeals and Interferences in Ex Parte Allen (Bd.App. & Int. April 3, 1987), held that claimed polyploid oysters are nonnaturally occurring manufactures or compositions of matter within the meaning of 35 U.S.C. 101. The Board relied upon the opinion of the Supreme Court in Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980) as it had done in Ex Parte Hibberd, 227 USPQ 443 (Bd.App. & Int., 1985), as controlling authority that Congress intended statutory subject matter to "include anything under the sun that is made by man." The Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.

The Board's decision does not affect the principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law. (Citations omitted).

A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being with its scope include the limitation "non-human" to avoid this ground of rejection. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissible form of expression. (Citation omitted).

Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a non-human "nonnaturally occurring manufacture or composition of matter--a product of human ingenuity" (Diamond v. Chakrabarty,) such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subject matter. [n.37]

The Notice was issued days after the Board decided Ex parte Allen [n.38], wherein the Board held that claimed polyploid oysters were non-naturally occurring manufactures patentable within the meaning of section 101 of the patent statute, thus rejecting the policy that "living entities were not patentable." [n.39] Prior to the Allen decision, the Board held in Ex parte Hibberd [n.40], that non-naturally occurring man-made multicellular plants were patentable under section 101.

*244 The Board in Hibberd and Allen applied Diamond v. Chakrabarty [n.41], the decision wherein the Supreme Court held that non-naturally occurring man-made living microorganisms were patentable subject matter pursuant to section 101. Prior to Chakrabarty, the PTO maintained a strong policy that living organisms were not patentable subject matter within the meaning of 35 U.S.C. § 101. [n.42] Following Chakrabarty, the PTO began issuing patents on single-celled microorganisms, but nonetheless continued to reject multicellular organisms as per se ineligible subject matter for patent protection. [n.43] It was not until Allen that the Board interpreted Chakrabarty

to literally "include anything under the sun that is made by man," as patentable subject matter under 35 U.S.C. § 101. [n.44]

More than a year after The Notice was published, certain nonprofit organizations including animal rights groups filed suit in the U.S. District Court for the Northern District of California challenging on procedural and substantive grounds the validity of the PTO Notice. [n.45] The plaintiff asserted, inter alia, that the Notice was a substantive rule and was issued without prior notice and an opportunity to comment pursuant to APA section 553. The district court held the Notice to be an interpretative rule, thus exempt from notice and comment procedures, and as a result granted the Commissioner's motion to dismiss for failure to state a claim under the APA. [n.46] The Federal Circuit affirmed the district court on other grounds; inter alia, since the PTO Notice was an interpretative rule, the nonprofit groups have no standing to assert *245 procedural harm in the Commissioner's failure to publish notice and receive comment prior to the promulgation of the rule. [n.47]

b. Interpretation of Prior Intra-agency Action

According to the Federal Circuit, the Notice, which outlines the genesis of the "new" section 101 interpretation, delineates the interpretations of section 101 set out by the Board in Allen and Hibberd. [n.48] "Thus, the Notice falls within the class of agency action which is merely interpretative of previous valid administrative action, and, as a result, represents no 'change' in the law by the Commissioner." [n.49] The Court cited Northern Illinois Gas Co. v. United States [n.50] and Gibson Wine Co., Inc. v. Snyder [n.51] to directly support its above proposition.

In Gibson Wine, a ruling issued by the agency that wine made from boysenberries may not be labeled "blackberry wine" was held to be an interpretative rule exempt from notice and comment, since the ruling interpreted the regulation stipulated in the Code governing the labeling of fruit wines. Northern Illinois yields similar results whereby the ruling made by the Secretary of the agency was upheld as interpretative of valid agency regulations.

The Federal Circuit failed to address a factual discrepancy between Animal and the two above cases: The "previous valid administrative action" in Northern Illinois and Gibson Wine are substantive rules that were published in the Code; while according to the facts in the present case, Allen and Hibberd are adjudicatory actions. The Court in Animal determined that interpretive rules delineating past adjudicative rulings, "falls within the [same] class of agency action" as adjudicative rulings interpreting regulations, without establishing a common nexus. Nor did the Court elaborate what elements constitute a "valid administrative action."

Interpretative rules are rules which merely clarify or explain existing law or regulations. [n.52] The Court must have implied that "the class of agency action which is merely interpretive," are interpretative rules *246 in general, whether originating from the

Commissioner or from the Board. Moreover, the "previous valid administrative action" can only mean any action taken by the Board or Commissioner that produced law, whether through rulemaking or adjudication. Following this pattern of logic, the conclusion can only be that the Federal Circuit intended to hold that a rule is interpretative if it interprets law originated either from rulemaking or adjudication.

To justify the above conclusion would require an inference to be drawn that the Federal Circuit views substantive rules and adjudicative rulings to be equivalent reflections of "existing law." Substantive rules--as in regulations published in the Code, do not have the same legal effect as adjudicative rulings. Regulations are legislative and have the force and effect of law, while adjudicative rulings are interpretive of statutes and regulations and therefore do not. The difference is that the Federal Circuit is bound to follow the regulation as law, while agency adjudicative resolution of law are reviewed de novo for correctness as matter of law. One analogy is that the Supreme Court is bound to the language dictating obviousness in 35 U.S.C. § 103, unless it is unconstitutional; however, the Supreme Court gives effect to the Federal Circuit's interpretation of obviousness, but cannot be bound by it. The statute and the Federal Circuit's interpretation of the statute via case law, are both valid reflections of the law.

c. Adjudicatory authority of the Board

Adjudication is a valid form of law-making pursuant to the grant of quasi-judiciary authority, unlike substantive rules which are promulgated pursuant to statutory quasi-legislative authority and APA notice and comment requirement. [n.53] The Federal Circuit in Animal emphasized that the "Board's authority to decide the section 101 issue rests on an independent grant in section 7(b), which requires the Board to decide patent validity issues when properly raised in Board Proceedings, and is independent from the Commissioner's authority to establish regulations." [n.54]

*247 In Animal, the functions of Commissioner and the Board cannot be said to merge and represent one entity called the "PTO" and that this "PTO" issued a Notice expanding the scope of Chakrabarty; and as a result the rule is substantive, therefore subject to notice and comment. The Board was authorized to issue rulings interpreting Chakrabarty to resolve the questions properly raised in adjudication, pursuant to section 7(b). The Supreme Court in Chenery held that an agency is not barred from utilizing ad hoc adjudication to formulate new standards of conduct even when prospective rulemaking is available. [n.55] "And the choice made between proceeding by general rule or by individual, ad hoc litigation is one that lies primarily in the informed discretion of the administrative agency." [n.56] The Board's decisions in Allen and Hibberd are products of a grant of judiciary power, and can stand on its own as precedent for the PTO.

d. Rulemaking Authority of the Commissioner

The legislative authority granted to the Commissioner in Section 6 of the patent statute is directed to the "conduct of proceedings" before the PTO. The Commissioner does not have the delegated legislative authority to promulgate substantive rules interpreting the substantive criteria under which a patent may be granted. [n.57] "That is not to say that the Commissioner does not have authority to issue such a Notice but, if not issued under the statutory grant, the Notice cannot possibly have the force and effect of law." [n.58] The Court can choose to defer to the interpretative rules of the Commissioner if they are correct as matter of law, and are consistent with previous interpretations. [n.59]

The legislative authority of the Commissioner is limited to the formulation of a road map to guide the patentee through the prosecution process, i.e., whether it may be the establishment of fees, abandonment and revival, of patent procedures, or guidelines on duties of disclosure. If consistent with the Constitution and the patent statute, these rules have the force and effect of law. [n.60]

The Commissioner's power to promulgate rules with the force and effect of law in the Code apparently is not restricted to subject matter within agency expertise. In 1977, the Commissioner amended rule 1.56 *248 to define the duty to disclose to the PTO. [n.61] Rule 1.56 codified the existing PTO policy on fraud and inequitable conduct which is consistent with the prevailing cases in the Federal Courts. The concept of fraud is clearly not within the scope of expertise of the PTO.

The court can invalidate a PTO regulation if it is inconsistent with statutory purpose. In Ethicon, Inc. v. Quigg, [n.62] the Commissioner exercised his discretion to delay reexamination proceedings pursuant to 37 C.F.R. § 1.565 and MPEP § 2286. The Court recognized the power of the Commissioner to make rules for the conduct of proceedings in the PTO, and the "the validity of a regulation promulgated thereunder will be sustained as long as it is 'reasonably related to the purpose of the enabling legislation.' ... However, the ultimate question here is whether the Commissioner's exercise of authority to stay a reexamination purportedly pursuant to section 6(a) conflicts with the laws governing reexaminations specifically.... If it does, it cannot stand." [n.63] The Court noted that an agency's interpretation of a statute it administers is entitled to deference, but the courts are the final authorities on issues of statutory construction, and "must reject administrative constructions of the statute, whether reached by adjudication or by rulemaking, that are inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement." [n.64]

The Commissioner issues interpretative rules on patentability in the Official Gazette for publication and in the Manual of Patent Examining Procedure (MPEP) for internaluse. The MPEP does not have the force of law, but it "has been held to describe procedures on which the public can rely." [n.65] The MPEP is a guide for patent attorneys and patent examiners on procedural matters. The Manual is not binding on the courts, but notwithstanding, it is an official interpretation of statutes or regulations with which it is not in conflict. [n.66] However, the MPEP is binding on the PTO:

We take judicial notice of the fact that the manual is used frequently by patent lawyers and agents in advising applicants and in preparing their various papers for filing in the

Patent Office, and also of the fact that examiners frequently cite provisions of the manual in their communications with patent *249 applicants. Under these circumstances we feel that an applicant should be entitled to rely not only on the statutes and Rules of Practice but also on the provision of the MPEP in the prosecution of his patent application. [n.67]

Since the public and the examiners rely on the interpretative rules and procedures in the MPEP for guidance in patent prosecutions, the PTO is estopped from changing position at will.

The Commissioner possesses many options for rulemaking, especially interpretative rules that inform the public on current PTO policies on prosecution procedures and on substantive issues of patentability, although the delegated legislative power of the Commissioner is limited to rules of Office proceedings. As an issue of deference, the distinction between rules having the force and effect of law and advisory rules on patentability is not significant. The Federal Circuit reviews agency rules for correctness as matter of law. If the rule does not conflict with higher authorities, the Court can give it deference.

V. SUMMARY and CONCLUSION

Animal Legal Defense Fund is the threshold opinion from the Federal Circuit to address the subject of substantive versus interpretative rulemaking in the PTO. In that opinion, the Court held to be interpretative a Notice issued by the Commissioner delineating prior adjudicative rulings by the Board. The Notice could not have been substantive because the Commissioner was only clarifying existing law; also, the Commissioner did not have the statutory authority to promulgate a substantive rule defining patentability. The Commissioner's delegated legislative authority only extends to matters of office proceedings, and not questions of patentability. On questions of patentability, the Commissioner can only issue interpretative rules.

According to the Court, the Board and the Commissioner are separate entities within the PTO authorized to resolve questions of law via their respective statutorily delegated power. The Board and the Commissioner do not collectively constitute one entity called the "PTO." The Board's authority to decide the section 101 issue rests on an independent grant in the patent statute, and its decisions are products of authorized adjudicatory rulemaking. The Notice issued by the Commissioner merely reflects the current state of law as interpreted by the Board, and since the rule did not create new law, it was interpretative and therefore exempt from notice and hearing requirements.

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[n.1]. 35 U.S.C. § § 6, 7 (1982). See generally H. Wamsley, RULEMAKING POWER of the COMMISSIONER of PATENT AND TRADEMARKS (PART 3), 64 J.Pat.Off. Soc'y 605 (1982).

[n.2]. 5 U.S.C. § 553.

[n.3]. Pub.L. No. 97-164, 96 Stat. 25 (relevant provisions codified in various sections of Title 28).

[n.4]. 28 U.S.C. § 1295(a)(1), (4) (1982).

[n.5]. 28 U.S.C. § 1295(a)(4)(A) (1982).

[n.6]. 18 USPQ2d 1677 (Fed.Cir.1991). The appeal arrived to the Federal Circuit on the district court's grant of the Commissioner's motion to dismiss. See Animal Legal Defense Fund v. Quigg, 710 F.Supp. 728, 9 USPQ2d 1816 (N.D.Cal.1989) (Affirmed on other grounds).

[n.7]. Animals-Patentability, 1077 Off.Gaz.Pat. Office 24 (April 21, 1987).

[n.8]. 35 U.S.C. § 101 provides the statutory definition of the subject matter upon which a patent may be granted: "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."

[n.9]. The animal rights appellants initially appealed the dismissal order to the Court of Appeals for the Ninth Circuit. While the Administrative Procedure Act (APA) created the causes of action, that court issued an order transferring the appeal to the Federal Circuit since the substantive issue on appeal was a quetion of patentable subject matter. See Animal Legal Defense Fund v. Quigg, 900 F.2d 195 (9th Cir.1990). Although the Federal Circuit's dominion over patent matters does not include rule making procedures which is governed by the APA, as a practical matter, disputes over the interpretation, or creation of patent rights would necessarily invoke subject matter jurisdiction. See Animal Legal Defense Fund, 18 USPQ2d at 1681, n. 5.

[n.10]. The Federal Circuit by ultimately deciding the case on procedural standing grounds does not undercut its discussion on the substantive issue. It is elementary for any court of law to resolve all procedural issues raised, i.e., standing, ripeness, mootness, prior to any consideration of the substantive issues. Moreover, the Federal Circuit buttressed its position on the substantive issue by an unanimous five judge panel.

[n.11]. The Supreme Court in Chrysler Corp. v. Brown, 441 U.S. 281, 302- 303 (1979), stated that a substantive rule--or a "legislative-type rule," as one "affecting individual rights and obligations." This characteristic is an important touchstone for distinguishing those rules that may be "binding" or have the "force of law." [Citations omitted].

That an agency regulation is "substantive," however, does not by itself give it the "force and effect of law." The legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes.

Likewise the promulgation of these regulations must conform with any procedural requirements imposed by Congress. [Citation omitted]. For agency discretion is limited not only by substantive, statutory grant of authority, but also by the procedural requirements which "assure fairness and mature consideration of rules of general application." [Citation omitted]. The pertinent procedural limitations in this case are those found in the APA.

[n.12]. See Cubanski v. Heckler, 781 F.2d 1421, 1426 (9th Cir.1986).

[n.13]. Id. at 1426.

[n.14]. Chrysler, 441 U.S. at 313; Mt. Diablo Hosp. Dist. v. Bowen, 860 F.2d 951, 956 (9th Cir.1988).

[n.15]. Powderly v. Schweiker, 704 F.2d 1092, 1098 (9th Cir.1983).

[n.16]. Animal, 18 USPQ2d at 1686.

[n.17]. 5 U.S.C. § 553(b) and (c) provide: (b) General notice of proposed rule making shall be published in the Federal Register, unless persons subjected thereto are named and either personally served or otherwise have actual notice thereof in accordance with law....

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments....

[n.18]. 5 U.S.C. § 553(b)(A) provides: Except when notice or hearing is required by statute, this subsection does not apply--

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice....

[n.19]. See, e.g., W.C. v. Bowen, 807 F.2d 1502, 1504 (9th Cir.1987); Alaniz v. Office of Personnel Management, 728 F.2d 1460, 1467 (Fed.Cir.1984).

[n.20]. Batterton v. Marshall, 648 F.2d 694, 703 (D.C.Cir.1980); See NLRB v. Wyman-Gordon Co., 394 U.S. 759, 764 (1969) (The APA notice and comment requirement was designed to assure fairness.)

[n.21]. Guardian Fed. Sav. & Loan Corp. v. Federal Sav. & Loan Insur. Corp., 589 F.2d 658, 662 (D.C.Cir.1978); See also National Tour Brokers v. United States, 591 F.2d 896, 902 (D.C.Cir.1978); Brown Express v. United States, 607 F.2d 695, 701 (5th Cir.1979).

[n.22]. New Jersey v. Department of HHS, 670 F.2d 1262, 1281 (3rd Cir.1981).

[n.23]. See 4 K. DAVIS, ADMINISTRATIVE LAW TREATISE,§ § 30.09-30.11 (1958).

[n.24]. 467 U.S. 837 (1984). The case concerned the Environmental Protection Agency's (EPA) interpretations of the Clean Air Act Amendment of 1977, which requires the EPA to limit emission from all "stationary sources." The EPA adopted the "bubble concept" interpreting the statutory term "statutory source" to mean an entire plant, rather than an individual piece of combustion equipment.

[n.25]. Id. at 864.

[n.26]. Id. at 843 n. 9.

[n.27]. Id. at 842.

[n.28]. Id. at 842-843.

[n.29]. Id. at 843.

[n.30]. Id.

[n.31]. 35 U.S.C. § 6(a) (1982) provides: the Commissioner ... may, subject to the approval of the Secretary of Commerce, establish regulations, not inconsistent with law, for the conduct of proceedings in the Patent and Trademark Office.

[n.32]. Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 13 USPQ2d 1628 (Fed.Cir.1990).

[n.33]. Id. 894 F.2d at 398, 13 USPQ2d at 1633.

[n.34]. 1 Stat. 109. Major changes were made in 1793, 1 Stat. 318, and in 1836, 5 Stat. 117.

[n.35]. Id.

[n.36]. See In re De Blauwe, 736 F.2d 699, 222 USPQ 191 (Fed.Cir.1984).

[n.37]. 1077 Off.Gaz.Pat. Office 24 (1987).

[n.38]. 2 USPQ2d 1425 (BD.Pat.Ap. & Int.1987), aff'd, 846 F.2d 77 (Fed.Cir.1988) (Table).

[n.39]. Id. at 1426-27.

[n.40]. 227 USPQ 443 (Bd.App. & Int.1985).

[n.41]. 447 U.S. 303 (1980). While the Supreme Court only held that live, non-naturally occurring microorganisms fell within the patentable subject matter covered by section 101, the PTO and courts have interpreted Chakrabarty broadly to mean that Congress

intended patentable subject matter to "include anything under the sun that is made by man."

[n.42]. See In re Chakrabarty, 571 F.2d 40, 197 USPQ 72 (C.C.P.A.1978); In re Bergy, 596 F.2d 952, 201 USPQ 352 (C.C.P.A.1979).

[n.43]. See Wasowski, The Evolution of Patentable Compositions of Matter: The United States Patent Office Accepts Genetically Altered Animals As Patentable Subject Matter Under 35 U.S.C. Section 101, 2:309 ADMIN.L.J. 309 (1988).

[n.44]. 2 USPQ2d at 1427.

[n.45]. Animal Legal Defense Fund v. Quigg, 710 F.Supp. 728, 9 USPQ2d 1816 (N.D.Cal.1989).

[n.46]. "The district court granted defendant's motion on the grounds that the challenged Notice fell within an exception to the public notice and comment requirements of the APA and that the Commissioner did not exceed his statutory authority in issuing the Notice." Animal Legal Defense Fund, 18 USPQ2d at 1679.

[n.47]. Id. at 22. Ultimately, the Court held that the appellants failed to meet the standing requirements of Article III § 2 of the Constitution. Id. at 43.

[n.48]. The Court did not address the Commissioner's statement that section 101 does not extend to humans, because none of the plaintiffs argue that its inclusion would serve to make the Notice "substantive." See Animal, No. 90-1364, at 16, n. 9.

[n.49]. Animal, 18 USPQ2d at 1684. (emphasis in original).

[n.50]. 833 F.2d 1582 (Fed.Cir.1987).

[n.51]. 194 F.2d 329 (D.C.Cir.1952).

[n.52]. Alcaraz v. Block, 746 F.2d 593, 613 (9th Cir.1984).

[n.53]. See B. SCHWARTZ, ADMINISTRATIVE LAW § 4.15 (2d ed. 1984). Rulemaking is the process by which an agency lays down new prescriptions to govern the future conduct of those subjected to its authority; adjudication is the process by which the agency applies either law or policy, or both, to the facts of a particular case. Id. at 190.

[n.54]. Animal, 18 USPQ2d at 1684. 35 U.S.C. § 7(b) provides: [7](b) The Board of Patent Appeals and Interferences shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents and shall determine priority and patentability of invention in interferences declared under section 135(a) of this title.

[n.55]. S.E.C. v. Chenery Corp., 332 U.S. 194, 202-203 (1947).

[n.56]. Id.

[n.57]. Animal, 18 USPQ2d at 1686.

[n.58]. Id.

[n.59]. See Madison Galleries, Ltd. v. United States, 870 F.2d 627 (Fed.Cir.1989).

[n.60]. See In re Rubinfield, 270 F.2d 391, 123 USPQ 210 (CCPA 1959).

[n.61]. See generally FMC Corp. v. Manitowoc Co., Inc., 835 F.2d 1411, 3 USPQ2d 1112 (Fed.Cir.1987), J.P. Stevens & Co. v. Lex Tex., Ltd., 747 F.2d 1553, 223 USPQ 1089 (Fed.Cir.1984), cer. denied, 474 U.S. 903 (1985).

[n.62]. 849 F.2d 1422 (Fed.Cir.1988).

[n.63]. Id. at 1425.

[n.64]. Id.

[n.65]. Id.

[n.66]. See Litton Systems, Inc. v. Whirlpool Corp, 728 F.2d 1423 (1984).

[n.67]. In re Kaghan, 387 F.2d 398, 401, 156 USPQ 130, 132 (CCPA 1967).