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PRACTICAL UTILITY: EVOLUTION SUSPENDED?

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I. INTRODUCTION: THE PRACTICAL UTILITY PROBLEM.

One of the most controversial lines of patent decisions of the nineteen- sixties began with Brenner v. Manson. [n.1] Together with In re Joly [n.2] and In re Kirk [n.3] these cases established the requirement that new chemical compounds possess some threshold level of usefulness, or "practical utility," to satisfy section 101 of the patent statute. [n.4] This requirement has been criticized as an indefinite, onerous one which discourages research in the pharmaceutical industry. [n.5] The increasingly competitive nature of the innovative pharmaceutical industry makes these concerns *204 particularly troublesome. [n.6] For the past twenty years, however, the United States Court of Appeals for the Federal Circuit and its predecessor, the Court of Customs and Patent Appeals, have clarified the practical utility requirement. [n.7] It should now be not nearly so burdensome as was once supposed.

In view of the effort that has gone into refining the practical utility requirement, it is surprising that the Federal Circuit has suggested it is a question of fact, [n.8] making future appellate review and further clarification of this requirement far more difficult than if it were classified a question of law. The need for clarity on the issue of practical utility has not, however, diminished with time. Instead, the district courts can be expected to encounter an increased number of challenges to patents under section 101 for failure to satisfy the practical utility requirement, and increasing numbers of patent applicants can expect their patent applications to be subjected to scrutiny on this issue in the U.S. Patent and Trademark Office.

Continued litigation of practical utility questions can be expected for economic reasons. Along with those sources of utility disputes which have existed since Brenner, the increasing importance of biotechnology research provides a likely additional source of disputes over whether the utility requirement has been satisfied--as most recently demonstrated by the patent controversy in connection with the Human Genome Project. [n.9] Indeed, the important role small, innovative companies have played in the biotechnology industry to date, combined with the way the practical utility requirement can prevent such companies from *205 achieving their goals, is likely to force confrontation over the practical utility requirement. [n.10]

Continued litigation of practical utility questions can be expected because the patent laws themselves create obstacles that inventors can overcome by basing their applications on minimal showings of utility and filing their applications early. For example: minimal

showings can reduce the number of inventors required to be named on an application by sections 111 and 116 and thereby reduce both prior art and joint ownership problems; [n.11] minimal showings can simplify enablement issues arising under section 112 [n.12] and thereby permit the earlier filing of broader claims; minimal showings can simplify operability questions arising under section 101 and circumvent potential operability rejections during prosecutionof the application; [n.13] and minimal showings can help an inventor establish an earlier actual reduction to practice and prevail should his application become involved in a priority contest. [n.14]

Procedural considerations indicate that the classification of practical utility as a question of fact will be troublesome. The issue is one which the U.S. Court of Appeals for the Federal Circuit is far better suited *206 to address than is a trial judge or jury. [n.15] A fact classification will make the outcome of an initial decision on this issue unpredictable, when a high degree of predictability is urgently needed by those engaged in pharmaceutical research. [n.16] Finally, classification of practical utility as a question of fact will likely increase rather than decrease the time the federal courts must invest in resolving disputes over this issue. [n.17]

As observed by Professor Chisum, there is no sound reason an alleged infringer should not be able to challenge the validity of a patent for failure to satisfy the practical utility requirement, [n.18] and hence no reason why district courts should not pass on this issue. It is equally clear, however, that the Federal Circuit should review district court conclusions on whether or not patents satisfy the practical utility requirement as conclusions of law, and not be restricted to reviewing them as a findings of fact.

This paper applies analyses developed in other areas of substantive law to the practical utility question. Section II below will briefly contend that the practical utility requirement is a mixed question of law and fact. Section III will review the problems which have been encountered in classifying other mixed questions as either questions of law or questions of fact for the purpose of deciding the scope of appellate review, and the factors which have been identified as relevant to the choice of classification. Section IV will review the development of the practical utility requirement since Brenner v. Manson, focusing on the factors which have influenced the decisions of appellate courts on this issue. Finally, Section V will show that the factors which should be considered when deciding whether a particular mixed question should be classified as law or fact for appellate review purposes uniformly indicate that the practical utility requirement should be classified as a question of law. Section VI notes in conclusion that there are no precedential barriers which should preclude the Federal Circuit from making this classification, and contends that the classification of practical utility as a question of law would be consistent with the historic view of the role of this requirement.

*207 II. PRACTICAL UTILITY AS A MIXED QUESTION OF LAW AND FACT

In Pullman-Standard v. Swint, [n.19] the Supreme Court defined mixed questions of law and fact as "questions in which the historical facts are admitted or established, the rule of

law is undisputed, and the issue is whether the facts satisfy the statutory standard." [n.20] Historical facts are factual findings which answer simple questions such as "who did what, when, where, how, why, or with what intent." [n.21] Resolution of a practical utility issue first requires determination of the requirements of section 101, as stated in Brenner v. Manson and subsequent judicial decisions. [n.22] The remaining steps involve determining the utility stated in the patent or patent application, and then deciding--in view of all the relevant facts-- whether this stated utility satisfies the practical utility requirement established by prior judicial decisions. [n.23] This series of steps places practical utility squarely within the definition of a mixed question stated by the Supreme Court in Swint.

Numerous other legal issues, aside from the practical utility requirement, are also considered mixed questions of law and fact. [n.24] For purposes of appellate review, some of these issues are treated as questions of law, while others are treated as questions of fact. The best example of a mixed question under the patent statute is the question of obviousness, which is classified as a question of law. [n.25] As discussed in the next section, classifying mixed questions as law or fact for the purpose of deciding the scope of appellate review has been a matter of considerable difficulty. Guidelines have nevertheless emerged which indicate that practical utility, like obviousness, should be classified as a question of law.

*208 III. APPELLATE REVIEW OF MIXED QUESTIONS OF LAW AND FACT

A. The problem of mixed questions under a bifurcated scheme of review.

In the federal courts, findings of fact, whether originally found by judge or jury, are treated with considerable deference by courts of appeal. [n.26] Questions of law, on the other hand, are freely reviewed by the appellate courts. [n.27] Questions of fact and law decided by the U.S. Patent and Trademark Office are treated similarly on appeal to the Court of Appeals for the Federal Circuit. [n.28] Mixed questions, which do not fit neatly into either category, must be classified in one category or the other to determine the scope of review. Unfortunately, they are frequently classified without any explanation of the reasons behind the choice made. [n.29] This judicial silence has led some commentators to suggest that findings of fact are simply those findings which appellate courts choose to leave to the trier of fact, [n.30] and has led some appellate courts to state that this area of law is in disarray. [n.31]

In spite of the skepticism which has been expressed over the quality of standard of review jurisprudence for mixed questions, a number of classification guidelines exist which can be used by the Federal Circuit to select the category in which the practical utility question should be classified. A starting point in identifying these guidelines is the commentary generated by the Supreme Court's decision in Commissioner v. Duberstein. [n.32] This commentary is as applicable to the patent utility question as it was to the taxation gift question raised in Duberstein. It outlines a variety of factors

which should be considered by the Federal Circuit before practical utility is classified as either a question of law or a question of fact.

*209 B. Commissioner v. Duberstein: A restrictive view?

In Commissioner v. Duberstein, the Supreme Court held that the question whether income was a "gift" for federal income tax purposes was a question of fact. The facts of this case are well known. In brief, Duberstein concerned two similar cases in which opposite results had been reached. One involved the transfer of a Cadillac to Duberstein from a business associate, as an expression of gratitude, after Duberstein had furnished him with information about potential customers. The other involved the transfer of $20,000 to Stanton, asa "gratuity" on his resignation as president of a corporate subsidiary of a church, after Stanton agreed to make no claim to a pension from the church. [n.33] The transfer to Duberstein was found to be taxable income by the tax court, while the transfer to Stanton was found to be a gift by the district court. Both decisions were reversed at the appellate level; one of these appellate decisions was reversed and the other was vacated by the Supreme Court. [n.34]

The Court's opinion emphasized that the transferor's intent was the primary consideration in deciding whether any one particular transfer was a gift, and stated that transfers to be considered gifts were those transfers motivated by "detached and disinterested generosity." [n.35] Without giving any rules which would reconcile these two cases, the Court went on to state as follows:

> Decision of the issue presented in these cases must be based ultimately on the application of the fact-finding tribunal's experience with the mainsprings of human conduct to the totality of the facts of each case. The non-technical nature of the statutory standard, the close relationship of it to the data of practical human experience, and the multiplicity of relevant factual elements, with their various combinations, creating the necessity of ascribing the proper force to each, confirm us in our conclusion that primary weight in this area must be given to the conclusions of the trier of fact. [n.36]

The Duberstein decision has been severely criticized. Focusing on its failure to use federal tax policy to resolve this issue, Professor Carrington succinctly observed that "[i]t is hard to see how the trier of fact's experience with the 'mainsprings' of life qualifies him for the clearest *210 insight into the Internal Revenue Code and its purposes." [n.37] Dean Griswold, in a well-known passage focusing on the need for predictability in the law, argued as follows:

> Should all tax questions simply be submitted to juries for judgment, representing a sample of the general public? Of course not. Certain questions are appropriate for jury decision. But there are also questions of law; and there are questions of mixed law and fact, where the legal element is the responsibility of the court. To overrate the function of the jury (or other trier of the facts) is to shirk the function of the court, and to fail to administer justice rationally, consistently, and soundly.
>
> Surely some guides and standards could be developed and laid down in cases like these.... It is no doubt true that a standard established by the Court as a construction of

the statutory provision would not decide every conceivable case that might arise. It is the nature of legal questions that many of them fall between earlier decisions, or very close to the line, and thus require further refinement, or even qualification, of earlier decisions in the field. But that is no reason for not providing guidance which will resolve a large proportion of the cases, and, even more important as a practical matter, will enable administrative officers and counsel advising clients to resolve many of the problems long before they develop into disputes or litigation. [n.38]

In view of the subjective nature of the inquiry involved in determining whether or not a transfer is a gift, Duberstein is not necessarily wrongly decided. [n.39] Neither, however, does Duberstein provide a broad rule for deciding how mixed questions should be classified when deciding the scope of appellate review. The Supreme Court's own comments in Duberstein, in the passage quoted above, [n.40] indicate that a decision on how any one particular mixed question should be classified depends on the unique set of circumstances which that question presents. In short, no black letter rules for classifying mixed questions exist.

C. Policy-based considerations in classifying mixed questions for purposes of review.

Duberstein, along with the commentary it has generated, has led to the identification of a number of factors which should be considered when deciding whether a mixed question like practical utility should be classified as law or fact.

To begin, the relative competence of the trial court and appellate court has emerged as a significant consideration in deciding on the deference to be accorded the fact-finder's conclusion. On some issues, the collective*211 insight of a panel of appellate judges is believed more likely to produce a correct result than the insight of the initial fact finder. [n.41] This factor would appear particularly significant in the area of patent law, where Congress has created a specialist appellate court, the United States Court of Appeals for the Federal Circuit, to review the decisions of trial courts of general jurisdiction. [n.42] Indeed, this court was created for the purpose of enhancing the uniformity and predictability of the patent laws. [n.43]

As pointed out by Professor Louis, however, appellate courts do not have unbridled discretion to classify mixed questions as law or fact on the basis of relative competence alone, as "any approach based solely on the relative fact- finding abilities of judges and jurors renders almost unnecessary and meaningless the current controversy concerning whether the seventh amendment or the due process clause permits a complexity exception to the right of trial by jury." [n.44] In view of the hostility some judges on the Federal Circuit have expressed towards the complexity exception, [n.45] it is clear that, while relative competence may be--and should well be--a significant factor in deciding whether practical utility should be classified as law or fact for purposes of review, it cannot be the only consideration.

Aside from relative competence, another important consideration in deciding whether to classify an issue as law or fact is whether or not the policy underlying the statute in question provides a useful resource for reaching a conclusion on how the statute should be applied in a given situation. If the policy underlying the law is helpful in formulating rules which can be applied by trial courts in subsequent cases, a panel of appellate judges is ordinarily considered better situated to contemplate *212 these policy considerations. [n.46] If, however, policy provides no useful guidance on how the question should be resolved, then, observes Professor Carrington, "there is no alternative but to rely on instinct, and the instinct of the trier of fact serves as well or better than any." [n.47]

A need for uniformity and predictability in the substantive area in which a mixed question resides is a factor which weighs in favor of classifying the question as one of law. Mixed questions which affect property rights are frequently classified as questions of law because of this need. [n.48] In some cases, this is because the statutory language underlying the issue is so broad and vague that no consistency could be achieved if the issue is classified as one of fact. [n.49] As to such statutes, the Fourth Circuit has noted that "where the facts of two cases are substantially the same, the cases should not be applied differently because trial judges have looked at them in a different way." [n.50]

Another way to approach the broad question of whether a need for predictability exists is to ask whether an incorrect determination of the question in one case might affect similar conduct of parties not involved in the litigation. [n.51] If so, classifying a question as one of law and stating rules in appellate decisions which govern such similar conduct helps practicing lawyers advise their clients on a course of conduct which will avoid litigation of the question in the future. [n.52] In such cases, the *213 classification of a mixed question as one of law should ultimately conserve the resources of both courts and parties by enabling parties to avoid litigation by following guidelines which the appellate court has previously set forth.

When an appellate court classifies a question as one of law, it commits itself to spending its time reviewing that question in the future. The time of an appellate court is, however, a limited resource, which the court should guard carefully: time spent reviewing one issue is time taken away from reviewing other issues. [n.53] As a practical matter, time limitations require an appellate court to consider whether classification of a particular question as one of law is a sensible commitment of resources, or whether the court can better promote uniformity and consistency in the law by classifying that question as one of fact and devoting its attention to other, more pressing, issues. When a particular mixed question is appropriate for a law classification, this time investment should be a fruitful one: as noted above, proper use of the classification power should generate rules which attorneys can use to advise clients of a course of conduct which should not require later resort to the courts to decide whether that course was correct.

As a final matter, it bears note that exercise of the classification power presents no Seventh Amendment problems. This power represents one of the established exceptions to the right to trial by jury, [n.54] and is the same power which permits issues such as obviousness [n.55] and enablement [n.56] to be classified as questions of law. [n.57]

The primary limitation on this power is that its exercise must be based on a balanced conclusion *214 resulting from the consideration of a number of inquiries [n.58]--it should not be invoked on a comparison of relative competence alone. [n.59]

D. An Example: United States v. McConney.

A recent example of the exercise of the classification power is United States v. McConney. [n.60] In that case, the Ninth Circuit held the "exigent circumstances" exception to the federal "knock-notice" requirement of the RICO Act a question of law. [n.61] McConney was an en banc decision in which the Ninth Circuit overruled its prior decision that the presence of exigent circumstances was a question of fact. [n.62]

In McConney, the Ninth Circuit observed that standard of review jurisprudence on mixed questions of law and fact was in disarray, and it resorted to the standard of review jurisprudence available on questions of pure law and pure fact for guidance on how the exigent circumstances question should be classified. [n.63] The court observed that the clearly erroneous rule stated in Rule 52(a) of the Federal Rules of Civil Procedure serves two objectives: first, it assigns responsibility for resolving factual disputes to the court best situated to weigh the evidence, and second, it relieves appellate courts of the burden of reviewing issues which they are not well suited to decide. [n.64] Free review of legal questions was noted to serve converse concerns. First, appellate courts are better structured to review legal questions because they are not encumbered with reviewing evidence, and because they can bring the collective judgment of at least three judges to bear on the issue; second, appellate rulings on legal issues become controlling precedent which may affect rights of other potential litigants in the future; finally, *215 appellate review of legal issues rather than factual issues which concern immediate litigants only is a sensible use of the appellate resource. [n.65] A mixed question, the Ninth Circuit observed, should be reviewed like a question of fact if these considerations favor decision by the trial court, and reviewed like a question of law if these considerations favor decision by the appellate court. [n.66]

Finding that the exigent circumstances question required an inquiry that went beyond historical facts, the court expressly overruled its prior decision on this issue and held the question of exigent circumstances to be one of law. [n.67] The question, said the court, involved balancing constitutional privacy concerns against societal values concerning the risks which police officers should be required to assume in the course of their duties: "a question no amount of fact-finding will answer." [n.68] Because the court viewed the issue as one which required value judgments about the policy underpinnings of the law, and one which would produce decisions of precedential importance, it announced that it "should not hesitate to review the district judge's determination independently." [n.69]

Our concern is not with whether or not the McConney decision was correct, but with the process by which that conclusion was reached. McConney illustrates that an appellate court can weigh a variety of considerations before deciding whether it will review a

particular mixed question as fact or law, and that such an approach is an appropriate one in deciding the classification to be made.

IV. EVOLUTION OF THE PRACTICAL UTILITY REQUIREMENT

A. Brenner v. Manson and In re Kirk

Contemporary authority addressing the practical utility requirement begins with the Supreme Court's decision in Brenner v. Manson. [n.70] Manson had filed an application for a process of preparing known steroids and requested that an interference be declared between his and *216 a previously filed application. The steroids produced were undergoing In vivo screening for tumor inhibition in mice, and adjacent homologs of the compounds were known to inhibit tumor growth in mice. [n.71]

The Patent and Trademark Office denied Manson's request for an interference on the grounds that the applicant had failed to adequately show any utility for the compounds produced by the process. On appeal, the C.C.P.A. reversed the P.T.O., stating that an application claiming a process for producing a known product need not show a utility for the product as long as the product was "not alleged to bedetrimental to the public interest." [n.72] The Supreme Court reversed the C.C.P.A., holding Manson unable to make the interference.

Manson advanced three arguments in the Supreme Court: first, that the known utility for the adjacent homologs of the products of the claimed process provided the requisite utility; second, that a chemical process is patentable if it yields the intended product and the product is not "detrimental" to the public interest; and third, that compounds, and the processes which produce them, are patentable if the compounds are the subject of serious scientific investigation. [n.73] The Court dismissed the first of these arguments by declining to overturn the Examiner's finding that there was not a sufficient likelihood that the steroid produced by the process would have tumor-inhibiting properties. [n.74]

As to Manson's second and third arguments, the Court found itself "remitted to an analysis of the problem in light of the general intent of Congress, the purposes of the patent system, and the implications of a decision one way or the other." [n.75] The Court observed that a decision to grant a patent encourages the dissemination of information, while the inability to obtain a patent may discourage disclosure of the process while uses for the product are sought. On the other hand, the Court expressed skepticism over the quality of information disclosed in patents, and suggested that any alleged pressures to keep unpatentable processes secret were exaggerated. [n.76] The Court's primary concern, however, was that the grant of claims in cases like Manson might block off large areas of future scientific research into end uses for the product. For these reasons, the Court concluded that, until a process is developed to the *217 point where "specific benefit exists in currently available form," an applicant is not entitled to a patent. [n.77]

The Manson Court commented that the arguments it had set forth would apply equally to product claims. [n.78] This comment was applied in In re Kirk, [n.79] where the C.C.P.A. affirmed the Patent and Trademark Office rejection of claims to new steroid compounds.

The claims in Kirk were rejected because the applicant failed to provide a specific allegation of utility. On appeal, the applicant argued that the utility requirement was satisfied, first, because the claimed compounds were disclosed to have biological activity "of the nature known for analogous steroidal compounds," and second, because the compounds were useful for the preparation of other useful steroidal compounds. [n.80]

The C.C.P.A. rejected the applicant's first argument because it found the expression "biological activity" too vague to meet the requirement of section 101. [n.81] The second argument was rejected because the applicant had not shown that the compounds to be prepared from these intermediates had a known use. [n.82]

Judge Rich filed a vigorous dissent in Kirk, with the arguments in this dissent almost entirely based on policy and precedent. Judge Rich noted that the term "useful" had been clarified in over a century of *218 judicial decisions, [n.83] that Manson and Kirk created unworkable problems in distinguishing useful from useless compounds, [n.84] that this line of decisions encouraged phony or contrived utilitystatements and a delay in disclosure of new compounds, [n.85] and that these decisions were based on an unsound "quid pro quo" view of the patent statute which seemed to require the disclosure of something of commercial value in a patent, when in fact one could never distinguish in advance which patents in any technology would have commercial value from those which would not. [n.86]

B. Nelson v. Bowler and the Intermediate years.

After Brenner, a number of decisions focused on whether patent applications on pharmaceutical inventions satisfied the enablement requirement of section 112. [n.87] In these decisions, the stated utility clearly satisfied the practical utility requirement, but the applications lacked detail on how these desirable results were to be achieved. One might surmise that applicants decided to make more bold predictions from their data and risk enablement rejections, rather than make more conservative statements on the implications of their data and risk encountering the obstacle of Brenner. Nevertheless, applicants taking this approach may have difficulty satisfying the enablement requirement during prosecution, as tests demonstrating the stated utility may not have been conducted, and the sufficiency of the disclosure under section 112 may be directly challenged by the Patent Examiner.

The decision in Nelson v. Bowler [n.88] demonstrates that at least some applicants are best served by stating a utility close to their data--and close to the limits of the Brenner requirement. In Nelson this was done to establish an early actual reduction to practice in

an interference. *219 Other applicants might choose this approach because they lack the time or resources to meet enablement or operability rejections, because they wish to simplify inventorship issues, or simply because they desire an early filing date. [n.89]

Nelson involved interference counts to substituted prostaglandins and intermediates for preparing these compounds, with Bowler having been awarded priority by the P.T.O. [n.90] The issue on appeal was whether Nelson had demonstrated a utility sufficient to establish an actual reduction to practice prior to the critical date. To do this, Nelson relied on two tests: an in vivo rat blood pressure test and an in vitro gerbil colon smooth muscle stimulation test. These tests had been found insufficient to demonstrate a practical utility by the Patent and Trademark Office. On appeal, the C.C.P.A. made the following observation on the policy aspects of the utility requirement:

Knowledge of the pharmacological activity of any compound is obviously beneficial to the public. It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility. [n.91]

While Bowler argued that Nelson's tests were not adequate because they did not show statistically significant differences, the C.C.P.A. stated that "a rigorous correlation is not necessary where the test for pharmacological activity is reasonably indicative of the desired response." [n.92] In response to Bowler's argument that these tests were only evidence of a potential utility, the C.C.P.A. emphasized that the tests directly evidenced the asserted utility. [n.93] Judge Rich concluded with the observation *220 that "every utility question arising in an interference must be decided on its own facts." [n.94] In view of the evidence as a whole the court was persuaded that Nelson had established an actual reduction to practice, and the decision of the P.T.O. was reversed.

C. Cross v. Iizuka: The latest refinement.

The Nelson decision has been adopted and extended by the Federal Circuit in Cross v. Iizuka, [n.95] which also involved a patent interference Iizuka had applied for a patent on a new group of imidazole derivatives. The application disclosed that these compounds inhibited the enzyme thromboxane synthetase in in vitro blood platelet microsome assays. The court found that this enzyme forms thromboxane A sub2 , that thromboxane A sub2 was a causal factor in platelet aggregation, and that platelet aggregation was associated with several mammalian disorders. [n.96] No evidence showed that the claimed compounds were active as enzyme inhibitors in vivo. [n.97]

Parent compounds which were structurally related to the claimed compounds were known to inhibit thromboxane synthetase both in vitro and in vivo. [n.98] Based on this, one expert witness, in uncontradicted testimony stated that the claimed compounds would similarly be expected to inhibit thromboxane synthetase in vivo. [n.99] The parent

compounds, like the *221 claimed compounds, had never been shown to have a practical therapeutic use. [n.100]

An interference on the claimed compounds was declared between Cross and Iizuka, with Iizuka prevailing. In reaching its decision, the Board of Interferences suggested that tests showing pharmaceutical activity may satisfy section 101 even when no specific therapeutic use for the compounds had been established. [n.101] Cross appealed, arguing that the Iizuka patent disclosure satisfied neither the practical utility requirement of section 101 nor the enablement requirement of section 112. [n.102] On appeal the Federal Circuit affirmed the decision of the Board of Interferences. [n.103]

Judge Kashiwa, in Iizuka, characterized the development of the law on the practical utility requirement since Brenner, and the policy implications of this development, as follows:

Our predecessor court has accepted evidence of in vivo utility as sufficient to establish a practical utility.... This in vivo testing is but an intermediate link in a screening chain which may eventually [lead] to the use of the drug as a therapeutic agent in humans. We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question. Successful in vitro testing will marshal resources and direct the expenditure of effort to further in vivo testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an in vivo utility. [n.104]

In the court's view, pharmaceutical activity in an in vitro assay is easiest to establish, pharmaceutical activity in an in vivo assay more difficult to establish, and therapeutic activity in the treatment of subjects most difficult to establish. Iizuka ultimately facilitates the early disclosure of new compounds by holding, in appropriate cases, [n.105] a demonstration of the easiest to establish activity--in vitro activity--sufficient to support a patent application.

*222 The Iizuka court stated and applied a three step analysis in reaching its decision:

(1) Determine the utility described in the application at issue (the "stated utility");

(2) determine whether the stated utility complies with the "practical utility" requirement of section 101 of the patent statute, as defined by prior judicial decisions; and

(3) determine, with respect to the stated utility, whether the application contains sufficient teachings to satisfy the enablement requirement of section 112. [n.106]

Iizuka does not hold that in vitro activity will always establish a practical utility. [n.107] With regard to the second step in the above analysis, the court cautioned that each case must be decided on its own, considering the relevant evidence as a whole. [n.108] In Iizuka, the court emphasized that the evidence concerning structurally related compounds established a "reasonable correlation" between in vitro test results and expected in vivo test results, and affirmed the decision of the P.T.O. [n.109]

After Iizuka, the most difficult issue in similar cases involving new pharmaceutical compounds appears to be the strength of the correlation between in vitro and in vivo activity. If the correlation is tenuous, proof of in vivo activity may be necessary to satisfy section 101. In such a case, section 112 would require that the application teach one skilled in the art how to use the claimed compounds in an in vivo assay. Iizuka should nevertheless expand the opportunities available for seeking patent protection on at least some new compounds early on during investigation of those compounds.

The first fact-finder to pass on practical utility questions is the U.S. Patent and Trademark Office. Preliminary indications are that the Patent and Trademark Office is not necessarily deciding questions of practical utility in the manner contemplated by the Federal Circuit in *223 Cross v. Iizuka. [n.110] It is therefore surprising that Iizuka also categorized this issue, which both the C.C.P.A. and the Federal Circuit labored to clarify on a number of occasions, as a question of fact, to receive only limited review in future appellate decisions from the various triers of fact--be they the Patent and Trademark Office or the District Courts.

V. PRACTICAL UTILITY SHOULD BE REVIEWED AS A QUESTION OF LAW

The Federal Circuit in Iizuka noted that a resolution of the utility question is dependent on the facts of each case. [n.111] This is true for all mixed questions, and does not mandate a conclusion that the issue be classified as one of fact. To the contrary, the factors which should be considered in determining how a particular mixed question should be classified for the purpose of appellate review uniformly indicate that practical utility should be classified as a question of law.

A. Economic policy considerations indicate practical utility should be reviewed as a question of law.

1. The benefits of the follow-on development process.

In Brenner v. Manson, the Supreme Court focused on the potential scope and economic value of patents when it decided that Manson had failed to satisfy the practical utility requirement. [n.112] The practical utility requirement, however, primarily affects the time when patent *224 applications are filed. [n.113] Economic analysis since Manson has revealed significant benefits to the public which are obtained when patents issue early.

The conventional, simplistic view of patent protection for pharmaceuticals is that it leads to a single company monopoly on the patented product which blocks others from entering the market until the patent expires. [n.114] Bernard Kemp, in a well-reasoned article concerning the "follow-on" development process, has pointed out that this view ignores the highly institutionalized practice by which pharmaceutical companies develop

related products having similar therapeutic properties during the term of patent protection for a breakthrough product. [n.115]

Kemp observes that, when a new drug is successfully marketed, the potential for sharing in this market leads competitors to develop around the patent and introduce their own related products. [n.116] The products developed later are the "follow-on" products. For the diuretic agents specifically studied by Kemp, the follow-on products came on the market one to four years after the breakthrough products were introduced. [n.117] The follow-on products provided patients and physicians with different therapeutic options, permitting better matching of treatment to individual patients. [n.118] In some cases, prices remained stable, but the enhanced efficacy of follow-on products enabled lower drug dosages at lower cost. [n.119] In other cases, the introduction of follow-on products lead to price competition. [n.120] In short, instead of being a barrier to entry, the success of a patented drug attracted competing research and development, provided the public with more treatment options, and produced more price competition among the drug manufacturers. It has even been suggested that the information revealed in the original patent helps competing researchers more quickly develop similar compounds which are sufficiently different to themselves be patented. [n.121]

Knowing of the follow-on development process, a company with a promising compound would not be expected to file a patent application *225 early. Instead, there would be an incentive to file late, to slow the onset of follow- on research. Most pharmaceutical companies, however, need some assurance that the benefits of their research will be protected by a patent if they are to invest additional resources in developing the product. The practical utility requirement serves the legitimate purpose of preventing the grant of patent protection on unreasonable speculation, which would injure the public by tying patent rights to the ability of a company to invest in patent filings rather than the ability of a company to invest in beneficial research. [n.122] If, however, a patent application is based on legitimate (albeit early-stage) research, and is filed early because the company seeking the patent needs early assurance of its patent position to justify its continued investment in developing the product, the economic benefits to the public arising from the follow-on development process should be considered in deciding whether the practical utility requirement has been satisfied. An appellate court is better situated to consider matters of economic policy such as these than is a trier of fact.

2. The trend towards consolidation in the pharmaceutical industry.

In his dissenting opinion in In re Kirk, Judge Rich observed that a strict practical utility requirement would make it difficult for small corporations which do not have extensive in vitro screening facilities to compete with large corporations in obtaining patents on new chemical compounds. [n.123] Judge Rich's concern was well-founded. The high cost of drug innovation has lead to predictions that small to medium-sized enterprises will no longer be able to compete in the pharmaceutical industry. [n.124] The planned merger between SmithKline Beckman Corp. and Beecham Group PLC, and the reasons stated for this merger, [n.125] verify these predictions. *226 For a small enterprise

attempting to enter the pharmaceutical industry, in vitro data may be the only data available at the time they must apply for a patent. An appellate court is better situated than a trial judge or jury to consider how a decision on practical utility might affect the trend towards consolidation in the pharmaceutical industry, and whether the question should be decided in a way which will assist the patent programs of small, innovative corporations. [n.126]

B. Patent policy considerations indicate practical utility should be reviewed as a question of law.

Decisions concerning the practical utility requirement are replete with references to policy considerations. The primary concern stated by the Supreme Court in Brenner v. Manson was that patentees not be able to block off areas of research of unknown scope without first providing some specific benefit to the public. [n.127] A countervailing policy consideration, stated by the C.C.P.A. in Nelson v. Bowler, was that the early disclosure of compounds with pharmaceutical activity be encouraged. [n.128] No amount of fact-finding will give a district court a complete answer when deciding which of these two opposing concerns should prevail in any one case. A sound understanding of the economic consequences of a decision one way or the other is clearly important in deciding these questions. Also important is an understanding of how the utility requirement interacts with other requirements of the patent statute, and an understanding of the policies behind these various requirements.

Among other things, the utility requirement interacts with the requirements that patents be enabling, [n.129] that patents disclose operable inventions, [n.130] that patents name all investors, [n.131] and that-- where two *227 or more applications for the same invention are made--the patent issues to the first to make the invention. [n.132] The requirement that patents be enabling serves the policy of insuring that patent applicants receive claims of a breadth and economic value which fairly compensates them for their contribution to technology. [n.133] As noted above, enablement issues may be simplified by resorting to a more minimal showing of utility, potentially permitting the applicant to obtain broader claims. [n.134] The requirement that patent applications disclose operable inventions serves the policy of insuring that patents are awarded to those who have expended the effort required to make an invention, and are not awarded for someone's speculation about what others may ultimately accomplish. [n.135] Operability problems may likewise be reduced by resort to a *228 more minimal showing of utility. [n.136] The requirement that all inventors be named on a patent serves the policy of limiting the benefits of the patent statute to those who actually exert inventive effort. [n.137] Potential joint ownership problems and prior art problems arising from this requirement can be circumvented by seeking the most minimal showing of utility which will pass the statutory requirement, decreasing the number of persons required to make the invention, and thereby reducing the number of inventors which must be named on the application. [n.138] The rules underlying the decision of priority contests serve the policy of encouraging the early disclosure of inventions. [n.139] Parties seeking to prevail in such contests have been compelled to seek the least sufficient showing of utility which will

satisfy section 101. [n.140] Abolition of interferences in favor of a first to file rule will similarly encourage early *229 filing of applications, and will likewise encourage patent applicants to base their applications on the minimum showing of utility possible.

With the patent statute itself generating an incentive for patent applicants to rely on the minimum showing of utility which will satisfy the utility requirement, decision of utility questions should not be left to the trier of fact. Instead, by classifying practical utility as a question of law, the Federal Circuit can articulate rules on how the utility requirement is to be satisfied which are founded on an understanding of how the requirement operates within the patent statute as a whole.

C. Procedural policy considerations indicate practical utility should be classified a question of law.

1. Prior appellate decisions are a useful resource in deciding utility questions.

If the Federal Circuit continues to provide rules on how the utility requirement is to be satisfied, prior judicial decisions indicate that these rules will affect the conduct of similarly situated parties in the future. For example, the C.C.P.A.'s decision in Nelson v. Bowler was an important precedent guiding the Federal Circuit to its decision in Cross v. Iizuka. [n.141] Just as Nelson affected Iizuka, these two decisions can likewise be expected to affect the conduct of other parties conducting pharmaceutical research in the future. [n.142] With courts using prior utility decisions to guide subsequent decisions, patent counsel can similarly be expected to look to prior decisions touching on this requirement for guidelines which will aid their clients in developing a research strategy which will make best use of the patent laws. At the least, patent counsel will be expected to advise their clients when, in the course of the screening of a new compound for biological activity, the practical utility requirement has been satisfied and an application should be filed. When the Federal Circuit states guidelines in its decisions which are likely to influence the conduct of other parties in the future, as it did in Iizuka, the wisdom of a party's reliance on patent counsel's interpretation of these decisions should be judged by the Federal Circuit, and not left to the instinct of the trier of fact.

*230 2. A need for predictability on the utility requirement exists.

If patent counsel can provide their clients more clear guidelines on how to satisfy the practical utility requirement, then these are guidelines that clients should be anxious to receive. Patent rights in general are speculative investments. [n.143] Pharmaceutical research in particular is an expensive and risky undertaking. [n.144] The high costs and risks of this research, combined with the speculative nature of the protection available for the fruits of the research, creates a need in those investing in such research for as much certainty and predictability in the patent laws as the courts can provide. In this respect,

the practical utility question is similar to other mixed questions affecting property rights, which--for similar reasons--have often been classified as questions of law. [n.145]

3. The Court of Appeals for the Federal Circuit is the forum most competent to decide utility questions.

The Court of Appeals for the Federal Circuit is a court of special jurisdiction, hearing appeals from all U.S. District Court decisions on actions arising under the Patent Act, as well as appeals from decisions of the Board of Patent Appeals and Interferences. [n.146] It was created in 1982 for the express purpose of harmonizing enforcement of the patent laws, [n.147] includes a number of judges experienced in patent law, and is aided by a staff of Technical Advisors. [n.148]

*231 These factors combine to give the Federal Circuit a distinct advantage over the district courts in applying the patent laws to complex technical and scientific subject matter--as Congress intended when the court was created. The Federal Circuit is, of course, bound by Rule 52(a) of the Federal Rules of Civil Procedure, cannot freely review questions of pure fact merely because it is better qualified to decide patent issues than some district courts, and has demonstrated proper concern for the rules allocating decision-making authority between trial and appellate courts. [n.149] When, however, a question is a mixed question rather than a question of pure fact, the Federal Circuit's competence in patent law is a factor which should be considered in deciding whether clarity in the law and uniform enforcement of the law will most nearly be achieved by classifying the issue as a question of law. Where other factors weigh in favor of a law classification--as is the case for the practical utility requirement--the special competence of the Federal Circuit to deal with the issue should not be ignored.

4. Review of practical utility disputes by the Federal Circuit would be a worthwhile investment of the appellate resource.

While no rigorous tabulation has been made, it appears that appellate courts in the past twenty years have been asked to review practical utility decisions far less often than, for example, decisions on the non-obviousness requirement. It is therefore doubtful that the express classification of practical utility as a question of law would appreciably increase the workload of the Court of Appeals for the Federal Circuit: it simply is not an issue frequently raised in the district courts. While some increase in the number of occasions on which practical utility is contested may be expected as more biotechnology patents are litigated, there is no reason to expect that the number of appeals generated by the practical utility question alone would be undue.

The practical utility requirement has generated considerable discussion among commentators, [n.150] reflecting a need for clear guidelines on this issue. In view of the value appellate decisions on questions of utility would have as precedent to similarly situated parties, and the reasonable number of appeals in which the issue is likely to be

raised, a law classification for practical utility would be a worthwhile investment of the Federal Circuit's time. Indeed, this time investment should promote *232 the efficient enforcement of the patent laws by enabling other parties to refer to these decisions and avoid litigation of this issue in the future. [n.151]

5. The factfinder's experience with the "mainsprings of human conduct" is not a useful resource in deciding utility questions.

In Commissioner v. Duberstein, where the question of whether a transfer was a "gift" under the tax laws was classified as a question of fact, the Supreme Court commented that gifts were motivated by "detached and disinterested generosity." [n.152] A decision on the gift question thus requires an inquiry into an individual's subjective intent. For such an inquiry, experience with the "mainsprings" of life is helpful, but no amount of experience with human conduct is helpful in deciding whether a "reasonable correlation" under the patent laws exists between in vitro test results and expected in vivo test results on the same compound. [n.153] While the Federal Circuit has not indicated to whom such correlations must appear reasonable, it is unlikely that an inquiry into the subjective intent of actual individuals is required, [n.154] and more likely that the reasonableness of such correlations must be interpreted in light of the economic policy implications of a decision one way or the other, [n.155] the policies underlying the patent laws, [n.156] and the policies underlying the allocation of decisionmaking authority between trial courts and appellate courts. While the ultimate conclusion of any decisionmaker on a specific utility question may be somewhat "subjective," the decisionmaker is not concerned with the "subjective intent" of a party. Instead, the decisionmaker is concerned with evaluating those factors which prior decisions have identified as relevant to deciding this issue. The nature of these factors indicates that practical utility, like obviousness, should be classified as a question of law.

*233 VI. CONCLUSION

The statement in Cross v. Iizuka that practical utility is a question of fact is dicta. In Iizuka, the decision of the Patent and Trademark Office was affirmed, hence the question of the standard of review to be applied was not raised. [n.157] Moreover, Iizuka cited as its authority for classifying practical utility as a question of fact a case concerning the operability requirement of section 101. [n.158] While operability is concededly a question of fact, it has little to do with practical utility, which has been treated as a requirement separate and distinct from operability at least since Brenner v. Manson. [n.159]

Because practical utility is a mixed question, the Federal Circuit can choose to review it as either a question of fact or a question of law. In making this choice, the court should consider the opportunities utility disputes will present it to make decisions which will address economic issues such as the follow-on drug development process [n.160] and the trend towards consolidation in the pharmaceutical industry. [n.161] The court should

consider the chances utility disputes will give it to explain how the practical utility requirement interacts with the patent statute as a whole--and to explain the policies underlying the various sections of this statute. [n.162] Finally, the court should address procedural policy issues and consider the important role precedent has played in previous utility decisions, [n.163]the substantial need for predictability in how the patent laws are applied, [n.164] the superior ability of the Federal Circuit over the district courts to decide utility questions, [n.165] the relatively small amount of time which the Federal Circuit would be required to invest in the free review of utility questions, [n.166] and the relatively minor contribution which experience with ordinary human conduct makes to *234 deciding this issue. [n.167] The economic policy considerations, the substantive law policy considerations, and the procedural law policy considerations all indicate that practical utility should be classified as a question of law.

By holding practical utility a question of law, the Federal Circuit would not be making a radical departure from established standards of review. To the contrary, a role for the courts in deciding utility questions has long been contemplated. Professor Robinson, [n.168] writing at the end of the nineteenth century, commented on this role as follows:

> [T]he court declares in what utility consists, and where the patented invention is manifestly frivolous or injurious to the public directs the jury to find accordingly; otherwise the jury determine[s] whether the invention is practically available for any useful purpose. [n.169]

Professor Robinson's views suggest the classification of practical utility as a question of law and operability as a question of fact. One hundred years later, Professor Robinson's classification continues to provide a sensible division of decision-making authority between the appellate courts and the triers of fact when the judicial system is confronted with disputes concerning complex technology.

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[n.1]. 383 U.S. 519 (1966).

[n.2]. 376 F.2d 906 (C.C.P.A.1967).

[n.3]. 376 F.2d 936 (C.C.P.A.1967).

[n.4]. 35 U.S.C. § 101. See generally 1 D. Chisum, Patents, § § 4.01- 4.04 (1988); Walterscheid, Insufficient Disclosure Rejections (Part II), 62 J.Pat.Off.Soc'y 229 (1980).

[n.5]. See Mirabel, "Practical Utility" is a Useless Concept, 36 Am.U.L.Rev. 811 (1987); Cooper, Patent Problem for Chemical Researchers-- The Utility Requirement After Brenner v. Manson, 18 Idea 23 (1976); Eggert, Uses, New Uses and Chemical Patents-- A Proposal, 51 J.Pat.Off.Soc'y 768 (1969); Comment, The Patentability of Chemical Intermediates, 56 Cal.L.Rev. 497 (1968); Velvel, A Critique of Brenner v. Manson, 49 J.Pat.Off.Soc'y 5 (1967); Meyer, Utility Requirement in the Statute, 49 J.Pat.Off.Soc'y 533 (1967).

[n.6]. The National Academy of Sciences has predicted that, while U.S. pharmaceutical firms will remain innovative and growing for the foreseeable future, their presence will diminish in the face of foreign firms which will be more innovative and will grow more rapidly. National Research Council, The Competitive Status of the U.S. Pharmaceutical Industry, 51 (1981). Professors Grabowski and Vernon reported in 1981 that the research intensities of pharmaceutical firms had been declining over the past two decades in connection with declining rates of return on pharmaceutical research and development, with these firms increasingly diversifying into nonpharmaceutical areas. Grabowski and Vernon, The Determinants of Research and Development Expenditures in the Pharmaceutical Industry, in Drugs and Health 3, 17 (R. Helms ed. 1981).

[n.7]. See infra section IV.

[n.8]. See Cross v. Iizuka, 753 F.2d 1040, 1044 n. 7 (Fed.Cir.1985). It has been argued that, while practical utility is now effectively treated as a question of law, it is inappropriate for judges to decide this issue. Mirabel, "Practical Utility" is a Useless Concept, 36 Am.U.L.Rev. 811, 812 (1987). The present paper argues to the contrary: With the law that has been established on the practical utility requirement over the past twenty years, to now classify the requirement as a question of fact would lead to turmoil in the application of this law.

[n.9]. See Roberts, Genome Patent Fight Erupts, 254 Science 184 (1991).

[n.10]. See infra note 126.

[n.11]. If, for example, in vivo testing would require an inventor to seek biological screening facilities from one who does not have a preexisting obligation to assign the invention to the same party as that inventor, resort to a more simple in vitro test within

that inventor's capabilities would circumvent prior art problems arising from section 102(f) of the patent statute. See 35 U.S.C. § 102(f) and 35 U.S.C. § 103; see also Kirk, 376 F.2d at 959 (The Rule of Manson raises joint inventorship problems because of 35 U.S.C. § 102(f), and permits only those having both chemical synthesis and biological screening facilities to obtain patents on new chemical compounds.). If two separate organizations--one with chemical synthesis capabilities and the other with biological screening capabilities--develop the compound together under a research agreement which provides for common assignment to thereby resolve section 102(f) problems, an inability to clearly distinguish those inventions which require the biological screening capability and are truly joint inventions from those which are not may nevertheless jeopardize the cooperative endeavor.

[n.12]. See Cross v. Iizuka, 753 F.2d 1040, 1044 (Fed.Cir.1985) (Compliance with the enablement requirement is evaluated with respect to the stated utility.).

[n.13]. See In re Jolles, 628 F.2d 1322, 1323-24, 1327-28 (C.C.P.A.1980) (utility requirement satisfied by claimed pharmaceutical compositions asserted useful for the treatment of leukemia where the active ingredients possessed a close structural relationship to compounds known useful in cancer chemotherapy, one claimed composition had been found useful in chemical studies, and eight claimed compositions had been found active in experimental mice); In re Malachowski, 530 F.2d 1402, 1404 (C.C.P.A.1976) (utility requirement satisfied by claimed pharmaceutical compositions asserted useful for treating arthritis where the compositions had been shown useful in animals only, though the claims also encompassed the treatment of humans).

[n.14]. See, e.g., Nelson v. Bowler, 626 F.2d 853 (C.C.P.A.1980).

[n.15]. See infra sections V C 3 and V C 5.

[n.16]. See infra section V C 2.

[n.17]. See infra sections V C 1 and V C 4.

[n.18]. 1 D. Chisum, Patents, § 4.04[5] (1988).
For example, whether a patentee had properly satisfied the utility requirement was raised as a defense by the accused infringer in Carter- Wallace, Inc. v. Riverton Laboratories, Inc., 433 F.2d 1034, 1038-40 (2d Cir.1970) and in Studiengesellschaft Kohle mbH v. Eastman Kodak Co., 616 F.2d 1315, 1338-39 (5th Cir.1980).

[n.19]. 456 U.S. 273 (1982).

[n.20]. Id. at 289 n. 19.

[n.21]. Louis, Allocating Adjudicative Decision Making Authority Between the Trial and Appellate Levels: A Unified View of the Scope of Review, The Judge/Jury Question, and Procedural Discretion, 64 N.C.L.Rev. 993, 993-4 n. 3 (1986).

[n.22]. Cross v. Iizuka, 753 F.2d 1040, 1044 (Fed.Cir.1985).

[n.23]. Id.

[n.24]. See generally 9 C. Wright, A. Miller and F. Elliott, Federal Practice and Procedure § 2589 (Suppl.1986).

[n.25]. See Panduit Corp. v. Dennison Mfg. Co. 810 F.2d 1561, 1566 (Fed.Cir.1987) ("With the involved facts [on obviousness] determined, the decisionmaker confronts a ghost, i.e., 'a person having ordinary skill in the art....' "); see generally 2 D. Chisum, Patents § 5.04[3][c] (1987).

[n.26]. Carrington, The Power of District Judges and the Responsibility of Courts of Appeals, 3 Ga.L.Rev. 507, 520 (1969).

[n.27]. See 9 C. Wright, A. Miller and F. Elliott, Federal Practice and Procedure § 2588 n. 44 (Suppl.1986) (and accompanying text).

[n.28]. See In re Caveney, 761 F.2d 671, 674 (Fed.Cir.1985).

[n.29]. See Louis, supra note 21 at 1002-03 ("Even though ultimate facts are neither fact nor law, courts have misleadingly persisted in expressing the treatment of ultimate facts in terms of the law/fact dichotomy. It must be understood, however, that the expression reveals only the choice and not the reasons for it.").

[n.30]. Carrington, supra note 26 at 518.

[n.31]. United States v. McConney, 728 F.2d 1195, 1200 (9th Cir.) (en banc), cert. denied, 469 U.S. 824 (1984).

[n.32]. 363 U.S. 278 (1960).

[n.33]. Id. at 280-83.

[n.34]. Id. at 281, 283, and 293.

[n.35]. Id. at 285.

[n.36]. Id. at 289. The technical nature of the practical utility standard and the remote relation of practical utility to everyday human life immediately distinguish the practical utility requirement from the gift standard.

[n.37]. Carrington, supra note 26 at 523.

[n.38]. Griswold, Foreword: Of Time and Attitudes--Professor Hart and Judge Arnold, 74 Harv.L.Rev. 81, 89 (1960) (emphasis added).

[n.39]. See Weiner, The Civil NonJury Trial and the Law-Fact Distinction, 55 Cal.L.Rev. 1020, 1049-50 (1967).

[n.40]. See supra note 36 and accompanying text.

[n.41]. On this point, Chief Judge Coffin has commented as follows:

[E]very important appellate court decision is made by a group of equals. This fact reflects the shrewd judgment of the architects of our state and federal judicial systems that an appellate judge is no wiser than a trial judge. His only claim to superior judgement lies in numbers; three, five, seven or nine heads are usually better than one. F. Coffin, The Ways of a Judge 58 (1980).

[n.42]. See 28 U.S.C. § 1295.

[n.43]. See S.Rep. No. 97-275, 97th Cong., 2d Sess. 3-6, reprinted in 1982 U.S.Code Cong. and Ad.News 11, 13-16; see also Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 1032 n. 21 (1985) (and accompanying text).

[n.44]. Louis, supra note 21 at 1033.

[n.45]. See SRI International v. Matsushita Electric Corp., 775 F.2d 1107, 1126-32 (Fed.Cir.1985) (Markey, C.J., additional views).

[n.46]. See supra notes 36-38 and accompanying text; Carrington, supra note 26 at 519; see also McConney, 728 F.2d at 1205 ("When ... the application of law to fact requires us to make value judgments about the law and its policy underpinnings, and when ... the application of law to fact is of clear precedential importance, ... we should not hesitate to review the district judge's determination independently.").

[n.47]. Carrington, supra note 26 at 519.

[n.48]. Louis, supra note 21 at 1034 ("Although the protection of property rights is no longer a general source of constitutional fact classifications, it remains one of the principal sources of the law classification.").

[n.49]. See, e.g., Louis, supra note 21 at 1035 (The determination of whether an act is "unfair" or "deceptive" under the North Carolina version of the Federal Trade Commission Act was likely classified as a question of law because these terms are so broad and vague that no consistent results could otherwise be achieved.).

It is difficult to conceive of a more broad and vague term than the word "useful" in section 101 of the patent statute. See Brenner v. Manson, 383 U.S. 519, 529 (1966) ("[A] simple, everyday word [like 'useful'] can be pregnant with ambiguity when applied to the facts of life.").

[n.50]. United Mine Workers v. Jewell Ridge Coal Corp., 145 F.2d 10, 12 (4th Cir.1944), aff'd, 325 U.S. 161 (1945); see also Weiner, supra note 39 at 1046.

[n.51]. See Weiner, supra note 39 at 1033-34. This inquiry focuses more on the similarity of facts from case to case than on the vagueness of the statutory standard.

[n.52]. See Griswold, supra note 38 and accompanying text; Carrington, supra note 26 at 523.

[n.53]. See Louis, supra note 21 at 1013-14.

[n.54]. See Louis, supra note 21 at 996 n. 19.

[n.55]. See supra note 25.

[n.56]. See Atlas Powder Co. v. E.I. DuPont de Nemours & Co., 750 F.2d 1569, 1576 (Fed.Cir.1984); see also Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co., 730 F.2d 1452, 1463 (Fed.Cir.1984).

[n.57]. Exercise of the classification power is not without active debate. The Federal Circuit most recently reaffirmed its classification of the issue of obviousness, over a strong dissent by Judge Newman, in Newell Companies v. Kenney Mfg. Co., 864 F.2d 757 (Fed.Cir.1988).

[n.58]. See Weiner, supra note 39 at 1024 ("The weight to be accorded the trial judge's views should depend not on meaningless terminology but on the relative strengths and weaknesses of a trial and appellate court."); Carrington, supra note 26 at 520 ("The scope of review must be shaped to particular factors in each case, such as the value of the substantive principle invoked, the likelihood of a misapplication resulting from stubborn disregard or limited understanding by the trier of fact, and the nature and extent of the evidence on which the findings rest.").

[n.59]. See supra notes 44-45 and accompanying text.

[n.60]. 728 F.2d 1195 (9th Cir.) (en banc), cert. denied, 469 U.S. 824 (1984).

[n.61]. McConney is technically an example of free review of a mixed question under the constitutional fact model rather than under the law model, see Louis, supra note 21 at 996 n. 19, but serves nevertheless as an example of the types of factors an appellate court should consider when deciding whether a particular mixed question should be reviewed as fact or law.

[n.62]. McConney, 728 F.2d at 1205.

[n.63]. Id. at 1202.

[n.64]. Id. at 1201.

[n.65]. Id.

[n.66]. Id. at 1202.

[n.67]. Id. at 1204-05.

[n.68]. Id. at 1205.

[n.69]. Id. The practical utility question similarly requires value judgments about the policy underpinnings of the law.

[n.70]. 383 U.S. 519 (1966). While there was considerable debate over the proper interpretation of earlier decisions concerning the practical utility requirement, this debate was at least partly settled by Manson. See generally infra notes 77 and 79.

[n.71]. Id. at 522.

[n.72]. Id.

[n.73]. Id. at 531-32.

[n.74]. Id. at 532.

[n.75]. Id. The Court thus based its decision on an analysis of policy, and not on an analysis of fact.

[n.76]. Manson, 383 U.S. at 533-34.

[n.77]. Id. at 534-35. The Supreme Court in Brenner, noting previous C.C.P.A. decisions such as In re Hitchings, 342 F.2d 80 (C.C.P.A.1965), expressed no view "as to the patentability of a process whose sole demonstrated utility is to yield a product shown to inhibit the growth of tumors in laboratory animals." Brenner, 383 U.S. at 531 n. 17. In Carter Wallace, Inc. v. Riverton Laboratories, Inc., 433 F.2d 1034, 1036, 1038-40 (2d. Cir.1970), the Second Circuit concluded that a new compound, meprobamate, had satisfied the utility requirement when it was shown to have anticonvulsant activity in mice even though no human use was known at the time the application was filed. See also In re Bergel, 292 F.2d 955 (C.C.P.A.1961); In re Krimmel, 292 F.2d 948 (C.C.P.A.1961); In re Dodson 292 F.2d 943 (C.C.P.A.1961).

[n.78]. Manson, 383 U.S. at 535.

[n.79]. 376 F.2d 936 (C.C.P.A.1967); See also In re Joly, 376 F.2d 906 (C.C.P.A.1967); In re Schmidt, 377 F.2d 639 (C.C.P.A.1967). These decisions resolved the split of views generated by In re Bremner, 182 F.2d 216, 217 (C.C.P.A.1950), in which claims to the compound polydihydropyran were held properly rejected where the specification provided no indication of how this compound was to be used, and In re Nelson, 280 F.2d 172, 180 (C.C.P.A.1960), in which claims to new steroids were held to satisfy section 101 where the compounds were alleged to have "utility as intermediates in the search for cheaper and shorter routes to the synthesis of steroids having therapeutic or similar ultimate utility."

[n.80]. Kirk, 376 F.2d at 939.

[n.81]. Id. at 941.

[n.82]. Id. at 945.

[n.83]. Id. at 953, 954-55.

[n.84]. Id. at 957.

[n.85]. Id. at 959-63.

[n.86]. Id. at 963-69.

[n.87]. See In re Fouche, 439 F.2d 1237 (C.C.P.A.1971); In re Gardner, 427 F.2d 786 (C.C.P.A.1970); Kawai v. Metlesics, 480 F.2d 880 (C.C.P.A.1973); see also ICI Industries, PLC v. Mossinghoff, 223 U.S.P.Q. (BNA) 769 (D.D.C.1984); Ex Parte Powers, 220 U.S.P.Q. (BNA) 924 (P.T.O.B.A.1982). Interestingly, in Powers, the Patent and Trademark Office suggested that the applicant would have been better served by attempting to establish an in vivo utility. See Powers, 220 U.S.P.Q. at 926 ("While [utility in the treatment of disease] may be established by standard animal tests ... none [have] been made of record."). See supra note 77; infra note 88.

[n.88]. 626 F.2d 853 (C.C.P.A.1980). While the Nelson decision does not cite back to Brenner, it pursues the issue concerning in vivo testing left open by the Court therein. See Brenner, 383 U.S. at 531 n. 17.

[n.89]. See supra notes 11-14 and accompanying text; infra notes 129-140 and accompanying text.

[n.90]. Nelson, 626 F.2d at 854-56.

[n.91]. Id. at 856.

[n.92]. Id. Bowler's argument on this point was reasonable in view of the rigorous standards to which tests alleged to establish an actual reduction to practice are ordinarily held. See, e.g., Knapp v. Anderson, 477 F.2d 588, 590 (C.C.P.A.1970) (Laboratory tests are acceptable for proving a reduction to practice only when a relation is established between the test conditions and the intended functional setting of the invention.).

[n.93]. Nelson, 626 F.2d at 857. Compare Nelson with Rey-Bellet v. Engelhardt, 493 F.2d 1380, 1384-85 (C.C.P.A.1974), where (a) tetrabenzine antagonism tests in mice were held insufficient for showing utility as an antidepressant in humans because there was insufficient experience with the test to show the necessary correlation between in vivo and therapeutic activity, (b) the same tetrabenzine antagonism test was held insufficient for showing utility in animals because it was not established that tetrabenzine antagonism is per se useful--and the record established that mice are not depressed, and (c) a weak tranquilizing activity shown in a Sidman avoidance test was held insufficient for proving that tranquilizing activity would be observed in man. Query whether Rey-

Bellet would be decided the same way today. A lack of correlation between the tetrabenzine antagonism test in mice and some therapeutic activity in humans or animals would still be problematic, but even a weak tranquilizing effect shown in a Sidman avoidance test might well be sufficient to directly evidence an asserted utility. See also Bingham v. Godtfredsen, 222 U.S.P.Q. (BNA) 632, 637 (Bd.Pat.Int.1984) ("A standard in vitro test may be sufficient to demonstrate pharmacological activity of a compound, i.e., a 'practical utility'." ... We do not consider the in vitro tests [submitted in this case] sufficient to establish [a reduction of practice] because there is no indication ... that any of the compositions used for these tests was suitable for treatment of a mammalian subject.").

[n.94]. Nelson, 626 F.2d at 858. That practical utility questions must be decided on their own facts does not require the issue to be classified as one of fact. All mixed questions--both those classified as questions of law and those classified as questions of fact--must be decided on their own facts. The considerations relevant to selecting the proper classification are discussed in section III supra.

[n.95]. 753 F.2d 1040 (Fed.Cir.1985).

[n.96]. Id. at 1042.

[n.97]. Id. at 1043.

[n.98]. Id. at 1048.

[n.99]. Id. at 1049.

[n.100]. Id. at 1048-49 n. 17.

[n.101]. Id. at 1043.

[n.102]. Id. at 1043-44.

[n.103]. Id. at 1052.

[n.104]. Id. at 1050-51.

[n.105]. See Id. at 1051 ("Today, under the circumstances of the instant case, ... in vitro utility is sufficient to comply with the practical utility requirement of § 101.").

[n.106]. Id. at 1044. The court in Iizuka explained that whether or not the enablement requirement is satisfied must be determined with reference to the stated utility. Clearly it is easier to establish, as did Iizuka, that one skilled in the art would be able to use the claimed compounds in an in vitro assay, than it is to establish that such a person could use them as therapeutic agents--or even use them in an in vivo assay.

[n.107]. Indeed, the Court in Iizuka noted that Cross had not satisfied his burden under Rey-Bellett of showing structural dissimilarities between the parent compound and the compound of the count. Iizuka, 753 F.2d at 1049.

[n.108]. Iizuka, 753 F.2d at 1048 ("Every utility question arising in an interference, in the final analysis, must be decided on the basis of its own unique factual circumstances.").

[n.109]. Id. at 1050.

[n.110]. In Hoffman v. Klaus, 9 U.S.P.Q.2d(BNA) 1657, 1660 (Bd.Pat.App.1988), the Patent and Trademark Office stated that practical utility was not established by in vitro collagenase inhibition activity because there was no evidence of a correlation between the tests and "the treatment of arthritis or for any other useful purpose." Under Cross v. Iizuka, the issue should be whether the in vitro collagenase inhibition test was correlated with an established in vivo screening test, and not with therapeutic efficacy. In Ex parte Maas, 9 U.S.P.Q.2d(BNA) 1746, 1747-48 (Bd.Pat.App.1987), the Patent and Trademark Office stated that practical utility was not established when there was "no correlation on this record between in vitro experiments and a practical utility in currently available form for humans or animals." This statement also appears to be a less than rigorous application of the three-step test set forth in Cross v. Iizuka. See supra note 132 and accompanying text.

[n.111]. While prior decisions similarly emphasize that utility determinations are fact-dependent, see, e.g., In re Nelson, 280 F.2d 172, 185 (C.C.P.A.1960) (Whether a compound is useful as an intermediate "is a question of fact to be determined in each case."), they also suggest that utility determinations should be treated as questions of law. See, e.g., Carter-Wallace, Inc. v. Riverton Laboratories. Inc., 304 F.Supp. 357, 372 (S.D.N.Y.1969), aff'd, 433 F.2d 1034 (2d. Cir.1970) (Questions of law are involved in

utility determinations). Decisions prior to Brenner v. Manson which suggest that practical utility is a question of fact are dated, if not obsolete.

[n.112]. See supra notes 73-77 and accompanying text.

[n.113]. See supra notes 11-14 and accompanying text.

[n.114]. See J. Egan, H. Higinbotham, and J. Weston, Economics of the Pharmaceutical Industry, 73-77 (1982).

[n.115]. Kemp, The Follow-On Development Process and the Market for Diuretics, in Drug Development and Marketing, 255 (R. Helms ed. 1975).

[n.116]. Id. at 255-56.

[n.117]. Id. at 265-66.

[n.118]. Id. at 266.

[n.119]. Id. at 268-69.

[n.120]. Id. at 273.

[n.121]. J. Egan, H. Higinbotham, and J. Weston, supra note 114 at 78.

[n.122]. Practical utility has been though of since at least Professor Robinson's time as a requirement which protects the public interest. See infra notes 168-169 and accompanying text.

[n.123]. In re Kirk, 376 F.2d 936, 959 (C.C.P.A.1967) ("[T]he rule of the majority ... plays into the hands of the large to gigantic corporation....").

[n.124]. The Organization for Economic Co-operation and Development has commented on this trend as follows:

Today dramatic increases in the cost of innovation probably represent the strongest single factor increasing concentration in the pharmaceutical industry. Small and medium innovative enterprises cease to be viable because of the increasing cost of innovation and are absorbed by larger firms or pull out of drug development.

Organization for Economic Co-operation and Development, The Pharmaceutical Industry, 26 (1985).

[n.125]. Koenig and Lublin, Global Drug Industry Appears to Be Headed For Big Consolidation, Wall St. J., April 13, 1989, at 1, col. 6.

[n.126]. The Department of Commerce reports that genetic engineering technologies "were pioneered by small technology-oriented firms supported by venture capital." U.S. Department of Commerce, A Competitive Assessment of the U.S. Pharmaceutical Industry, 67-68 (1984). It is disturbing to note that, in Ex parte Maas, 9 U.S.P.Q.2d(BNA) 1746, 1747-48 (Bd.Pat.App.1987), a patent application on a genetically engineered vaccine was denied because the in vitro and in vivo test results available were held insufficient to satisfy the practical utility requirement, when it apparently would have taken one to two years to develop additional animal screening procedures. The obstacles a small, innovative corporation faces in a situation like this are clear.

[n.127]. See supra notes 75-77 and accompanying text.

[n.128]. See supra note 91 and accompanying text.

[n.129]. See supra note 12 and accompanying text.

[n.130]. See supra note 13 and accompanying text.

[n.131]. See supra note 11 and accompanying text; infra note 138 and accompanying text.

[n.132]. See supra notes 14 and 88-109 and accompanying text.

[n.133]. See In re Hogan, 559 F.2d 595, 605-06 (C.C.P.A.1977) (Questions of enablement "orbit about the more fundamental question: To what scope of protection is this applicant's particular contribution to the art entitled?").

[n.134]. An important inquiry in deciding whether claims are enabled is the predictability of the factors which the invention involves. See, e.g., In re Fisher, 427 F.2d 833, 839 (C.C.P.A.1970); see generally Sibley, Factual Inquiries in Deciding the Question of Enablement, 70 J.Pat.Off.Soc'y 115 (1988). If the minimal environment in which utility can be established is more predictable than other environments in which utility might be proven--as in vitro test environments are generally more predictable than in vivo test environments--then resort to a more minimal showing of utility places the applicant in a better position to argue or demonstrate the allowability of broader claims.

[n.135]. " 'Operability,' in the patent lexicon, is quite different from 'utility.' Operability's function is to assist in determinations of [a bona fide] reduction to practice.... Operability is the hallmark of [a bona fide] reduction to practice." P. Goldstein, Copyright, Patent, Trademark and Related State Doctrines, 493 (2d ed. 1981). See also In re Eltgroth, 419 F.2d 918, 922 (C.C.P.A.1970) ("Undoubtedly, the alleged utility of control of the aging process in living organisms and the significant beneficial results flowing therefrom is adequate [to satisfy the utility requirement.] Yet, there is a conspicuous absence of proof thereof ... [W]e find the instant record too speculative to satisfy the requirement of 35 U.S.C. § 101."); In re Woody, 331 F.2d 636, 639-40 (C.C.P.A.1964) (Claims to a method of forming underground caverns in salt formations with a nuclear explosion, which method had never been carried out, properly rejected as unenabled under section 112 and inoperative under section 101.).

[n.136]. For example, if a new compound is expected to be useful in a known in vitro assay, and other evidence indicates that operability in that in vitro assay would be sufficient to establish a practical utility, then a patent applicant could presumably obtain a constructive reduction to practice of the compound without running afoul of the operability requirement by describing the use of the compound in that assay before the in vitro tests had been conducted--assuming no more than routine skill is required to demonstrate that the compound is operable in those tests. Cf. Rey-Bellet v. Engelhardt, 493 F.2d 1380, 1387 (C.C.P.A.1974) (A "mental formulation" rises to the level of a conception if "the inventor has conceived the means of putting that formulation in the hands of the public where no more than routine skill would be required to do so."); GAF Corp. v. Amchem Products, Inc., 514 F.Supp. 943, 973 (E.D.Pa.1981) ("[S]ubmission of a chemical without predictability of activity is not invention.").

[n.137]. See Monsanto Co. v. Kamp, 269 F.Supp. 818, 824 (D.D.C.1967) ("To constitute a joint invention, it is necessary that each of the inventors work on the same subject

matter and make some contribution to the inventive thought and to the final result."); See generally 1 D. Chisum, Patents, § 2.01 et seq. (1988).

[n.138]. For a discussion of the complexities which Brenner v. Manson causes when two or more parties are involved in the development of a new chemical composition, see 1 D. Chisum, Patents, § 2.02[5] (1988). If a more simple showing of utility is sufficient, there is less chance that one who synthesizes a new compound will need to collaborate with a person having expertise in biologicalscreening procedures, and a greater chance that that inventor will be able to develop and employ his own screening procedure to satisfy the utility requirement. See also supra note 11 and accompanying text.

[n.139]. See Paulik v. Rizkalla, 760 F.2d 1270, 1275 (Fed.Cir.1985) ("We affirm the longstanding rule that too long a delay may bar the first inventor from reliance on an early reduction to practice in a priority contest.").

[n.140]. See, e.g., D'Silva v. Drabek, 214 U.S.P.Q.(BNA) 556, 562 (Bd.Pat.Int.1981) (proof of lack of mammalian toxicity not necessary to demonstrate practical utility for insecticidal compounds).

[n.141]. See Cross v. Iizuka, 753 F.2d 1040, 1045, 1046-47, 1050-51 (Fed.Cir.1985).

[n.142]. See generally Hoffman v. Klaus, 9 U.S.P.Q.2d(BNA) 1657, 1660 (Bd.Pat.App.1988); Ex parte Maas, 9 U.S.P.Q.2d(BNA) 1746, 1747-48 (Bd.Pat.App.1987): In re Hirsch, Pat.Trademark & Copyright J. (BNA) Vol. 34, No. 850, at 588 (Bd.Pat.App. July 31, 1987).

[n.143]. Judge Rich, in his dissenting opinion in Kirk, made the following observation on the speculative commercial value of patents:

> [P]atentability, in legal theory, has nothing to do with commercial value. It seems probable that the majority of inventions actually patented have little or no commercial value. Many, however, have tremendous value. Not every horse places in a race, but those which do make the race very attractive. Therein lies the incentive.

In re Kirk, 376 F.2d 936, 963 (C.C.P.A.1967).

[n.144]. "The problem of the U.S. pharmaceutical industry is not paucity of basic research, but the enormous cost and risk involved in development." U.S. Department of Commerce, A Competitive Assessment of the U.S. Pharmaceutical Industry, 99 (1984). See also Clymer, The Changing Costs and Risks of Pharmaceutical Innovation, in The Economics of Drug Innovation, 109 (J. Cooper ed. 1970).

[n.145]. See Louis, supra note 21 at 1006, 1034-1035.

[n.146]. See 28 U.S.C. § 1295; see also 28 U.S.C. § § 1291 and 1292.

[n.147]. See supra note 43.

[n.148]. The history behind the Federal Circuit's use of technical advisors is discussed in Rich, Thirty Years of This Judging Business, 14 AIPLA Quart.J. 139, 141-42 (1986). On the propriety of the Federal Circuit's use of technical advisors, see generally Godbold, Fact Finding by Appellate Courts--An Available and Appropriate Power, 12 Cum.L.Rev. 365 (1982).

[n.149]. See, e.g., Revlon, Inc. v. Carson Products, Inc., 803 F.2d 676, 678 (Fed.Cir.1986) ("Determining the weight and credibility of the evidence is the special province of the trier of fact.").

[n.150]. See supranotes 5 and 8.

[n.151]. See supra notes 51-53 and accompanying text.

[n.152]. Duberstein, 363 U.S. at 285.

[n.153]. Duberstein, in contrast, involved a non-technical issue on which experience with human conduct was believed helpful. See supra note 36 and accompanying text.

[n.154]. For an argument in favor of a subjective standard of utility, see Comment, The Patentability of Chemical Intermediates, 56 Cal.L.Rev. 497, 514-15 (1968).

[n.155]. See generally Geweke and Weisbrod, Some Economic Consequences of Technological Advance in Medical Care: The Case of a New Drug, in Drugs and Health, 235 (R. Helms ed. 1981).

[n.156]. This would be consistent with the approach taken for obviousness, which is reviewed as a question of law. See supra note 26. Indeed, in view of the greater similarity of facts between different practical utility disputes as compared to different non-obviousness disputes, the case is more compelling for classifying practical utility as a question of law than it is for classifying non-obviousness as a question of law.

[n.157]. Cross v. Iizuka, 753 F.2d 1040, 1052 (Fed.Cir.1985).

[n.158]. Iizuka cited Raytheon Co. v. Roper Corp. for the proposition that practical utility is a question of fact. Iizuka, 753 F.2d at 1044 n. 7. Raytheon, however, concerned operability, and not practical utility. See Raytheon Co. v. Roper Corp., 724 F.2d 951, 956 (Fed.Cir.1983), cert. denied, 469 U.S. 835 (1984).

[n.159]. See supra note 135.

[n.160]. See supra section V A 1.

[n.161]. See supra section V A 2.

[n.162]. See supra section V B.

[n.163]. See supra section V C 1.

[n.164]. See supra section V C 2.

[n.165]. See supra section V C 3.

[n.166]. See supra section V C 4.

[n.167]. See supra section V C 5.

[n.168]. Professor Robinson is a key figure in the history of the patent laws. 1 D. Chisum, Patents, Preface at v (1988).

[n.169]. W. Robinson, The Law of Patents for Useful Inventions, § 1075 (1890).