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OPINION LETTER AS TO THE PATENTABILITY OF CERTAIN INVENTIONS ASSOCIATED WITH THE IDENTIFICATION OF PARTIAL cDNA SEQUENCES

Rebecca S. Eisenberg
Robert P. Merges[*]

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[*] ©1996 Rebecca S. Eisenberg and Robert P. Merges. Ms. Eisenberg is a Professor of Law at the University of Michigan Law School and Mr. Merges is a Professor of Law at the University of California at Berkeley School of Law. The views expressed in this article are solely those of the authors. This article was originally written as an opinion letter for the National Institutes of Health and remains substantially in its original form.

sequences. The applications include many different claims, which for convenience we divide into the following groups:

- *Sequence* claims (claims 1-3, 17-18, and 25-43 in the '195 application, and 1-3 and 19-20 in the '911 application)
- *Full gene* claims (claims 4-18 and 47-54 in the '195 application and 4-16 in the '911 application)
- *Purified form* claims (claims 19 in the '195 application and 21 in the '911 application)
- *Construct* claims (claims 20-21 in the '195 application and 22-23 in the '911 application)
- *Panel* claims (claim 22 in the '195 application and 24 in the '911 application)
- *Antisense* claims (claims 23 in the '195 application and 25 in the '911 application)
- *Triple helix* claims (claims 24 in the '195 application and 26 in the '911 application)

The '831 application, which initially covered the first 315 ESTs as well as the method for obtaining them, was subsequently converted into a statutory invention registration covering only the method claims before being rejected by the patent examiner. We do not address the patentability of the method claims except insofar as it relates to the patentability of the other claims. The sequences of the '831 application are included in the 2,421 sequences covered by the '195 application, which is a continuation-in-part of '831. The claims of '195 were finally rejected by the Patent and Trademark Office ("PTO") in August of 1993. The claims of the '911 application, covering an additional 4,448 sequences, were rejected by the PTO in a first office action in December of 1993. NIH abandoned all three applications in February of 1994.

III. UTILITY

Perhaps the issue that has drawn the most attention in public discussions of the patentability of the NIH cDNA sequences is whether these sequences have patentable utility.

it will silently sink into contempt and disregard."[8] In this view the utility requirement merely serves to withhold patents on harmful inventions, and it is the function of the market to limit the value of patents on inventions of only minimal utility.

This was probably the dominant view of the utility requirement in the United States through the middle of the twentieth century, except in the case of inventions claimed to have value in the treatment of human disease. Such inventions were subjected to a higher standard of proof of utility, particularly in the days before the safety and efficacy of pharmaceutical products were separately monitored by the Food and Drug Administration, on the ground that issuance of a patent might mislead the public by appearing to represent a government imprimatur of the value of a so-called "patent medicine."[9] Modern courts have explicitly disclaimed this higher standard of utility for pharmaceuticals,[10] yet the double standard seems to live on as a practical matter, as will become apparent from a review of the cases.

The U.S. Supreme Court suggested a larger role for the utility requirement in *Brenner v. Manson.*[11] The invention at issue in that case was a new process for making certain known steroids. The patent examiner rejected the claims on the ground that the applicant had failed to disclose any utility for the chemical compounds produced by the process. The Board of Appeals within the Patent Office affirmed the rejection, but the Court of Customs and Patent Appeals reversed, holding that an operative process for producing a known product satisfies the utility requirement so long as the product is not alleged to be detrimental to the public interest. The Supreme Court reversed again in an opinion that raised at least as many questions as it answered about the utility requirement.[12]

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[8] *Id.*

[9] Mahler v. Animarium Co., 111 F. 530, 537 (8th Cir. 1901).

[10] *In re* Langer, 503 F.2d 1380, 183 U.S.P.Q. (BNA) 689 (C.C.P.A. 1974).

[11] 383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).

[12] *Id.* at 536, 148 U.S.P.Q. (BNA) at 696.

This question has been particularly difficult to answer for pharmaceutical inventions, which often involve separately discovered products and uses. Decisions of the U.S. Court of Appeals for the Federal Circuit and its predecessor, the U.S. Court of Customs and Patent Appeals, have upheld the sufficiency of disclosures of pharmacological activity *in vitro* as establishing the practical utility of a novel compound.[18] In *Cross v. Iizuka*, the Federal Circuit acknowledged that "*in vitro* 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," but nonetheless concluded that this link was sufficient to establish a practical utility for the compound, noting: "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."[19] This suggests a more hospitable attitude toward the patenting of early stage pharmaceutical inventions than would be supported under a strict reading of *Brenner v. Manson*.

However, in recent years biotechnology patent practitioners perceived an increasing strictness on the part of the PTO in its application of the utility requirement, particularly in the context of claims to methods of treatment or to pharmaceutical compositions. A series of decisions from the PTO Board of Patent Appeals and Interferences ("the Board") reflects this trend,[20] which may finally be coming to an end in light of very recent developments in the PTO and the Federal Circuit.[21]

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[18] Cross v. Iizuka, 753 F.2d 1040, 224 U.S.P.Q. (BNA) 739 (Fed. Cir. 1985); Nelson v. Bowler, 626 F.2d 853, 206 U.S.P.Q. (BNA) 881 (C.C.P.A. 1980).

[19] *Cross*, 753 F.2d at 1051, 224 U.S.P.Q. (BNA) at 748.

[20] *See, e.g., Ex parte* Sudilovsky, 21 U.S.P.Q.2d (BNA) 1702 (Bd. Pat. App. & Interf. 1992); *Ex parte* Aggarwal, 23 U.S.P.Q.2d (BNA) 1334 (Bd. Pat. App. & Interf. 1991); *Ex parte* Balzarini, 21 U.S.P.Q.2d (BNA) 1892 (Bd. Pat. App. & Interf. 1991).

[21] These recent developments are the publication of new Utility Examination Guidelines by the PTO, PTO Utility Examination Guidelines, 60 Fed. Reg. 36,263 (1995), and the decision of the Federal Circuit in *In re* Brana, 51 F.3d 1560, 34 U.S.P.Q.2d (BNA) 1436 (Fed. Cir. 1995), both discussed *infra*.

tests customarily used and accepted as predicative [sic] of human activity for the type of chemical tested" and "commensurate with the scope of utility asserted and the subject matter claimed."[26]

The Board took a similar approach in another case involving a method of treatment claim, *Ex parte Sudilovsky*.[27] In that case the Board affirmed rejection for failure to demonstrate utility of claims to a method for inhibiting onset of or treating tardive dyskenesia, noting that the record indicated lack of predictability in the art and that the specification did not disclose experimental data or test results.[28]

Two recent developments may signal an end to the trend in the PTO toward increasingly restrictive applications of the utility requirement. First, the PTO has published new Utility Examination Guidelines admonishing examiners that a rejection for lack of utility is inappropriate if the applicant makes an assertion of utility that would be credible to a person of ordinary skill in the field or if the invention has a well-established utility.[29] An accompanying legal analysis prepared by the PTO affirms that inventions asserted to have utility in the treatment of human or animal disorders are subject to the same utility requirement as inventions in other fields of technology, and that "[O]ffice personnel should not construe § 101, under the logic of 'practical' utility or otherwise, to require that an applicant demonstrate that a therapeutic agent based on a claimed invention is a safe or fully effective drug for humans. . . . These general principles are equally applicable to situations where an applicant has claimed a process for treating a human or animal disorder."[30] These guidelines grew out of a PTO hearing in October 1994 on intellectual property issues of concern to the biotechnology industry, at which numerous witnesses complained that the PTO had been mishandling the utility requirement and inappropriately

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[26] *Id.*

[27] 21 U.S.P.Q.2d (BNA) 1702 (Bd. Pat. App. & Interf. 1992).

[28] *Id.* at 1705.

[29] PTO Utility Examination Guidelines, 60 Fed. Reg. 36,263 (1995).

[30] *Legal Analysis Supporting Utility Examination Guidelines*, 50 Pat., Trademark & Copyright J. (BNA) 297, 300 (Jul. 20, 1995) [hereinafter *Utility Examination Guidelines*].

undertaking or involve implausible scientific principles."[35] The burden was initially on the PTO to provide evidence showing that someone of ordinary skill in the art would reasonably doubt the asserted utility.[36] The PTO had not met this burden, and thus the burden of proof did not shift back to the applicants for rebuttal. However, even if the burden had been shifted, the court was satisfied that the applicants had proferred sufficient rebuttal evidence to establish the utility of the compounds in the form of data showing significant antitumor activity *in vivo* in mouse models.[37] The court dismissed the PTO's argument that *in vivo* tests in animals are not sufficiently predictive of therapeutic efficacy in humans to establish utility with a sharp reminder to the PTO of its limited role in the regulation of pharmaceuticals:

> The Commissioner, as did the Board, confuses the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption. . . . FDA approval . . . is not a prerequisite for finding a compound useful within the meaning of the patent laws. . . . Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. . . . Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.[38]

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[35] *Id.* at 1566, 34 U.S.P.Q.2d (BNA) at 1441 (citing *In re* Jolles, 628 F.2d 1322, 1327, 206 U.S.P.Q. (BNA) 885, 890 (C.C.P.A. 1980)).

[36] *Id.*

[37] *Id.* at 1567, 34 U.S.P.Q.2d (BNA) at 1441-42.

[38] *Id.* at 1567, 34 U.S.P.Q.2d (BNA) at 1442-43.

application failed to disclose a practical utility for polypropylene. That application disclosed that polypropylene is "plastic-like" and that it may be pressed into a flexible film with a characteristic infrared spectrum. A previous court in another proceeding had rejected Ziegler's argument that the disclosure that polypropylene is "plastic-like" established its utility, and Ziegler was therefore precluded from relitigating this issue.[43] Thus the only remaining question was whether the disclosure that polypropylene is solid and that it may be pressed into a flexible film with a characteristic infrared spectrum was sufficient to establish a practical utility for the material. In affirming the PTO's determination that it did, the Federal Circuit echoed the concerns over premature filings expressed by the Supreme Court in *Brenner v. Manson*:[44] "We are convinced that, at best, Ziegler was on the way to discovering a practical utility for polypropylene at the time of the filing of the German application; but in that application Ziegler had not yet gotten there."[45] The court concluded: "While we are cognizant of Ziegler's noteworthy contributions to polymer chemistry, we must nevertheless abide by the principle underlying 35 U.S.C. § 101 that a patent 'is not a reward for the search, but compensation for its successful conclusion.'"[46]

Under the standards set by these cases, the inventions claimed in the NIH patent applications may well lack patentable utility, although the issue is not entirely free from doubt. We turn to the specific facts of the Venter applications.

B. *Utility Of The NIH Inventions*

Plainly, these applications were drafted with the possibility of a utility rejection in mind. The specifications are replete with imaginative suggestions for how to use the claimed sequences, individually or in panels, many of which are set forth in prophetic (untested) examples. The specification recites that ESTs may be used as probes to isolate coding sequences and complete genes, which may then be mapped to chromosomal locations. They may be used as chromosome markers. Complete genes,

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[43] *Ziegler*, 992 F.2d at 1201, 26 U.S.P.Q.2d (BNA) at 1604.

[44] 383 U.S. 519, 535, 148 U.S.P.Q. (BNA) 689, 696 (1966).

[45] *Ziegler*, 992 F.2d at 1203, 26 U.S.P.Q.2d (BNA) at 1605.

[46] *Id.* (quoting *Brenner*, 383 U.S. at 536, 148 U.S.P.Q. (BNA) at 696).

> claims. The instant application does not teach one of skill in the art the significance of any putative result of any of the tests or processes alluded to in the application. Although the oligonucleotides embraced by the claims may be hybridized to a variety of different preparations of other nucleic acids, one of skill in the art has no clue as to the significance of any results of such hybridization because the instant application fails to provide any basis for the interpretation of any putative results. Thus, given the invention in its currently available form, others would be compelled to experiment, interpret results, and invent a patentable utility for the claimed nucleotides.

In other words, the recited utilities were inadequate because a skilled person reading the specification would have to engage in further undue experimentation in order to put the claimed inventions to the suggested uses.

As noted above, in order to satisfy the utility requirement, a patent applicant must not only disclose a specific, practical use for the claimed invention but must also provide a disclosure that enables others working in the same field to use the invention in the described manner without having to do more than routine experimentation. Whether this enablement dimension of the utility requirement has been satisfied as to the recited utilities depends on the state of knowledge in the field at the time of filing and the level of skill among ordinary practitioners working in the field.[48] Working examples in the specification may help in satisfying this requirement, particularly if they indicate that the applicant has successfully put the invention to the recited uses. Prophetic examples that describe how to do something the applicants have not yet done in their own laboratories are less probative of enablement, but they may be sufficient if there is no reason to doubt that the instructions are adequate to make the invention

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[48] *In re* Vaeck, 947 F.2d 488, 495-96, 20 U.S.P.Q.2d (BNA) 1438, 1444 (Fed. Cir. 1991); *In re* Sichert, 566 F.2d 1154, 1161, 196 U.S.P.Q. (BNA) 209, 215 (C.C.P.A. 1977).

data that would identify the significance of any particular sequence to any particular disease.

We lack the technical expertise to evaluate which of the remaining utilities would be met with skepticism by skilled persons in the field or would require undue experimentation to carry out. Uses of the disclosed sequences as probes for diagnosing disease gene regions or to control gene expression through triple helix formation or DNA or RNA antisense molecules seem particularly vulnerable to challenge on this basis. Each of these utilities seems to require a subsequent research effort that appears fraught with uncertainty on the basis of the limited information provided in the specification and the state of the art.

The asserted utility of panels of sequences for tissue typing or for forensic identification purposes may also be vulnerable on this ground. The utility of the sequences in tissue typing depends on the sequences being variably expressed in different types of tissue. The specification states that subtractive hybridization was used to selectively remove sequences shared by a cDNA library from a human lung fibroblast cell line, but it does not indicate which of the remaining sequences is unique to brain tissue. Similarly, the utility of the sequences for forensic identification purposes depends on their being polymorphic. The specification states that eighty-five percent of the sequences appear to come from noncoding regions and that polymorphisms are particularly common in noncoding regions, but it does not indicate which, if any, of the sequences is in fact polymorphic. Perhaps these difficulties can be overcome by using panels that are so large that the likelihood of variable expression by tissue type or polymorphisms across individuals becomes overwhelming. But in that case the asserted utilities would only seem to support the patentability of these large panels, and not of smaller panels or of individual sequences.

A related problem is that the disclosure gives only limited guidance as to which of the sequences (or which combinations of sequences) are suitable for which of these uses. The process of selection may itself involve undue experimentation. As Examiner Martinell stated in reference to the panel claims, "[T]he panel of oligonucleotides in claim 22 has no patentable utility because the instant application fails to disclose a single such panel out of the astronomical number of such panels possible and disclose any use for such a putative panel in its currently available form." Moreover, even if the disclosure is fully enabling as to how to select appropriate sequences or panels, the disclosed utilities will only support the patentability of those

intuition that NIH was claiming too much in light of the very preliminary information that they had disclosed.[54] It seems likely that the PTO and the courts might have a similar reaction, and that a utility rejection would present an appealing doctrinal basis for expressing that view.

Use of the ESTs as markers presents a closer question. Assuming that the disclosure is sufficiently enabling to allow the sequences to be mapped, the mapped sequences may be useful as markers right away without waiting to learn what genes they come from or the functions of those genes. Such markers are sold commercially, albeit to researchers. Does the existence of a commercial market among researchers confer patentable utility on research reagents? Existing caselaw does not unambiguously resolve this question, and policy arguments could be made on either side of the issue. One could argue that research tools are like the process for making the steroid at issue in *Brenner v. Manson*[55]—merely a means for facilitating subsequent research and not yet offering any "specific benefit . . . in currently available form." Moreover, there are reasons to be wary of patents on research tools, including concerns that they might be licensed on an exclusive basis to the detriment of subsequent research.[56] On the other hand, genetics research is big business, and private firms are playing a growing role in generating tools for the use of genetics researchers in the public and private sectors. Withholding patent protection from research tools could undermine incentives to develop such tools in the private sector and to make them available to researchers. In the absence of patent protection, a public institution such as NIH will presumably place its research tools in the public domain; the same cannot necessarily be expected of the private firms whose sequencing efforts in recent years have far outpaced those of NIH. Under these circumstances, it is not clear whether

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[54] *See e.g.*, Robin Herman, *The Great Gold Rush: U.S. Rankles Other Countries With Preemptive Strike in the Race to Patent Human Genes*, WASHINGTON POST, June 16, 1992, at Z11; Earl Lane, *Debate Over Gene Patent Application; Scientists Argue NIH's Claim Will Choke a Free Flow of Data*, NEWSDAY, May 19, 1992, at 55.

[55] 383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).

[56] For an expanded discussion of this issue focussing on the controversy over these particular patent applications, see Rebecca S. Eisenberg, *Technology Transfer and the Genome Project: Problems with Patenting Research Tools*, 5 RISK: HEALTH, SAFETY & ENV'T 163 (1994).

the claim language to avoid covering subject matter that has been disclosed in the prior art.

On the other hand, the novelty standard is at the same time quite exacting, particularly for broadly worded claims, in the following sense: If a prior art reference discloses something that falls within the scope of a claim, the entire claim is invalid, even though much of what the claim covers has not been disclosed in the prior art, and even if the applicant's disclosure makes a significant contribution to the art that was beyond the contemplation of those familiar with the prior art. For example, if a patent is issued with a generic claim covering what is believed to be a new class of chemicals, and it is subsequently discovered that a chemical previously in use by others for an unrelated purpose belongs in that class and is therefore covered by the claim, the claim is invalid in its entirety.

B. *Novelty Of The NIH Inventions*

Because the novelty of a claimed invention is defeated by finding in the prior art a single embodiment falling within the scope of the claim language, it can be treacherous for broadly-worded claims, particularly if the subject matter covered by the claims cannot be readily identified, and the prior art can therefore not be searched effectively. Consider, for example, the August 20, 1992 rejection of the '195 application, which included a rejection for lack of novelty of claims that, as initially drafted, covered portions of the disclosed sequences that were at least fifteen nucleotides in length. Among the prior art references cited by the examiner was a Pharmacia P-L Biochemicals 1984 Product Reference Guide. This catalog listed among the commercial reagents for sale two oligodeoxynucleotides, oligo(dA) and oligo(dT), consisting of chains of repeated A and T nucleotides, respectively. These commercially available sequences were sufficient to defeat the novelty of the original broadly-worded claims because some of the sequences disclosed in the specification included at least one run of fifteen or more A or T nucleotides, and because the claim language was drafted to cover portions of the sequences of at least fifteen nucleotides. NIH responded to this particular rejection by narrowing the claims to cover only fragments of at least 150 nucleotides, but even the amended claims might be subject to a similar challenge.

Those claims that cover undisclosed gene fragments may be particularly vulnerable to challenge on this basis at a later date because there is no way of searching the prior art at present to determine whether it

whether the invention represents a big enough technical advance to merit a patent.

A. *Background And Applicable Law*

A new and useful invention that someone of ordinary skill in the field would consider obvious in light of the prior art may not be patented.[61] Whether an invention satisfies this standard depends on (1) the scope and content of the prior art; (2) the level of ordinary skill among practitioners in the field of the invention; and (3) the differences between the invention and the prior art.[62] This determination turns on evaluation of technical facts that are beyond our ken. Nonetheless, the Federal Circuit has repeatedly stated that determinations of obviousness are ultimately legal judgments,[63] and so we turn to the relevant case law.

We begin by noting that existing case law leaves some uncertainty as to the proper analytical approach to take in determining the obviousness of a novel DNA sequence. A major source of confusion is a lack of clarity in the cases as to whether the requisite nonobviousness is to be found in the method of obtaining the sequence or in the sequence itself. Section 103 of the Patent Act recites that "[p]atentability shall not be negatived by the manner in which the invention was made."[64] This inartful language is generally understood to mean that an invention may be patentable even if it was arrived at through tedious but routine experimentation rather than through ingenious insight.[65] As long as the end result is nonobvious, the path by which the inventor got there should not defeat patentability. This principle has been particularly important in the chemical arts, where methods for synthesizing new chemicals are often obvious to practitioners of ordinary skill. Such new compounds may be deemed prima facie obvious if they are

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[61] Graham v. John Deere, 383 U.S. 1, 11, 148 U.S.P.Q. (BNA) 459, 464 (1966) (citing Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248 (1851)).

[62] 35 U.S.C. § 103 (1994); id. at 11, 148 U.S.P.Q. (BNA) at 464.

[63] *In re* Deuel, 51 F.3d 1552, 1557, 34 U.S.P.Q.2d (BNA) 1210, 1214 (Fed. Cir. 1995).

[64] 35 U.S.C. § 103 (1994).

[65] *Graham*, 383 U.S. at 15 n.7, 148 U.S.P.Q. (BNA) at 474 n.7.

> process for making the EPO gene, despite the fact that it is products (genes and host cells) that are claimed in the patent, not processes. We have directed our attention accordingly, and do not consider independently whether the products would have been obvious aside from the alleged obviousness of a method of making them.[69]

Two years later, the court appeared to focus more on the structure of a DNA sequence than on the method of obtaining it in reversing a determination of obviousness in the case of *In re Bell*.[70] The claimed inventions in that case were DNA and RNA molecules encoding human insulin-like growth factors I and II ("IGFs"). The Board concluded that prior art disclosing the amino acid sequences for the proteins and a general method for isolating genes for which a portion of the amino acid sequence is known by preparing nucleotide probes was enough to make the entire nucleotide sequence prima facie obvious. The Federal Circuit reversed in an opinion that stressed the unpredictability of the structure of the DNA sequence arising from the degeneracy of the genetic code:

> It may be true that, knowing the structure of the protein, one can use the genetic code to hypothesize possible structures for the corresponding gene and that one thus has the potential for obtaining that gene. However, because of the degeneracy of the genetic code, there are a vast number of nucleotide sequences that might code for a specific protein. In the case of IGF, Bell has argued without contradiction that the [amino acid sequences disclosed in the prior art] could be coded for by more than 10^{36} different nucleotide sequences, only a few of which are the human sequences that Bell now claims. Therefore, given the nearly infinite number of

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[69] *Id.* at 1207 n.3, 18 U.S.P.Q.2d (BNA) at 1031 n.3.

[70] 991 F.2d 781, 784, 26 U.S.P.Q.2d (BNA) 1529, 1532 (Fed. Cir. 1993).

This left open the possibility that broadly worded claims to a DNA sequence encoding a protein with a known amino acid sequence might be rejected as obvious. The basis for the distinction would be that the prior art might make obvious *a* DNA sequence encoding the protein, but not *the* particular sequence covered by the claim.[73]

Second, in *In re Bell*[74] the Federal Circuit interpreted the prior art cited by the examiner as discouraging or "teaching away from" a successful method for finding the target gene because the disclosed method suggested designing a probe based on an amino acid sequence specified by unique codons. This approach would not have worked for finding the IGF genes, because one of them had only a single amino acid with a unique codon and the other had none. The salience of these facts to the court is inconsistent with its apparent focus earlier in the same opinion on structure rather than on the method of obtaining the gene and suggests that it might have reached a different decision if prior art had been cited that suggested a broader range of probing strategies.

The Board distinguished *In re Bell* on this latter basis in *Ex parte Deuel*.[75] In that case the prior art disclosed a partial amino acid sequence for heparin binding growth factors ("HBGFs") and general cloning methods. In holding that this was sufficient to make the gene prima facie obvious, the Board distinguished *Bell* on the ground that in that case the prior art taught away from a viable process for cloning the gene, while in *Deuel* the applicants did not challenge the examiner's assertion that the probing procedure set forth in the prior art would have allowed isolation of the gene

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[73] The Board distinguished *Bell* in part on this basis in *Ex parte* Movva, 31 U.S.P.Q.2d (BNA) 1027 (Bd. Pat. App. & Interf. 1993). In that case, the Board affirmed rejection of claims to DNA sequences and recombinant DNA molecules encoding swine growth hormone or polypeptides displaying the biological activity of swine growth hormone where the claims were drafted to include degenerate sequences encoding the same protein. "If the reasonable expectation of success found to be lacking in *Bell* can be analogized to the likelihood of hitting the center of the bulls-eye on a dart board, the present reasonable expectation of success would be more akin to merely hitting any spot on the dart board." *Id.* at 1034.

[74] 991 F.2d at 785, 26 U.S.P.Q.2d (BNA) at 1532.

[75] 33 U.S.P.Q.2d (BNA) 1445, 1449 (Bd. Pat. App. & Interf. 1993), *rev'd sub nom; In re* Deuel, 31 F.2d 1552, 34 U.S.P.Q.2d (BNA) 1210 (Fed. Cir. 1995).

> of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein. No particular one of these DNAs can be obvious unless there is something in the prior art to lead to the particular DNA and indicate that it should be prepared. . . . This is so even though one skilled in the art knew that some DNA, albeit not in purified and isolated form, did exist. The [claimed DNA sequences] are specific compounds not suggested by the prior art.[80]

The court stated that the PTO's focus on methods for isolating the claimed DNA sequences was "misplaced because the claims at issue define compounds, not methods,"[81] and cited *In re Bell* for the principle that "the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs."[82] That the prior art might have been sufficient to motivate those working in the field to prepare an undefined cDNA coding for a known or partially known protein did not make obvious any particular resulting cDNA sequence: "The fact that one can conceive a general process in advance for preparing an *undefined* compound does not mean that a claimed *specific* compound was precisely envisioned and therefore obvious."[83] This language suggests that a DNA sequence must be "precisely envisioned," and not merely readily obtainable, in order to be obvious. Thus the specific cDNA sequences set forth in the patent application were not made obvious by the disclosure of a partial amino acid sequence and general cloning methods.

Second, the court concluded that the prior art did not render obvious the broader generic claims to all DNA sequences encoding HBGFs, although

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[80] *Id.* at 1558-59, 34 U.S.P.Q.2d (BNA) at 1215.

[81] *Id.* at 1559, 34 U.S.P.Q.2d (BNA) at 1215.

[82] *Id.*

[83] *Id.* at 1560, 34 U.S.P.Q.2d (BNA) at 1216.

disclosed in the prior art. Moreover, reactions in the scientific community to news of the NIH patent filings indicate that some scientists at the time viewed the technology used to obtain the sequences as not requiring more than ordinary inventive skill.[86]

On the other hand, perhaps it could be argued that the prior art discouraged or taught away from the approach taken by Venter and his colleagues in the relevant time period. The '195 specification indicates that, contrary to the expectations of the scientific community, the applicants had used cDNA screening and sequencing to discover a large number of heretofore unknown human genes. If the prior art gave reason to doubt that the method used would yield the results obtained, it might be argued that the method was nonobvious, and that the nonobviousness of the method should confer patentability on the results (i.e., the sequences). But even if the method used by Venter and his colleagues was nonobvious as of the '831 filing date, this fact would at most confer patentability on sequences claimed prior to the time that the method was placed in the public domain. Once the method was publicly disclosed, the nonobviousness of any subsequently discovered sequences could not be predicated on the nonobviousness of the method itself, because the method would be in the prior art. Thus the potential significance of the nonobviousness of the Venter methodology in making an affirmative case for patentability is quite limited.

Even if the method used to obtain the sequences is obvious, it does not necessarily follow that the sequences themselves are also obvious. Although the matter is by no means free from doubt, we now think it is more likely than not that the Federal Circuit would focus on the structure of the claimed sequences rather than on the method of obtaining them in assessing their obviousness. The decisions of the Federal Circuit in *In re Bell*[87] and *In re Deuel*[88] suggest that if the prior art does not include structurally similar sequences, the sequences themselves will not be deemed obvious. Under this approach, at the very least those claims that are narrowly drawn to specific, novel sequences with no significant partial homologies to known sequences will probably be considered nonobvious. On the other hand, any

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[86] *See e.g.*, John Casey, *The Gene Kings*, BUSINESS WEEK, May 22, 1995, at 25.

[87] 991 F.2d 781, 26 U.S.P.Q.2d (BNA) 1529 (Fed. Cir. 1993).

[88] 51 F.3d 1552, 1558, 34 U.S.P.Q.2d (BNA) 1210, 1215 (Fed. Cir. 1995).

and Sequencing the Human Genome devotes a couple of pages to analyzing the relative merits of cDNA sequencing versus genomic DNA sequencing, suggesting that there was significant (if, in the view of the authors of that report, misguided) support for focussing the resources of the Human Genome Project initially on sequencing large libraries of cDNAs.[90] It does not necessarily follow that other investigators would be motivated to undertake large-scale partial sequencing of randomly selected cDNA clones of the sort pursued by Venter, as opposed to more focussed searches for particular genes of interest.

But whatever the level of motivation to engage in such sequencing prior to Venter's 1991 disclosure, that disclosure set off a frenzy of cDNA sequencing activity that continues to this day. Under these circumstances it seems reasonable to conclude that, at least since late 1991, the prior art has disclosed enough to motivate others working in the field to find new ESTs through random partial sequencing of clones from cDNA libraries. Therefore, the sequences obtained subsequent to that date by Venter and others through the same general method might be deemed prima facie obvious, even if there are no structurally similar sequences in the prior art, for the same reason that past decisions have held novel chemicals prima facie obvious when the prior art discloses structurally similar compounds: in both cases, the prior art provides motivation to use familiar methods to construct the claimed inventions. We reiterate, however, that the Federal Circuit so far has not taken this approach, and that its decisions in *In re Bell*[91] and *In re Deuel*[92] cast some doubt on its willingness to do so.

It could be argued that finding prima facie obviousness on the basis of the method of sequencing alone violates the statement in section 103 of the Patent Act[93] that "patentability shall not be negatived by the manner in which the invention was made."[94] On the other hand, a finding of prima

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[90] NATIONAL RESEARCH COUNCIL, MAPPING AND SEQUENCING THE HUMAN GENOME (1988).

[91] 991 F.2d 781, 26 U.S.P.Q.2d (BNA) 1529 (Fed. Cir. 1993).

[92] 51 F.3d 1552, 34 U.S.P.Q.2d (BNA) 1210 (Fed. Cir. 1995).

[93] 35 U.S.C. § 103 (1994).

[94] *Id.*

since 1991 has plainly disclosed enough information to motivate those working in the field to apply routine sequencing techniques to obtain partial sequences for randomly selected clones from cDNA libraries, and that all sequences obtained since that date should therefore be deemed prima facie obvious. However, the Federal Circuit has not endorsed this analytical approach, and its most recent decisions suggest a far lower standard of nonobviousness for DNA sequences. If any of the sequences are considered prima facie obvious, it does not appear that NIH has sustained its burden of showing that the sequences possess surprising or unexpected properties.

While recent Federal Circuit decisions suggest that the nonobviousness requirement may be more readily satisfied for ESTs than was previously thought, these decisions also call into question a key argument in favor of patenting ESTs. In the debate over patenting ESTs, some people argued that if ESTs were published without obtaining patent protection, their disclosure would render obvious, and therefore unpatentable, the full-length genes of which they are a part, thereby preventing subsequent researchers and firms who wish to develop commercial products based on such genes from obtaining exclusive rights under a patent.[98] Patents on ESTs, and on the full-length genes that could be obtained by using ESTs as probes, would therefore provide an otherwise unavailable source of exclusive rights to protect the interests of those who develop commercial products related to genes for which ESTs have been publicly disclosed.

This argument hinges on disclosure of partial DNA sequences rendering full-length genes obvious. But if partial or even full amino acid sequences for a protein are not sufficient to make the corresponding DNA sequence obvious, it seems unlikely that a partial DNA sequence would make the full-length DNA sequence obvious. Thus the Federal Circuit's position that the obviousness of a method for obtaining a DNA sequence is irrelevant to the obviousness of the sequence itself is a two-edged sword in the debate over patenting ESTs, serving on one hand to reduce the force of an argument against the patentability of ESTs, while on the other hand undermining arguments for the necessity of obtaining such patents to safeguard the commercial viability of future products.

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[98] *See, e.g.*, Reid Adler, *Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization*, 257 SCIENCE 908, 911-12 (1992).

sequences, including those sequences that may be partially disclosed in public databases, before they publish their results.

VI. DISCLOSURE

In recent years, the Federal Circuit and the PTO have frequently invoked the disclosure requirements set forth in section 112 of the Patent Act in rejecting or holding invalid patent claims involving DNA sequences.[101] We believe that many of the claims in these applications may be vulnerable to challenge on these grounds, particularly the full gene claims and the panel claims.

Section 112 of the Patent Act provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.[102]

The courts and the PTO read the first paragraph of this provision as imposing three distinct requirements: (1) a written description of the invention; (2) an enabling disclosure of how to make and use the invention; and (3) disclosure of the best mode of practicing the invention known to the

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[101] *In re* Deuel, 51 F.3d at 1560, 34 U.S.P.Q.2d (BNA) at 1216; Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1213, 18 U.S.P.Q.2d (BNA) 1016, 1027 (Fed. Cir.) *cert. denied sub nom,* Genetics Inst., Inc. v. Amgen, Inc., 112 S.Ct. 169 (1991).

[102] 35 U.S.C. § 112 (1994).

The enablement requirement should not present a significant barrier to the patenting of DNA sequences that have been fully and accurately set forth in the specification. But some of the claims extend beyond those disclosed sequences to cover other sequences (including full genes operably coding for human gene products) that might ultimately be obtained by using the ESTs as probes. In rejecting the claims of the '195 application for failure to provide an enabling disclosure, the examiner noted that the specification lacked information about the coding regions of the disclosed DNA sequences, and questioned whether the ESTs in fact have coding regions:

> Applicants assert that one of skill in the art can determine coding regions with routine skill and then spend three pages briefly outlining the cloning, selection, sequencing, and sequence analyses and judgments needed to make the determination. These manipulations are more than routine experimentation. . . . Even though the ESTs of the instant application were derived from cDNA, the application fails to establish that each and every expressed sequence has a protein coding region or whether a given EST that has a protein coding region is eventually translated. Some of the RNAs from which the ESTs were derived may not be mRNAs or may be mRNAs that are not translated.

Whether these prophetic claims are enabled by the disclosure is ultimately a technical question that is beyond our expertise. Nonetheless, we note that decisions of the Federal Circuit in biotechnology cases seem to reflect a more generous view than the examiner appears to hold of how much experimentation may be tolerated before a disclosure will be considered nonenabling. For example, in *In re Wands*,[105] the Federal Circuit reversed a rejection of claims to an immunoassay utilizing monoclonal high affinity immunoglobulin M antibodies, even though the antibodies described in the disclosure could not be produced without going through extensive procedures to prepare hybridomas and to screen them for production of the desired antibodies. The court noted that there was a high level of skill in the

[105] 858 F.2d 731, 8 U.S.P.Q.2d (BNA) 1400 (Fed. Cir. 1988).

A case involving somewhat analogous facts is *Ex parte Tanksley*[108] in which the Board affirmed the examiner's rejection of claims to tomato cDNA clones on grounds of obviousness and failure to identify distinctly the claimed inventions. The Board went on to note that, in the event of further prosecution, the examiner should consider whether undue experimentation is required to practice the invention given that each of the uses suggested by applicants for their inventions involved, as a preliminary step, the identification of clones of interest, a procedure that the prior art suggested involves significant difficulty. A similar argument could be made with respect to many of the claims in the NIH applications, which cover DNA sequences that may not be put to use without first identifying, through nonroutine experimentation, which of the many sequences are of interest for which possible purposes.

The enabling disclosure requirement also serves as a limitation on the permissible breadth of patent claims, providing a basis for rejecting broad, generic claims for which only a small number of embodiments have been disclosed. A number of decisions have invalidated broad patent claims to DNA sequences on the ground that the disclosure is not as broad as the claims. For example, in *Amgen, Inc. v. Chugai Pharmaceutical*,[109] the Federal Circuit affirmed a lower court decision holding invalid a broad generic claim covering all DNA sequences that will encode any polypeptide having an amino acid sequence sufficiently duplicative of erythropoietin (EPO) to possess the property of increasing production of red blood cells. The basis for the holding was that the broad claim was not adequately enabled by the disclosure in the specification of details for preparing only a few EPO analog genes:

> Amgen has claimed every possible analog of a gene containing about 4,000 nucleotides, with a disclosure only of how to make EPO and a very few analogs. . . . Considering the structural complexity of the EPO gene, the manifold possibilities for change in its structure, with attendant uncertainty as to

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[108] 26 U.S.P.Q.2d (BNA) 1384, 1388 (Bd. Pat. App. & Interf. 1992).

[109] 927 F.2d 1200, 18 U.S.P.Q.2d (BNA) 1016 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

the full gene claims[114] and the panel claims,[115] and are no better supported in the specification. Indeed, these broad NIH claims may be particularly vulnerable to challenge on this ground because the specifications contain no empirically-tested working examples to support them.

The Federal Circuit stressed the importance of working examples in *In re Vaeck*.[116] In that case the applicant claimed a chimeric gene comprising a gene for an insecticidal protein derived from a *Bacillus* bacterium united with a DNA promoter effective for expressing the *Bacillus* gene in a host cyanobacterium, as well as plasmids containing the chimeric gene and host cyanobacteria expressing the gene. The specification disclosed two particular *Bacillus* species as sources of insecticidal protein and nine genera

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[114] Representative of the full gene claims are claims 4 and 10 of the '195 application. As amended, the language of claim 4 reads as follows:

> An isolated polynucleotide operably coding for a native human polypeptide or protein, which includes a region coding for the same amino acid sequence as a native human coding region corresponding to a sequence designated as one of [the disclosed ESTs].

As amended, the language of claim 10 reads as follows:

> An isolated polynucleotide coding for a human protein or polypeptide, which includes a coding region corresponding to [one of the disclosed ESTs]; or a polynucleotide complementary thereto.

Each of these claims potentially covers a great many sequences, none of which has been set forth in the specification.

[115] Consider, for example, claim 22 of the '195 application, which, as amended, claims:

> A panel of at least 100 isolated polynucleotides having the sequences of [one of the EST's or a fragment thereof at least 150 base pairs in length].

An astronomical number of such panels could be constructed out of the disclosed sequences, but no such panel is actually disclosed in the specification much less tested to see if it can be used for tissue typing or forensic identification as asserted.

[116] 947 F.2d 488, 495, 20 U.S.P.Q.2d (BNA) 1438, 1444 (Fed. Cir. 1991).

description' requirement is broader than to merely explain how to 'make and use;' the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*"[120] In other words, while the purpose of the enablement requirement is to put the public in possession of the invention, the purpose of the written description requirement is to ensure that the inventor was in possession of the invention as of the filing date and is therefore entitled to claim that date as the prima facie date of invention. The written description requirement most commonly presents a problem in cases where an applicant subsequently seeks to claim the benefit of a previous filing date in support of claims that were not included in the application as originally filed,[121] but in *Fiers v. Revel* the Federal Circuit invoked the written description requirement in rejecting prophetic claims to a DNA sequence filed before the inventor had actually obtained the sequence.[122]

Fiers v. Revel was a three-way priority contest among rival foreign claimants to patent rights in the DNA sequence coding for human fibroblast beta-interferon ("β-IF"). Understanding this decision requires a brief digression into arcane rules for determining priority of invention under U.S. patent law. Section 102(g) of the Patent Act calls for determining priority of invention by reference to the competing claimants' respective dates of conception and reduction to practice of the invention, and also "the reasonable diligence of one who was first to conceive and last to reduce to practice." Reduction to practice may be either "actual" (i.e., making a tangible embodiment of the invention in the laboratory) or "constructive" (i.e., filing a patent application that provides an adequate disclosure of the invention). Filing a foreign patent application is sufficient to establish

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[120] Vas-Cath v. Mahurkar, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d (BNA) 1111, 1116 (Fed. Cir. 1991) (emphasis in original).

[121] This may happen when an applicant adds new claims by amendment, or seeks the benefit of the filing date of an earlier-filed foreign or U.S. application for claims of a later-filed application, or, in an interference proceeding, when rival applicants claim patent rights corresponding to an interference count that differs somewhat from the claims they had originally filed.

[122] Fiers v. Revel, 984 F.2d 1164, 1170-71, 25 U.S.P.Q.2d (BNA) 1601, 1606 (Fed. Cir. 1993).

a broader claim to the DNA itself without limitation as to the means by which it is obtained.[126]

The court invoked a similar principle in dismissing Revel's claim to priority on the basis of his earlier-filed Israeli patent application.[127] The Israeli application disclosed a method for isolating a fragment of the DNA coding for β-IF as well as a method for isolating mRNA coding for β-IF, but did not disclose a complete DNA sequence. The Federal Circuit concurred

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[126] A product-by-process claim is a claim to a product defined in the claim language in terms of the method by which it is made. Most decisions hold that such claims are limited in scope to products made by the particular method recited in the claim language and would not cover identical products made by other methods. *See, e.g.*, Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 842, 23 U.S.P.Q.2d (BNA) 1481, 1488 (Fed. Cir. 1992), although, there is some authority for the view that the recited process does not limit the scope of product-by-process claims. *See, e.g.*, Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1583, 18 U.S.P.Q.2d (BNA) 1001, 1016 (Fed. Cir. 1991). Following *Fiers*, NIH submitted new claims 44-55 of '195 in product-by-process form. The Federal Circuit did not clearly indicate that such claims would be patentable in *Fiers*, but merely stated that disclosure of an enabling method for obtaining a gene would *at most* support a claim to the gene in product-by-process form:

> Our statement in *Amgen* that conception may occur, *inter alia*, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. . . . Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute a conception of the substance claimed as a process. Conception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties.

984 F.2d at 1169, 25 U.S.P.Q.2d (BNA) at 1604-05. Even if the NIH disclosures are considered enabling as to the full gene claims, we note that, if those claims are limited to full genes obtained by the recited process, the effective scope of the patent monopoly would be quite narrow, as would the commercial significance of the patents.

[127] *Fiers*, 984 F.2d at 1170-71, 25 U.S.P.Q.2d (BNA) at 1606.

We think it is unlikely that the Board will read the *Fiers* decision narrowly. In *Fiddes v. Baird*,[130] the Board cited *Fiers* in a priority contest over inventorship of recombinant DNA molecules encoding fibroblast growth factors ("FGFs"). Baird claimed priority on the basis of an application that set forth the amino acid sequence for bovine pituitary FGF and a theoretical DNA sequence encoding that protein, along with a method for obtaining a cDNA corresponding to the protein, but not the naturally occurring gene encoding the protein. The Board held that this disclosure did not contain a written description for the broad class of mammalian FGFs, and further questioned whether the disclosure was enabling even for Baird's narrower claims to the native gene encoding bovine pituitary FGF.[131]

One could try to distinguish these cases by arguing that the written description requirement, like the enablement requirement, becomes easier to satisfy as the state of knowledge advances in a field. The standard is whether the written description is adequate to convey to other skilled practitioners in the field that the applicant was in possession of the invention at the time of filing. As genetics research has advanced, it may have become increasingly routine to use a probe to find a gene, such that by the time of the NIH filings other practitioners might have regarded someone who had found an EST as being for all practical purposes in possession of the corresponding full-length gene.

One problem with this line of argument is that it seems to overlook the distinction that the Federal Circuit has consistently maintained between the enablement and written description requirements. Indeed, in *Fiers v. Revel*[132] the court rejected the priority claims of both Fiers and Revel without challenging their assertions that their disclosures were enabling.

The message that emerges from these decisions is that the patentability of a DNA sequence is doubtful until one can set forth the actual sequence. Unless the Federal Circuit and PTO retreat from this position, it is unlikely that an applicant could claim a full-length gene by disclosing nothing more than a partial sequence and a probing methodology. The

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[130] 30 U.S.P.Q.2d (BNA) 1481, 1483 (Bd. Pat. App. & Interf. 1993).

[131] *Id.*

[132] 984 F.2d at 1171, 25 U.S.P.Q.2d (BNA) at 1605-06.

interests behind the requirement for clear and definite claim language are thus squarely implicated by the facts of this case.

In sum, the requirements of an enabling disclosure, written description of the invention, and definiteness of claim language appear not to be satisfied for many of the claims of these patent applications, particularly those claims that cover sequences and panels of sequences that are not set forth in the specification. While we lack the technical expertise to offer a definitive opinion on the question of enablement, the absence of working examples and the apparent need for nonroutine screening in order to identify which sequences or panels are suitable for which purposes, suggest that the claims may be vulnerable to challenge on enablement grounds. Moreover, the breadth of some of the claims appears to exceed the scope of enablement under the standards of recent Federal Circuit and Board decisions, particularly in light of the absence of empirically-tested working examples. Claims directed to sequences that are not set forth in the specification also appear to lack an adequate written description as that requirement was articulated for DNA sequences by the Federal Circuit in *Fiers v. Revel.*[136] The absence of sequence information supporting these claims also makes the scope of the claims indefinite, in violation of the statutory requirement that the claims "particularly [point] out and distinctly [claim]" the subject matter of the invention.[137] Those claims that are limited to the sequences that have actually been identified and set forth in the specification are not vulnerable to these challenges.

VII. CONCLUSION

We believe that most of the claims set forth in the NIH patent applications probably are not patentable. Although the matter is not entirely free from doubt, we believe that it is more likely than not that the Federal Circuit would hold all of the claims invalid for lack of utility. The asserted utilities that appear most likely to satisfy the "practical utility" standard of *Brenner v. Manson*[138] either involve vaguely defined medical or therapeutic uses, with no indication in the specification of which sequences will serve

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[136] 984 F.2d at 1172, 25 U.S.P.Q.2d (BNA) at 1607.

[137] 35 U.S.C. § 112 (1994).

[138] 383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).

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COMMENTS ON THE PATENTABILITY OF CERTAIN INVENTIONS ASSOCIATED WITH THE IDENTIFICATION OF PARTIAL cDNA SEQUENCES

Scott A. Chambers[*]

I. INTRODUCTION

The thorough analysis by the letter's authors is quite valuable in advancing the discussion of this important topic. However, there are two additional points that should be considered, one philosophical and one technological.

II. THE PHILOSOPHICAL POINT

The philosophical point is a disagreement with the authors' belief that "there are reasons to be wary of patents on research tools, including concerns that they might be licensed on an exclusive basis to the detriment of subsequent research."[1] Patents that cover research tools are no more dangerous than patents that cover any other aspect of human endeavor. A patent is most powerful when used to enjoin others from making, using, and selling the invention. Injunctive relief is equitable in nature and, when the public good is affected, the courts have been quite willing to deny such

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[1] Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 19 (1995).

A prohibition against patents on "research tools" is an unnecessary broadening of the Court's position in *Brenner v. Manson*,[4] which considered only the utility of an invention that provided research chemists with a subject to "work on," i.e., a "research subject." Expressed Sequence Tags ("ESTs") could fit into either position, but their duality should not preclude patentability.

The authors' analysis primarily considers the one aspect of the duality, utility of ESTs *as a topic for* further research and disregards their utility *in* further research. Perhaps the problem is that ESTs are usually considered only in their human embodiment. The patent system cannot take such a narrow view. The patent system must consider ESTs of humans as it considers ESTs of plants or bacteria or other animals. Taking this wider view removes the moral or ethical stigma associated with patenting parts of the human genome. With the wider view, it is clear that ESTs are simply the biological equivalent of a roadmap. However, a roadmap can be an essential tool. Just as you would not want to drive to Seattle, Washington without a roadmap, you would not contemplate extensive genetic engineering without knowing where a gene was located. Thus, if a practitioner knew that a valuable gene was 10 centimorgans from the centromere on chromosome 3 of the tomato (computed by non-molecular methods of genetic analysis, methods which have been developed and put to use for decades before gene cloning), the researcher would greatly benefit from a nucleic acid sequence closely linked to that same location. Instead of just randomly choosing a sequence somewhere in the tomato genome, the researcher could begin the search in a very defined and limited area. To continue the roadmap analogy, if you wanted to drive to Seattle, would you rather randomly start driving on a road or choose a road that went in the general direction of Seattle?

If the patent applicant provided precise chromosomal map locations for each of the EST fragments, sufficient utility for 35 U.S.C. § 101 might be present. Numerous scientific articles have stated that precise marker locations are very important to the Human Genome Project ("HGP").[5] This

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[4] 383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).

[5] Mark D. Adams et al., *Complementary DNA Sequencing: Expressed Sequence Tags and Human Genome Project*, 252 SCIENCE 1651 (1991); Maynard Olson et al., *A Common Language for Physical Mapping of the Human Genome*, 245 SCIENCE 1434 (1989).

the market. As a result, we must be willing to provide patent protection in this area.

III. THE TECHNOLOGICAL POINT

The technological point not covered in the previous letter is the degeneracy of the genetic code. Three nucleotide bases—forming a codon—are used by the cell to designate each amino acid found in a protein or peptide. However, with very few exceptions, many different codons designate the same amino acid. Even though the genome has only one or two different sequences for a specific gene, the protein gene product can be made by an incredibly large number of different nucleic acid sequences. This degeneracy protects biotechnology from overreaching by the inventors of particular ESTs, as long as the claims are commensurate in scope to the invention disclosed. Denial of patent protection in this area would not benefit the public.

A number of companies have provided hundreds (or thousands) of EST fragments.[6] If such companies' applications parallel the viewpoint of the initial NIH applications, they claim the EST fragments, all cDNA molecules comprising those fragments (therefore, all complete cDNA's), all proteins containing peptides coded by those cDNA fragments (therefore all complete proteins), and all antibodies to those proteins. Adopting a position that any protein has per se utility, e.g., as food, could result in utility and patentability for the most valuable potential products—proteins and antibodies—without any immediate benefit to the public. Fortunately, the Patent and Trademark Office's position is that the utility threshold is higher than that.[7] This position avoids the possibility that the simple disclosure of an EST could lock-up science in this area.

Patent applications involving ESTs are concerned with several inventive aspects: (1) claims to the EST oligonucleotide sequences; (2) claims to the total cDNA oligonucleotide sequence; (3) claims to any protein fragment of the EST; (4) claims to the entire protein; and (5) claims to an

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[6] Eliot Marshall, *The Company That Genome Researchers Love to Hate*, 266 SCIENCE 1800 (1994); Thomas D. Kiley, *Patents on Random Complementary DNA Fragments?*, 257 SCIENCE 915 (1992).

[7] *See* PTO Utility Examination Guidelines, 60 Fed. Reg. 36,263 (1995).

frequent DOE characterization of this insubstantial change is that the potential infringement is performing substantially the same function, in substantially the same way, to achieve substantially the same result.[11] A nucleic acid sequence patented on the basis of marker utility could be modified to accomplish an entirely different end not provided in the original grant. It is difficult to argue that hybridization probe function (i.e., to localize a DNA sequence) is substantially the same as the function of an expression vector (i.e., to produce a protein). It is similarly difficult to argue that a hybridization probe functions in substantially the same way as an expression vector. It is likewise difficult to argue that a hybridization is substantially the same as making a protein. Failing any prong of the DOE test would lead to a finding of noninfringement. Thus, even expanding the literal claim to the breadth provided by the DOE would not cover making and using a vastly different nucleic acid.

Consequently, the focus of the intellectual property community and scientific community should not be on the utility of the ESTs, but instead it should be on the breadth of any issued claims. As long as the breadth is commensurate with the disclosed invention, the patent system will continue to promote the progress of the useful arts.

[11] *E.g.*, Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 901-02, 221 U.S.P.Q. (BNA) 669, 679 (Fed. Cir.), *cert. denied*, 469 U.S. 857 (1984).

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REPLY TO COMMENTS ON THE PATENTABILITY OF CERTAIN INVENTIONS ASSOCIATED WITH THE IDENTIFICATION OF PARTIAL cDNA SEQUENCES

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A brief reply is in order to clarify our position on the patenting of research tools.

We stand by the statement that "there are reasons to be wary of patents on research tools,"[1] but that statement should not be understood as a broad condemnation of patents on research tools in all contexts. Indeed, immediately after the cited language our opinion letter acknowledges that withholding patent protection from research tools could undermine private incentives to develop research tools and to make them available to investigators or lead to greater reliance on trade secrecy. Unlike the government, which purports to pursue patent rights for the purpose of facilitating technology transfer, private firms pursue patents in order to earn a return on investments in R&D that would otherwise be unprofitable. Thus, even in cases where patents do nothing to facilitate technology transfer, private firms may invoke justifications for their claims of proprietary rights in the results of research that they have paid for. These justifications have considerably less force when applied to the results of research paid for by the government.

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[*] © 1996 Rebecca S. Eisenberg and Robert P. Merges.

[1] Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 19 (1995).

payee in its role as patent holder. More troubling still, owners of patents on research tools may find it more lucrative to license their patents on an exclusive basis rather than on a non-exclusive basis, a strategy that could choke other research efforts before they get off the ground.

Dr. Chambers suggests that the downside risk of patents on research tools is minimal because the courts have the equitable power to withhold injunctive relief against researchers. But in spite of the equitable character of injunctive relief, there is only a small handful of cases in which courts have withheld permanent injunctions once patent infringement is proven, and researchers would be foolish to count on getting such a break. And even if at the end of the day researchers are able to beat the odds and avoid injunctive relief, the prospect of a damage remedy alone can be expected to deter socially productive uses of research tools.

We concede that proprietary rights may enhance incentives to develop further research tools in the private sector, and it may be that on balance the research enterprise will benefit more from the development of these new tools than it loses by allowing those who develop research tools to restrict access to them. Surely it is better to have research tools available on a restricted basis than it is to have them entirely unavailable because they don't exist. But this argument is only persuasive to the extent that, in the absence of patents, research tools would not be developed.

When the government is picking up the tab, it may be better still to have research tools freely available in the public domain. Government is uniquely situated to enrich the public domain, a fact that we should not lose sight of in the prevailing climate of enthusiasm for private appropriation of government-sponsored research discoveries.

We do not urge these considerations upon the PTO in its determinations of what is patentable, but we believe they are appropriate considerations for a public institution such as NIH to weigh in deciding when it should pursue patents on its own discoveries, and when it would be wiser to dedicate those discoveries to the public domain.

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BARE-FISTED COMPETITION OR PALMING OFF? PROTECTION OF PRODUCT DESIGN AS TRADE DRESS UNDER THE LANHAM ACT

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of product design[6] as protectable trade dress.[7] This expansion has been encouraged by courts and commentators alike.[8]

Expanded protection of trade dress is consistent with the purposes of the Lanham Act when the trade dress at issue serves to identify the source of the product, thereby reducing the likelihood of consumer confusion.[9]

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[6] For purposes of this article, "product design" refers to the physical attributes of a product itself, rather than those of the product's packaging or labeling. The design of a product may be necessary for the product to perform its intended function, or may be chosen merely to make the product more appealing to potential consumers. Other factors frequently influencing product design choices include: ergonomics or ease of use, product safety, compatibility with other products, ease of repair, and cost of manufacture.

[7] *Stormy Clime*, 809 F.2d at 974, 1 U.S.P.Q.2d (BNA) at 2028 (noting that "the design of a product may function as its 'packaging,' thereby entitling the manufacturer to trade dress protection for the appearance of the product"). "Trade dress" has been broadly defined to "involve[] the total image of a product . . . includ[ing] features such as size, shape, color or color combinations, texture, graphics, or even particular sales techniques" John H. Harland Co. v. Clarke Checks, Inc., 711 F.2d 966, 980, 219 U.S.P.Q. (BNA) 515, 528 (11th Cir. 1983); *see also* 1 MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 8.01[3] (3d ed. 1995) (noting that traditional definition of "trade dress" has been "stretched to include the shape and design of the product itself [so that] the field of law once referred to as unfair competition by 'product simulation,' has now been folded into that corner of trademark and unfair competition law called 'trade dress'").

[8] *See* Jay Dratler, Jr., *Trademark Protection for Industrial Designs*, 1988 U. ILL. L. REV. 887 (1988) (arguing for increased use of trademark law for protection of product design); *see also Two Pesos*, 505 U.S. at 773, 23 U.S.P.Q.2d (BNA) at 1085 (finding trade dress and trademarks to be legal equivalents, "serv[ing] the same statutory purpose," with "no persuasive reason to apply different analysis to the two"). The Court's approach in *Two Pesos* has been criticized as failing to recognize "very real differences between . . . types of trade dress." Joan L. Dillon, *Two Pesos: More Interesting for What It Does Not Decide*, 83 TRADEMARK REP. 77, 86 (1993).

[9] The primary purpose of Lanham Act trademark protection is to "secure to the owner of the mark the goodwill of his business and to protect the ability of consumers to distinguish among competing producers." *Two Pesos*, 505 U.S. at 774, 23 U.S.P.Q.2d (BNA) at 1086 (quoting Park 'N Fly, Inc. v. Dollar Park and Fly, Inc., 469 U.S. 189, 198, 224 U.S.P.Q. (BNA) 327, 331 (1985)).

Section II of this Article examines the often conflicting objectives of trademark and patent law, as they are applied to trade dress embodying product design. Section III considers the inconsistencies which arise when courts improperly apply the Lanham Act to elements of product design and examines the constitutional and policy problems resulting from such misapplication. Section IV recommends a judicial approach which recognizes legitimate differences between trade dress and product design and applies the Lanham Act and patent laws consistently with congressional intent.

II. PROTECTION OF TRADE DRESS UNDER THE LANHAM ACT VERSUS UNDER THE PATENT SYSTEM

Because the modern definition of trade dress encompasses a broad variety of product elements, legal inquiry in this area may simultaneously involve several fields of intellectual property law.[13] When courts and practitioners become involved in trade dress issues, it is important that they recognize the potential applicability of various legal doctrines which are often overlapping and sometimes conflicting.[14] This Article concentrates on the interface of patent and trademark law as applied to the design of a product. While both legal regimes presently extend protection to what courts have come to call "trade dress," patent and trademark protection differ greatly in their objectives and effects.

A. *Trade Dress Protection Under The Lanham Act*

The primary objectives of trademark law are: (1) to reduce consumer search costs by identifying the source of the goods and reducing the likelihood of confusion; and (2) to provide an incentive to producers to maintain or improve the quality of their goods by protecting the investment

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[13] *See supra* text accompanying notes 2-7 (describing scope of "trade dress").

[14] *See* Kewannee Oil Co. v. Bicron Corp., 416 U.S. 470, 181 U.S.P.Q. (BNA) 673 (1974) (overlap between trade secrets and patents); *In re* Yardley, 493 F.2d 1389, 181 U.S.P.Q. (BNA) 331 (CCPA 1974) (overlap between copyright and patent); Mazer v. Stein, 74 S. Ct. 460, 100 U.S.P.Q. (BNA) 325 (1954) (overlap between design patent and copyright); *In re* Mogen David Wine Corp., 328 F.2d 925, 140 U.S.P.Q. (BNA) 575 (CCPA 1964) (overlap between design patents and trademarks).

referred only to a product's packaging and labeling.[22] Since the early 1980s, however, courts have expanded this definition to include the shape and design of the product itself.[23] Under this expanded definition of trade dress, "prior distinctions between 'package' or 'container' and 'product configuration' became blurred and hardly worth defending."[24]

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[22] Stormy Clime Ltd. v. Progroup, Inc., 809 F.2d 971, 974, 1 U.S.P.Q.2d (BNA) 2026, 2028 (2d Cir. 1987); *see also* 1 MCCARTHY, *supra* note 7, § 7.25[5]. The traditional interpretation of "trade dress" extended protection to features such as: the color and shape of an antifreeze container, First Brands Corp. v. Fred Meyer, Inc., 809 F.2d 1378, 1381, 1 U.S.P.Q.2d (BNA) 1779, 1782 (9th Cir. 1987); ice cream wrappers and packaging, Ambrit, Inc. v. Kraft, Inc., 812 F.2d 1531, 1533-35, (11th Cir. 1986); the configuration of a juice bottle, Sicilia Di R. Biebow & Co. v. Cox, 732 F.2d 417, 425 (5th Cir. 1984); and the bottle design and labeling of garden chemicals, Chevron Co. v. Voluntary Purchasing Groups, Inc., 659 F.2d 695, 706, 212 U.S.P.Q. (BNA) 904, 914 (5th Cir. 1981), *cert. denied*, 457 U.S. 1126 (1982).

[23] "Trade dress" has been broadly defined to "involve[] the total image of a product . . . includ[ing] features such as size, shape, color or color combinations, texture, graphics or even particular sales techniques." John H. Harland Co. v. Clarke Checks, Inc., 711 F.2d 966, 980, 219 U.S.P.Q. (BNA) 515, 528 (11th Cir. 1983); *see also* 1 MCCARTHY, *supra* note 7, § 8.01[3]. Elements of product design to which trade dress protection has been extended include: the body design of an automobile, Ferrari S.P.A. v. Roberts, 944 F.2d 1235, 1240, 20 U.S.P.Q.2d (BNA) 1001, 1006 (6th Cir. 1991); the design of a clamping tool, Clamp Mfg. Co. v. Enco Mfg. Co., 870 F.2d 512, 515-16, 10 U.S.P.Q.2d (BNA) 1226, 1229 (9th Cir. 1989); the design of a beverage dispenser, Service Ideas, Inc. v. Traex Corp., 846 F.2d 1118, 1123-24, 6 U.S.P.Q.2d (BNA) 1937, 1941 (7th Cir. 1988); the design of a folding table, Vaughan Mfg. Co. v. Brikam Int'l, Inc., 814 F.2d 346, 349-50, 1 U.S.P.Q.2d (BNA) 2067, 2069-70 (7th Cir. 1987); the design of a fishing reel, Brunswick Corp. v. Spinit Reel Co., 832 F.2d 513, 524-25, 4 U.S.P.Q.2d (BNA) 1497, 1506-07 (10th Cir. 1987); design of luggage, *LeSportsac*, 754 F.2d at 76-77, 225 U.S.P.Q. (BNA) at 658-59; design of Rubik's cube puzzle toy, Ideal Toy Corp. v. Plawner Toy Mfg., 685 F.2d 78, 82-82, 216 U.S.P.Q. (BNA) 102, 106 (3d Cir. 1982); and the design of a twin-hopper semitrailer truck, Truck Equip. Serv. Co. v. Fruehauf Corp., 536 F.2d 1210, 1223, 191 U.S.P.Q. (BNA) 79, 90 (8th Cir.), *cert. denied*, 429 U.S. 861 (1976).

[24] Jerome H. Reichman, *Design Protection and the New Technologies: The United States Experience in a Transnational Perspective*, 19 U. BALT. L. REV. 6, 87 (1990); *see also* 1 MCCARTHY, *supra* note 7, § 7.25[5] (noting that "[f]or all practical purposes, there should be no difference in the substantive law of product simulation whether one uses the labels 'trademark,' 'trade dress,' or simply 'unfair competition'"); *accord* Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 773, 23 U.S.P.Q.2d (BNA) 1081, 1085 (1992) (stating "the

> First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.[31]

Unlike trademark protection, which is of indefinite duration, patent protection is statutorily limited to twenty years for utility patents[32] and fourteen years for design patents.[33]

In order to qualify for a utility patent, an invention must meet three explicit conditions: novelty, utility, and nonobviousness.[34] To meet the "novelty" requirement, the invention must not have been known or used by others before the discovery of the invention by the inventor in the United States, must not have been patented or described in a printed publication before the discovery of the invention by the inventor in the United States or more than one year prior to the date of the patent application, and must not have been in public use or on sale in the United States more than one year prior to the date of the patent application.[35] To meet the "utility" requirement, an invention must be "capable of performing the functions for which it was intended and capable of producing good and satisfactory results which are beneficial to the arts and to the country."[36] The "nonobviousness" condition requires that the invention or discovery be sufficiently innovative to represent a substantial inventive step beyond the

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[31] Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262, 201 U.S.P.Q. (BNA) 1, 4 (1979).

[32] 35 U.S.C. § 154(a)(2) (Supp. 1995). On June 8, 1995, the term of utility patents changed from 17 years from the date of issuance to 20 years from the date of filing a U.S. patent application.

[33] 35 U.S.C. § 173 (1994).

[34] 2 LIPSCOMB'S WALKER ON PATENTS § 6:1 (1986).

[35] 1 *id.* § 4:1 (discussing 35 U.S.C. § 102).

[36] 1 *id.* § 5:2.

patented article.[44] The patent statutes represent Congress' attempt to strike an efficient balance between these costs and benefits. The limited duration of patent protection gives inventors a period of time to profit from monopoly pricing on their inventions, after which the invention passes to the public domain and competitors are free to enter the market by copying the patented article. The novelty, usefulness, and nonobviousness requirements for utility patents and the ornamental requirement for design patents insure sufficient benefit from the invention to justify the societal costs of protection. Furthermore, inventions for which protection is sought must be publicly disclosed, thus enabling others to expand on the new technology, thereby further benefiting society.

III. ADDRESSING THE INCONSISTENCIES RESULTING FROM LANHAM ACT PROTECTION OF PRODUCT DESIGN

Protection of the design elements of an article of manufacture is an issue which falls squarely within the realm of patent law.[45] Congress has weighed the costs and benefits of this protection, and has sought to achieve the most efficient balance through the patent statutes. Because of the broad definition courts currently give to the term "trade dress," however, protection under the Lanham Act overlaps patent protection for many elements of product design. Congress' cost-benefit balance is frequently upset when courts expand trade dress protection so far as to permit patent-like protection of potentially unlimited duration to elements of product design.[46]

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[44] ADAM SMITH, THE WEALTH OF NATIONS 54 (Knopf ed. 1991) (1776) ("The price of monopoly is upon every occasion the highest which can be got.").

[45] *See* Qualitex Co. v. Jacobson Prods. Co., 115 S. Ct. 1300, 1304, 34 U.S.P.Q.2d (BNA) 1161, 1163 (1995) ("It is the province of patent law, not trademark law, to encourage invention by granting inventors a monopoly over new product designs . . . .").

[46] Some commentators have argued that judicial extension of trade dress law to protect product design features, more properly the subject of design patents is permissible because patent law is expensive and time consuming. *See* Dratler, *supra* note 8, at 891-95 (arguing for extended use of trade dress protection due to patent law's high standards of novelty and nonobviousness, low rate of success when design patents are challenged in litigation, and delay and expense in prosecuting a design patent); Ralph S. Brown, *Design Protection: An Overview*, 34 U.C.L.A. L. REV. 1341, 1356 (1987) (arguing that because of expense, time, and treatment by

between the mark and the product, along with the degree to which the mark describes the product—is unsuited for application to the product itself."[50] In so holding, the Third Circuit recognized the risk that designation of product design as trade dress may go beyond the Lanham Act's intended scope of protection.[51]

1. Source Designation

The first requirement of a trade dress infringement action, that the trade dress distinguish the product's source, can be satisfied by showing that the trade dress is inherently distinctive or that it has acquired distinctiveness through secondary meaning.[52] Trademarks are often classified in the following categories of increasing distinctiveness: 1) generic; 2) descriptive; 3) suggestive; 4) arbitrary; or 5) fanciful.[53] The latter three categories "are deemed inherently distinctive and are entitled to protection."[54] Descriptive marks, while not inherently distinctive, may acquire distinctiveness through

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[50] Duraco Prods., Inc. v. Joy Plastic Enter., 40 F.3d 1431, 1434, 32 U.S.P.Q.2d (BNA) 1724, 1725 (3d Cir. 1994) (noting that "traditional trade dress doctrine does not 'fit' a product configuration case because unlike product packaging, a product configuration differs fundamentally from a product's trademark, insofar as it is not a symbol according to which one can relate the signifier (the trademark, or perhaps the packaging) to the signified (the product)"). *But see* Stuart Hall Co. v. Ampad Corp., 51 F.3d 780, 34 U.S.P.Q.2d (BNA) 1428 (8th Cir. 1995) (declining to adopt Third Circuit' s approach).

[51] *Duraco*, 40 F.3d at 1447, 32 U.S.P.Q.2d (BNA) at 1737 ("We believe that courts should exercise restraint so as not to undermine Congress's repeated determinations not to afford virtually perpetual protection to product configurations with an expansive construction of section 43(a).").

[52] 1 MCCARTHY, *supra* note 7, § 7.23[2]; *see also* Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 23 U.S.P.Q.2d (BNA) 1081 (1992) (protecting inherently distinctive restaurant interior as trade dress).

[53] *See Two Pesos*, 505 U.S. at 768, 23 U.S.P.Q.2d (BNA) at 1083 (citing Abercrombie & Fitch Co. v. Hunting World, Inc., 537 F.2d 4, 9, 189 U.S.P.Q. (BNA) 759, 764 (2d Cir. 1976)); Zatarains, Inc. v. Oak Grove Smokehouse, Inc., 698 F.2d 786, 790, 217 U.S.P.Q. (BNA) 988, 993 (5th Cir. 1983).

[54] *Two Pesos*, 112 S. Ct. at 2757, 23 U.S.P.Q.2d (BNA) at 1083.

finite competitive variations that . . . are equally acceptable to consumers."[60] Allowing a producer to foreclose competitors from even one of these variations should not be permitted in the absence of a valid patent.

2. Likelihood Of Confusion

To satisfy the second requirement, the plaintiff must show that the trade dress at issue is infringed in a manner which creates a likelihood of confusion.[61] This requires proof that consumers or other members of the public will likely be confused as to source, sponsorship, connection, or approval because of the similarities in trade dress.[62]

By prohibiting one manufacturer from "palming off" his goods as those of another manufacturer, the Lanham Act protects both the manufacturer and the consumer. The manufacturer risks harm to its goodwill, which often reflects a substantial economic investment, when another's goods are passed off as his. The consumer likewise may suffer from such unscrupulous business practices, both through increased search costs and the risk of purchasing goods of lower quality than expected.

When one producer copies the trademark or "traditional" trade dress of another, consumer confusion is likely to occur. This generalization, however, is not necessarily applicable when a producer copies the configuration of another's product. This is so because "one cannot automatically conclude from a product feature or configuration—as one can from a product's arbitrary name, for example—that, to a consumer, it functions primarily to denote the product's source."[63] As a general rule, consumers are much more likely to see a product's configuration as an indicia of its function or use, rather than of its source. Thus, consumer

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[60] *Id.* at 1448, 32 U.S.P.Q.2d (BNA) at 1738 (emphasis added).

[61] 1 MCCARTHY, *supra* note 7, § 7.23[2].

[62] 1 *Id.*

[63] *Duraco*, 40 F.3d at 1441, 32 U.S.P.Q.2d (BNA) at 1731; *see also* RESTATEMENT (THIRD) OF UNFAIR COMPETITION, §16 cmt. b (Tentative Draft No. 2, 1990) ("[I]t is less common for consumers to recognize the design of a product as an indication of source.").

among the courts as to whether the plaintiff bears the burden to negate functionality or the defendant bears the burden to prove functionality.[68] Two main categories of functionality have been recognized by courts—utilitarian functionality and aesthetic functionality.

The Supreme Court has defined utilitarian functionality to include product features essential to the use or purpose of the article or . . . affect[ing] the cost or quality of the article.[69] The circuit courts have articulated the test for utilitarian functionality in a variety of ways,[70] the most

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protection would clearly clash with the objectives of patent law by granting a perpetual monopoly. *Id.*; *see also Qualitex*, 115 S. Ct. at 1304, 34 U.S.P.Q.2d (BNA) at 1163 ("The functionality doctrine prevents trademark law, which seeks to promote competition by protecting a firm's reputation, from instead inhibiting legitimate competition by allowing a producer to control a useful product feature."). A recent decision from the Federal Circuit, however, appears to have neglected the nonfunctionality requirement, setting forth a two-part test for trade dress infringement under the Lanham Act: (1) inherent or acquired distinctiveness; and (2) likelihood of confusion. Imagineering, Inc. v. Van Klassens, Inc., 53 F.3d 1260, 34 U.S.P.Q.2d (BNA) 1526 (Fed. Cir. 1995). This oversight is particularly troubling in this case, as the trade dress at issue involved the "wide slats, scooped seat boards and arms, rounded edges, notched and curved legs, and angled backrests," id. at 1262, 34 U.S.P.Q.2d (BNA) at 1527 of a chair; all arguably functional elements, contributing to the comfort or aesthetic appeal of the product. Whether the total combination of these elements was nonfunctional was not addressed by the court.

[68] 1 MCCARTHY, *supra* note 7, § 7.26[3][d].

[69] Inwood Lab., Inc. v. Ives Lab., Inc., 456 U.S. 844, 851 n.10, 214 U.S.P.Q. (BNA) 1, 4 n.10 (1982). In a more recent case, the Court noted that "a design is legally functional, and thus unprotectable, if it is one of a limited number of equally efficient options available to competitors and free competition would be unduly hindered by according the design trademark protection." *Two Pesos*, 505 U.S. at 775, 23 U.S.P.Q.2d (BNA) at 1086. The Court found that this requirement "serves to assure that competition will not be stifled by the exhaustion of a limited number of trade dresses." *Id.* Most recently, the Court stated that a product feature was functional "if exclusive use of the feature would put competitors at a significant non-reputation-related disadvantage." *Qualitex*, 115 S. Ct. at 1304, 34 U.S.P.Q.2d (BNA) at 1164.

[70] *See* 1 MCCARTHY, *supra* note 7, § 7.26[3][a] (listing, by circuit, various functionality tests).

protectable as trade dress. Between the two extremes, the case for trade dress protection was found to weaken "the more clearly the arrangement . . . serves the purpose of the product . . . especially where the competitor copying such features has taken some significant steps to differentiate its product."[76]

The doctrine of utilitarian functionality will, in almost all instances, prevent trademark law from invading the realm of utility patent law. If the design elements in question obviously possess utilitarian functionality, courts consistently require that any protection be sought through the means of a utility patent.[77]

Aesthetic functionality, by contrast, has received less than unanimous acceptance by reviewing courts.[78] Under this doctrine, visually attractive designs lacking functionality in the traditional utilitarian sense, may be deemed "aesthetically functional," and hence free for all to copy.[79] The 1938 Restatement of Torts commented that "[w]hen goods are bought largely for their aesthetic value, their features may be functional because they definitely contribute to that value and thus aid the performance of an object for which

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[76] *Id.*

[77] *See* Qualitex Co. v. Jacobson Prods. Co., 115 S. Ct. 1300, 1304, 34 U.S.P.Q.2d (BNA) 1161, 1164 (1995).

[78] *See* 1 MCCARTHY, *supra* note 7, § 7.26[4][b] (noting that a "majority of courts have rejected the theory of aesthetic functionality with varying degrees of zeal"); *see also* Anthony L. Fletcher & David J. Kera, *The 45th Year of the Administration of the Lanham Trademark Act of 1946*, 82 TRADEMARK REP. 1041, 1147 (1992) (noting that "[t]he easiest way to deal with the difficulties of aesthetic functionality is to deny that it exists"). It has been argued that "aesthetic functionality is a misnomer," and that aesthetic functionality analysis by courts "seems to primarily revolve around the source identification potential of a design" and is merely secondary meaning analysis by another name. Bradford J. Duft, *Aesthetic Functionality*, 73 TRADEMARK REP. 151, 153 (1983); *see also* 1 MCCARTHY, *supra* note 7, § 7.26[5] (commenting that trademark law "does not need the theory of 'aesthetic functionality'" and would be better served by applying the "merely ornamental" rule to deny trademark protection when there is no secondary meaning attached to the feature in question).

[79] 1 MCCARTHY, *supra* note 7, § 7.26[4][a].

and to stimulate the exercise of the inventive faculties in improving the appearance of articles of manufacture.[86] Through the design patent, Congress sought to allow the inventor of an ornamental design to reap the benefits of that design for a limited time and under limited circumstances. Extending Lanham Act protection to ornamental designs allows the designer to sidestep the requirements and limitations of patent law, while granting him protection of potentially infinite duration.[87]

This result is avoided by courts which adopt the doctrine of aesthetic functionality. This doctrine dictates that when a particular design is chosen because of its beauty or ornamentality, rather than because the design identifies the product's source, protection for that design should be based on design patent law, rather than the Lanham Act. Courts which have rejected the doctrine would do well to reconsider its application in cases seeking to protect product design as trade dress.

B. *The Inherent Conflict Between Patent And Lanham Act Protection Of Product Design As Trade Dress*

In *Sears, Roebuck & Co. v. Stiffel Co.*,[88] and its companion case *Compco Corp. v. Day-Brite Lighting, Inc.*,[89] the Supreme Court recognized that state unfair competition laws enacted to prohibit the copying of product design were inconsistent with federal design patent laws. The *Sears-Compco* Court recognized that the federal patent laws represented Congress' balance of the costs and benefits of product design protection.[90] Product design which was not protected by a design patent or other federal statutory protection was found by the Court to be in the public domain, free for all competitors to

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[86] Gorham Co. v. White, 81 U.S. 511 (1872); Hueter v. Compco Corp., 179 F.2d 416, 84 U.S.P.Q. (BNA) 312 (7th Cir. 1950).

[87] *See Qualitex*, 115 S. Ct. at 1304, 34 U.S.P.Q.2d (BNA) at 1163 ("If a product's functional features could be used as trademarks, however, a monopoly over such features could be obtained without regard to whether they qualify as patents and could be extended forever (because trademarks may be renewed in perpetuity).").

[88] 376 U.S. 225, 140 U.S.P.Q. (BNA) 524 (1964).

[89] 376 U.S. 234, 140 U.S.P.Q. (BNA) 528 (1964).

[90] *See Sears*, 376 U.S. at 231-32, 140 U.S.P.Q. (BNA) at 527-28.

construction of the Lanham Act will interfere with federal patent laws in much the same manner as the state unfair competition statutes struck down in *Sears-Compco* and *Bonito Boats*.[97]

By reviewing the relevant language of the patent statutes and Section 43(a) of the Lanham Act, considering the purposes underlying each, and applying standard rules of statutory construction, it becomes clear that the concerns of *Sears-Compco* and *Bonito Boats* weigh against extending trade dress protection under the Lanham Act to elements of product design. When courts extend the definition of trade dress beyond the labeling and packaging of a product, to include elements of product design, they are reaching beyond the scope of the Lanham Act in a manner which frustrates Congress' objectives behind federal patent law.

Darby Drug Co., 601 F.2d 631, 642, 202 U.S.P.Q. (BNA) 548, 557 (2d Cir. 1979) (noting that *Sears-Compco* cases do not limit actions under § 43(a) of the Lanham Act); D.C. Comics v. Filmation Assoc., 486 F. Supp. 1273, 1277, 202 U.S.P.Q. (BNA) 112, 115 (S.D.N.Y. 1980) (noting that "*Sears-Compco* and their progeny . . . are inapposite to claims predicated on federal statute, because the federalism concerns underlying *Sears-Compco* are simply not implicated by such claims"); General Pool Corp. v. Hallmark Pool Corp., 259 F. Supp. 383, 151 U.S.P.Q. (BNA) 372, 375 (N.D. Ill. 1966) (stating that *Sears-Compco* applies only to state law).

[97] *See* Stormy Clime Ltd. v. Progroup, Inc., 809 F.2d 971, 977-78, 1 U.S.P.Q.2d (BNA) 2026, 2031 (2d Cir. 1987) (recognizing "[c]ourts must proceed with caution in assessing claims to unregistered trademark protection in the design of products so as not to undermine the objectives of the patent laws," and cautioning that "[s]ince trademark protection extends for an unlimited period, expansive trade dress protection for the design of products would prevent some functional products from enriching the public domain"); *see also Ferrari*, 944 F.2d at 1248, 20 U.S.P.Q.2d (BNA) at 1013 (Kennedy, J., dissenting) (arguing that majority's extension of trade dress protection to automobile body design "misconstrues the scope of protection afforded by the Lanham Act," was "contrary to the language and purpose of the Lanham Act, and runs afoul of Supreme Court precedent [citing *Bonito Boats*, *Sears* and *Compco*]"). Additionally, application of *Sears-Compco's* rationale to the Lanham Act is less problematic when it is recalled that the Lanham Act is a federal statute which was enacted to reflect *state* common law of unfair competition. *See supra* note 17.

A. Trade Dress Or Product Design? Drawing A Fine But Necessary Line

As a first step, courts should look at the elements of the product which are being claimed as trade dress. A more focused effort must be made to distinguish between elements which are truly trade dress and those which are more properly designated as elements of the product's "design."[109]

A product's trade dress traditionally referred only to its packaging and labeling, and not to design elements of the product itself.[110] Examples of such traditional trade dress found by courts to be protectable included: the color and shape of an antifreeze container;[111] ice cream wrappers and packaging;[112] the configuration of a juice bottle;[113] and the bottle design and

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[109] The Eighth Circuit's recent decision in Stuart Hall Co. v. Ampad Corp., 51 F.3d 780, 34 U.S.P.Q.2d (BNA) 1428 (8th Cir. 1995), is an example of a decision in which the court appears to have misconstrued the type of "trade dress" involved. *Stuart Hall* rejected the Third Circuit's *Duraco* approach, "declin[ing] to create a distinction between protection of packaging and protection of product configuration, as such a distinction would run contrary to the holding of *Two Pesos*." *Id.* at 788, 34 U.S.P.Q.2d (BNA) at 1434. The Eighth Circuit, however, appears to have improperly determined that the "trade dress" at issue in *Stuart Hall* involved a product configuration, rather than packaging. The case involved calendar and form pads "*packaged* with a 'false cover' . . . differentiating the pads from ordinary lined pads." *Id.* at 783, 34 U.S.P.Q.2d (BNA) at 1429 (emphasis added). Clearly, if what differentiates the goods is the manner in which they are *packaged*, the "trade dress" at issue is not a product configuration.

[110] *Stormy Clime*, 809 F.2d at 974, 1 U.S.P.Q.2d (BNA) at 2028; *see also* 1 MCCARTHY, *supra* note 7, § 7.25[5].

[111] First Brands Corp. v. Fred Meyer, Inc., 809 F.2d 1378, 1381, 1 U.S.P.Q.2d (BNA) 1779, 1780 (9th Cir. 1987).

[112] Ambrit, Inc. v. Kraft, Inc., 812 F.2d 1531, 1533-35, 1 U.S.P.Q.2d (BNA) 1161, 1162-63 (11th Cir. 1986).

[113] Sicilia Di R. Biebow & Co. v. Cox, 732 F.2d 417, 425 (5th Cir. 1984).

the design of a Rubik's cube puzzle toy;[123] and the design of a twin-hopper semitrailer truck.[124]

In the recent *Two Pesos, Inc. v. Taco Cabana, Inc.*[125] decision, the United States Supreme Court reiterated this broad definition of trade dress,[126] and stated that because "the protection of trademarks and trade dress under § 43(a) serves the same statutory purpose," there was "no persuasive reason to apply different analysis to the two."[127] In so stating, the Court missed an opportunity to recognize very real and legitimate practical differences between trademarks and certain types of trade dress. One commentator has noted that the Court's analysis in *Two Pesos* related primarily to trade dress consisting of "arbitrary, discrete elements, often capable of being federally registered as trademarks."[128] This analysis, addressing types of trade dress which are "objectively discernible, [and] capable of presentation in a discrete—rather than amorphous—form,"[129] is difficult to square with a broad definition of trade dress which recognizes the "total image of a product" as protectable. For example, the trade dress in dispute in *Two Pesos* was the overall decor of a Mexican restaurant, comprising a combination of functional elements such as tables and chairs, and nonfunctional elements

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[123] Ideal Toy Corp. v. Plawner Toy Mfg., 685 F.2d 78, 82, 216 U.S.P.Q. (BNA) 102, 106 (3d Cir. 1982).

[124] Truck Equip. Serv. Co. v. Fruehauf Corp., 536 F.2d 1210, 1213, 191 U.S.P.Q. (BNA) 79, 81-82 (8th Cir.), *cert. denied*, 429 U.S. 861 (1976).

[125] 505 U.S. 763, 23 U.S.P.Q.2d (BNA) 1081 (1992).

[126] *Id.* at 765 n.1, 23 U.S.P.Q.2d (BNA) at 1082 n.1 (quoting the broad "total image of a product" definition of trade dress articulated in John H. Harland Co. v. Clarke Checks, Inc., 711 F.2d 966, 980, 219 U.S.P.Q. (BNA) 515, 528 (11th Cir. 1983)).

[127] *Id.* at 770, 23 U.S.P.Q.2d (BNA) at 1085. *But see* Qualitex Co. v. Jacobson Prods. Co., 115 S. Ct. 1304, 1308, 34 U.S.P.Q.2d (BNA) 1163, 1167 (1995) (recognizing that "[t]rademark law helps the holder of a mark in many ways that 'trade dress' protection does not").

[128] Dillon, *supra* note 8, at 86.

[129] *Id.*

Elements such as the packaging and labeling of a product which fall within the traditional definition of trade dress[135] and technical trademarks[136] are clearly protectable under the Lanham Act. Beyond this, however, courts should hesitate to call attributes of the product itself "trade dress." Some product attributes may truly serve no other purpose than source-identification.[137] If this is the case, trade dress protection will serve the goals of the Lanham Act without infringing upon the role of patent law. Otherwise, courts must be cognizant of the potential for upsetting the congressional balance embodied in the patent laws.

B. Application Of The Lanham Act To Elements Of Product Design

As a second step, courts should reconsider how traditional trade dress doctrine is to be applied in cases involving product design. In order to prevail on a claim for trade dress infringement under Section 43(a) of the Lanham Act, a plaintiff must plead and prove three basic elements of his claim.[138] These elements should be reevaluated for their applicability to trade dress comprising product design.

First, the validity of the trade dress must be established by showing that it is recognized by customers as identifying and distinguishing the

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[135] *See supra* text accompanying note 5 (discussing scope of traditional definition of trade dress).

[136] *See supra* text accompanying note 18 (discussing technical trademarks).

[137] One possible example of a product attribute serving only source-identifying purposes is demonstrated by Application of Minnesota Mining and Mfg. Co., 335 F.2d 836 (C.C.P.A. 1964), in which the triangular shape of a cake of dry chemical served no other purpose than to identify its manufacturer. Where the shape serves any purpose (for example, economy of manufacture, compatibility with packing or handling devices, identification of the type of chemical, aesthetic appeal to customers, etc.), however, the design might rightly be considered functional. *See In re* Tesco Chemicals, Inc., 181 U.S.P.Q. (BNA) 59 (T.T.A.B. 1973) (finding cylindrical shape of chemical pellets functional based on compatibility with feeder device).

[138] *See supra* text accompanying notes 45-87 (discussing unsuitability of traditional trademark doctrine in cases involving product configuration).

Rather than rejecting the possibility that a product configuration could be inherently distinctive, however, a better approach is that suggested by the Third Circuit in *Duraco Products., Inc. v. Joy Plastic Enterprises, Ltd.*[146] *Duraco* sets out a three-part test whereby, to be inherently distinctive, a product configuration must be: (i) unusual and memorable; (ii) conceptually separable from the product; and (iii) likely to serve primarily as a designator of origin of the product.[147] This rationale permits a producer to use the configuration of its product to signify itself as the source, without unduly restricting the producer's competitors.

To satisfy the second requirement of a trade dress infringement action, the plaintiff must show that his trade dress is infringed in a manner which creates a likelihood of confusion.[148] As discussed above,[149] however, courts must be cautious in extending Lanham Act protection to trade dress comprising product designs. While the "palming off" of goods is to be condemned, such condemnation should not come at the expense of the free and unbridled "bare-knuckled" competition which is essential to our economy. Thus, courts hearing trade dress infringement cases where the trade dress at issue involves product design, must be cautious to insure that their decisions are directed to eliminating consumer confusion, and not robust competition.

The final requirement of a successful trade dress action is that of nonfunctionality.[150] The Third Restatement clearly recognizes the potential

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typically the restaurant or its decor being sold, but rather the food and services *contained within* the restaurant.

[146] 40 F.3d 1431, 32 U.S.P.Q.2d (BNA) 1724 (3rd Cir. 1994).

[147] *Id.* at 1448-49, 32 U.S.P.Q.2d (BNA) at 1738.

[148] 1 MCCARTHY, *supra* note 7, § 7.23[2].

[149] See supra text accompanying notes 63-65 (noting consumer confusion less likely in product configuration cases than in typical "palming off" cases).

[150] *See supra* text accompanying notes 66-87 (discussing functionality and arguing for increased application of aesthetic functionality doctrine in product configuration cases).

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APPLYING THE EFFECTS TEST THEORY OF PERSONAL JURISDICTION IN PATENT INFRINGEMENT ACTIONS

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infringement actions, it favors a corporate[3] intentional infringer[4] being subject to personal jurisdiction in the patentee's home forum.[5]

In *Calder*, a well-known, professional entertainer, Shirley Jones, a California resident, brought a libel suit against *The National Enquirer* (a national tabloid news magazine based in Florida) in a California state court. Specifically, Jones claimed that she suffered libelous injuries in California stemming from an article written, edited, and prepared for publication almost entirely in Florida.[6] Although the Court found that the two petitioners (the article's author and the President of *The National Enquirer*, respectively) were both Florida residents and had no relevant contacts with California,[7] it found that California was the "focal point of both the story and of the harm suffered."[8] Accordingly, the Court held that jurisdiction over the petitioners in California was proper as a result of the "effects" in California of their Florida conduct.[9] In addition, the Court saw the effects test as

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[3] This theory and the present Article presuppose a corporate defendant because only corporate infringers "reside," and thus are subject to venue, wherever they are subject to personal jurisdiction. 28 U.S.C. §§ 1391(c), 1400(b) (1994); *see* VE Holding Corp. v. Johnson Gas Appliances Co., 917 F.2d 1574, 16 U.S.P.Q.2d (BNA) 1614 (Fed. Cir. 1990), *cert. denied*, 499 U.S. 922 (1991). *See generally* Darin J. Gibby, *Congress Stopped Short in Amending the Law of Venue in Patent Infringement Cases: VE Holding Corp. v. Johnson Gas Appliance Co.*, 1992 B.Y.U. L. REV. 1229 (proposing the repeal of 28 U.S.C. § 1400(b) to allow for uniform venue among all classes of infringers).

[4] *See infra* part III.

[5] The particular venue requirements of trademark and copyright cases and their impact on the application of the effects test in those types of cases will not be explored. However, that does not preclude examining what trademark and copyright cases say, in general, about the effects test. *See infra* part VI.

[6] *Calder*, 465 U.S. at 784.

[7] *Id.* at 785-86.

[8] *Id.* at 789.

[9] *Id.*

III. WHAT IS AN "INTENTIONAL INFRINGER?"

Under *Calder*, in order to apply the effects test in a patent infringement action, the infringer must be an "intentional infringer."[12] For jurisdictional purposes, the concept of intentional infringement is broad, and includes both willful and lesser culpable classes of infringement. For example, an intentional infringer may be a willful infringer—someone who knowingly and recklessly fails to meet their affirmative duty of due care toward a valid U.S. patent[13] and who may therefore be subject to enhanced damages[14] and/or attorneys' fees.[15] On the other hand, an intentional infringer may also be someone of lesser culpability. For example, an intentional infringer may be someone who intentionally goes about a certain course of conduct with knowledge of a patent but without reckless disregard of the patentee's rights—such as when an infringer commences a course of action based on the competent opinion of counsel that the course of action does not constitute infringement. While an infringer in such a circumstance would probably not be subject to enhanced damages as would a willful infringer, they could still be found to be an intentional infringer given that a party should be held to have assumed the risk that the opinion on which it relies may be wrong. Both of these examples, however, are distinguishable from situations where a party intentionally proceeds with a certain course of action only to later find out that they are infringing a valid and enforceable patent of which they had no notice; such a situation creates liability for infringement but does not rise to the level of intentional

554 (D.N.J. 1987). *See also* Dakota Indus., Inc. v. Dakota Sportswear, Inc., 946 F.2d 1384, 1391, 20 U.S.P.Q.2d (BNA) 1450, 1455 (8th Cir. 1991) ("*Calder* requires the consideration of additional factors when an intentional tort is alleged.").

[12] *Supra* note 10 and accompanying text.

[13] *See, e.g.*, Ryco, Inc. v. Ag-Bag Corp., 857 F.2d 1418, 8 U.S.P.Q.2d (BNA) 1323 (Fed. Cir. 1988).

[14] 35 U.S.C. § 284 (1994).

[15] 35 U.S.C. § 285 (1994).

there was a better rule. After reviewing case law on point and a law review article that surveyed the various cases and reviewed alternative approaches,[20] the court rejected the situs of the patentee rule in favor of the rule which states that the injury of patent infringement is felt where the infringing sale is made.[21] The court found this rule better because it indicates where the more meaningful economic loss to the patentee occurs,[22] brings the rule in patent cases into line with the rule in trademark and copyright cases,[23] and does not improperly place the jurisdictional spotlight on the plaintiff.[24]

In rejecting the situs of the patentee rule, the court held that a plaintiff's contacts with a forum (for example, the residence of the patentee in a patent infringement action) should not be a determinative consideration of where jurisdiction over a defendant may lie.[25] Under the situs of the patentee rule, regardless of the defendant's conduct, as long as a patent is being infringed somewhere, even if innocently, the patentee can sue in his home forum because that is where the tortious injury occurs—where

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[20] David Wille, *Personal Jurisdiction Over Aliens in Patent Infringement Actions: A Uniform Approach Toward The Situs of the Tort*, 90 MICH. L. REV. 658 (1991).

[21] *Beverly Hills Fan*, 21 F.3d at 1569-71, 30 U.S.P.Q.2d (BNA) at 1010-12; *see also* North Am. Phillips Corp. v. American Vending Sales, Inc., 35 F.3d 1576, 1579, 32 U.S.P.Q.2d (BNA) 1203, 1205 (Fed. Cir. 1994) (further defining the rule so that the injury of patent infringement occurs where the offending act of making, using, or selling the infringing device or process occurs).

[22] *Beverly Hills Fan*, 21 F.3d at 1571, 30 U.S.P.Q.2d (BNA) at 1011.

[23] *Id.*

[24] *Id.*

[25] *Id.* While this is true in constitutional terms, it is not what the situs of the patentee rule actually requires. Merely claiming that a tortious injury occurs in the patentee's forum under the situs of the patentee rule (jurisdiction authorized) does not remove the requirement that the defendant have minimum contacts with that forum (jurisdiction constitutional). The effects test provides the needed minimum contacts.

jurisdictional authorization.[30] Second, while the effects test results in jurisdiction in the patentee's forum, it does not improperly allow jurisdiction to be based on "random, attenuated, or fortuitous" events. Rather, under the effects test, when a defendant intentionally sets out on a particular course of conduct to cause a particular result, the result cannot be said to be "random, attenuated, or fortuitous."[31] Thus, the jurisdictional spotlight is correctly on the defendant.[32]

V. THE EFFECTS TEST VERSUS THE STREAM OF COMMERCE THEORY

Under the effects test, one looks to the intentionality of the defendant's actions as directed against a particular plaintiff. The stream of commerce theory, on the other hand, typically applies in product liability actions or other situations where the injury was not specifically directed toward a particular person. Thus, analogizing to patent infringement cases, where infringing devices enter the forum[33] by true happenstance but are intentionally created as part of a plan to harm the plaintiff financially, minimum contacts and thus jurisdiction would probably be found under the effects test but not under the stream of commerce theory.

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[30] Interface Biomedical Labs. v. Axiom Medical, Inc., 600 F. Supp. 731, 739 n.6, 225 U.S.P.Q. (BNA) 146, 151 n.6 (E.D.N.Y. 1985).

[31] The diversity case of Coblentz GMC/Freightliner, Inc. v. General Motors Corp., 724 F. Supp. 1364 (M.D. Ala. 1989) reasoned that:

> when a defendant intentionally takes some action with the knowledge that the result will be harm to a specific victim in another state, the picture involves more than mere foreseeability or the likelihood that fortuitous and undirected conduct will have an effect in that state. When the conduct is intentional and is directed at a victim in another state, the defendant may be held to have expected its conduct to have an effect in that state, and further to have expected that the victim will bring suit for redress there.

Id. at 1368.

[32] *Cf.* Laitram Corp. v. OKI Elec. Co., 30 U.S.P.Q.2d (BNA) 1527, 1530-31 (E.D. La. 1994) (applying the effects test but distinguishing between relying on the defendant's, and not the plaintiff's, actions).

[33] Assuming the narrow view of *Calder* is followed. *See infra* part VII.

> having been acquired from one of Coors' licensed distributors, if not from Coors itself.[38]

As an initial matter, these facts would seem to indicate that Coors purposefully avoided the introduction of its product into New Jersey. Such an indication would therefore tend to support a finding that since the defendant did not purposefully avail itself of New Jersey law, personal jurisdiction should not attach.[39]

The court reasoned, however, that due process allowed jurisdiction under New Jersey's long-arm statute.[40] The court further reasoned that because Coors had constructive notice of Horne's patent,[41] Coors was aware that if the products it placed into the stream of commerce infringed Horne's patent, they would cause injury to the patent owner in whatever state he resided.[42] Thus, the court concluded, exercising jurisdiction over Coors in New Jersey, Horne's residence, would not offend traditional notions of fairness, nor would it exceed any constitutional limitations.[43]

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[38] *Horne*, 684 F.2d at 258, 217 U.S.P.Q. (BNA) at 17-18. The opinion does not indicate if defendant Coors was intentionally or purposefully selling beer directly into the New Jersey forum.

[39] *Cf.* Land-O-Nod, Co. v. Bassett Furniture Ind., Inc., 708 F.2d 1338, 1341, 219 U.S.P.Q. (BNA) 281, 283 (8th Cir. 1983) (in finding no jurisdiction, the court held that "the purposeful conduct by [defendants], as evidenced by their failure to fill the order placed [in the forum], appears to be aimed at avoiding distribution of the controversial product line in [the forum].").

[40] *Horne*, 684 F.2d at 260, 217 U.S.P.Q. (BNA) at 17.

[41] *See id.* The court's citation to 35 U.S.C. § 271, in this context, is puzzling: section 271 merely creates liability for infringement and does not speak of, or even imply anything about, "constructive" knowledge.

[42] *Id.* Most interpretations of *Horne* rely more upon the court's statement that a patent should have a fictional situs at the residence of its owner, rather than the intentional conduct of Coors. *E.g.*, Wille, *supra* note 18, at 667 nn.65-66; *see also* Hupp v. Siroflex of America, Inc., 848 F. Supp. 744, 746, 32 U.S.P.Q.2d (BNA) 1842, 1843 (S.D. Tex. 1994) (relying upon *Horne* for the proposition that the injury of patent infringement occurs where the patentee resides if infringing articles are found there).

[43] *Horne*, 684 F.2d at 260, 217 U.S.P.Q. (BNA) at 17.

B. Starline Optical Corp. v. Caldwell[50]

Other cases demonstrate that the effects test as applied in infringement actions require alleged tortious conduct in a commercial context. In *Starline Optical Corp. v. Caldwell*, for example, the plaintiff filed a declaratory judgement action in his home forum, New Jersey, to determine whether the defendant's patent was valid.[51] The defendant's only contacts with New Jersey were a cease and desist letter his attorney in Texas sent to the plaintiff, a telephone call between plaintiff's and defendant's counsel, and a letter from defendant to plaintiff in reply to a letter from the plaintiff.[52] With respect to *Calder*, the *Starline Optical* court first emphasized that a declaratory judgment action does not sound in tort.[53] Then, citing *Dollar Savings Bank v. First Security Bank of Utah*,[54] the court stated that the effects test does not apply to non-tortious claims related to commercial transactions, and "any allegation of general economic effect is insufficient . . . to sustain personal jurisdiction."[55]

Starline Optical can be characterized as belonging to a line of cases which support the general proposition that "courts tend to find no jurisdiction if the patent owner's only contact with the forum is the sending of a letter asserting its patent rights."[56] Thus, in pure declaratory judgment

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[50] 598 F. Supp. 1023, 225 U.S.P.Q. (BNA) 577 (D.N.J. 1984).

[51] *Id.* at 1025, 225 U.S.P.Q. (BNA) at 578.

[52] *Id.*, 225 U.S.P.Q. (BNA) at 577-78.

[53] *Id.* at 1026, 225 U.S.P.Q. (BNA) at 579.

[54] 746 F.2d 208 (3d Cir. 1984).

[55] *Starline Optical*, 598 F. Supp. at 1027, 225 U.S.P.Q. (BNA) at 579.

[56] 6 CHISUM § 21.02[3][a], at 21-169 & n.24 (1995); *see also* Akro Corp. v. Luker, 45 F.3d 1541, 33 U.S.P.Q.2d (BNA) 1505 (Fed. Cir. 1995) (jurisdiction over patentee in the accused infringer's home forum was proper when, in addition to having sent the warning letters to the accused infringer in his home forum, the patentee had an exclusive licensing arrangement with one of the accused infringer's competitors in the accused infringer's home forum), *cert. denied*, 155 S. Ct. 2277 (1995).

not arise from the effects of Katzman's intentional acts.[64] Thus, the court held that jurisdiction was not proper under the effects test.[65]

D. Dakota Industries, Inc. v. Dakota Sportswear, Inc.[66]

Calder has been applied in trademark infringement cases as well. In *Dakota Industries, Inc. v. Dakota Sportswear, Inc.*, the court specifically analogized to *Calder* when stating that "this case involves intentional tortious wrongdoing—namely, the use of the trademark with knowledge of the infringement."[67] The court based its observation on the fact that "evidence [supported] Industries' contention that Sportswear knowingly and intentionally infringed on the trademark."[68] While there was "at least some suggestion" that infringing goods were actually shipped into the forum by the defendant, the holding did not rely upon this fact; instead, the court reasoned more simply that this fact "further bolstered" its conclusion.[69]

Dakota Industries is primarily significant in that it appears to suggest, for the first time, that under a broad effects test theory, due process may not require that infringing goods be found in the forum. Nevertheless, because of the importance the court attached to the fact that passing off occurred in

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[64] *Id.* at 563 n.15 (recognizing that *Horne* had never been explicitly overruled and was therefore binding, the court decided against its application on the theory that patents (*Horne*) and copyrights (*Educational Testing Service*) should not be subject to the same standards of analysis). *But cf.* Beverly Hills Fan Co. v. Royal Sovereign Corp., 21 F.3d 1558, 1571, 30 U.S.P.Q.2d (BNA) 1001, 1011 (focusing on location of infringing sales brings patent law into line with the rule applied in trademark and copyright cases).

[65] *Educational Testing Serv.*, 631 F. Supp. at 564-65. Jurisdiction over Katzman, however, was found under the traditional analysis. *Id.* at 562. Thus, all discussion of the effects test appears to be dicta.

[66] 946 F.2d 1384, 20 U.S.P.Q.2d (BNA) 1450 (8th Cir. 1991).

[67] *Id.* at 1391, 20 U.S.P.Q.2d (BNA) at 1455.

[68] *Id.*

[69] *Id.*

the issue in order to avoid any suggestion that it was allowing an extra-territorial application of the patent laws.[79]

F. Amp Inc. v. Methode Electronics, Inc.[80]

Another important infringement jurisdiction case is *Amp Inc. v. Methode Electronics, Inc.* Because the facts in controversy have been placed under seal, specific details of the case remain very sketchy.[81] Nonetheless, even though the court concluded that the facts supported finding jurisdiction under the effects test,[82] it declined to do so reasoning that it could not square the effects test with the stream of commerce test.[83] Based on this finding, one might conclude that *Horne* is no longer good law.[84] Whatever the case, the court declined to find jurisdiction under the effects test.[85]

G. Laitram Corp. v. OKI Electric Industry Co.[86]

The most recent case prior to *Beverly Hills Fan* that applied the effects test is *Laitram Corp. v. OKI Electric Industry Co.* After distinguishing the effects test from the situs of the patentee rule,[87] the court found that "there is sufficient evidence to indicate OKI Electric knew of the existence of the

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[79] *See infra* note 116.

[80] 823 F. Supp. 259, 27 U.S.P.Q.2d (BNA) 1888 (M.D. Pa. 1993).

[81] *See id.* at 267, n. 6, 27 U.S.P.Q.2d (BNA) at 1894 n.6.

[82] *Id.* at 268, 27 U.S.P.Q.2d (BNA) at 1895.

[83] *But see supra* part V.

[84] *Amp*, 823 F. Supp. at 268, 27 U.S.P.Q.2d (BNA) at 1895. However, *Calder*, not *Horne*, is the key to the effects test.

[85] *Id.* at 267-68, 27 U.S.P.Q.2d (BNA) at 1894-95 (finding general jurisdiction over the defendant based on its substantial ties to Pennsylvania, and not on the effects test; in this respect, the court's entire discussion of the effects test appears to be dicta).

[86] 30 U.S.P.Q.2d (BNA) 1527 (E.D. La. 1994).

[87] *Id.* at 1530-31. *See also supra* part IV.

after the plaintiff put the defendants on notice of possible infringement.[94] Based on this circumstance, the court concluded that "the defendants' conduct in this case was [as] equally intentional [as in *Honeywell* and *Dakota*]."[95] Accordingly, the court implicitly recognized that intentional conduct can be used as a basis or factor in showing minimum contacts for the purpose of establishing jurisdiction.

Second, in footnote 15 of its decision,[96] the court again recognized the significance of intentional infringement. Specifically, footnote 15 cites various cases from other courts supporting the importance of an established distribution network to the constitutional application of the stream of commerce theory. Of the cases cited in that footnote in which jurisdiction was found,[97] there was also strong evidence that the defendant acted intentionally. By contrast, of the cases cited in the footnote in which jurisdiction was not found, there was no evidence that the defendant acted

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[94] *Id.*

[95] *Id.*

[96] *Id.* at 1565 n.15, 30 U.S.P.Q.2d (BNA) at 1007 n.15.

[97] The cases cited are Dakota Indus., Inc. v. Dakota Sportswear, Inc., 946 F.2d 1384, 1391, 20 U.S.P.Q. (BNA) 1450, 1455 (8th Cir. 1994); Honeywell, Inc. v. Metz Apparatewerke, 509 F.2d 1137, 1139, 184 U.S.P.Q. (BNA) 387, 388 (7th Cir. 1975) (noting that "Metz began negotiating with Honeywell for a . . . license, but negotiations ultimately reached an impasse and in October 1970, Metz informed Honeywell that '[s]ince a further delay could not be accepted . . . I have decided to effect deliveries [of Metz units] to the United States immediately'") (quotes by court). The *Honeywell* court further noted that "Metz was acting with knowledge that exportation of the accused devices into the United States would infringe Honeywell's patent rights." *Id.* at 1144, 184 U.S.P.Q. (BNA) at 392; Kearns v. Wood Motors, Inc., 204 U.S.P.Q. (BNA) 485, 490 (E.D. Mich. 1978) (declining to find that the defendants were "unknowing contributors to the acts of infringement," and finding that "since March 21, 1978, when this suit was filed, the two German corporations have been aware of the allegations of patent infringement as well as the existence of Dr. Kearns' patents"); Engineered Sports Prod. v. Brunswick Corp., 362 F. Supp. 722, 725, 179 U.S.P.Q. 486, 489 (D. Utah 1973) ("four of the defendants . . . have dispatched executive officers to Utah where they have discussed and purchased plaintiff's ski boot materials").

Although it was not apparent to the court that the broadcasts into Indiana were critical,[103] Chief Judge Posner expressed the following view:

> In *Calder*, as in all the other cases in which jurisdiction over a suit involving intellectual property . . . was upheld, the defendant had done more than bring about an injury to an interest located in a particular state. The defendant had also "entered" the state in some fashion, as by the sale of magazines containing defamatory material. Well, we have that here too, because of the broadcasts, so we needn't decide whether the addition is indispensable.[104]

Thus, while the Seventh Circuit declined to determine whether such "austere grounds of jurisdiction" (such as instances where the defendant has not "entered" the forum in some way) comported with due process,[105] the court did give some insight regarding the constitutional limitations on the application of the effects test.[106]

J. *Recent Decisions*

Two recent decisions discussing *Calder* in the context of jurisdiction over inducers of infringement are *Energy Absorption Systems, Inc. v. Roadway Safety Services, Inc.*[107] and *Sauer, Inc. v. Kanzaki Kokyukoki Manufacturing. Co.*[108] Unfortunately, the courts in these cases reached opposite results. In *Energy Absorption Systems*, the court, relying heavily upon the Federal Circuit's pronouncements on what it takes to be an inducer of infringement, particularly the requirement that the inducement must be active and

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[103] *Id.* at 411, 31 U.S.P.Q.2d (BNA) at 1813.

[104] *Id.* at 412, 31 U.S.P.Q.2d (BNA) at 1813.

[105] *Id.*

[106] *See generally id.*

[107] 30 U.S.P.Q.2d (BNA) 1325 (N.D. Ill. 1994).

[108] 853 F. Supp. 1106, 33 U.S.P.Q.2d (BNA) 1526 (S.D. Iowa 1994).

patentee resides[114] in the forum,[115] yet no infringing acts are committed in the forum.[116] However, such an expansive application of the effects test may not be capable of uniform implementation due to limitations imposed by differences between state long-arm statutes. Furthermore, whether such an application of the effects test even comports with due process depends on how expansively the Federal Circuit will apply *Calder*'s due process analysis.

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[114] A further limit might be that the patentee only "technically" resides in the forum. For example, the corporation may be incorporated in Delaware, yet have no presence there except for that required under Delaware law. In this situation, the patentee could probably not sue in Delaware, because the patentee has no presence in Delaware, and therefore feels no real effects there. Further, the defendant cannot be accused of aiming conduct at the patentee in Delaware. This situation exemplifies a difficulty in applying the effects test in the realm of a patentee who is a multi-forum entity. That is, it is difficult to determine where the plaintiff resides. *Cf.* Beverly Hills Fan Co. v. Royal Sovereign Corp., 21 F.3d 1558, 1570 n.28, 30 U.S.P.Q.2d (BNA) 1001, 1011 n.28 (Fed. Cir. 1994) (using this difficulty as a factor in deciding that the place of infringement rule is superior to the situs of the patentee rule), *cert. dismissed*, 155 S. Ct. 18 (1994). This difficulty should not, however, be used as a tool for weakening the effects test.

[115] This Article does not consider the situation where the patentee does not reside in the forum. *Cf.* Wiss, *supra* note 2, at 1171 ("[C]ourts should not require that the plaintiff reside in the forum state for jurisdiction under the intentional effects test. Instead, they should consider the degree to which the defendant knew the plaintiff would suffer injury there.").

[116] This may be helpful in finding personal jurisdiction over alleged foreign Process Patent Act infringers. 35 U.S.C. § 271(g) (1994). In non-Process Patent Act situations, care will have to be taken in non-extraterritorial application of the U.S. patent laws. *See generally* Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 173 U.S.P.Q. 769 (1972) (finding that Congress did not intend the patent laws to apply outside the United States).

from the market by intentionally carrying out the claimed invention.[128] Now assume, for whatever reason, that infringing acts are never committed in P's home forum.[129]

Under these facts, P still feels the effects of the defendant's intentional acts, which were specifically targeted against P, regardless of whether infringing acts occur in P's home forum, especially if P resides in a forum which does not happen to have a large market for his goods. P will still have to determine what course of action to take in response to the infringer's intentional acts and may be financially devastated by the infringer's intentional attempt to displace P from markets in other states.[130] Under this scenario, P's injuries are not the mere incidental economic effects that some courts refuse to consider;[131] rather, these effects must be thought of as what the defendant actually intended to occur. While this might appear to make the jurisdictional spotlight shine on P, as described in part IV, because P's problems are caused by the defendant's intentional acts specifically directed against him, the jurisdictional spotlight does indeed shine on the defendant and his intentional acts. Therefore, whether infringing acts are committed in the forum need not be a *controlling* factor under *Calder*, the intellectual property effects test cases (such as *Horne* and *Laitram*), or under other analogous effects test cases.[132] However, considering the emphasis that the

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[128] Under these facts, should the opinion later turn out to be wrong, the infringer would be an intentional infringer but probably not a willful infringer.

[129] In a situation like this, even if jurisdiction and venue are proper in the patentee's home forum under the effects test, it is likely the defendant will probably have strong grounds for transfer out of that forum and into his home forum, or some other forum meeting the requirements of 28 U.S.C. § 1400(b) (1994) and with which he has more significant contacts. Courts will have to be cautious in granting such a motion because it would be against the very policy inherent in the effects test.

[130] *Cf. Calder*, 465 U.S. at 789 (petitioners knew their article "would have a devastating effect upon respondent").

[131] *See* Dollar Sav. Bank v. First Sec. Bank of Utah, 746 F.2d 208, 213 (3d Cir. 1984).

[132] *Cf.* Lex Computer & Mgmt. v. Eslinger & Pelton, P.C., 676 F. Supp. 399 (D.N.H. 1987), wherein plaintiff's business, which was located in New Hampshire, was damaged there when defendant intentionally sent

would cause harm in the forum state.[137] Apparently, because in the *Amp* court's view, *Horne* does not require this additional finding, it is arguable that the court concluded that *Horne* is no longer good law. Nonetheless, it can also be argued that the *Amp* court did not fully consider the *Horne* decision—particularly as to the type of intentional conduct that must be found in order to satisfy due process. In fact, *Horne* made *Amp's* "additional finding" to the extent that *Horne* concluded that defendant Coors apparently knew of Horne's patent and intentionally infringed it anyway.[138] Furthermore, Coors' intentional acts of infringement were directly aimed at Horne and are not analogous to those of an innocent infringer. These are the very distinctions that *Calder* made between different types of culpable conduct further suggesting that the *Amp* court was wrong in believing that *Horne* was abrogated.

Narco[139] also made distinctions between different types of intentional activities. First, *Narco* found an "important distinction" between intentional activity which foreseeably causes injury in the forum and intentional acts specifically targeted at the forum.[140] Apparently, the latter supports jurisdiction under the effects test of *Calder*.[141] *Narco* also considered the "critical difference" between an intentional act which has an effect in the forum and an act taken for the very purpose of having an effect in the forum.[142] Again, the latter apparently supports jurisdiction under *Calder's* effects test. Despite *Narco's* final jurisdictional holding, under its view of the effects test, having actual knowledge of a patent and proceeding with a

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[137] *See Amp*, 823 F. Supp. at 266, 27 U.S.Q.P.2d (BNA) at 1894.

[138] *See supra* text accompanying notes 37-49.

[139] Narco Avionics, Inc. v. Sportsman's Market, Inc., 792 F. Supp. 398, 24 U.S.P.Q.2d (BNA) 1283 (E.D. Pa. 1992).

[140] *Id.* at 408, 24 U.S.P.Q.2d (BNA) at 1291.

[141] *But cf.* Kulter Films v. Covent Garden, 860 F. Supp. 1055, 1062 (D.N.J. 1994) (citing *Covenant Bank* for the proposition that under *Calder*, "defendant's actions must be expressly aimed at the forum state and not just the plaintiff"); Covenant Bank For Sav. v. Cohen, 806 F. Supp. 52, 56 (D.N.J. 1992) (paraphrasing the *Narco* test to the point that it still requires normal minimum contacts to be found).

[142] *Narco*, 792 F. Supp. at 408, 24 U.S.P.Q.2d (BNA) at 1291.

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PROTECTION FOR COLOR UNDER U.S. TRADEMARK LAW

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The prohibition against protecting color per se rested on two major policy considerations. First, to grant exclusive rights in colors would deplete the available choices and be anticompetitive.[5] Second, if color per se was protectable, trademark infringement suits would devolve into questions of shade confusion that the judiciary would find difficult to decide.[6]

(2d Cir. 1959), *cert. denied*, 362 U.S. 919, 124 U.S.P.Q. (BNA) 535 (1960); Tas-T-Nut Co. v. Variety Nut & Date Co., 245 F.2d 3, 113 U.S.P.Q. (BNA) 493 (6th Cir. 1957); Fram Corp v. Boyd, 230 F.2d 931, 109 U.S.P.Q. (BNA) 4 (5th Cir. 1956); Mershon Co. v. Pachmayr, 220 F.2d 879, 105 U.S.P.Q. (BNA) 4 (9th Cir.), *cert. denied*, 350 U.S. 885, 107 U.S.P.Q. (BNA) 362 (1955); Life Savers Corp. v. Curtiss Candy Co., 182 F.2d 4, 85 U.S.P.Q. (BNA) 440 (7th Cir. 1950); Diamond Match Co. v. Saginaw Match Co., 142 F. 727 (6th Cir.), *cert. denied*, 203 U.S. 589 (1906); Deere & Co. v. Farmhand, Inc., 560 F. Supp. 85, 217 U.S.P.Q. (BNA) 252 (S.D. Iowa 1982), *aff'd per curiam*, 721 F.2d 253 (8th Cir. 1983); Funnelcap, Inc. v. Orion Indus., Inc., 421 F. Supp. 700, 192 U.S.P.Q. (BNA) 517 (D.C. Del. 1976); Vitarroz Corp. v. River Brand Rice Mills, Inc., 266 F. Supp. 981, 153 U.S.P.Q. (BNA) 398 (S.D.N.Y. 1967); Delamere Co. v. Taylor-Bell Co., 249 F. Supp. 471, 148 U.S.P.Q. (BNA) 368 (S.D.N.Y. 1966); Chun King Sales, Inc. v. Oriental Foods, Inc., 136 F. Supp. 659, 108 U.S.P.Q. (BNA) 400 (S.D. Cal. 1955), *modified on other grounds*, 244 F.2d 909, 113 U.S.P.Q. (BNA) 404 (9th Cir. 1957); Campbell Soup Co. v. Armour & Co., 81 F. Supp. 114, 79 U.S.P.Q. (BNA) 14 (D.C. Pa. 1948), *aff'd*, 175 F.2d 795, 81 U.S.P.Q. (BNA) 430 (3d Cir.), *cert. denied*, 338 U.S. 847, 83 U.S.P.Q. (BNA) 543 (1949); Radio Corp. of Am. v. Decca Records, Inc., 51 F. Supp. 493, 58 U.S.P.Q. (BNA) 531 (S.D.N.Y. 1943); James Heddon's Sons v. Millsite Steel & Wire Works, Inc., 35 F. Supp. 169 (E.D. Mich. 1940), *aff'd*, 128 F.2d 6, 50 U.S.P.Q. (BNA) 465, 53 U.S.P.Q. (BNA) 579 (6th Cir. 1942), *reh'g denied*, 51 U.S.P.Q. (BNA) 84 (Comm'r Pats. 1941), *cert. denied*, 317 U.S. 674, 55 U.S.P.Q. (BNA) 493 (1942); Southern Calif. Fish Co. v. White Star Canning Co., 45 Cal. App. 426, 187 P. 981 (1920); H.P. Hood & Sons, Inc. v. Whiting Milk Co., 186 N.E.2d 904, 136 U.S.P.Q. (BNA) 421 (Mass. 1963); Mr. Gasket Co. v. Travis, 299 N.E.2d 906, 179 U.S.P.Q. (BNA) 811 (Ohio 1973); Pacific Coast Condensed Milk Co. v. Frye & Co., 85 Wash. 133, 147 P. 865 (1915). *See also* 1 JEROME GILSON, TRADEMARK PROTECTION AND PRACTICE § 2.11 (1992); 1 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 7.16 (3d ed. 1995). *But see* Yellow Cab Transit Co. v. Louisville Taxicab & Transfer Co., 147 F.2d 407, 64 U.S.P.Q. (BNA) 348 (6th Cir. 1945); Water Gremlin Co. v. Ideal Fishing Float Co., 401 F. Supp. 809, 188 U.S.P.Q. (BNA) 388 (D.C. Minn. 1975); Clifton Mfg. Co. v. Crawford-Austin Mfg. Co., 12 S.W.2d 1098 (Tex. Civ. App. Ct. 1929).

[5] 1 MCCARTHY, *supra* note 4, § 7.16 [2] at 7-70 to 71.

[6] 1 MCCARTHY, *supra* note 4, § 7.16[2], at 7-71 to 72.

Owens-Corning appealed to the Federal Circuit. In a two-to-one decision, the court reversed the TTAB and held that Owens-Corning was entitled to a trademark registration under Section 2(f).[12] In reaching this decision, the majority considered: (1) whether color alone is ever protectable as a trademark; (2) whether the color "pink" serves as a trademark, i.e., is distinctive, in this case; and (3) whether any policy considerations preclude the grant of trademark protection.

The Federal Circuit began its analysis by noting that the Lanham Act was intended to liberalize the subject matter of trademark protection. Under the Act, "trademark registration became available to many types of previously excluded indicia" of origin.[13] Therefore, the court found, color marks were no longer barred from registration.

2. Color Depletion Theory

The court commented on the color depletion theory, which had its genesis in the Third Circuit's decision in *Campbell Soup Co. v. Armour & Co.*[14] In that case, the Third Circuit refused protection for the red and white colors of Campbell's soup labels, reasoning that there are a limited number of colors and that it would be unwise policy, from a competitive viewpoint, to permit trademark registrants to claim protection for color. In *Owens-Corning*, the Federal Circuit found that this theory "is not faulted for appropriate application, but following passage of the Lanham Act, courts have declined to perpetuate its per se prohibition which is in conflict with the liberating purpose of the Act."[15] The court emphasized that each case must be decided on its own facts.

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[12] *In re* Owens-Corning Fiberglas Corp., 774 F.2d 1116, 227 U.S.P.Q. (BNA) 417 (Fed. Cir. 1985).

[13] *Id.* at 1119, 227 U.S.P.Q. (BNA) at 418.

[14] 175 F.2d 795, 81 U.S.P.Q. (BNA) 430 (3d Cir.), *cert. denied*, 338 U.S. 847, 83 U.S.P.Q. (BNA) 543 (1949).

[15] Owens-Corning, 774 F.2d at 1120, 227 U.S.P.Q. (BNA) at 419.

ornamentation, and therefore does not serve the trademark function of acting as an indicia of source, the court concluded that if "convincing evidence" is presented to the contrary, color may be protected.[22]

The court found such "convincing evidence" in *Owens-Corning*. It pointed out that the color "pink" was advertised since 1956, and that Owens-Corning had spent over $42 million on consumer advertising, much of which emphasized the distinctive "pink" color of its product.[23] Moreover, the court added, consumer recognition as to the source of "pink" insulation had reached fifty percent in 1981.[24]

Though holding that Owens-Corning was entitled to a registration under Section 2(f) of the Lanham Act, the court cautioned that, by their very "nature," color marks carry a "difficult burden in demonstrating distinctiveness and trademark character."[25]

4. Dissenting Opinion

Judge Bissell, in dissent, "adhere[d] to the view that 'the law is well-settled that the overall color of a product . . . cannot be a trade identity designation, nor is it entitled to registration.'"[26] Judge Bissell noted that this "was the law long before the 1946 Lanham Act, it continued to be the law after the Act, and it ought to be the law in this case."[27]

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[22] *Id.*

[23] *Id.* at 1125-29, 227 U.S.P.Q. (BNA) at 423-25.

[24] *Id.* at 1127, 227 U.S.P.Q. (BNA) at 424.

[25] *Id.*

[26] *Id.* at 1128, 227 U.S.P.Q. (BNA) at 425 (citing 3 RUDOLF CALLMANN, THE LAW OF UNFAIR COMPETITION, TRADEMARKS AND MONOPOLIES § 18.13 (4th ed. 1983)).

[27] *Id.* Judge Bissell articulated four reasons for the court not to discard this "established jurisprudence:" (1) all the regional circuits that had considered the issue had concluded that color per se is not registrable; (2) the current interpretation of the Lanham Act adequately protects the use of color as an element of a trademark, *see, e.g., In re* Data Packaging Corp., 453 F.2d 1300, 1303, 172 U.S.P.Q. (BNA) 396, 398 (C.C.P.A. 1972); Quabaug

Referring to the decision in *Life Savers Corp. v. Curtiss Candy Co.*,[31] in which the Seventh Circuit concluded that color is not subject to trademark protection except in connection with some definite arbitrary symbol or device, the court rejected Nutrasweet's claim for relief.[32] Echoing the concerns of Judge Bissell in her *Owens-Corning* dissent, the Seventh Circuit explicitly rejected *Owens-Corning*. The court emphasized that "[c]onsistency and predictability of the law are compelling reasons for not lightly setting aside a settled principle of law,"[33] and that there was no need to change the law. Color, Senior Judge Reynolds noted, may be protected as an element of overall trade dress but if alone protected as a trademark, infringement actions could soon degenerate into questions of shade confusion.[34] Finally, the Seventh Circuit explained that "if each of the competitors presently in the tabletop sweetener market were permitted to appropriate a particular color for its product, new entrants would be deterred from entering the market. The essential purpose of trademark law is to prevent confusion, not to bar new entrants into the market."[35]

2. *Master Distributors, Inc. v. Pako Corp.*

In contrast to *Nutrasweet*, when the Eighth Circuit faced the color per se issue in *Master Distributors, Inc. v. Pako Corp.*,[36] it followed *Owens-Corning*, allowing protection for color alone. In *Master Distributors*, the plaintiff sought common law trademark protection for the color "blue" for leader splicing tape. The defendant, which manufactured and sold its own brand of blue leader splicing tape, moved for partial summary judgment on the ground that a plaintiff cannot assert trademark rights in the color "blue." The plaintiff urged the district court to follow the *Owens-Corning* majority, while the defendant referred the court to the *Owens-Corning* dissent.

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[31] 182 F.2d 4, 85 U.S.P.Q. (BNA) 440 (7th Cir. 1950).

[32] Nutrasweet Co., 917 F.2d at 1027, 16 U.S.P.Q.2d (BNA) at 1962.

[33] *Id.*

[34] *Id.*

[35] *Id.* at 1028, 16 U.S.P.Q.2d (BNA) at 1962.

[36] 986 F.2d 219, 25 U.S.P.Q.2d (BNA) 1794 (8th Cir. 1993).

to protect a particular shade of color.[40] "Until secondary meaning has been established in every distinguishable shade of color and in no color at all, a highly improbable situation, there will always be an option available to a new market entrant,"[41] Judge Gibson declared.

Neither was the court persuaded by the shade confusion argument. It agreed with the position that deciding likelihood of confusion among color shades should prove no more difficult than deciding confusion in cases involving word marks.[42]

Finally, the court found nothing inconsistent between the doctrine of functionality and protection of color trademarks. It is clear, Judge Gibson noted, that if color is essential to the utility of a product or is the natural color of the product, i.e., the color serves a functional purpose, then no party may acquire exclusive trademark rights in that feature or color.[43]

In rejecting the argument that consistency and predictability mandate that color alone be denied trademark protection, the Eighth Circuit pointed out that even prior to *Owens-Corning*, some courts were protecting color marks upon a showing of secondary meaning.[44] Moreover, Judge Gibson said, "we believe that establishing a per se prohibition against protection of a color mark would cause confusion and inconsistency."[45] To deny protection to color alone "would essentially render a valid color trademark

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[40] *Id.* at 223, 25 U.S.P.Q.2d (BNA) at 1796.

[41] *Id.* at 223, 25 U.S.P.Q.2d (BNA) at 1797.

[42] *Id.*

[43] *Id.* at 224, 25 U.S.P.Q.2d (BNA) at 1797; *see In re* Owens-Corning Fiberglas Corp., 774 F.2d 1116, 1118, 227 U.S.P.Q. (BNA) 417, 419 (Fed. Cir. 1985); Clifton Mfg. Co. v. Crawford-Austin Mfg. Co., 12 S.W.2d 1098 (Tex. Civ. App. 1929).

[44] Master Distributors, Inc., 986 F.2d at 224, 25 U.S.P.Q.2d (BNA) at 1797.

[45] *Id.*

since, in this case, color was used in connection with a nonfunctional shape in the blue label, and the shape had acquired secondary meaning.[52]

Finally, in *First Brands Corp. v. Fred Meyer, Inc.*,[53] the Ninth Circuit was confronted with a claim that Union Carbide's yellow-colored, "F-style" shaped, one gallon antifreeze jug was subject to trade dress protection. The district court denied plaintiff relief. On appeal, Carbide argued that *Owens-Corning* invalidated the color depletion theory. However, the Ninth Circuit read *Owens-Corning* more narrowly and affirmed the district court's decision. *Owens-Corning*, the court commented, "continues to apply the color depletion theory unless there is no competitive need for the color in a particular industry. The Federal Circuit merely declined to establish a per se prohibition against registering colors as trademarks."[54]

C. Qualitex v. Jacobson *Litigation*

1. Background And Lower Court Opinions

Since the 1950s, Qualitex Company used a special shade of "green-gold" color on the pads that it made and sold to dry cleaning firms for use on dry cleaning presses. In 1989, Jacobson Products, a competitor, began to sell its own press pads to dry cleaning firms. Jacobson's pads were a similar "green-gold" color.

In 1991, Qualitex obtained a federal trademark registration for the "green-gold" color of its press pads.[55] Qualitex sued Jacobson for both trademark infringement and unfair competition under the Lanham Act.[56] At trial, the evidence revealed that other manufacturers used other colors on

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[52] *Id.*

[53] 809 F.2d 1378, 1 U.S.P.Q.2d (BNA) 1779 (9th Cir. 1987).

[54] *Id.* at 1382, 1 U.S.P.Q.2d (BNA) at 1781.

[55] U.S.P.T.O. Reg. No. 1,633,711 (Feb. 2, 1991).

[56] Qualitex Co. v. Jacobson Prods. Co., 21 U.S.P.Q.2d (BNA) 1457 (C.D. Cal. 1991), *aff'd in part, rev'd in part*, 13 F.3d 1297, 29 U.S.P.Q.2d (BNA) 1277 (9th Cir. 1994), *rev'd*, 115 S. Ct. 1300, 34 U.S.P.Q.2d (BNA) 1161 (1995).

should not be registered for color alone."[66] The court relied upon both the color depletion and shade confusion arguments and noted that "adequate protection is available when color is combined with distinctive patterns or designs or combined in distinctive logos."[67]

Qualitex filed a petition with the U.S. Supreme Court seeking review of the Ninth Circuit's ruling on the "color alone" issue. The Supreme Court granted certiorari in order to resolve the conflict among the circuits on the registrability of color.[68] A number of organizations, including the International Trademark Association, filed amicus briefs in support of Qualitex. The Solicitor General of the United States also filed a brief in support of Qualitex.

2. Supreme Court Decision

In its opinion in *Qualitex*, the Supreme Court unanimously held that the Lanham Act permits the registration of a trademark that consists, purely and simply, of a color.[69] As long as the color has acquired secondary meaning and is not functional, it is eligible for protection.[70]

Writing for the Court, Justice Breyer noted that both the language of the Lanham Act and the basic underlying principles of trademark law would seem to include color within the universe of things that can function as a trademark. He pointed out, for example, that the definition of a "trademark" includes any "'word, name, symbol, or device, or any combination thereof.'"[71] The courts and the United States Patent and Trademark Office ("PTO"), the Court observed, have recognized shapes, sounds, and smells as trademarks.

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[66] *Id.*

[67] *Id.*

[68] Qualitex Co. v. Jacobson Prods. Co., 115 S. Ct. 632 (1994).

[69] Qualitex Co. v. Jacobson Prods. Co., 115 S. Ct. 1300, 34 U.S.P.Q.2d (BNA) 1161 (1995).

[70] *Id.* at 1304, 34 U.S.P.Q.2d (BNA) at 1164.

[71] *Id.* at 1302, 34 U.S.P.Q.2d (BNA) at 1162 (quoting 15 U.S.C. § 1127 (1994)).

its source,[79] and have allowed competitors to copy the color of machinery to ensure aesthetic compatibility.[80]

While Jacobson relied upon several pre-Lanham Act cases in support of the position that the law does not recognize protection for color per se, the Supreme Court agreed with the Federal Circuit's comment in *Owens-Corning* that the Lanham Act had significantly changed and liberalized U.S. trademark law.[81] Justice Breyer also noted that when the Lanham Act was amended in 1988, the definition of a "trademark" was left unchanged.[82] Moreover, the court emphasized, the 1988 amendments were enacted against the following background: (1) the Federal Circuit had decided *Owens-Corning*; (2) the U.S. Patent and Trademark Office had adopted a clear policy permitting registration of color as a trademark; and (3) the report of the U.S. Trademark Association's Trademark Review Commission (which formed the basis for the 1988 amendments) recommended that "the terms 'symbol, or device' . . . not be deleted or narrowed to preclude registration of such things as a color, shape, smell, sound, or configuration which functions as a mark."[83]

Finally, the Court rejected the argument that protection for color alone is not necessary since a company can protect color as part of overall trade dress and may rely upon trade dress protection if a competitor copies its color.[84] Justice Breyer observed that there may be instances where it

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[79] *Id.* (citing Inwood Labs., Inc. v. Ives Labs., Inc., 456 U.S. at 858 n.20, 214 U.S.P.Q. (BNA) at 7 n.20).

[80] *Id.* (citing Deere & Co. v. Farmhand, Inc., 560 F. Supp. 85, 98, 217 U.S.P.Q. (BNA) 252, 262 (S.D. Iowa 1982) (color "green" for farm machinery found functional because farmers wanted their machinery to match), *aff'd*, 721 F.2d 253 (8th Cir. 1983); Brunswick Corp. v. British Seagull Ltd., 35 F.3d 1527, 1532, 32 U.S.P.Q.2d (BNA) 1120, 1123 (Fed. Cir. 1994) (color "black" held functional because black is compatible with wide variety of boat colors), *cert. denied*, 115 S. Ct. 1426 (1995)).

[81] *Id.* at 1307, 34 U.S.P.Q.2d (BNA) at 1166.

[82] *Id.*

[83] *Id.* (quoting *The United States Trademark Association Trademark Review Commission Report and Recommendations to USTA Presidential Board of Directors*, 77 TRADEMARK REP. 375, 421 (1987)).

[84] *Id.* at 1308, 34 U.S.P.Q.2d (BNA) at 1167.

In prosecuting an application seeking protection for color, a trademark attorney must be prepared to respond to the following inquiries from the examiner: (1) for how long and in what manner has the applicant used and advertised the color; (2) do others in the industry use color for their products; and (3) is the color the natural color of the product.[92] Also, an applicant will usually have to submit representative samples of advertising and promotional material.[93]

E. *Discussion*

As a policy matter, the Supreme Court correctly decided that color alone should be eligible for federal trademark protection. The use of color can be an important part of a product's marketing strategy and serve as a source identifier. While uses of color which serve a functional purpose would be ineligible for protection, many uses of color are not functional.[94] When a business has invested advertising dollars to associate the source of the product with a distinctive, nonfunctional color in the consumer's mind, protection should be available.

Further, an automatic prohibition against protection for color violates the general principle of American jurisprudence that per se rules are not favored in the law.[95] Moreover, the preamble to section 2 of the Lanham Act provides that "[n]o trademark shall be refused registration . . . on account of its nature."[96]

With respect to the shade confusion theory, as the Supreme Court pointed out, likelihood of confusion in cases involving color marks should be no more difficult to determine than likelihood of confusion in cases

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[92] *Id.*

[93] *Id.*

[94] Studies have demonstrated that colors have different meanings, though these may vary among cultures. Laurence Jacobs et al., *Cross-cultural Colour Comparisons: Global Marketers Beware!*, 8 INT'L MARKETING REV. 21 (1991).

[95] Continental T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36 (1977).

[96] 15 U.S.C. § 1052 (1994).

for over thirty years in a market where many purchasers relied upon color to identify the goods.[102]

While it may be the unusual case where color alone can be protected, some companies will be able to meet the "substantial" burden of proof imposed by the PTO.[103] The use of a particular color for a product over a long period of time, while highly relevant, is not determinative. Proof that the color is not the natural color of the product and is actually a somewhat unusual color for that product, will increase the possibility of securing trademark protection.[104] To achieve trademark protection, a company will also have to demonstrate that its advertising was designed to promote the product's color, and that consumers associate that color with the product.[105] To increase the likelihood of registrability for color, a company could use the color in point-of-sale displays, use the color on packaging, and coordinate the color in promotional efforts, including giveaways. The use of slogans can also highlight the importance of the color to the product. Finally, a company can inform the public that it considers a color to be its trademark through use of the appropriate symbols.[106]

III. PROTECTION OF COLOR AS PART OF OVERALL TRADE DRESS

Prior to the Supreme Court's decision in *Qualitex*, it was unclear whether color alone was subject to trademark protection; however, it has long been the law in the United States that color combined with words, designs, symbols, or other arbitrary and distinctive matter may be given protection. Many decisions have held that various combinations of colors or defined shapes in a certain color are protectable. For example, Gucci has

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[102] Qualitex Co. v. Jacobson Prods. Co., 21 U.S.P.Q.2d (BNA) 1457 (C.D. Cal. 1991), *aff'd in part, rev'd in part*, 13 F.3d 1297, 29 U.S.P.Q.2d (BNA) 1277 (9th Cir. 1994), *rev'd*, 115 S. Ct. 1300, 34 U.S.P.Q.2d (BNA) 1161 (1995).

[103] The PTO requires evidence that the public associates the color with a particular source and that affording protection for the color will not hinder effective competition.

[104] TMEP, *supra* note 90, § 1202.04(e).

[105] Kelly, *supra* note 89, at C10.

[106] *See id.*

Other courts have held that merely applying color to logical divisions of a product, such as to the panels of a basketball[113] or soccer ball,[114] will be perceived only as decoration, not as a trademark.

The color of liquid products has usually not qualified for trademark protection on grounds of functionality. The producer of the pink-colored stomach remedy "Pepto-Bismol," for example, was held to have no rights to the color pink for such products. The court, in finding pink functional, referred to its purported soothing "psychosomatic effect."[115] Likewise, injunctive relief was denied against the sale of a look-alike private label version of "Listerine" mouthwash because the amber color of the product was said to signify any unflavored, medicinal mouthwash.[116]

IV. CLAIMING COLOR AS FEATURE OF MARK

Many applicants for federal trademark registration in the United States assert color as a feature of the mark. In filing an application for a mark consisting of color(s), the color(s) must be designated on the drawing by marking the appropriate areas of the mark according to the linings for indicating color which are set forth in Trademark Rule 2.52(e).[117] For example, vertical lines are used to designate the colors "red" or "pink" and horizontal lines are used to designate the color "blue." If the drawing contains lining for color, there must be a statement in the record explaining what color(s) are designated by the lining in the mark.[118] If the drawing

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[113] American Basketball Ass'n v. AMF Voit, Inc., 358 F. Supp. 981, 177 U.S.P.Q. (BNA) 442 (S.D.N.Y.), *aff'd*, 487 F.2d 1393, 180 U.S.P.Q. (BNA) 290 (2d Cir. 1973), *cert. denied*, 416 U.S. 986, 181 U.S.P.Q. (BNA) 685 (1974).

[114] *In re* Soccer Sport Supply Co., 507 F.2d 1400, 184 U.S.P.Q. (BNA) 345 (C.C.P.A. 1975).

[115] Norwich Pharmacal Co. v. Sterling Drug, Inc., 271 F.2d 569, 123 U.S.P.Q. (BNA) 372 (2d Cir. 1959), *cert. denied*, 362 U.S. 919, 124 U.S.P.Q. (BNA) 535 (1960).

[116] Warner-Lambert Co. v. McCrory's Corp., 718 F. Supp. 389, 12 U.S.P.Q.2d (BNA) 1884 (D.N.J. 1989).

[117] 37 C.F.R. § 2.52(e) (1994).

[118] TMEP, *supra* note 90, § 807.06(a).

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contains lining for color, the statement in the record that the mark on the drawing is lined to designate specified color(s) is understood as indicating that color is a feature of the mark.[119] However, even though the drawing is lined for color, an applicant still has the option of asserting that it does not consider color to be a feature of the mark. If that is the case, a statement to that effect, e.g., "but no claim is made to color" or "but color is not a feature of the mark," will be entered in the record.[120]

V. CONCLUSION

U.S. trademark law provides significant protection to color. As a result of the Supreme Court's decision in *Qualitex*, businesses may be even more inclined to use color as a marketing tool. This should result in the issuance of more "color" registrations by the PTO. There will probably be more litigation in this area to fine tune the scope of protection for color. Traditional trademark law analysis will be applied in carrying out these tasks. Therefore, as long as the color has acquired secondary meaning and is nonfunctional, it should be protectable.

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[119] *Id.* § 807.06(b).

[120] *Id.* § 807.06(c).

obtained protection of the green, red, and white stripes used on handbags, clothing, and watches.[107] Chevron was able to protect the horizonal red, yellow, and white bands on a bottle of garden chemical products.[108] Kodak successfully claimed protection for its "familiar Kodak yellow" background with red, black, or both colors, used in distinctive printing.[109] Cross was found to have trademark rights in a colored conical top of a pen against a pen barrel of contrasting color.[110]

Of course, not all uses of color will qualify for protection. The more distinctive and arbitrary the design upon which a color is imposed, the more likely the design, including the color(s), will be protectable. In *Campbell Soup Co. v. Armour & Co.*,[111] for example, the court held that Campbell Soup could not assert trademark protection in a label divided into the colors red and white. The court noted:

> Color is a perfectly satisfactory element of a trademark if it is used in combination with a design in the form, for example, of a picture or a geometrical figure. . . . The mere division of a label into two background colors, as in this case, is not, however, distinct or arbitrary.[112]

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[107] Gucci Am., Inc. v. Dart, Inc., 715 F. Supp. 566, 12 U.S.P.Q.2d (BNA) 1912 (S.D.N.Y. 1989).

[108] Chevron Chem. Co. v. Voluntary Purchasing Groups, Inc., 659 F.2d 695, 212 U.S.P.Q. (BNA) 904 (Former 5th Cir. 1981), *cert. denied*, 457 U.S. 1126 (1982).

[109] Eastman Kodak Co. v. Fotomat Corp., 317 F. Supp. 304, 165 U.S.P.Q. (BNA) 444 (N.D. Ga. 1969), *appeal dismissed*, 441 F.2d 1079 (5th Cir. 1970).

[110] A.T. Cross Co. v. TPM Distrib., Inc., 226 U.S.P.Q. (BNA) 521 (D. Minn. 1985).

[111] 175 F.2d 795, 81 U.S.P.Q. (BNA) 430 (3d Cir.), *cert. denied*, 338 U.S. 847, 83 U.S.P.Q. (BNA) 543 (1949).

[112] *Id.* at 798-99, 81 U.S.P.Q. (BNA) at 433.

involving word or design marks. In fact, they might be easier to resolve. In making likelihood of confusion determinations involving word marks, for example, courts are directed to focus on the sight, sound, and meaning of the marks involved.[97] In contrast, cases involving color marks would require courts to focus solely on appearance.[98]

The color depletion theory argument, if valid, could be used, albeit to a lesser extent, with respect to protecting word marks. Further, some experts estimate that the available number of color variations distinguishable by the human eye exceeds ten million,[99] so it is unlikely that depletion will be a real problem.

While there is sound justification for a high standard of proof for protection of color, a total bar is inappropriate, and was rightfully rejected by the Supreme Court. The *Owens-Corning* and *Qualitex* cases prove that, in certain cases, color alone can function as a trademark. Owens-Corning had used the color "pink" for home insulation since 1956 and spent over $42 million from 1972 to 1981 advertising the color on television, radio, and other media.[100] Survey evidence revealed that fifty percent of the public associated "pink" insulation with a single source.[101] Qualitex used its "green-gold" color

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[97] 1 GILSON, *supra* note 4, § 5.02 (citing numerous cases which stand for this principle).

[98] "There do exist scientifically accurate methods for objectively defining a color shade, whether or not the human eye can distinguish them." 1 MCCARTHY, *supra* note 4, § 7.16[1], at 7-69 (citing Olay Co. v. Cococare Prods., Inc., 218 U.S.P.Q. (BNA) 1028 (S.D.N.Y. 1983), *motion for clarification of injunction denied*, 223 U.S.P.Q. (BNA) 122 (S.D.N.Y. 1983)); *see also* Brian Richard Henry, *Right Hat, Wrong Peg:* In re Owens-Corning Fiberglas Corporation *and the Demise of the Mere Color Rule*, 76 TRADEMARK REP. 389, 402 (1986); William J. Keating, *Development of Evidence to Support Color-Based Trademarks*, 9 J.L. & COM. 1 (1989).

[99] Henry, *supra* note 98, at 402.

[100] *In re* Owens-Corning Fiberglas Corp., 774 F.2d 1116, 1125-29, 227 U.S.P.Q. (BNA) 417, 423-25 (Fed. Cir. 1985).

[101] *Id.* at 1127, 227 U.S.P.Q. (BNA) at 424.

would be difficult, if not impossible, for a company to place a design on a product.[85] He also noted that trademark law provides the owner of a mark with many advantages that trade dress law does not.[86] These advantages include the ability to record a trademark registration with the U.S. Customs Service to stop entry of infringing imports[87] and the triggering of the statutory presumptions relating to validity and ownership of the mark and the exclusive right to use of the mark.[88]

D. *Patent And Trademark Office Procedure And Policy*

As the Supreme Court noted in *Qualitex*, the PTO permits registration of color as a trademark. In addition to the "green-gold" color in issue in *Qualitex*, the PTO has also registered, for example, the color "orange" for chlorinated polyvinyl chloride molding compounds, the color "white" for reciprocating saw blades, and the color "yellow" for corrugated plastic tubing.[89]

In contrast, the PTO's Trademark Manual of Examining Procedure ("TMEP") states that color is usually perceived as an ornamental feature of goods and as a result is usually unregistrable.[90] The burden of proof for establishing the registrability of color alone is "substantial," and the applicant must submit evidence that the color has acquired distinctiveness and is not functional. "A color may be functional if it serves a utilitarian purpose or yields a utilitarian or functional advantage . . . or . . . if it accomplishes economies in manufacture or use."[91]

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[85] *Id.*

[86] *Id.*

[87] 15 U.S.C. § 1124 (1994); 19 U.S.C. § 1526(a) (1994).

[88] *See* 15 U.S.C. § 1057 (1994).

[89] *See* David M. Kelly, *Qualitex Makes Visible The Strategic Spectrum*, NAT'L L.J., May 8, 1995, at C10.

[90] U.S. DEPARTMENT OF COMMERCE, TRADEMARK MANUAL OF EXAMINING PROCEDURE § 1202.04(e) (2d ed. 1993) [hereinafter TMEP].

[91] *Id.*

"If a shape, a sound, and a fragrance can act as symbols, why, one might ask, can a color not do the same?"[72]

The Court addressed and dismissed each of the four policy arguments advanced by Jacobson Products to explain why the law should forbid the use of color alone as a trademark.[73] With respect to the shade confusion argument, Justice Breyer determined that it will be no more difficult for courts to resolve infringement suits involving colors than suits involving word or design marks.[74] Responding to Jacobson's argument that lighting affects the perceptions of protected color, the Court indicated that courts could, if necessary, replicate lighting conditions under which a colored product is normally sold.[75]

The Court also rejected Jacobson's color depletion argument, reasoning that "it relies on an occasional problem to justify a blanket prohibition."[76] To the extent that a "color depletion" or "color scarcity" problem does exist, Justice Breyer commented, the trademark doctrine of functionality may be applied to bar protection for the color involved.[77] The functionality doctrine, the Court declared, forbids the grant of trademark protection where doing so will put a competitor in a significant competitive disadvantage because the feature is "'essential to the use or purpose of the article'" or "'affects [its] cost or quality.'"[78] For example, Justice Breyer pointed out that courts have permitted the copying of the color of a medical pill where the color served to identify the kind of medication in addition to

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[72] *Id.* at 1303, 34 U.S.P.Q.2d (BNA) at 1162.

[73] *Id.* at 1305-08, 34 U.S.P.Q.2d (BNA) at 1164-67.

[74] *Id.* at 1305, 34 U.S.P.Q.2d (BNA) at 1164-65.

[75] *Id.*

[76] *Id.* at 1305, 34 U.S.P.Q.2d (BNA) at 1165.

[77] *Id.* at 1306, 34 U.S.P.Q.2d at 1165.

[78] *Id.* (quoting Inwood Labs., Inc. v. Ives Labs., Inc., 456 U.S. 844, 850 n.10, 214 U.S.P.Q. (BNA) 1, 4 n.10 (1982)).

their press pads.[57] The evidence also demonstrated that the use of the "green-gold" color does not improve the press pad's performance.[58] Therefore, the color served no functional purpose.[59]

In granting protection to Qualitex's "green-gold" color, the district court emphasized that the color was non-primary.[60] Indeed, the court seemed to read *Owens-Corning* as being applicable only to those cases involving non-primary colors.[61] The court remarked that since plaintiff's "green-gold" color is not a primary or secondary color, its appropriation and exclusive use by Qualitex will not deprive competitors of the right to use a primary color. "There is a competitive need in the press pad industry for color," the court remarked, "but the range of tones of available distinctive suitable colors, which need not be primary colors, is in the hundreds, if not thousands."[62] According to the court, "[i]n recognizing the trademark as valid, there is no danger of color depletion. There are hundreds or thousands of distinctive shades of greens, yellows, blues, and browns or tans available to the competitors."[63]

The Ninth Circuit, however, reversed on the issue of trademark infringement and ordered the cancellation of Qualitex's federal trademark registration.[64] The court interpreted the Lanham Act to preclude the registration of "color alone" as a trademark.[65] After canvassing the relevant authorities, the court "conclude[d] that the better rule is that a trademark

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[57] *Id.* at 1458.

[58] *Id.* at 1460.

[59] *Id.*

[60] *Id.*

[61] *Id.* at 1462.

[62] *Id.* at 1460.

[63] *Id.*

[64] Qualitex Co. v. Jacobson Prods. Co., 13 F.3d 1297, 29 U.S.P.Q.2d (BNA) 1277 (9th Cir. 1994), *rev'd*, 115 S. Ct. 1300, 34 U.S.P.Q.2d (BNA) 1161 (1995).

[65] *Id.* at 1302, 29 U.S.P.Q.2d (BNA) at 1280.

registration ineffective and unenforceable,"[46] the court observed, and "this would be extremely confusing and inconsistent."[47]

3. Other Circuit Court Decisions

Three other federal courts of appeals had the opportunity to review and comment on the *Owens-Corning* holding. In these cases, however, the courts were able to reach a decision without explicitly accepting or rejecting the Federal Circuit's decision.

In *AmBrit, Inc. v. Kraft, Inc.*,[48] the Eleventh Circuit was presented with the argument that the color "royal blue" on a textured foil wrapper for ice cream should be protected. AmBrit cited *Owens-Corning* for the proposition that U.S. trademark law protects color alone. The Eleventh Circuit responded that "[e]ven if we were to accept the logic of that decision, we would still preclude [the plaintiff] from attempting to monopolize the color royal blue because there is no evidence that the color royal blue can or does serve an origin indicating function in connection with the sale of ice cream products."[49]

The color "blue" was in issue again in *Keds Corp. v. Renee International Trading Corp.*[50] There, Keds sought protection for its blue "Keds" label on the heel portion of most of its shoes. In contrast to the facts in *AmBrit*, however, Keds had obtained a federal trademark registration for its blue label. The First Circuit, in upholding an award of relief to Keds, determined first that the color "blue" was not functional.[51] It then noted that the color depletion theory had been criticized in *Owens-Corning*. The court determined, however, that it "need not decide whether color alone can be trademarked"

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[46] *Id.* at 224, 25 U.S.P.Q.2d (BNA) at 1798.

[47] *Id.*

[48] 805 F.2d 974, 1 U.S.P.Q.2d (BNA) 1161 (11th Cir. 1986), *rereported*, 812 F.2d 1531 (11th Cir. 1986), *cert. denied*, 481 U.S. 1041 (1987).

[49] *Id.* at 992, 1 U.S.P.Q.2d (BNA) at 1175, 812 F.2d at 1548.

[50] 888 F.2d 215, 12 U.S.P.Q.2d (BNA) 1808 (1st Cir. 1989).

[51] *Id.* at 221, 12 U.S.P.Q.2d (BNA) at 1812.

The district court, after canvassing the post-*Owens-Corning* cases, sided with the defendant, basing its decision on both the shade confusion and color depletion theories.[37] On appeal, the Eighth Circuit reversed.[38] Writing for the court, Judge Gibson rejected the notion that, as a matter of law, color alone cannot be afforded trademark protection.

> [This court is] not persuaded by the three traditional arguments against protection—the color depletion theory, shade confusion, and the functionality doctrine. Nor are we impressed by the argument that 'consistency and predictability' require a per se prohibition against trademark protection for color alone. We believe that not allowing manufacturers to protect color marks when all the traditional requirements have been met will actually promote inconsistency and confusion.[39]

Focusing on the color depletion theory, the court found nothing improper in allowing a manufacturer "who has met all the normal requirements for obtaining trademark protection," including secondary meaning,

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[37] Master Distributors, Inc. v. Pako Corp., 777 F. Supp. 744, 21 U.S.P.Q.2d (BNA) 1929 (D. Minn. 1991), *rev'd*, 986 F.2d 219, 25 U.S.P.Q.2d (BNA) 1794 (8th Cir. 1993). The court noted that the plaintiff had not limited itself to any particular shade of blue. Even if it had, the court added, it is unclear how far from that shade the defendants would have to deviate in order to sell a blue leader splicing tape that would not infringe. The district court also emphasized that "if plaintiff can appropriate blue, then other competitors will appropriate other colors. . . . Eventually, there would be no room for new competitors in the leader splicing tape market, merely because existing manufacturers hold trademarks in the available colors." *Id.* at 750, 21 U.S.P.Q.2d (BNA) at 1933. The district court distinguished the case before it from *Owens-Corning* in that none of Owens-Corning's competitors colored their insulation. Thus, color depletion was remote. "Therefore, even if the Court followed the *Owens-Corning* majority in rejecting a per se bar on mere color trademarks, it would conclude that defendants were entitled to partial summary judgment under the color depletion theory." *Id.* at 750 n.2, 21 U.S.P.Q.2d (BNA) at 1933 n.2.

[38] Master Distributors, Inc. v. Pako Corp., 986 F.2d 219, 25 U.S.P.Q.2d (BNA) 1794 (8th Cir. 1993).

[39] *Id.* at 222, 25 U.S.P.Q.2d (BNA) at 1796.

B. *Split Among Courts Of Appeals*

1. *Nutrasweet Co. v. Stadt Corp.*

Any hope that *Owens-Corning* would be widely followed by other courts of appeals was dashed by the Seventh Circuit's decision in *Nutrasweet Co. v. Stadt Corp.*[28] In that case, Nutrasweet, the manufacturer of the blue-packaged sugar substitute product "Equal," sought to enjoin the defendants from packaging their sugar substitute product in similar pastel blue packets. Nutrasweet had not obtained federal trademark protection for the color "blue" and brought its action for trade dress infringement under Section 43(a) of the Lanham Act.[29] The issue before the court was "whether mere color should ever be accorded trade-dress protection under Section 43(a)."[30]

Rubber Co. v. Fabiano Shoe Co., 567 F.2d 154, 161, 195 U.S.P.Q. (BNA) 689, 694 (1st Cir. 1977); (3) the majority's decision might create a barrier to other lawful competition in the home insulation trade; and (4) the courts would face difficulty in deciding infringement suits involving color marks. *Owens-Corning*, 774 F.2d at 1129-31, 227 U.S.P.Q.2d (BNA) at 426-27.

[28] 917 F.2d 1024, 16 U.S.P.Q.2d (BNA) 1959 (7th Cir. 1990), *cert. denied*, 499 U.S. 983 (1991).

[29] 15 U.S.C. § 1125(a) (1994).

[30] Nutrasweet Co., 917 F.2d at 1026, 16 U.S.P.Q.2d (BNA) at 1961. It remains to be seen what impact, if any, the decision of the U.S. Supreme Court in Two Pesos, Inc. v. Taco Cabana, Inc., 112 S. Ct. 2753, 23 U.S.P.Q.2d (BNA) 1081, *reh'g denied*, 113 S. Ct. 20 (1992), will have on the protection for single colors. The Court in *Two Pesos* held that inherently distinctive trade dress is protectable under Section 43(a) of the Lanham Act absent any need to establish secondary meaning. It is far more likely that trade dress, which relates to the overall image and appearance of a product or service, may be inherently distinctive than would be color alone. Color, as part of a product's inherently distinctive trade dress, may be protectable absent secondary meaning but it seems unlikely that any color alone would be sufficiently unique to qualify for trademark protection absent proof of secondary meaning. Indeed, Justice Breyer's decision in *Qualitex* seems to assume that secondary meaning will always have to be established before color alone will be protected.

3. Other Arguments Against Registration

According to the majority opinion, color alone would not be protectable if it served a functional purpose, that is, "'if it is essential to the use or purpose of the article or if it affects the cost or quality of the article.'"[16] To protect a color that was functional, the court noted, would have an adverse affect on competition. In this case, the court ruled, the color "pink" does not deprive competitors of any reasonable right or competitive need.[17] Owens-Corning, the Federal Circuit observed, is the only manufacturer that colors its insulation and there are only a small number of producers.[18]

In dismissing the argument that protection for color would create a legal quagmire by requiring courts to engage in shade confusion analysis, the court stated that it "agree[d] with the [Trademark Trial and Appeal] Board that '[d]eciding likelihood of confusion among color shades . . . is no more difficult or subtle than deciding likelihood of confusion where word marks are involved.'"[19] In conclusion, the *Owens-Corning* majority found that the color "pink" performed no functional purpose and that protection of the color is consistent with the twin purposes of trademark law—to protect the public against confusion and to secure to the trademark owner the good will of his business.[20]

The opinion next focused on the TTAB's finding that the color "pink" was not protectable because it had not acquired secondary meaning; that is, it had not become distinctive of Owens-Corning's goods. The TTAB had stated that color is "really nothing other than a type of product ornamentation."[21] While agreeing with the TTAB that color is usually perceived as

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[16] *Id.* at 1121, 227 U.S.P.Q. (BNA) at 419 (quoting Inwood Labs., Inc. v. Ives Labs., Inc., 456 U.S. 844, 850 n.10, 214 U.S.P.Q. (BNA) 1, 4 n.10 (1983) (citing Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 238, 140 U.S.P.Q. (BNA) 524, 530-31 (1964)).

[17] *Id.*

[18] *Id.* at 1122, 227 U.S.P.Q. (BNA) at 420.

[19] *Id.* at 1123, 227 U.S.P.Q. (BNA) at 421.

[20] *Id.* at 1124, 227 U.S.P.Q. (BNA) at 421.

[21] *Id.* at 1124, 227 U.S.P.Q. (BNA) at 422.

Despite these long-held concerns, in 1985, the United States Court of Appeals for the Federal Circuit[7] ("Federal Circuit") held in *In re Owens-Corning Fiberglas Corp.*[8] that the color "pink" for home insulation was registrable as a trademark. At the time, this holding was thought to represent a major change in the law. However, as several other courts of appeals refused to follow the Federal Circuit's lead, *Owens-Corning* did not result in widespread trademark protection for color per se.[9] The resulting conflict was only recently resolved by the Supreme Court in the *Qualitex* decision, wherein the Court held that color alone may be registered.

A. *In re* Owens-Corning Fiberglass Corp.

1. Background

Owens-Corning sought federal trademark protection for the color "pink" as uniformly applied to its fibrous glass residential insulation. Registration was sought pursuant to Section 2(f) of the Lanham Act,[10] which provides that marks which have become "distinctive" of one's goods, i.e., have acquired secondary meaning, may be protected. The U.S. Patent and Trademark Office's Trademark Trial and Appeal Board ("TTAB") found that while color per se is subject to trademark protection, Owens-Corning had not demonstrated that the color "pink" was distinctive of its goods and, therefore, did not function as a trademark.[11]

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[7] The U.S. Court of Appeals for the Federal Circuit was created in October 1982 as a result of a merger of the U.S. Court of Claims and the U.S. Court of Customs and Patent Appeals. Federal Court Improvements Act of 1982, Pub. L. No. 97-164, 96 Stat. 25. Its jurisdiction includes appeals from adverse determinations of the Patent and Trademark Office ("PTO") on applications to register a trademark. 28 U.S.C. § 1295(a)(4)(B) (1994).

[8] 774 F.2d 1116, 227 U.S.P.Q. (BNA) 417 (Fed. Cir. 1985).

[9] *See* Jeffrey M. Samuels and Linda B. Samuels, *Color Trademarks: Shades of Confusion*, 83 TRADEMARK REP. 554 (1993).

[10] 15 U.S.C. § 1052(f) (1994).

[11] *In re* Owens-Corning Fiberglas Corp., 221 U.S.P.Q. (BNA) 1195 (T.T.A.B. 1984).

I. INTRODUCTION

Compared with most national trademark laws, the U.S. trademark statute ("Lanham Act") affords significant protection to color.[1] The United States Supreme Court's March 1995 decision in *Qualitex Co. v. Jacobson Products Co.*[2] clarified that color alone is registrable. Further, trademark owners can protect color as part of a product's trade dress and can claim color as a feature of a mark. The purpose of this article is to familiarize the reader with the scope of U.S. trademark law vis-a-vis color, with an emphasis on recent developments regarding the registrability of color alone.

II. PROTECTION FOR COLOR ALONE

Few principles of U.S. trademark law[3] were as firmly established as the prohibition against protection for color alone. While color, when combined with words, designs, symbols, or other arbitrary and distinguishing matter, had been protectable, color alone was not.[4]

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[1] It is worth noting that under the North American Free Trade Agreement, a trademark is defined as including "colors." North American Free Trade Agreement, Dec. 8, 1993, U.S.-Can.-Mex., art. 1708(1), 32 I.L.M. 289 [hereinafter NAFTA]. The General Agreement of Tariffs and Trade defines a trademark to include a "combination of colors." General Agreement on Tariffs and Trade, *opened for signature* Oct. 30, 1947, art. 15(1), 61 Stat. A3, 55 U.N.T.S. 187 [hereinafter GATT].

[2] 115 S. Ct. 1300, 34 U.S.P.Q.2d (BNA) 1161 (1995).

[3] The first federal trademark statute, 16 Stat. 210, was enacted in 1870. It was declared unconstitutional in *United States v. Steffens* (Trademark Cases), 100 U.S. 82 (1879), and was replaced by the Act of 1881, ch. 138, 21 Stat. 502. A new trademark act was passed in 1905, ch. 592, 33 Stat. 724, and supplemented in 1920, ch. 104, 41 Stat. 533. In 1946, a major revision of U.S. trademark law, known as the Lanham Act, was enacted, ch. 540, 60 Stat. 427. This Act, as amended, is now codified in 15 U.S.C. § 1051 *et seq.* (1994).

[4] *See* North Shore Labs. Corp. v. Cohen, 721 F.2d 514, 221 U.S.P.Q. (BNA) 17 (5th Cir. 1983); Dallas Cowboys Cheerleaders, Inc. v. Pussycat Cinema, Ltd., 604 F.2d 200, 203 U.S.P.Q. (BNA) 161 (2d Cir. 1979); Quabaug Rubber Co. v. Fabiano Shoe Co., 567 F.2d 154, 195 U.S.P.Q. (BNA) 689 (1st Cir. 1977); Volkswagenwerk Aktiengesell-Schaft v. Rickard, 492 F.2d 474, 181 U.S.P.Q. (BNA) 611, 182 U.S.P.Q. (BNA) 129 (5th Cir. 1974); Norwich Pharmacal Co. v. Sterling Drug, Inc., 271 F.2d 569, 123 U.S.P.Q. (BNA) 372

course of conduct that may not be willful infringement, but certainly is not innocent, should be considered as committing an act directed or aimed at the patentee for the very purpose of having an effect on her, wherever she resides. No one intentionally copies a patent unless it is economically advantageous to do so. Thus, acts such as designing around, or infringing a patent opined by an attorney to be invalid or unenforceable, are still acts intended to have the very purpose of taking business away from, and thus cause an injury to, a patentee, wherever she resides.[143] Accordingly, intentional infringement meets the definitions of intentional activity described in *Narco* and shows that by making the proper inquiry into the defendant's intent, most courts' concerns about the effects test can be resolved.

IX. CONCLUSION

Although there may be issues left to resolve, it appears that the effects test may become a valuable tool for a patentee. Many of these issues, such as the breadth of its application and preventing the extra-territorial application of the patent laws, can be resolved by the Federal Circuit. However, as long as there are different state long-arm statutes and the Federal Circuit continues to emphasize the importance of satisfying these statutes, no uniform application of the test will result. As a consequence, the Federal Circuit will not be able to comply with the congressional mandate that it unify the application of the patent laws due in no small part to a dilemma of its own unintentional creation.

[143] Two activities held not to be intentional conduct calculated to injure a patentee in his home forum, which therefore do not support jurisdiction under *Calder* are: an alleged infringer's filing of a declaratory judgement action, *see* Whistler Corp. v. Solar Elecs., 684 F. Supp. 1126, 1131, 7 U.S.P.Q.2d (BNA) 1647, 1650-51 (D. Mass. 1988), and an infringer's filing of an Abbreviated New Drug Application for a patented drug, *see* Glaxo, Inc. v. Genpharm Pharmaceuticals, Inc., 796 F. Supp. 872, 876-77 (E.D.N.C. 1992).

Supreme Court in *Calder* placed on the presence of injuring articles in the plaintiff's home forum, the likelihood that such a broad theory would be followed is hard to determine.

VIII. TYPE OF INTENT REQUIRED

One last point that needs to be explored concerns just what type of intent is needed under the effects test. Some courts, not realizing what type of intent is actually needed, will either hold that the effects test does not apply to the facts before it, or that the effects test results in too broad a jurisdictional theory. These concerns are unwarranted.

For example, the court in *Amp*,[133] fearing too broad an application of the effects test, declined to follow an expansive view of *Horne*[134] which would allow the owner of intellectual property to sue in its home forum whenever "intentional acts are alleged."[135] The *Amp* court apparently also concluded that such an expansive view would improperly allow jurisdiction based on infringement later thought to be innocent.[136] The court was correct in remarking that finding personal jurisdiction in the patentee's home forum would be improper under the effects test in such a situation; rather, there must be an additional finding that the defendant purposefully availed himself of the forum state and could reasonably have foreseen that his action

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defamatory letters (that plaintiff was infringing defendant's patent) to plaintiff's customers outside of New Hampshire. *Id.* at 401, 404-05; Velco Group Corp. v. Billarant, 692 F. Supp. 1443, 10 U.S.P.Q.2d (BNA) 1115 (D.N.H. 1988) (similar to, and applying, *Lex Computer*).

[133] Amp Inc. v. Methode Elecs., Inc., 823 F. Supp. 259, 27 U.S.P.Q.2d (BNA) 1888 (M.D. Pa. 1993).

[134] Horne v. Adolf Coors, Co., 684 F.2d. 255, 217 U.S.P.Q. (BNA) 15 (3d Cir. 1982). However, the effects test is controlled by *Calder*, not *Horne*.

[135] *Amp*, 823 F. Supp. at 266, 27 U.S.P.Q.2d (BNA) at 1894.

[136] This is analogous to designing intentionally a product which is thought unreasonably to be safe, but actually is defective, and which causes an injury in a distant forum such as the mere untargeted negligence referred to in *Calder*. *See Calder*, 465 U.S. at 789.

C. *Limits Imposed By Due Process Constraints*

Due process considerations will determine whether it will be required that infringing goods were found, or that infringing acts were committed, in the subject forum, before jurisdiction over the defendant is proper. In making this due process determination, the Federal Circuit's final decision will probably be based on the weight given by the Federal Circuit (or the U.S. Supreme Court) to the fact that in *Calder* libelous copies of *The National Enquirer* were found in the forum.[125]

Rigidly comparing a case of patent infringement with *Calder* seemingly analogizes the infringing goods or acts with the libelous copies of *The National Enquirer* found in the forum. Under this rigid comparison, it is rather easily concluded that in order to find jurisdiction under the effects test to comport with due process, at least some infringing goods or acts will always be required in the forum.[126]

A broader comparison with *Calder*, however, supports the argument that infringing acts need not occur in the forum because although the libelous copies of *The National Enquirer* are discussed in *Calder*, the focus of the analysis was actually on the defendant's intent to injure the plaintiff and not how that injury was inflicted. After all, one of the fundamental tenets of *Calder* is that when a defendant is a "primary [participant] in an alleged wrongdoing intentionally directed at a [forum] resident, . . . jurisdiction over them [in the forum] is proper on that basis."[127]

Here, for example, assume that an infringer decides to enter a specific market dominated by a specific patentee's (P's) patent. The infringer determines that the best way to enter the market is to analyze P's patent, have an unquestionably competent invalidity or unenforceability opinion rendered thereon, and then intentionally try to displace the patent and P

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[125] Calder v. Jones, 465 U.S. 783, 784 (1984); *see* Core-Vent Corp. v. Nobel Indus. AB, 11 F.3d 1482 (9th Cir. 1993).

[126] The bulk of the infringing goods or acts need not be found in the forum. *See* Beverly Hills Fan Co. v. Royal Sovereign Corp., 21 F.3d 1558, 1568 n.21, 30 U.S.P.Q.2d (BNA) 1001, 1009 n.21 (citing Keeton v. Hustler Magazine Corp., 465 U.S. 770, 779-780 (1984)).

[127] *Calder*, 465 U.S. at 790.

knowing,[109] concluded that the case presented the very type of intentional conduct required by *Calder*.[110] Thus, finding that the plaintiff (for purpose of the jurisdictional question) proved the defendant did induce infringement, the court upheld jurisdiction under *Calder*.[111]

The *Sauer* court, on the other hand, merely accepted the defendant's argument that "at best, [it] is accused of intentionally inducing infringement of Sauer's patents, with the *foreseeable* effect of causing an injury in Iowa, not with the purpose of doing so."[112] Thus, rejecting the *Calder* theory, as well as others, jurisdiction over the defendant was not found.[113] *Energy Absorption Systems* is the more persuasive outcome because it takes the more realistic view of what really goes through the mind of an inducer of infringement—i.e., the intent to injure a patentee by encouraging another's infringement of the patentee's patent.

VII. THE EXTREME LIMITS OF THE EFFECTS TEST

A. *Introduction*

Having established that the Federal Circuit implicitly supports the effects test, the next question is what scope the court will give the test in future applications. A broad application of the effects test would occur in situations where a defendant intentionally infringes a patent and the

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[109] *See Energy Absorption Sys.*, 30 U.S.P.Q.2d (BNA) at 1327 (citing Manville Sales Corp. v. Paramount Systems Inc., 917 F.2d 544, 16 U.S.P.Q.2d (BNA) 1587 (Fed. Cir. 1990)).

[110] *Energy Absorbtion Sys.*, 30 U.S.P.Q.2d (BNA) at 1328-29.

[111] *Id.* Note that while *Energy Absorption Systems* also relies upon the now rejected "situs of the patentee rule" in finding jurisdiction over the defendant in the patentee's home forum, 30 U.S.P.Q.2d (BNA) at 1327, this does not effect the constitutional application of *Calder*. *See infra* part VII.

[112] *Sauer*, 853 F. Supp. at 1109 n.6, 33 U.S.P.Q.2d (BNA) at 1528 n.6 (emphasis in original).

[113] *Id.* at 1109, 33 U.S.P.Q.2d (BNA) at 1528.

intentionally.[98] Thus, the Federal Circuit has recognized that the degree to which the defendant's actions are intentional is a factor in the due process analysis and it appears that the Federal Circuit would, under the right circumstances, apply the effects test. How broad this application might be, however, remains to be seen.

I. Indianapolis Colts Inc. v. Metropolitan Baltimore Football Club[99]

Indianapolis Colts Inc. v. Metropolitan Baltimore Football Club, at both the district and appellate court levels, speaks briefly to the effects test and *Calder*. For example, the district court stated that jurisdiction in Indiana would be proper in that "the evidence also suggests that all the defendants knew, prior to their decision to use the marks in question, that the Colts operate in Indiana and that the Colts would consider themselves harmed in Indiana by defendants' use of the mark."[100] While the Seventh Circuit affirmed jurisdiction[101] on the basis that broadcasts of Baltimore CFL (Canadian Football League) Colts games into Indiana on ESPN caused an injury in Indiana,[102] the court also commented on the effects test and *Calder*.

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[98] Gould v. P.T. Krakatau Steel, 957 F.2d 573 (8th Cir.) (Products liability action wherein plaintiff was hurt unpacking defendant's product. This is but one example of the mere untargeted negligence from which the Supreme Court distinguished its *Calder* holding.), *cert. denied*, 113 S. Ct. 304 (1992); Martson v. Gant, 351 F. Supp. 1122, 1125, 176 U.S.P.Q. (BNA) 180, 182 (E.D. Va. 1972) (evidence showed that the defendant took no steps "that would have tended to aid or abet the alleged infringement [in the forum]").

[99] 31 U.S.P.Q.2d (BNA) 1801 (S.D. Ind.), *aff'd*, 34 F.3d 410, 31 U.S.P.Q.2d (BNA) 1811 (7th Cir. 1994). Yet one more trademark decision applying *Calder* is Mendocino Brewing Co. v. Bridgeport Brewing Co., 735 F. Supp. 356, 16 U.S.P.Q.2d (BNA) 1974 (N.D. Cal. 1990) (no intentional acts found).

[100] *Indianapolis Colts*, 31 U.S.P.Q.2d (BNA) at 1804 (citing *Honeywell* as authority).

[101] *Indianapolis Colts*, 34 F.3d at 416, 31 U.S.P.Q.2d (BNA) at 1817.

[102] *Id.* at 412, 31 U.S.P.Q.2d (BNA) at 1813.

Laitram patent, and the residence of the patent holder in Louisiana, so as to establish the requisite minimum contacts necessary for the exercise of personal jurisdiction under the 'effects' test of *Calder*."[88] *Laitram* recognizes that under the effects test, not only is it important that the patentee resides in the forum, but also that the infringer has knowledge of the patent and of the patentee's residence in the forum. Concededly, in *Laitram*, infringing products were found in Louisiana and were attributed to OKI Electric under the stream of commerce theory.[89] However, because the court's finding as quoted above fails to acknowledge the location of infringing products or infringing activity in the forum as a prerequisite (or even a factor) in its application of the *Calder* effects test, it would appear that even if the products had not found their way into Louisiana, this court would have concluded that jurisdiction under the effects test would still have been proper. Thus, *Laitram* strongly supports, albeit both by implication and at the district court level, that under a broad effects test theory, due process does not require that infringing goods or acts be found in the forum.

H. Beverly Hills Fan Co. v. Royal Sovereign Corp.[90]

In *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, while never actually mentioning the effects test, the court hinted that it would support this theory of jurisdiction. First, in its due process analysis, the court compared the intentional nature of the defendants' conduct in both *Honeywell, Inc. v. Metz Apparatewerke*[91] and *Dakota Industries, Inc. v. Dakota Sportswear, Inc.*[92] with the defendants' conduct in the case before it.[93] Specifically, the court observed that the defendants in the case at bar shipped infringing fans into Virginia

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[88] *Id.* at 1531 (emphasis in original).

[89] *Id.* at 1530.

[90] 21 F.3d 1558, 30 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 1994), *cert. dismissed*, 155 S. Ct. 18 (1994).

[91] 509 F.2d 1137, 184 U.S.P.Q. (BNA) 387 (7th Cir. 1975).

[92] 946 F.2d 1384, 20 U.S.P.Q.2d (BNA) 1450 (8th Cir. 1991); *see supra* part VI.D.

[93] *Beverly Hills Fan*, 21 F.3d at 1567-68, 30 U.S.P.Q.2d (BNA) at 1009.

the forum,[70] *Dakota Industries* seems to require that some infringing activity be found in the forum before the effects test can be applied. This requirement appears to be constitutionally mandated, and not statutorily required as in *Beverly Hills Fan*.[71]

E. Narco Avionics, Inc. v. Sportsman's Market, Inc.[72]

In *Narco Avionics, Inc. v. Sportsman's Market, Inc.*, conflicting evidence existed as to whether two foreign defendants,[73] one of whom manufactured an allegedly infringing device in Japan and then sold it to the other in Japan,[74] had actual knowledge of Narco's patent.[75] For the purpose of a motion to dismiss, however, the court credited plaintiff's assertions that the defendant had actual knowledge of the patent.[76] In any event, the court did not recognize that actual knowledge of the patent is an important consideration to courts applying the effects test in the intellectual property context. Seemingly missing this point, the court found that jurisdiction over a foreign manufacturer under the effects test does not comport with due process[77] where "the allegedly infringing product was sold to forum residents by an independent U.S. distributor, under its name, with whom the foreign defendants had no corporate relationship and over whom they exercised no control or oversight."[78]

While it is true that the *Narco* court did not give enough weight to the knowledge element, one possible explanation is that the court side-stepped

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[70] *See id.*

[71] *See infra* part VII.

[72] 792 F. Supp. 398, 24 U.S.P.Q.2d (BNA) 1283 (E.D. Pa. 1992).

[73] The U.S. distributor did not contest jurisdiction.

[74] *Narco Avionics*, 792 F. Supp. at 400, 24 U.S.P.Q.2d (BNA) at 1284.

[75] *Id.* at 401, 24 U.S.P.Q.2d (BNA) at 1285.

[76] *Id.*

[77] *Id.* at 408-09, 24 U.S.P.Q.2d (BNA) at 1291-92.

[78] *Id.* at 408, 24 U.S.P.Q.2d (BNA) at 1291.

actions that do not involve the alleged infringer claiming it was libeled by the patentee,[57] the effects test does not appear to apply.

C. Educational Testing Service v. Katzman[58]

In *Educational Testing Service v. Katzman*, the *Calder* test was applied to a suit involving copyright infringement. Specifically, the Educational Testing Service ("ETS") alleged that Katzman had violated its copyrights to the Scholastic Aptitude Test.[59] In addition to minimum contacts, ETS argued that Katzman was subject to jurisdiction in its home forum (New Jersey) because of what ETS characterized "as intentional conduct that Katzman knew would injure ETS in New Jersey."[60]

The court found that jurisdiction did not exist under the effects test because the specific facts of the case rendered the effects test inapplicable. The court stated it was "undisputed that, with Pre-Test, Katzman copyrighted materials containing twenty questions which allegedly infringe on ETS' copyright. Further, Katzman provided those questions to Pre-Test, a New Jersey corporation."[61] ETS' amended complaint, however, contained "no allegation of infringement by Pre-Test."[62] Nor was Katzman alleged to be either a contributory infringer or vicariously liable for Pre-Test's infringement.[63] The court concluded, therefore, that ETS' cause of action did

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[57] *See infra* note 130.

[58] 631 F. Supp. 550 (D.N.J. 1986). For another copyright case applying *Calder*, see Exam-Prep Ctrs., Inc. v. Computer Dynamics Partnership, 1989 Copyright L. Rep. (CCH) 26,508 (E.D. La. 1989).

[59] *Educational Testing Serv.*, 631 F. Supp. at 551. Co-defendant Pre-test, and its president, Robert Schiller, were dismissed according to a consent order. *Id.* at 552 n.4.

[60] *Id.* at 554.

[61] *Educational Testing Serv.*, 631 F. Supp. at 564.

[62] *Id.* at 564-65.

[63] *Id.* at 564 n.16.

While *Horne* leaves many issues unresolved, the court apparently concluded that Coors intentionally infringed Horne's patent. For instance, the court held that the case itself was "indistinguishable" from its decision in *Paolino v. Channel Home Centers.*[44] In *Paolino*, the court reasoned that "[the trade secret infringer] *became aware* that its manufacture and sale of Paolino's apparatus would cause harm to his intellectual property because it *knowingly received his disclosure* in confidence."[45] Analogizing these facts to *Horne* supports the contention that the court concluded that Coors not only had knowledge of Horne's patent, but that it intentionally infringed the patent as well. The court did not discuss whether it regarded Coors as a willful infringer or not.

Other factual evidence suggests, however, that Coors may have possessed actual knowledge of Horne's patent. For example, the fact that Horne brought his action[46] on a statutory claim of contributory infringement,[47] which requires that a defendant knowingly infringed,[48] implicitly suggests that the patentee reached this same conclusion.

Finally, while relevant, the presence of infringing articles in New Jersey did not appear controlling in *Horne*. Indeed, in *Paolino*, defendant Air Control was charged with an intentional course of action which would destroy Paolino's trade secret and cause harm to Paolino in Pennsylvania "no matter where the misappropriation occurred."[49]

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[44] 668 F.2d 721, 217 U.S.P.Q. (BNA) 453 (3d Cir. 1981).

[45] *Horne*, 684 F.2d at 259-60, 217 U.S.P.Q. (BNA) at 17 (emphasis added).

[46] *Id.* at 256, 217 U.S.P.Q. (BNA) at 16.

[47] 35 U.S.C. § 271(c) (1994).

[48] *See, e.g.*, Aro Mfg. Co. v. Convertible Top Co., 377 U.S. 476, 141 U.S.P.Q. (BNA) 681 (1964); Kearns v. Wood Motors, Inc., 204 U.S.P.Q. (BNA) 485, 490, n.6 (E.D. Mich. 1978).

[49] *Paolino*, 668 F.2d 721, 724, 217 U.S.P.Q. (BNA) 453, 455 (3d Cir. 1981); *see also* Unix Sys. Labs., Inc. v. Berkeley Software Design, Inc., 27 U.S.P.Q.2d (BNA) 1721, 1728-29 (D.N.J. 1993) (unpublished opinion) (following *Calder, Poalino*, and *Horne*, in the trade secret context).

In the patent infringement context, stream of commerce cases[34] focus on how infringing devices enter the forum. In the same context, however, the effects test looks to how and why the infringing product was made: for example, with or without knowledge of the patent, and may not be controlled by whether infringing goods are actually found in the forum.[35]

VI. Application Of The Effects Test To Intellectual Property Cases[36]

A. Horne v. Adolf Coors, Co.[37]

The important Third Circuit case of *Horne v. Adolf Coors, Co.*, although decided before *Calder*, foreshadowed the *Calder* decision in many significant respects. Although *Horne* is usually regarded as a stream of commerce case, it is more meaningfully understood as an effects test case.

Horne involved a patent infringement claim where the defendant had very little contact with the forum where the suit was brought. Specifically, the court found that

> Coors . . . neither solicits nor accepts orders for its product from New Jersey. [Coors] concedes that Coors beer is sold in that state, but attributes those sales to what it calls a "bootleg market" which it actively discourages . . . . The Coors beer sold [in New Jersey] concededly originated with Coors,

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[34] Max Daetwyler Corp. v. R. Meyer, 762 F.2d 290, 226 U.S.P.Q. (BNA) 305 (3d Cir.) (criticizing Horne v. Adolf Coors Co., 684 F.2d 255, 217 U.S.P.Q. (BNA) 15 (3d Cir. 1982)), *cert. denied*, 474 U.S. 980 (1985). *Beverly Hills Fan* Court found *Max Daetwyler Corp.* unpersuasive. *Beverly Hills Fan*, 21 F.3d at 1568, 30 U.S.P.Q.2d (BNA) at 1009. *See infra* part VI.H.

[35] *See infra* part VII.

[36] In each of these cases the plaintiff was a resident of the forum.

[37] 684 F.2d 255, 217 U.S.P.Q. (BNA) 15 (3d Cir. 1982). *Horne* is often criticized. However, the Federal Circuit did not repudiate or criticize *Horne* in *Beverly Hills Fan*, as it did *Max Daetwyler*. *See supra* note 34.

jurisdiction is authorized[26] under the forum's "tortious injury" long-arm statute.[27] Thus, whenever a patentee relocates from jurisdiction to jurisdiction, so does the possible forum for a cause of action the patentee might have against infringers. While advantageous to patentees, such a circumstance seemingly defeats the purpose of the minimum contacts analysis, which was developed precisely to prevent this kind of shifting jurisdiction over a defendant—jurisdiction based on "random, fortuitous or attenuated" events.[28]

By contrast, the effects test is different. First, when the requirements of the effects test are met,[29] jurisdiction is not merely authorized, it is constitutional. In other words, the effects test is irrelevant to the question of

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[26] Personal jurisdiction over a defendant requires jurisdiction to be both authorized by the forum's long-arm statute (statutory question) and to comport with due process (constitutional test). *See, e.g.*, Dakota Indus., Inc. v. Dakota Sportswear, Inc., 946 F.2d 1384, 1387-88, 20 U.S.P.Q.2d (BNA) 1450, 1452 (8th Cir. 1991).

[27] Long-arm statutes generally come in two types: single act and due process. Single act statutes have specific provisions which must be met before jurisdiction over a defendant is authorized. In patent cases, it is usually argued that the infringer has caused a "tortious injury" within the forum. A due process long-arm statute generally states that jurisdiction over the defendant is authorized as long as it is constitutional. For discussions on applying long-arm statutes and the problems they pose in federal question litigation, see Irene D. Sann, *Personal Jurisdiction in Federal Question Suits: Towards a Unified and Rational Theory for Personal Jurisdiction Over Non-Domiciliary and Alien Defendants*, 16 PAC. L.J. 1 (1984); Marilyn J. Berger, *Acquiring* in Personam *Jurisdiction in Federal Question Cases: Procedural Frustration Under Federal Rule of Civil Procedure 4*, 1982 UTAH L. REV. 285.

[28] Burger King Corp. v. Rudzewicz, 471 U.S. 462, 475 (1985) (citations omitted).

[29] This assumes that the requirements of the forum long-arm statute are met. For example, when a tortious injury occurs in the forum within the meaning of *Beverly Hills Fan*, 21 F.3d at 1569-71, and North Am. Phillips Corp. v. American Vending Sales, Inc., 35 F.3d 1576, 1579, 32 U.S.P.Q.2d (BNA) 1203, 1203 (Fed. Cir. 1994). *See supra* note 21.

infringement—it would likely be considered "innocent infringement" instead.[16]

The analysis must consider whether subjecting the intentional infringer to expanded jurisdictional rules gives the patentee too strong a weapon and frustrates the policies of patent law, including the promotion of "designing around." Nonetheless, it is true that in any situation in which the effects test is applied, if the patentee can make the required prima facie jurisdictional showing, he will have a strong weapon. For example, the more egregious the infringer's conduct toward intentionally harming the patentee, the more likely that the exercise of jurisdiction in the patentee's home forum will comport with due process. However, this weapon is purely procedural; as a matter of substantive law, the actual liability of the infringer remains the same. Nevertheless, distinguishing between classes of infringers is valid as an integral part of the fact-specific jurisdictional analysis of *Calder*, which requires courts to look at the relationship between "the defendant, the forum, and the litigation."[17]

IV. THE EFFECTS TEST VERSUS THE SITUS OF THE PATENTEE RULE

Under the effects test, the patentee will be able to obtain jurisdiction over the alleged infringer in the patentee's home forum when the defendant is alleged to be an intentional infringer. This is different, however, from the "situs of the patentee rule" recently rejected in *Beverly Hills Fan Co. v. Royal Sovereign Corp.*[18] The situs of the patentee rule states that "since intellectual property rights relate to intangible property, no particular physical situs for the property exists. If a legal situs must be chosen, it is not illogical to pick the residence of the owner."[19] The *Beverly Hills Fan* court, however, thought

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[16] Under 35 U.S.C. § 271(a) (1994), lack of notice and lack of intent to infringe are not defenses on the issue of infringement. *See* 4 DONALD S. CHISUM, CHISUM ON PATENTS § 16.02[2], at 16-17 (1995).

[17] Calder v. Jones, 465 U.S. 783, 788 (1984) (citations omitted).

[18] 21 F.3d 1558, 30 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 1994).

[19] *Id.* at 1570, 30 U.S.P.Q.2d (BNA) at 1011; *see also* Acrison, Inc. v. Control & Metering, Ltd., 730 F. Supp. 1445, 14 U.S.P.Q.2d (BNA) 1833 (N.D. Ill. 1990); Honeywell, Inc. v. Metz Apparatewerke, 509 F.2d 1137, 184 U.S.P.Q. (BNA) 387 (7th Cir. 1975).

distinguishing between negligent and intentional tortious wrongs. In the Court's view:

> petitioners are not charged with mere untargeted negligence. Rather, their intentional, and allegedly tortious, actions were expressly aimed at California. [The petitioners knew their article] would have a potentially devastating impact upon respondent. And they knew that the brunt of that injury would be felt by respondent in the State in which she lives and works and in which the National Enquirer has its largest circulation. Under these circumstances, petitioners must "reasonably anticipate being haled into court there" to answer for the truth of the statements in their article. An individual injured in California need not go to Florida to seek redress from persons who though remaining in Florida, knowingly cause injury in California. . . .
>
> . . . In this case, petitioners are primary participants in an alleged wrongdoing intentionally directed at a California resident, and jurisdiction over them is proper on that basis.[10]

Because jurisdiction was proper under the effects test, the Court declined to consider whether the investigative activities of the article's author, including a trip to California and numerous phone calls to California, could form an independent basis for jurisdiction.[11]

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[10] *Id.* at 789-90 (citations omitted). The broad language of the last two sentences quoted above shed substantial doubt on the parts of Educational Testing Serv. v. Katzman, 631 F. Supp. 550, 563 (D.N.J. 1986) and Amp Inc. v. Methode Elecs. Inc., 823 F. Supp. 259, 266, 27 U.S.P.Q.2d (BNA) 1888, 1893-94 (M.D. Pa. 1993), which conclude that *Calder* should be limited to its facts and not applied outside the libel arena. Furthermore, all the other decisions applying *Calder* in the intellectual property context have done so without considering whether *Calder* should be limited to its facts.

[11] *Calder*, 456 U.S. at 787 n.6. One court has misinterpreted this footnote to mean that *Calder* abolishes traditional minimum contacts analysis. *See Educational Testing Serv.*, 631 F. Supp. at 563 n.14. However, the Supreme Court's footnote simply means that the effects test provides *another* way of showing whether minimum contacts exist. *Accord* Coblentz GMC/Freightliner, Inc. v. General Motors Corp., 724 F. Supp. 1364, 1369 (M.D. Ala. 1989); Shapiro v. Sun Life Ins. Co. of Canada, 117 F.R.D. 550,

I. INTRODUCTION

Now that the Federal Circuit has decided that all personal jurisdiction issues will be controlled by Federal Circuit law,[1] it will be up to it to determine whether, and to what extent, the effects test theory of personal jurisdiction will apply in patent cases. In general, the effects test theory of personal jurisdiction focuses on the effects of a defendant's intentional actions towards a specific and identifiable plaintiff in the plaintiff's home forum. In patent cases, the effects test allows a patentee to obtain jurisdiction over the defendant in the patentee's home forum when the defendant is an alleged intentional infringer. This Article examines the basis for this theory, its application to date in intellectual property cases, and how it may be applied by the Federal Circuit.

II. THE *Calder v. Jones* EFFECTS TEST

The modern effects test theory of personal jurisdiction is derived from the U.S. Supreme Court's decision in *Calder v. Jones*.[2] Applied in patent

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[1] *See* Beverly Hills Fan Co. v. Royal Sovereign Corp., 21 F.3d 1558, 1564, 30 U.S.P.Q.2d (BNA) 1001, 1006 (Fed. Cir. 1994), *cert. dismissed*, 115 S. Ct. 18 (1994).

[2] 465 U.S. 783 (1984). *See generally* Catherine J. Wiss, Note, *Personal Jurisdiction Over Non-Resident Publishers and Authors: What Contacts are Needed After Keeton v. Hustler Magazine Inc., and Calder v. Jones*, 34 CATH. U. L. REV. 1125, 1164-71 (1985); Linda Von Quintus, *Relaxation of the Strict Application of the Minimum Contact Theory to a Theory of "Intentional Conduct" Allegedly Calculated to Cause Injury in the Distant Forum*, 10 J. Marshall L. Rev. 308 (1985).

application of aesthetic functionality to trade dress issues.[151] Courts which have rejected this doctrine in the past should reconsider its application, at least to cases alleging product configuration to be protectable as trade dress. The doctrine recognizes that consumers may favor a product configuration which they find aesthetically pleasing, regardless of that product's source. By limiting Lanham Act protection of such configurations through the application of the doctrine of aesthetic functionality, courts will encourage "bare-knuckled" competition among producers of these unpatented products.

V. CONCLUSION

Recent court decisions have extended the traditional definition of trade dress to include the configuration or design of articles of manufacture. In doing so, these courts often permit trademark protection under the Lanham Act to interfere with the cost-benefit balance Congress sought to achieve through the patent laws. Courts must make an effort to distinguish legitimate trade dress, protected under the Lanham Act, from product design, protectable by design or utility patent. When design attributes serve purposes other than mere source-identification, the Lanham Act must not be interpreted so broadly as to frustrate the congressional and Constitutional objectives of patent law.

Practitioners in the intellectual property field may argue that the approach suggested by this article will weaken the protection afforded intellectual property. It is the author's belief, however, that just the opposite is true. Protecting what has come to be known as "trade dress" under the appropriate legal regime ("traditional" trade dress such as packaging and labeling under the Lanham Act and product design under utility and design patent law), is more consistent with the purposes behind each type of intellectual property protection, and will lead to a more reasoned application of each by courts of law.

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[151] RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 17 cmt. c (Tentative Draft No. 2, 1990). However, the Restatement would not deny trademark protection to every feature with aesthetic functionality, only those "confer[ring] a significant benefit that cannot practically be duplicated by the use of alternative designs." *Id.*

source of the product.[139] Having rejected the traditional trademark categories of distinctiveness,[140] how then can it be determined whether a product configuration serves to distinguish the product's source? Clearly, the easiest way is to demonstrate that the product configuration has secondary meaning or "acquired" distinctiveness.[141] Where secondary meaning cannot be established, there is authority for denying trade dress protection altogether based on a presumption that product configurations can never be inherently distinctive.[142] Such a holding could be squared with the Supreme Court's holding in *Two Pesos, Inc. v. Taco Cabana, Inc.*[143] *Two Pesos* addressed only "whether trade dress which is inherently distinctive is protectable,"[144] and did not define what makes trade dress inherently distinctive. Also, *Two Pesos*, "which dealt with the decor of a Mexican restaurant, is more akin to a product packaging case than a product configuration case."[145]

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[139] 1 MCCARTHY, *supra* note 7, § 7.23[2].

[140] *See supra* text accompanying notes 52-60 (opposing adoption of traditional trademark "categories" of distinctiveness in product configuration cases).

[141] Secondary meaning attaches to a product configuration when the configuration "is associated in the minds of prospective customers with the source from which the article came to such an extent that demand for the particular article depends upon the business reputation or standing of its maker." American Fork & Hoe Co. v. Stampit Corp., 125 F.2d 472, 474, 52 U.S.P.Q. (BNA) 210, 212 (6th Cir. 1942), *cited by* Duraco Prods., Inc. v. Joy Plastic Enter., 40 F.3d 1431, 1443, 32 U.S.P.Q.2d (BNA) 1724, 1733-34 (3d Cir. 1994). Secondary meaning, however, "has not been established when the form of the article, in the minds of the public, is primarily associated with the article, rather than a particular producer." *Id.* at 1443, 32 U.S.P.Q.2d (BNA) at 1734.

[142] *See* RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 16 cmt. b (Tentative Draft No. 2, 1990) ("Product designs are not . . . considered inherently distinctive; such designs are protectable only upon proof of secondary meaning.").

[143] 112 S. Ct. 2753, 23 U.S.P.Q.2d (BNA) 1081 (1992).

[144] *Id.* at 2757, 23 U.S.P.Q.2d (BNA) at 1083.

[145] *Duraco*, 40 F.3d at 1445, 32 U.S.P.Q.2d (BNA) at 1735. *But see* Stuart Hall Co. v. Ampad Corp., 51 F.3d 780, 34 U.S.P.Q.2d (BNA) 1428 (8th Cir. 1995) (perceiving restaurant decor more akin to product configuration). The more reasoned approach would seem to be that of *Duraco*, as it is not

such as lighting, decorations, and color combinations.[130] Unlike discrete elements of trade dress such as labels, bottle shapes, or packaging containers, a restaurant's "total image" may change depending on the rearrangement or deletion of any one of its many components, and will vary based on the viewer's perspective, point of view, or taste.[131]

In past cases, the Court has itself drawn distinctions between trade dress comprising labeling, packaging, and traditional word or symbol trademarks, and trade dress comprising the design of the product itself. In *Sears, Roebuck & Co. v. Stiffel Co.*,[132] for example, the Court recognized that states could legitimately "protect businesses in the use of their *trademarks, labels, or distinctive dress in the packaging of goods* so as to prevent others, by imitating such markings, from misleading purchasers as to the source of the goods."[133] Yet in the same paragraph, when examining the design of the product itself, the Court permitted direct copying of the lamp's design, even while recognizing that "of course there could be 'confusion' as to who had manufactured these nearly identical articles. But mere inability of the public to tell two identical articles apart is not enough to support an injunction against copying that which the federal patent laws permit to be copied."[134] Thus, the Court seemed to recognize that the unpatented design of the product itself was less protectable than the article's "traditional" trade dress (i.e. trademarks, labels, or distinctive dress in the packaging). Likewise, the Court seemed to recognize that any protection of the product's *design* must be under the patent laws, and that absent patent protection, the design fell into the public domain.

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[130] *Two Pesos*, 505 U.S. at 765, 23 U.S.P.Q.2d (BNA) at 1082.

[131] Dillon, *supra* note 8, at 86.

[132] 376 U.S. 225, 140 U.S.P.Q. (BNA) 524 (1964).

[133] *Id.* at 232, 140 U.S.P.Q. (BNA) at 528 (emphasis added).

[134] *Id.*

labeling of garden chemicals.[114] Since the early 1980s, however, courts have greatly expanded this definition to "involve[] the total image of a product . . . includ[ing] features such as size, shape, color or color combinations, texture, graphics or even particular sales techniques."[115] Design features to which protection has been extended under this broad definition of trade dress include: restaurant decor;[116] the body design of an automobile;[117] the design of a clamping tool;[118] the design of a beverage dispenser; [119]the design of a folding table;[120] the design of a fishing reel;[121] the design of luggage;[122]

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[114] Chevron Co. v. Voluntary Purchasing Groups, Inc., 659 F.2d 695, 706, 212 U.S.P.Q. (BNA) 904, 913 (5th Cir. 1981), *cert. denied*, 457 U.S. 1126 (1982).

[115] John H. Harland Co. v. Clarke Checks, Inc., 711 F.2d 966, 980, 219 U.S.P.Q. (BNA) 515, 528 (11th Cir. 1983); *see also* 1 MCCARTHY, *supra* note 7, § 8.01[3] (noting that traditional definition of "trade dress" has been "stretched to include the shape and design of the product itself. Thus, the field of law once referred to as unfair competition by 'product simulation,' has now been folded into that corner of trademark and unfair competition law called 'trade dress'").

[116] Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 23 U.S.P.Q.2d (BNA) 1081 (1992).

[117] Ferrari S.P.A. v. Roberts, 944 F.2d 1235, 1240, 20 U.S.P.Q.2d (BNA) 1001, 1006 (6th Cir. 1991).

[118] Clamp Mfg. Co. v. Enco Mfg. Co., 870 F.2d 512, 515-16, 10 U.S.P.Q.2d (BNA) 1226, 1228-29 (9th Cir. 1989).

[119] Service Ideas, Inc. v. Traex Corp., 846 F.2d 1118, 1123-24, 6 U.S.P.Q.2d (BNA) 1937, 1940-41 (7th Cir. 1988).

[120] Vaughan Mfg. Co. v. Brikam Int'l, Inc., 814 F.2d 346, 349-50, 1 U.S.P.Q.2d (BNA) 2067, 2069-70 (7th Cir. 1987).

[121] Brunswick Corp. v. Spinit Reel Co., 832 F.2d 513, 524-25, 4 U.S.P.Q.2d (BNA) 1497, 1505-06 (10th Cir. 1987).

[122] LeSportsac, Inc. v. K-mart Corp., 754 F.2d 71, 76-77, 225 U.S.P.Q. (BNA) 654, 657-58 (2d Cir. 1985).

the risk of interference with patent law, courts should more closely examine the articles they term protectable "trade dress" under the Lanham Act. Traditional trade dress, such as packaging, labeling, and word or symbol marks is clearly protectable under the Lanham Act, and such protection does not interfere with the efficient operation of the patent system. Product design, on the other hand, is more appropriately protected under design or utility patent law, thus requiring courts to consider the inevitable conflicts resulting from an extended definition of trade dress.

IV. A SUGGESTED JUDICIAL RESOLUTION

Numerous courts have recognized the risk that an overly broad application of trademark law may interfere with the proper operation of our federal patent laws.[108] There are, however, no clear guidelines for courts faced with cases calling for application of the Lanham Act to elements of trade dress comprising product configuration. The following is a preliminary set of guidelines, recommended by the Author, as the basis for judicial development in this area of the law.

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[108] *See* Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 769, 23 U.S.P.Q.2d (BNA) 1081, 1084 (1992) (discussing the requirement that design be nonfunctional to qualify for Lanham Act protection); Duraco Prods., Inc. v. Joy Plastics Ltd., 40 F.3d 1431, 32 U.S.P.Q.2d (BNA) 1724 (3d Cir. 1994); Ferrari S.P.A. v. Roberts, 944 F.2d 1235, 1240-41, 20 U.S.P.Q.2d (BNA) 1001, 1005-06 (6th Cir. 1991) (discussing the overlap between Lanham Act protection and federal patent and design patent protection for automotive body design); *Stormy Clime*, 809 F.2d at 977-78, 1 U.S.P.Q.2d (BNA) at 2031 (noting that "[c]ourts must proceed with caution in assessing claims to unregistered trademark protection in the design of products so as not to undermine the objectives of the patent laws"); *see also* Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 140 U.S.P.Q. (BNA) 524 (1964) (invalidating state unfair competition law as in conflict with federal patent laws); *accord* Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234, 140 U.S.P.Q. (BNA) 528 (1964); *Bonito Boats*, 489 U.S. at 166-68, 9 U.S.P.Q.2d (BNA) at 1859 (invalidating state unfair competition statute, reiterating concern over interference with objectives of federal patent law expressed in *Sears* and *Compco*, and noting "[i]t is for Congress to determine if the present system of design and utility patents is effectual in promoting the useful arts in the context of industrial design").

The first step in construing any statute is to look at the plain meaning of the language of the statute.[98] Section 43(a) of the Lanham Act creates a civil cause of action against:

> Any person who, or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false of misleading description of fact, or false or misleading representation of fact . . . .[99]

Nothing in this statutory language mandates the broad construction recent court decisions have given the term "trade dress." The language of the Act purports to extend to any "word, term, name, symbol, or device, or any combination thereof," used in connection with goods or services. Expanding trade dress protection to product design does not serve this statutory language any better than the traditional definition of trade dress.[100] The Supreme Court, in fact, has recognized that "the 'protection' granted a particular design under the law of unfair competition is thus limited to one context where consumer confusion is likely to result; the design 'idea' itself may be freely exploited in all other contexts."[101] By protecting the packaging and labeling of a product, the traditional definition of trade dress adequately prevented consumer confusion and was consistent with the language of the Lanham Act.

Although expanding the definition of trade dress to include elements of product design is not expressly prohibited by the language of the Lanham Act, doing so clearly interferes with the Constitutional and congressional

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[98] *See* Greyhound Corp. v. Mt. Hood Stages, Inc., 437 U.S. 322, 330 (1978) (noting that "[l]ogic and precedent dictate that '[t]he starting point in every case involving construction of a statute is the language itself'" (quoting Blue Chip Stamps v. Manor Drug Stores, 421 U.S. 723, 756 (1975) (Powell, J., concurring)).

[99] 15 U.S.C. § 1125(a) (1994).

[100] *See supra* text accompanying note 5 (discussing traditional definition of trade dress).

[101] Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 158, 9 U.S.P.Q.2d (BNA) 1847, 1855 (1989).

copy.[91] State laws which limited the ability of competitors to freely copy unpatented product design were struck down in both *Sears* and *Compco.*

Twenty-five years later, in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*,[92] the Court unanimously reaffirmed *Sears-Compco,* striking down a Florida unfair competition statute which prohibited the copying of unpatented boat hulls.[93] The Court again recognized that federal patent laws embodied Congress' "careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy."[94] To give effect to this congressional balance, the Court required that "state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws."[95]

Sears-Compco and *Bonito Boats* addressed *state* unfair competition laws aimed at preventing copying of unpatented elements of product design. Whether their rationale should apply to protection of unpatented design under the Lanham Act—a *federal* unfair competition statute—is an issue which has divided the courts. The majority of courts considering the issue have limited *Sears-Compco* to preemption of state unfair competition laws, refusing to deny relief under the Lanham Act despite potential conflict with federal patent law.[96] Other courts have recognized that an overly broad

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[91] *Id.* at 231-32, 140 U.S.P.Q. (BNA) at 528 ("To allow a State by use of its law of unfair competition to prevent the copying of an article which represents too slight an advance to be patented would be to permit the State to block off from the public something which the federal law has said belongs to the public."); *Compco,* 376 U.S. at 237, 140 U.S.P.Q. (BNA) at 530 ("[W]hen an article is unprotected by a patent or a copyright, state law may not forbid others to copy that article.").

[92] 489 U.S. 141, 9 U.S.P.Q.2d (BNA) 1847 (1989).

[93] *Id.*

[94] *Id.* at 146, 9 U.S.P.Q. (BNA) at 1850.

[95] *Id.* at 152, 9 U.S.P.Q.2d (BNA) at 1852.

[96] *See* Ferrari S.P.A. v. Roberts, 944 F.2d 1235, 1241, 20 U.S.P.Q.2d (BNA) 1001, 1006-07 (6th Cir. 1991) (noting that actions under Lanham Act are not limited by doctrine of *Sears-Compco* or *Bonito Boats*); Ives Labs., Inc. v.

the goods are intended."[80] This comment was largely ignored until 1952, when the Ninth Circuit in *Pagliero v. Wallace China Co.*[81] denied trademark protection to a floral design on plates, which was determined to be aesthetically functional. *Pagliero* announced a broad definition of aesthetic functionality, holding that "[i]f the particular feature is an important ingredient in the commercial success of the product, the interest in free competition permits its imitation in the absence of a patent or copyright."[82]

Although a handful of courts have relied on *Pagliero* to deny trademark protection because of aesthetic functionality,[83] the majority of cases seem to reject the doctrine.[84] The new Restatement of Unfair Competition appears to reject *Pagliero's* broad "ingredient in the commercial success" standard, but recognizes that "[w]hen aesthetic considerations play a significant role in the purchasing decisions of prospective consumers, a design feature that substantially contributes to the aesthetic appeal of a product may sometimes qualify as 'functional.'"[85]

Because of the inconsistent judicial application of the doctrine of aesthetic functionality, trade dress protection of product design elements is much more likely to interfere with design patents than with utility patents. Congress enacted the design patent statute to encourage the decorative arts

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[80] RESTATEMENT OF TORTS § 742 cmt. a (1938).

[81] Pagliero v. Wallace China Co., 198 F.2d 339, 95 U.S.P.Q. (BNA) 45 (9th Cir. 1952).

[82] *Id.* at 343, 95 U.S.P.Q. (BNA) at 48.

[83] *See, e.g.*, International Order of Job's Daughters v. Lindeburg & Co., 633 F.2d 912, 208 U.S.P.Q. (BNA) 718 (9th Cir. 1980), *cert denied*, 452 U.S. 941 (1981); Famolare, Inc. v. Melville Corp., 472 F. Supp. 738, 203 U.S.P.Q. (BNA) 68 (D. Haw. 1979).

[84] 1 MCCARTHY, *supra* note 7, § 7.26[4][b] (delineating approach to aesthetic functionality by circuit). *But see* Qualitex Co. v. Jacobson Prod. Co., 115 S. Ct. 1300, 1304, 34 U.S.P.Q.2d (BNA) 1161, 1163, 1161 (1995) (citing with approval Inwood Lab., Inc. v. Ives Lab, Inc., 456 U.S. 844, 214 U.S.P.Q. (BNA) 1, 9 (1982) (White J., consurring) (adopting *Pagliero*'s "important ingredient in the commercial success" standard)).

[85] RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 17 cmt. c (Tentative Draft No. 2, 1990).

easily understood being that given by the Federal Circuit: a design feature is functional if the article works better because it is in this particular shape.[71] The question of functionality of a product's trade dress is a factual inquiry,[72] focusing not on the usefulness of the product overall, but rather on the utility of that exact element or feature of the product claimed as protectable trade dress.[73] Four factors have been identified by courts as bearing on the utilitarian functionality issue:

> (1) the existence of a utility patent which discloses the utilitarian advantages of the design evidences functionality;
> (2) advertising or promoting the functional or utilitarian advantages of the design element claimed as trade dress;
> (3) the availability of alternative designs which perform the utility function equally well; and
> (4) whether the design embodies a simpler, cheaper, or superior method of manufacturing the product.[74]

Elements of a product's trade dress may possess utilitarian functionality, and yet serve to identify the product's source. At least one court has analyzed utilitarian functionality on a continuum—purely functional elements at one end, protectable only by patent law, and "distinctive and arbitrary arrangements of predominantly ornamental features that do not hinder potential competitors from entering the same market with differently dressed versions of the product"[75] at the other end,

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[71] *In re* R.M. Smith, Inc., 734 F.2d 1482, 1484 222 U.S.P.Q. (BNA) 1, 3 (Fed. Cir. 1983).

[72] 1 MCCARTHY, *supra* note 7, § 7.26[3][c].

[73] Dallas Cowboys Cheerleaders, Inc. v. Pussycat Cinema, Ltd., 604 F.2d 200, 203 U.S.P.Q. (BNA) 161 (2d Cir. 1979), *cited in* 1 MCCARTHY, *supra* note 7, § 7.26[3][b].

[74] *In re* Morton-Norwich Prods., Inc., 671 F.2d 1332, 213 U.S.P.Q. (BNA) 9 (C.C.P.A. 1982).

[75] Stormy Clime Ltd. v. ProGroup, Inc., 809 F.2d 971, 977, 1 U.S.P.Q.2d (BNA) 2026, 2031 (2d Cir. 1987).

confusion is much less likely to result from copying a competitor's product configuration than from copying his packaging or labeling.

While the "palming off" of goods is to be condemned, such condemnation should not come at the expense of the free and unbridled competition which is the lifeblood of the American economy. In an effort to protect healthy "bare-knuckled" competition, courts have long recognized a competitor's right to copy another's unpatented products.[64] Indeed, "[e]xploiting the goodwill of the article, the attractive features, of whatever nature, that the product holds for consumers—is *robust* competition; only deceiving consumers, or exploiting the goodwill of another producer is *unfair* competition."[65]

3. Nonfunctionality

The final requirement is that of nonfunctionality.[66] Because trademark law does not protect functional elements, the claimed trade dress cannot be dictated by utilitarian concerns.[67] There is a split of authority

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[64] *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 165, 9 U.S.P.Q.2d (BNA) 1847, 1857-58 (1989) ("[I]t has been well established that in the case of an expired patent, the federal patent laws *do* create a federal right to 'copy and use'"); Flagg Mfg. Co. v. Holway, 59 N.E. 667, 667 (Mass. 1901) ("In the absence of a patent the freedom of manufacture cannot be cut down under the name of preventing unfair competition. All that can be asked is that precautions shall be taken . . . to prevent . . . deception."); Qualitex Co. v. Jacobson Prods. Co., 115 S .Ct. 1300, 1304, 34 U.S.P.Q.2d (BNA) 1161, 1163 (1995) (noting that patent law permits monopoly of limited time, "after which competitors are free to use the innovation"); *Duraco*, 40 F.3d at 1445, 32 U.S.P.Q.2d (BNA) at 1735 ("What the courts of equity condemned was not bare-knuckled competition, but fraud and deceit, which are worked when one 'palms off' one's goods as those of another.").

[65] *Duraco*, 40 F.3d at 1445, 32 U.S.P.Q.2d (BNA) at 1735.

[66] 1 MCCARTHY, *supra* note 7, § 7.23[2]; *see also* Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 769, 23 U.S.P.Q.2d (BNA) 1081, 1084 (1992) ("[E]ligibility for protection under § 43(a) depends on nonfunctionality.").

[67] 1 MCCARTHY, *supra* note 7, § 7.23[2]. If the feature contributes to the product's utility or the economy of manufacture, it will be deemed "functional," and not capable of trademark protection. 1 *Id.* § 7.26[1]. If functional features were protected as trademarks or trade dress, such

secondary meaning, and thus become registrable.[55] Generic marks may not be registered, and indeed, a mark may lose its validity if it becomes generic.[56]

Whether such categories of distinctiveness should be applied to trade dress comprising product design in the same manner as they are applied to trademarks is highly questionable.[57] When the trade dress in question comprises the configuration or design of the product itself, it is difficult to imagine how it can be any more than "descriptive" of the goods, as in fact, it *is* the goods. The Third Circuit recognized this, noting "[t]he difficulty is that, perhaps unlike product packaging, a product configuration differs fundamentally from a product's trademark, insofar as it is not a symbol according to which one can relate the signifier (the trademark, or perhaps the packaging) to the signified (the product). Being constitutive of the product itself and thus having no dialectical relationship to the product, the product's configuration cannot be said to be 'suggestive' or 'descriptive' of the product, or 'arbitrary' or 'fanciful' in relation to it."[58]

If product design is protected from copying by competitors under the Lanham Act, it seems that *any* perceptible feature of a product would serve to distinguish the originator's goods from those of others.[59] Allowing such protection would be especially problematic because product design, unlike trademarks and traditional trade dress (such as packaging or labeling), is subject to "exhaustion." While there is a "practically inexhaustible set of distinct but approximately equivalent variations" of *packaging and labeling* options available for any given product, that product's *configuration* "has

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[55] *Id.*

[56] *Id.*

[57] *See* Duraco Prods., Inc. v. Jay Plastics Enter., 40 F.3d 1431, 1434, 32 U.S.P.Q.2d (BNA) 1724, 1731 (3d Cir. 1994) ("Some courts have nonchalantly applied the trademark generic/descriptive/suggestive/arbitrary/fanciful taxonomy in the product configuration context (though none of them has inquired whether it makes sense to do so.)").

[58] *Id.*

[59] *Id.* at 1447, 32 U.S.P.Q.2d (BNA) at 1737 (noting that even the basic design of a light bulb would designate its source if only one producer were permitted to make light bulbs).

A. *Protection Of Product Design As Trade Dress Is Inconsistent With, And Beyond The Intended Scope Of, The Lanham Act*

In order to prevail on a claim for trade dress infringement under Section 43(a) of the Lanham Act, a plaintiff must plead and prove three basic elements of his claim. First, the validity of the trade dress must be established by showing that it is recognized by customers as identifying and distinguishing the source of the product.[47] Second, the trade dress must be infringed in a manner which creates a likelihood of confusion.[48] Finally, the trade dress must be nonfunctional.[49]

These traditional requirements of a trade dress action should be reevaluated prior to their wholesale adoption by courts considering cases involving product configurations alleged to be protectable trade dress. In its recent *Duraco* decision, the Third Circuit Court of Appeals noted that "the very basis for the trademark taxonomy—the descriptive relationship

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courts, "design patent remains a Cinderella who never goes to the ball"); Thomas B. Lindgren, *The Sanctity of the Design Patent, Illusion or Reality*, 10 OKLA. CITY U. L. REV. 195,198 (1985) (noting the "common belief among patent attorneys that one should not go through the expense and energy of obtaining a design patent . . . as the economic value of obtaining this exclusive grant is minimal under the best of circumstances"). These arguments, and the related arguments for a legislative overhaul of the design patent system, are flawed. Design protection laws have been introduced in virtually every session of Congress since 1917, yet have never been enacted. Duraco Prods., Inc. v. Joy Plastic Enter., 40 F.3d 1431, 1446, 32 U.S.P.Q.2d (BNA) 1724, 1736 (3d Cir. 1994). The fact that Congress has not seen fit to amend the design patent laws likely reflects congressional satisfaction with the status quo. The expense and difficulty in obtaining a design patent, and the requirements of novelty and nonobviousness likely reflect Congress' belief that designs which are not sufficiently inventive and ornamental to meet these requirements should remain in the public domain, free for all to copy and exploit at will. These determinations involve a delicate balance of the costs and benefits of patent protection. Such balancing is clearly the role of the legislature, and courts must not substitute their judgment in this matter for that of the legislature.

[47] *See* 1 MCCARTHY, *supra* note 7, § 7.23[2] at 7-97 to 98.

[48] 1 *Id.*

[49] 1 *Id.*

known prior art existing at the time of invention.[37] Inventions meeting these requirements may be registered with the United States Patent and Trademark Office, and upon approval and the payment of a statutory fee, a utility patent will be issued.

To qualify for a design patent, the design of an object must meet these same novelty and nonobviousness standards, but need not be useful.[38] In addition, a design must be "ornamental" to be patentable.[39] Congress' intent in enacting design patent law was to encourage the decorative arts[40] and to stimulate the exercise of the inventive faculties in improving the appearance of articles of manufacture.[41] The Patent and Trademark Office defines an object's "design" as "the visual characteristics or aspects displayed by the object."[42] The term of a design patent is fourteen years.[43]

Both utility and design patents reflect a congressional balance of the costs and benefits of their respective protection. The benefit sought to be achieved through the patent system is the encouragement of invention and the advancement of technology and science. The cost of creating this incentive is paid by consumers, who must pay a monopoly price for the

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[37] 2 *id.* § 6:2 (discussing 35 U.S.C. § 103).

[38] 5 *id.* § 16.1.

[39] 35 U.S.C. § 171 (1994).

[40] Gorham Co. v. White, 81 U.S. 511, 524 (1872).

[41] Hueter v. Compco Corp., 179 F.2d 416, 84 U.S.P.Q. (BNA) 312 (7th Cir. 1950); *see also* 5 WALKER, *supra* note 34, § 16:3.

[42] U.S. PAT. & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINATION PROCEDURE § 1502 (5th ed. 1983). Courts have articulated that "[d]esign, in the view of the patent law, is that characteristic of a physical substance which, by means of lines, images, configuration and the like, taken as a whole, makes an impression, through the eye upon the mind of the observer." Pelouze Scale & Mfg. Co. v. American Cutlery Co., 102 F. 916 (7th Cir. 1900).

[43] 35 U.S.C. § 173 (1994).

In order to prevail on a claim for trade dress infringement under Section 43(a) of the Lanham Act, a plaintiff must plead and prove three basic elements of his claim. First, the validity of the trade dress must be established by showing that it is recognized by customers as identifying and distinguishing the source of the product.[25] Second, the trade dress must be infringed in a manner which creates a likelihood of confusion.[26] Finally, the trade dress must be nonfunctional.[27]

B. *Protection Of Product Design Under Federal Patent Law*

The Constitution grants Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[28] Pursuant to this power, Congress enacted the patent laws currently codified in Title 35 of the United States Code. Section 101 authorizes the issuance of a utility patent, subject to certain conditions, to the inventor of "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[29] In addition to the utility patent, Congress has authorized the issuance of design patents for invention of "any new, original and ornamental design for an article of manufacture."[30] The Supreme Court has outlined the policies behind the federal patent system as follows:

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protection of trademarks and trade dress under § 43(a) serves the same statutory purpose" and finding "no persuasive reason to apply different analysis to the two"). *But see* Qualitex Co. v. Jacobson Prods. Co., Inc., 115 S. Ct. 1300, 1308, 34 U.S.P.Q.2d (BNA) 1161, 1167 (1995) (recognizing that "[t]rademark law helps the holder of a mark in many ways that 'trade dress' protection does not").

[25] 1 MCCARTHY, *supra* note 7, § 7.23[2] at 7-97 to 98.

[26] 1 *Id.*

[27] 1 *Id.*

[28] U.S. CONST. art. I, § 8, cl. 8.

[29] 35 U.S.C. § 101 (1994).

[30] 35 U.S.C. § 171 (1994).

in a trademark's reputation.[15] To a lesser extent, trademark law serves to promote the creation of new words and to stimulate new design features.[16] Trademark law grants the first user of a valid trademark the exclusive right to use that mark for a period of potentially infinite duration.

Unlike patent and copyright law which are of statutory and constitutional origin, trademark law has its roots in state common law.[17] Traditional state common law did not recognize configurations of product packaging, or of the product itself, as "technical trademarks," but afforded them legal protection under the law of unfair competition.[18] While state common law continues to influence trademark regulation, the Lanham Act, enacted by Congress in 1946, has become "the premier vehicle by which to assert trade dress protection . . . in the federal courts."[19]

Section 43(a) of the Lanham Act,[20] which prohibits marketing a product conveying false designation of origin, has consistently been interpreted as entitling the first manufacturer of a product to an unregistered trademark in the trade dress of the product.[21] Trade dress traditionally

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[15] William M. Landes & Richard A. Posner, *Trademark Law: An Economic Perspective*, 30 J.L. & ECON. 265, 268-70 (1987).

[16] *Id.* at 271-73.

[17] EDMUND W. KITCH & HARVEY S. PERLMAN, LEGAL REGULATION OF THE COMPETITIVE PROCESS 250 (4th ed. 1991); *see also* Kohler Co. v. Moen, Inc., 12 F.3d 632, 647, 29 U.S.P.Q.2d (BNA) 1241, 1253 (7th Cir. 1993) (Cudahy, J., dissenting) (noting that the Lanham Act "essentially federalizes the common law" of trademarks and unfair competition).

[18] 1 MCCARTHY, *supra* note 7, § 7.23[1]. "Technical trademarks" have traditionally included "designations consisting of words or other symbols adopted to identify the source of goods or services." RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 16 cmt. a (Tentative Draft No. 2, 1990).

[19] 1 MCCARTHY, *supra* note 7, § 7.23[2].

[20] 15 U.S.C. § 1125(a) (1994).

[21] LeSportsac, Inc. v. K Mart Corp., 754 F.2d 71, 75, 225 U.S.P.Q. (BNA) 654, 656 (2d Cir. 1985).

Traditional trade dress doctrine served this purpose well, recognizing that packaging and labeling function primarily as source-identifying features of a product, deserving protection under the Lanham Act. Much of the recent expansion of trade dress protection goes beyond merely reducing the likelihood of consumer confusion as to source, however, allowing unpatented product design features to be shielded from copying by competitors. When courts extend trade dress protection to design features of the product itself, rather than merely the product's packaging or labeling, they risk upsetting the delicate balance of interests which Congress has established through the patent system.[10] A recent decision by the Third Circuit Court of Appeals appears to recognize this potential for overbroad application of trade dress protection, perhaps signaling an end to the expansion of trade dress doctrine into the area of product design, or perhaps setting up a split between the circuit courts of appeals in this area, potentially requiring Supreme Court resolution.[11]

This Article argues that courts must make a greater effort to distinguish the design of a product itself from that of a product's packaging or labeling, recognizing that the former is typically protectable, if at all, only under the patent laws, whereas the latter is generally trade dress, protectable under the Lanham Act. Extending trade dress protection to unpatented design elements of the product itself may be proper in the rare instances where the design serves *only* source-identifying purposes. Where the design serves any significant purpose other than source identification, however, Congress has specified that patent law, rather than trademark law, is the appropriate means of protecting the design.[12]

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[10] *See* Qualitex Co. v. Jacobson Prods. Co., 115 S.Ct. 1300, 1304, 34 U.S.P.Q.2d (BNA) 1161, 1163 (1995) ("It is the province of patent law, not trademark law, to encourage invention by granting inventors a monopoly over new product designs . . . .").

[11] Duraco Prods., Inc. v. Joy Plastic Enter., 40 F.3d 1431, 32 U.S.P.Q.2d (BNA) 1724 (3d Cir. 1994). *But see* Stuart Hall Co. v. Ampad Corp., 51 F.3d 780, 34 U.S.P.Q.2d (BNA) 1428 (8th Cir. 1995) (declining to adopt Third Circuit's approach).

[12] *See Duraco*, 40 F.3d at 1434, 32 U.S.P.Q.2d (BNA) at 1725 (noting that product configuration is inherently distinctive, and thus protectable as trade dress, only when there is "a high probability that a product configuration serves a virtually exclusive identifying function for consumers").

I. INTRODUCTION

The scope of protection afforded under the Lanham Act[1] has steadily expanded in recent years to include such things as color,[2] scent,[3] and a wide array of items designated as "trade dress."[4] The trade dress of a product traditionally referred only to its packaging and labeling.[5] Modern courts, however, have greatly expanded this definition, freely recognizing elements

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[1] Section 43(a) of the Trademark Act of 1946 (Lanham Act), 15 U.S.C. § 1125(a) (1988), *amended by* Trademark Law Revision Act, Pub. L. No. 100-667, 102 Stat. 3935 (1988) is the premier vehicle for trade dress protection in the federal courts.

[2] *See* Qualitex Co. v. Jacobson Prods. Co., 115 S. Ct. 1300, 34 U.S.P.Q.2d (BNA) 1161 (1995) (holding that Lanham Act permits registration of a trademark that consists, purely and simply, of a color); *In re* Owens-Corning Fiberglas Corp., 774 F.2d 1116, 227 U.S.P.Q. (BNA) 417 (Fed. Cir. 1985) (extending trademark protection to the color pink for Fiberglas insulation).

[3] *See In re* Clarke, 17 U.S.P.Q.2d (BNA) 1238 (T.T.A.B. 1990) (extending trademark protection to scented yarn and thread).

[4] *See, e.g.*, Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 23 U.S.P.Q.2d (BNA) 1081 (1992) (protecting restaurant decor as trade dress); Ferrari S.P.A. v. Roberts, 944 F.2d 1235, 20 U.S.P.Q.2d (BNA) 1001 (6th Cir. 1991) (holding automotive body design protectable as trade dress); Sicilia di R. Biebow & Co. v. Cox, 732 F.2d 417 (5th Cir. 1984) (holding that the shape of a bottle is protectable trade dress); Dallas Cowboys Cheerleaders, Inc. v. Pussycat Cinema, Ltd., 604 F.2d 200, 203 U.S.P.Q. (BNA) 161 (2nd Cir. 1979) (protecting design of cheerleader uniforms as trade dress).

[5] Stormy Clime Ltd. v. Progroup, Inc., 809 F.2d 971, 974, 1 U.S.P.Q.2d (BNA) 2026, 2028 (2d Cir. 1987).

Nonetheless, we disagree with Dr. Chambers' statement that "[p]atents that cover research tools are no more dangerous than patents that cover any other aspect of human endeavor."[2]

The primary difficulty with patents or other proprietary rights in research tools is that they can be used to restrict access to discoveries that are likely to have the greatest social value if they are widely disseminated to researchers who are taking different approaches to different problems. True believers in intellectual property might argue that if widespread dissemination is socially valuable, patent owners will be well motivated to disseminate their research tools widely through licensing. Indeed, in many cases, owners of patents on research tools will perceive researchers as customers for their patented products. For example, owners of patents on research reagents will generally maximize their profits by making the reagents widely available to anyone who wants them in anonymous market transactions. Even when researchers are not ordinary consumers of a patented invention, patent owners may welcome the use of their inventions by researchers, perhaps hoping that their research efforts will enhance the value of the patented inventions.

But there are reasons to fear that we can not always rely on a market for licenses to achieve optimal dissemination of research tools. For one thing, not all research tools are of a character that permits widespread distribution in an anonymous market. Sometimes face-to-face negotiations will be necessary in order to secure a license and, in these cases, researchers may be called upon to disclose what it is that they plan to do with the patented research tools before they are ready to do so. Researchers who do not want to disclose the directions of their research in its early stages may be reluctant to tip their hand by requesting a license.

Moreover, a significant research project might require access to a great many research tools. If each of these tools requires a separate license and royalty payment, the costs and administrative burden could mount quickly. This could be a particularly unattractive outcome for an institution such as NIH that may find itself in the position of royalty-payor in its role as research sponsor at least as often as it finds itself in the position of royaltee-

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[2] Scott A. Chambers, *Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 53, 53 (1995).

antibody to the protein or fragment. Claims of the second variety would lack a written descriptive basis of the entire gene.[8] Claims of the latter three varieties appear to be perfect examples of claims that lack utility under 35 U.S.C. § 101. Claims to a fragment or protein with an unknown structure and size, an unknown activity and function, and an unknown use simply have no section 101 utility. In the same vein, an antibody directed to an unknown portion of an unknown protein with an unknown structure and size, an unknown activity and function, and an unknown use simply has no section 101 utility. Such examples fit precisely within the cautions of *Brenner v. Manson*,[9] that applicants should not be allowed to swallow-up entire areas of technology without providing something of value to the public. However, because of the potential uses of ESTs, the claims of the first variety likely possess sufficient utility to withstand a rejection under 35 U.S.C. § 101.

The concern that providing protection for the EST could lock-up the use of the protein or an antibody to the protein may not be correct. Because of the degeneracy of the genetic code, simply changing a few nucleotide bases creates an entirely new molecular entity of DNA while the protein product of the DNA transcription/expression remains unchanged. Even ignoring changes to the first two bases of a codon could provide a nucleic acid that differed by more than thirty percent from the EST sequence. Such a sequence would not be expected to show the same chromosomal marker utility that was displayed by the original EST, indeed, such a sequence would lack any supportable disclosed utility under section 101. However, the sequence could code for the same amino acids as the original EST.

Arguments that a patentee will nevertheless gain coverage under the Doctrine of Equivalents ("DOE") are tenuous because the DOE operates only in situations where an article, use, or process is an insubstantial change from the claimed invention.[10] Most codons can be changed in at least the third position and still signal the use of the same amino acid. Changing up to thirty percent of a chemical moiety is not an insubstantial change. The

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[8] Fiers v. Revel, 984 F.2d 1164, 1170-71, 25 U.S.P.Q.2d 1601, 1606 (Fed. Cir. 1993).

[9] 383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).

[10] Hilton Davis Chemical Co. v. Warner-Jenkinson Co., 62 F.3d 1512 (Fed. Cir. 1995); Graver Tank and Mfg. Co. v. Linde Air Prod. Co., 339 U.S. 605, 80 U.S.P.Q. (BNA) 451 (1949).

project represents a 3-5 billion dollar market. Any element that is fundamental to a $3 billion market has utility. The fact that the HGP is a research expenditure is irrelevant. Research is an important market in which the United States is a world leader. The patent system should not be balkanized by providing protection in certain markets but ignoring others. The patent system must be firmly committed to protection of inventions even if they are important only to the research market.

The use of EST markers as probes for genetic lesions represents another utility. Many diseases have been localized to very precise cytological locations on the chromosome. Providing researchers with a large battery of probes permits them to rapidly choose probes that correlate closely with the disease locus, thereby speeding the development of diagnostic probes. It is faster and easier to create a diagnostic probe when the molecular biology profession is armed with an arsenal of molecular entities having known genomic locations.

Presently, researchers can identify a disease by looking at a large family and determining what part of what chromosome is in common for all individuals with the disease. This research gives a chromosomal "MAP" position. However, a MAP position is determined either cytologically (i.e., with a microscope) or by an analysis of crossover frequency (i.e., pedigree analysis). MAP positions are many orders of magnitude more gross than a molecular location. Thus, there is no way to tell what DNA or gene is at a precise MAP location on the chromosome. In contrast, the EST markers can identify the precise location of their corresponding DNAs. There is a natural fit between the cytological and molecular types of research because each needs the other: a perfect fit for cross licensing. If we patent ESTs, then researchers can simply go to the databases authorized by 35 U.S.C. §§ 8-13 and determine if any potential markers are known. Moreover, if the patent is drawn narrowly, the right to exclude will be of little or no hinderance to scientists researching other aspects of the cell.

More importantly, what is the alternative to providing patent protection? If a company possesses large numbers of characterized ESTs, such knowledge could advance science by several years. Without patent protection, such knowledge will be maintained as a trade secret and benefit only those with access to the information. Without a potential for patent protection, the market will be unwilling to provide the capital that is needed for future research and development. Indeed, uncertainty as to the possibility of protection interferes with proper valuation of the invention in

relief.[2] Consequently, a patent only permits exclusion of others from using the invention under certain circumstances. Whether a district court would enjoin pure research is problematic in view of the public good that arises from research.[3] Moreover, even if a researcher mistakenly uses a patented invention, the prospect of enforcement of the patent right is unlikely. Suits against infringing researchers are generally impractical—both the information costs and the expense involved in litigating against numerous researchers outweigh any potential recoveries for infringement.

Finally, the relevant question is "what is taken from the public if an injunction is granted?" To be entitled to a patent, the research tool must have been both novel and nonobvious and thus not part of the public domain. Therefore, enjoining the use of a patented research tool takes nothing from the public.

Avoidance of patents on research tools ignores the fact that research itself is an industry. Chemical compounds, which are in fact useful to research chemists in their work and commercial in the sense that they are manufactured, sold, and purchased for that purpose, should be provided protection—if indeed we wish to promote progress in such a field of endeavor. It is inherently easier to purchase a research chemical than to expend the time and energy necessary to manufacture it yourself. Inventions such as the ultracentrifuge, magnetic resonance imaging, and the mass spectrometer originally served the research market alone and obtained investment capital from the sale of research equipment alone. Their present status in medicine and chemistry might not have been reached without protection of that investment.

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[2] *E.g.*, Hybritech Inc. v. Abbott Labs., 849 F.2d 1446, 7 U.S.P.Q.2d (BNA) 1191 (Fed. Cir. 1988) (enjoining particular aspects of infringing activity but permitting continued production of infringing test kits because "the public interest is served best by the availability of these kits"); Vitamin Technologists, Inc. v. Wisconsin Alumni Research Found., 146 F.2d 941, 64 U.S.P.Q. (BNA) 285 (9th Cir.) *cert. denied*, 325 U.S. 876 (1945) (denying injunctive relief to patent owner when its enforcement would be against the public interest).

[3] *But cf.* Roche Prods., Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, 221 U.S.P.Q. (BNA) 937 (Fed. Cir. 1984) (commercial testing which is necessary for the business of a party is nevertheless an infringing activity; the case was legislatively narrowed by 35 U.S.C. § 271 (e)).

which diagnostic or therapeutic purposes, or else would require further non-routine experimentation to carry out. Those utilities that are most credibly enabled on the face of the specification, such as use of the ESTs as markers or probes, are most vulnerable to the challenge that they do not amount to practical utility in currently available form.

The claims that cover sequences and panels of sequences that have not been specifically set forth in the applications are vulnerable to challenge on a number of further grounds. Particularly significant in light of recent caselaw is that they are not supported by an adequate written decision. They may also lack an enabling disclosure or be overly broad relative to the scope of disclosure. Because they cannot be effectively compared to the prior art and do not give clear notice of what they cover, they may be challenged as lacking the requisite clarity and definiteness of claim language. Moreover, it is impossible to determine whether they satisfy the novelty standard.

We are uncertain on the basis of existing caselaw whether any of the sequences satisfy the nonobviousness requirement. Most likely to be vulnerable to a rejection for obviousness are those sequences that are similar to sequences disclosed in the prior art and were obtained through a method that was disclosed or suggested in the prior art. Such sequences might be considered prima facie obvious, in which case it would be necessary to show that they have surprising properties not shared by the prior art sequences in order to establish their patentability. On the other hand, in cases where there are no similar sequences in the prior art, recent Federal Circuit decisions suggest that this approach improperly conflates the method of identifying the sequences with the sequences themselves. Because they are most likely to satisfy the requirements of enablement, written description, and particularity of claim language, the claims that are most likely to be patentable are those that are limited to the actual ESTs disclosed in the patent applications. Patent rights that are limited to such claims are unlikely to be an effective vehicle for technology transfer, however. The primary value of such sequences is in their use as research tools, a use that is unlikely to be inhibited by the absence of patent rights. Indeed, the use of ESTs as research tools might be more attractive to researchers and institutions who are assured that NIH does not and will not claim patent rights to subsequent discoveries that might be facilitated by access to the sequences.

written description requirement, as recently construed in cases involving claims to DNA sequences, appears to be an insurmountable hurdle for all of the claims in the NIH applications that go beyond the sequences actually set forth in the specification. Even a fully enabling disclosure of how to use a probe to find a full-length gene will not be sufficient to support a claim to the full-length gene, except perhaps in narrow, product-by-process form. In that case, as a practical matter, it may be that the allowable claims could not confer a commercially effective monopoly in anything more than the ESTs themselves.

C. *Definiteness*

A further difficulty for some of the claims is the requirement that the claim language "particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention."[133] The purpose of the requirement for definite claim language is twofold: (1) to allow proper examination for patentability; and (2) to give notice to the public of what constitutes infringement.[134] This requirement is likely to be particularly problematic for claims to sequences that have not been identified in the specification. In *Ex parte Tanksley*,[135] the Board affirmed the examiner's rejection of claims to selected tomato cDNA clones that had not been sequenced and, for the most part, had not been identified by biological function, on the ground that the clones had not been adequately described to allow either proper examination in comparison to the prior art or adequate notice to the public of what the claims cover.

We have already noted in the discussion of novelty above that many of the claims cover sequences that are not set forth in the specification and that may not even include sequences set forth in the specification. Thus, for example, claim 17 of '195 covers any polynucleotide fragment of at least 150 base pairs from any gene corresponding to any of the disclosed ESTs. There is no way that an examiner can effectively search the prior art to see if it includes any sequences covered by this claim. Nor does the claim language give notice to the public of the scope of its coverage. Both of the policy

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[133] 35 U.S.C. § 112 (1994).

[134] Graver Tank & Mfg. v. Linde Air Prod. Co., 336 U.S. 271, 277, 80 U.S.P.Q. (BNA) 451, 453 (1949).

[135] 26 U.S.P.Q.2d (BNA) 1384, 1386 (Bd. Pat. App. & Interf. 1992).

with the finding of the Board that Revel's disclosure was insufficient to satisfy the "written description" requirement of section 112 of the Patent Act,[128] noting that the Board had correctly stated that this provision requires a disclosure that is adequate to convey to others in the same field that the inventor was in possession of the claimed invention as of the filing date:

> An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. Revel's specification does not do that. . . . A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA. . . . As we stated in *Amgen* and reaffirmed above, such a disclosure just represents a wish, or arguably a plan, for obtaining the DNA. If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. To paraphrase the Board, one cannot describe what one has not conceived.[129]

This decision potentially presents a major obstacle to the patenting of prophetic claims to DNA sequences that have not yet been set forth in the specifications and would appear to render unpatentable most of the commercially significant claims of the NIH applications. Only those claims that are limited to the disclosed ESTs themselves, and perhaps product-by-process claims to other sequences obtained through the use of those sequences as probes, would appear to satisfy the written description requirement as articulated by the Federal Circuit in *Fiers*.

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[128] *Id.* at 1170, 25 U.S.P.Q.2d (BNA) at 1606.

[129] *Id.* at 1170-71, 25 U.S.P.Q.2d (BNA) at 1606.

priority as of the foreign filing date so long as the foreign application meets the disclosure requirements of U.S. patent law, but an applicant who seeks to prove a priority date prior to the filing date may not rely on any activities that occurred overseas.[123]

Fiers sought to establish priority by proving that he was first to conceive of the invention and was diligent thereafter up to his British filing date. His British application included a disclosure of the complete DNA sequence for the gene. He claimed that his conception occurred when he disclosed a method for isolating the gene to American scientists who brought his protocol back to the United States. These scientists submitted affidavits stating that the protocol was enabling—i.e., that one of ordinary skill in the field would have been able to follow the protocol to isolate β-IF DNA without undue experimentation. Fiers sought to distinguish the *Amgen* decision on this basis, arguing that, in contrast to the uncertainties attending the method held to be nonenabling in that case (screening a genomic DNA library with fully degenerate probes to find the EPO gene), his own method for finding the β-IF gene could have been easily carried out by one of ordinary skill in the art. The Federal Circuit rejected this narrow reading of *Amgen*,[124] holding that "irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility."[125] In other words, proof that the applicants were in possession of an operative method of obtaining the DNA was not sufficient to establish conception of the DNA itself. Conception only of a process for making the DNA would at most support a subsequent product-by-process claim to the DNA obtained by the disclosed process, and would not support

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[123] 35 U.S.C. §§ 102(g), 104 (1994). The implementing legislation for the North American Free Trade Agreement changed U.S. law to permit inventive activities in Canada and Mexico to be proven in support of a priority claim. North American Free Trade Agreement Implementation Act of 1994, Pub. L. No. 182, 107 Stat. 2057.

[124] *Fiers*, 984 F.2d at 1168, 25 U.S.P.Q.2d (BNA) at 1604.

[125] *Id.* at 1169, 25 U.S.P.Q.2d (BNA) at 1604.

of cyanobacteria as useful hosts, but gave only a single working example detailing the transformation of one strain of cyanobacteria. In affirming the examiner's rejection for lack of enablement of the full breadth of the claims, the Federal Circuit noted that "[t]here is no reasonable correlation between the narrow disclosure in appellants' specification and the broad scope of protection sought in the claims encompassing gene expression in any and all cyanobacteria."[117] More recently, in *In re Goodman,*[118] the Federal Circuit affirmed rejection of broad claims to a method for producing mammalian peptides in plant cells supported by a disclosure of only a single working example involving the expression of gamma-interferon in tobacco plants. The court concluded that the specification did not adequately enable the broad scope of the claims.

Enablement is a peculiarly fact-driven inquiry, and the facts of these cases can certainly be distinguished from the NIH applications. Nonetheless, these and other decisions of the Federal Circuit and the Board suggest a parsimonious attitude toward claim scope for biotechnology patents, restricting claimants to that which they have demonstrated can be done successfully through their own working examples. While the Federal Circuit consistently has affirmed that it is sometimes appropriate to allow generic claims covering more than the particular examples disclosed in the specification even in unpredictable fields,[119] as the number of variations embraced by a claim multiply, the court seems to disapprove of broad patent claims that are supported by only a small number of working examples. This trend does not bode well for broad prophetic claims, such as most of those sought by NIH, that are not supported by any empirically-tested working examples.

B. *Written Description*

A related difficulty in claiming subject matter that goes beyond what the inventor has actually reduced to practice is the written description requirement. The Federal Circuit views this requirement as "separate and distinct" from the enablement requirement: "The purpose of the 'written

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[117] *Id.*

[118] 11 F.3d 1046, 1052, 29 U.S.P.Q.2d (BNA) 2010, 2015 (Fed. Cir. 1993).

[119] *E.g., Vaeck*, 947 F.2d at 496, 20 U.S.P.Q.2d (BNA) at 1445.

> what utility will be possessed by these analogs, we consider that more is needed concerning identifying the various analogs that are within the scope of the claim, methods for making them, and structural requirements for producing compounds with EPO-like activity. It is not sufficient, having made the gene and a handful of analogs whose activity has not been clearly ascertained, to claim all possible genetic sequences that have EPO-like activity.[110]

The Board took a similar approach in *Ex parte Ishizaka,*[111] affirming rejection on grounds of obviousness of claims to DNA sequences encoding glycosylation inhibiting factors ("GIFs") and setting forth as a new ground of rejection failure to provide an enabling disclosure corresponding to the breadth of the claims. The claims purported to cover fragments of the disclosed nucleotide sequences of as few as eighteen to twenty bases which are capable of being used as hybridization probes to obtain additional nucleic acids encoding GIF, as well as "a sequence of nucleotides effectively homologous" to such sequences, defined in the specification to mean at least fifty percent homologous. The Board noted that there was no disclosure in the specification showing that any such small fragments had been or could be so employed by others without undue experimentation[112] and cited *Amgen* in concluding that the broad claims to fragments and homologous sequences were not adequately enabled.[113]

The NIH patent applications contain many claims that are comparable to those held invalid in these decisions, including, in particular,

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[110] *Id.* at 1214, 18 U.S.P.Q.2d (BNA) at 1027-28.

[111] 24 U.S.P.Q.2d (BNA) 1621, 1625-26 (Bd. Pat. App. & Interf. 1992).

[112] *Id.* at 1626.

[113] *Id.*

monoclonal antibody art, that all of the methods needed to practice the invention were well known to those of ordinary skill in the art, that the disclosure provided considerable direction and guidance on how to practice the invention and presented working examples, that the nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibodies with desired characteristics, and that practitioners in this field routinely engage in such screening.

Many decisions of the Board involving claims to DNA sequences coding for proteins of known function and partially known amino acid sequence indicate that techniques for obtaining cDNAs using hybridization probes are well-known in the art.[106] It arguably follows that the use of ESTs as probes to obtain full genes does not involve undue experimentation.

On the other hand, a salient distinction between these prior decisions and the present case is that the Venter applications for the most part do not suggest the use of any particular EST as a probe for finding any particular gene, whereas the disclosures at issue in the prior cases suggested the use of particular probes to find target genes. The work that remains to be done to find a target gene is analogous to searching for a particular individual in a telephone directory that has the names and addresses omitted. Even if we assume that each phone number will lead the caller to someone—an assumption that may or may not have a valid corollary for ESTs—the compilation of information is of limited value in finding any given person, even if that person does in fact have a telephone number in the directory and would pick up the phone if the correct number were dialed. Nor, to our knowledge, is this sort of screening effort routine in the field, in contrast to the effort involved in screening hybridomas to identify producers of desired antibodies that the Federal Circuit concluded did not amount to undue experimentation in *In re Wands*.[107] Therefore, it might be argued that undue experimentation is required to find full genes of interest using the Venter disclosures.

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[106] *See, e.g., Ex parte* Deuel, 33 U.S.P.Q.2d (BNA) 1445 (Bd. Pat. App. & Interf. 1993), *rev'd on other grounds sub nom., In re* Deuel, 51 F.3d 1552, 34 U.S.P.Q.2d (BNA) 1210 (Fed. Cir. 1995); *Ex parte* Movva, 31 U.S.P.Q.2d (BNA) 1027 (Bd. Pat. App. & Interf. 1993).

[107] 858 F.2d 731, 8 U.S.P.Q.2d (BNA) 1400 (Fed. Cir. 1988).

inventor at the time of filing.[103] The second paragraph further requires that the claim language clearly define the invention.

An inventor who is able to comply with these requirements may obtain a patent covering subject matter that she has not yet actually reduced to practice in the laboratory. Thus the Venter applications claim not only the specific ESTs that had actually been identified and sequenced, but also complementary sequences, allelic variations and portions thereof, full genes corresponding or hybridizing to any of the foregoing sequences, fragments of such full genes, vectors containing any such sequences or genes, panels of ESTS or sequence fragments, and antisense oligonucleotides or triple helix probes capable of blocking expression of the products of the full genes.

The examiner rejected the claims of the '195 application for lack of an enabling disclosure, lack of an adequate written description of the inventions, and indefiniteness of the claim language. We consider each of these issues in turn.

A. *Enablement/Scope*

The requirement of an enabling disclosure of how to make and use the invention is justified as a means of ensuring that the public receives its quid pro quo for the patent monopoly. To the extent that it focuses on disclosure of how to *use* an invention, this requirement overlaps with the utility requirement discussed above.

Enablement is a particularly important limitation on the patentability of prophetic claims to inventions that the applicant has not yet actually reduced to practice. What is required is a disclosure that would allow a person of ordinary skill in the field to reduce the invention to practice without "undue experimentation."[104] What constitutes "undue experimentation" varies from one field to the next.

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[103] Glaxo, Inc. v. Novopharm Ltd., 52 F.3d 1043, 34 U.S.P.Q.2d (BNA) 1565 (Fed. Cir. 1995); Transco Prods., Inc., v. Performance Contracting, Inc., 38 F.3d 551, 32 U.S.P.Q.2d (BNA) 1077 (Fed. Cir. 1994); Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 19 U.S.P.Q.2d (BNA) 1111 (Fed. Cir. 1991).

[104] Fiers v. Revel, 984 F.2d 1164, 25 U.S.P.Q.2d (BNA) 1601 (Fed. Cir. 1993); Cross v. Iizuka, 753 F.2d 1040, 224 U.S.P.Q. (BNA) 739 (Fed. Cir. 1985).

Although we think it is unlikely that disclosure of ESTs will make the corresponding full-length genes obvious and therefore unpatentable, disclosure of full-length genes may well render obvious related genes with similar DNA sequences. We can foresee this issue arising in the near future as the owners of private EST databases take newly discovered genes of interest that are published by others, compare them to the previously undisclosed sequences in their databases, obtain full-length sequences for any ESTs that show similarities to the newly identified genes, and file patent applications on them. If such a strategy is successful, it could give the owners of EST databases the power to fence-in the patent rights of those who have identified new genes of interest by obtaining patents on all related genes. Will these related genes be considered prima facie obvious by virtue of their structural similarity to the publicly disclosed sequences? Certainly the initial disclosure of one member of an interesting gene family would provide motivation to others working in the field to probe available sequence databases for related genes, perhaps with a reasonable expectation of success.[99] Yet structural similarity, rather than motivation and reasonable expectation of success, seems to be the cornerstone of the Federal Circuit's nonobviousness analysis in this area to date.[100] Moreover, some of the more expansive language from *In re Deuel* could be understood as requiring that the prior art allow the structure of the subsequently discovered genes to be "precisely envisioned" before they would be considered obvious, suggesting a rather exacting standard of structural similarity. Resolution of the issue may thus turn on the degree of similarity between the prior art sequences and the related sequences found through use of the EST databases. Those who discover new genes of interest and do not wish to have their patent rights fenced in would be well advised to identify and claim related

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[99] As more sequences are entered in public domain databases that are freely available to the scientific community, the likelihood of success in finding related genes increases, making it more likely that the related genes would be deemed obvious. On the other hand, sequences that could only be obtained through access to a proprietary sequence database that is not generally available to the scientific community might still be considered nonobvious if the database were not included in the prior art.

[100] *See In re* Deuel, 51 F.3d 1552, 1558, 34 U.S.P.Q.2d (BNA) 1210, 1214 (Fed. Cir. 1995). *But cf. In re* Jones, 958 F.2d 347, 349-50, 21 U.S.P.Q.2d (BNA) 1941, 1943 (Fed. Cir. 1992) ("[G]eneralization is to be avoided insofar as specific structures are alleged to be prima facie obvious one from the other.").

facie obviousness does not necessarily "negative" patentability, but merely shifts to the applicant the burden of showing unexpected properties of the claimed inventions not present or suggested in the prior art. This approach has the benefit of withholding patent protection from newly discovered chemicals until the inventor is in a position to disclose more about them than their structure alone. But perhaps lack of utility is a more appropriate doctrinal basis for rejecting such applications than obviousness.

If prima facie obviousness is established, could NIH sustain its burden of showing unexpected properties for the claimed sequences? Perhaps they could do so with a little more work, but we do not believe that they have done so to date. For the most part all that we know about the disclosed sequences is that they are portions of human genes, which is to be expected of partial sequences obtained from human cDNA. In *Ex parte Anderson*,[95] the Board affirmed an obviousness rejection of claims to a DNA sequence encoding a mature human interleukin-3 ("IL-3") protein having a proline residue at position 8 over prior art disclosing a DNA sequence encoding an IL-3 protein having serine at position 8. The structural similarity gave rise to a prima facie case of obviousness and shifted to the applicants the burden of offering rebuttal evidence showing that the claimed compositions possess unexpected improved properties or properties that the prior art does not have.[96] The Board held that the fact that the claimed IL-3 sequence with proline at position 8 was the dominant allele was not sufficient to overcome the prima facie case of obviousness without an explanation of the practical advantages that come from having possession of the dominant allele.[97] NIH has not even made this much of a showing about the properties of its sequences.

In sum, although the nonobviousness of the claimed sequences is uncertain, on the basis of recent decisions of the Federal Circuit we think it is more likely than not that nonobviousness could be established for those sequences that are not similar to any previously known sequences. If any of the sequences show partial sequence similarity to known sequences, they may be considered prima facie obvious. One could argue that the prior art

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[95] 30 U.S.P.Q.2d (BNA) 1866 (Bd. Pat. App. & Interf. 1993).

[96] *Id.* at 1869.

[97] *Id.* at 1870.

sequences that have significant partial similarities to known sequences may be considered prima facie obvious if they were obtained through an obvious method and if the prior art sequences were of sufficient interest to motivate the search for other, similar sequences.

Although the Federal Circuit now twice has endorsed this structural approach to determinations of obviousness for DNA sequences of specifically identified genes, it is still not entirely clear that the court would eschew consideration of the obviousness of the method of obtaining sequences in considering the patentability of random partial cDNA sequences of unknown function of the sort claimed in the NIH patent applications. Such an approach would seem to make all novel DNA sequences patentable, however trivial the scientific advance that led to their identification. This position collapses the novelty and nonobviousness requirements for DNA sequences. Moreover, a rigid requirement of structural similarity to a known sequence before a DNA sequence will be considered prima facie obvious seems to ignore the reason why structural similarities have been considered relevant to past determinations of the obviousness of new compounds in favor of rote incantation of the facts on which prior decisions have turned, a dubious basis for deciding new cases involving new facts.

The reason that structural similarity to a compound in the prior art has been considered relevant to prima facie obviousness in past decisions in the chemical field is that the usefulness of a prior art compound is presumed to provide the motivation to search for homologues.[89] With this motivation, it is likely that others working in the field will use known methods to find similar compounds, and only if the compounds obtained from such a search possess surprising properties not present in the prior art will they be nonobvious and therefore patentable.

A superficial analogy to these past cases might seem to call for an inquiry into whether the prior art disclosed sequences that were structurally similar to those found by Venter. But a more reasoned approach instead might ask whether the prior art provided comparable motivation to others working in the field to do what Venter and his colleagues did in 1991. While we have not undertaken a comprehensive review of the technical literature, we note that the 1988 report of the National Research Council on Mapping

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[89] *In re* Dillon, 919 F.2d 688, 16 U.S.P.Q.2d (BNA) 1897 (Fed. Cir. 1990).

the court suggested that such broad claims might have been obvious if the full amino acid sequence for the protein had been disclosed in the prior art:

> Such an idea might have been obvious from the *complete* amino acid sequence of the protein, coupled with knowledge of the genetic code, because this information may have enabled a person of ordinary skill in the art to envision the idea of, and, perhaps with the aid of a computer, even identify all members of the claimed genus. The [prior art] reference, however, only discloses a partial amino acid sequence, and thus it appears that, based on the above analysis, the claimed genus would not have been obvious over this prior art disclosure.[84]

The court noted, however, that in the absence of disclosure in the specification of how to obtain any DNA sequences coding for HBGFs other than the specific cDNAs set forth in the application, these broader claims might not be fully supported by an enabling disclosure.[85]

B. *Nonobviousness Of The NIH Inventions*

Turning to the facts of the NIH applications with these cases in mind, we first distinguish between the method used to obtain the sequences and the sequences that were thereby obtained. We note that the '831 application claimed the method used to obtain the sequences as a patentable invention. Because '831 was converted to a Statutory Invention Registration ("SIR") and because the claims of a SIR are not examined for novelty and nonobviousness, the PTO did not pass on the obviousness of the method, and we lack the technical competence to make this determination ourselves. Nonetheless, there is some evidence on the face of the specifications that the methods (described as employing "conventional automated DNA sequencing technology") and materials (commercially available and custom-made cDNA libraries) used to obtain the sequences were substantially

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[84] *Id.*

[85] *Id.*

without undue experimentation and with a reasonable expectation of success.[76] The Board noted that they "do not lightly dismiss appellants' argument that the examiner has not given sufficient weight to the structure or form of the compound or composition, and has improperly concentrated on the method of making it,"[77] yet, in the end, they did not waver from this process-centered approach.[78]

The Federal Circuit very recently reversed this decision of the Board in an opinion that calls into question both of these possible limitations on the reach of its previous decision in *In re Bell*.[79] First, the court reaffirmed that the obviousness of a DNA sequence is to be determined by reference to its chemical structure rather than by considering the manner of its isolation. The court squarely held that a cDNA sequence was not rendered prima facie obvious by prior art disclosures of a partial amino acid sequence for a protein, plus a general method of isolating a cDNA molecule, if there are no structurally similar DNA molecules in the prior art:

> A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy

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[76] *Id.*

[77] *Id.*

[78] *See also Ex parte* Tanksley, 26 U.S.P.Q.2d (BNA) 1384 (Bd. Pat. App. & Interf. 1992) (affirming rejection of claims to tomato cDNA clones that included ribulose biphosphate carboxylase ("RuBPC") genes in part on grounds of obviousness, where they were isolated in a manner disclosed in the prior art and the procedures utilized to establish the function of those clones were all well-known in the art, whether or not the exact sequence of any of the clones was identical to the sequence of previously disclosed RuBPC clones); *Ex parte* Movva, 31 U.S.P.Q.2d (BNA) 1027 (Bd. Pat. App. & Interf. 1993) (affirming rejection of claims to DNA sequence and recombinant DNA molecules coding for swine growth hormone based on evidence that, at the time of the invention, one of ordinary skill in the art had ample reason to isolate a DNA sequence encoding swine growth hormone and would have found it obvious to do so using known processes with a reasonable expectation of success).

[79] *In re* Deuel, 51 F.3d 1552, 1559, 34 U.S.P.Q.2d (BNA) 1210, 1215 (Fed. Cir. 1995).

> possibilities suggested by the prior art, and the failure of the cited prior art to suggest which of those possibilities is the human sequence, the claimed sequences would not have been obvious.[71]

Although this language suggests a very generous attitude toward the nonobviousness of DNA sequences, the court went on to note several facts present in that case that could limit its precedential value in other cases.

First, the court noted that Bell's sequence claims were narrow:

> Bell does not claim all of the 10^{36} nucleic acids that might potentially code for IGF. Neither does Bell claim all nucleic acids coding for a protein having the biological activity of IGF. Rather, Bell claims only the human nucleic acid sequences coding for IGF. Absent anything in the cited prior art suggesting which of the 10^{36} possible sequences suggested by [the prior art] corresponds to the IGF gene, the PTO has not met its burden of establishing that the prior art would have suggested the claimed sequences.[72]

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[71] *Id.* at 784, 26 U.S.P.Q.2d (BNA) at 1532. One Board case also arguably takes a structural approach to determining the obviousness of a claimed DNA sequence. Fiddes v. Baird, 30 U.S.P.Q.2d (BNA) 1481 (Bd. Pat. App. & Interf. 1993). In that case, the Board stressed structural differences between the prior art DNA sequence for mammalian and bovine basic fibroblast growth factors (FGFs) and the claimed DNA sequence encoding human basic FGF, rather than processes for obtaining the target genes, in concluding that the claimed sequences were not rendered obvious by the prior art. But that case had somewhat idiosyncratic facts, including that the Board elsewhere had held the prior art patent to be nonenabling, thus making it difficult to generalize from its holding. Moreover, the Board cited the process-focussed nonobviousness holding in *Amgen* in support of its decision, making it unclear whether it was the nonobviousness of the structure of the sequence or the nonobviousness of the method of obtaining the sequence (or both) that provided the basis for the decision.

[72] *Bell*, 991 F.2d at 784, 26 U.S.P.Q.2d (BNA) at 1532.

structurally similar to known compounds, but a patent applicant may nonetheless rebut the case of prima facie obviousness by showing that the compounds possess new and unexpected properties not present or suggested in the prior art.[66] The focus is on the product and its properties rather than on the method of making the product.

On the other hand, some cases have upheld the patentability of obviously desirable products on the basis of evidence that inventive skill was required to figure out how to make them,[67] although arguably if the inventiveness resides in the method of making the product rather than in the product itself only the method should be patentable.

Some early cases addressing the patentability of DNA sequences focussed on the obviousness of the method used to isolate the sequence rather than attempting to address separately the obviousness of the sequence itself. For example, in *Amgen Inc. v. Chugai Pharmaceutical Co.*,[68] a defendant in an infringement action challenged the validity of a patent claiming a purified and isolated DNA sequence encoding human erythropoietin ("EPO") and host cells transformed with such a sequence. The district court rejected this challenge on the basis of its finding that the probing and screening methods used by the inventor to isolate the gene were nonobvious. The Federal Circuit affirmed, but suggested in a footnote that it was not clear whether the analytical approach to this issue taken by the parties and the district court was correct:

> We note that both the district court and the parties have focused on the obviousness of a

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[66] *In re* Dillon, 919 F.2d 688, 691, 16 U.S.P.Q.2d (BNA) 1897, 1900 (Fed. Cir. 1990).

[67] *E.g., In re* Pilkington, 411 F.2d 1345, 162 U.S.P.Q. (BNA) 145 (C.C.P.A. 1969) (applicant who invented a "float glass" process for making sheet glass that was free of imperfections was entitled to claim the product itself in a product-by-process claim and should not be limited to obtaining process claims); Shaw v. E.B. & A.C. Whiting Co., 417 F.2d 1097, 162 U.S.P.Q. (BNA) 580 (2d Cir. 1969) (patent on an artificial filament adapted for use as brush bristles was valid where the means of making such a product was nonobvious), *cert. denied*, 397 U.S. 1076 (1970).

[68] 927 F.2d 1200, 18 U.S.P.Q.2d (BNA) 1016 (Fed. Cir.), *cert. denied sub nom.*, Genetics Inst., Inc. v. Amgen, Inc., 112 S. Ct. 169 (1991).

discloses sequences covered by these claims. For example, claim 17 of the '195 application covers polynucleotide fragments at least 150 base pairs in length from any gene corresponding to any of the disclosed ESTs. Such a fragment could be from a remote region of the gene and have a DNA sequence that is completely dissimilar to anything disclosed in the specification. Since there is no way at present to determine what all of these sequences are, one cannot search the prior art to determine whether the claims are valid. A claim that does not define the invention with sufficient clarity to allow a proper search of the prior art may be invalid for lack of definiteness of the claim language, as discussed more fully below.[60] But even if a patent were to issue on such a claim, the claim could later be challenged on the basis of prior art existing at the time of the filing that becomes salient at a later date when it is realized that one of the ESTs corresponded to a gene that had previously been fully or partially sequenced. If any sequence covered by the claims may be found anywhere in the prior art, any claim covering that sequence would be invalid in its entirety.

While we are not in a position to offer a definitive opinion on the novelty of the claimed sequences, it is worth noting that the examiner also has not conducted an exhaustive search of the sequences embraced by the claims. Instead, the examiner searched the prior art for matches to 15-mer regions from a small number of the disclosed ESTs. The examiner noted that an exhaustive search of all possible 15-mer regions in just the 2,421 sequences disclosed in '911 would have taken until the year 2035 to complete. It is not clear to us why the examiner was unable to search public sequence databases for exact matches to any 15-mer region from any of the disclosed sequences in the time available to him, but given that he did not conduct such a search, it is possible that the prior art includes exact matches to fragments even of the disclosed sequences that did not come to his attention. The potential for overlooking pertinent prior art is magnified when one considers the possibility that undisclosed (and therefore unsearchable) sequences covered by the claims might also exist in the prior art. The broader the claims, the more likely they are to lack novelty.

V. NONOBVIOUSNESS

Whereas the novelty requirement asks whether a claimed invention is identically disclosed in the prior art, the nonobviousness requirement asks

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[60] *See infra* Part VI. C.

a strong view of the utility requirement for DNA sequences or other research tools would on balance promote subsequent research or retard it.

In sum, although the utility issues raised by these patent applications have no clear answers, in light of recent caselaw it is not surprising that the PTO rejected the claims of the '195 application for lack of utility, nor would we be surprised to see the Federal Circuit affirm the rejection on this ground. The primary reasons for this reaction are: (1) many of the asserted utilities involve use for vaguely identified diagnostic or therapeutic purposes, with no indication of the particular diagnostic or therapeutic purposes for which any particular sequence or group of sequences might be used; (2) most of the sequences may not be put to the asserted uses without further experimentation which appears to go beyond routine experimentation, and the outcome of which is uncertain; and (3) the utilities that appear least problematic on enablement and operability grounds—use of the sequences as probes for finding full-length cDNAs or as chromosome markers—are most vulnerable to challenge on the ground that they are merely of interest to researchers and don't yet amount to practical utility in currently available form.

IV. NOVELTY

Two fundamental requirements for patent protection are that the invention be new and that it be nonobvious.[57] Both of these requirements were invoked by the examiner in rejecting the '195 and '911 applications.

A. *Background And Applicable Law*

An invention is new if it does not exist in the prior art (i.e., if it has not been disclosed in prior patents or publications and was not known or used by others).[58] The novelty requirement is technical in that the claimed invention must be identically disclosed in a single prior art reference in order to be unpatentable.[59] Thus patent lawyers who have the relevant prior art references before them may often avoid novelty rejections by tinkering with

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[57] 35 U.S.C. §§ 102, 103 (1994).

[58] 35 U.S.C. § 102 (1994).

[59] RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 221 U.S.P.Q. (BNA) 385 (Fed. Cir.), *cert. dismissed*, 468 U.S. 1228 (1984).

sequences or panels that are useful for those purposes and not the others. To the extent that the disclosed utilities work only for some of the sequences or only for some panels of sequences, the claims are overly broad.

Of all the asserted utilities for the ESTs, the most credibly operable and enabled are the use as probes to obtain full cDNA sequences and the use as chromosome markers. Although only a small handful of cDNAs corresponding to ESTs had actually been fully sequenced as of the filing date, the same procedure could be readily followed by other skilled persons in the field if they were motivated to do so. Similarly, although only a small fraction of the ESTs had actually been mapped to chromosomes as of the filing date, mapping the others according to the methods disclosed in the specification may involve no more than routine experimentation.[51] But these uses may be particularly vulnerable to challenge under *Brenner v. Manson* as representing utility only as an object of study in subsequent research rather than showing "specific benefit . . . in currently available form."

Use of the ESTs as probes to obtain full cDNA sequences has no practical benefit unless and until the full sequences themselves may be used for some purpose beyond research. Subsequent research may well prove some of the genes useful for diagnostic or therapeutic purposes, but the information disclosed in the specification fails to identify which of the genes will be useful, or for which purposes. Practical utility of the sequences awaits determination of the function of the genes they are associated with, thus implicating the concern for premature filing underlying the decisions in *Brenner v. Manson*[52] and *In re Ziegler*.[53]

This concern with premature filing seems particularly on target in this context because it parallels the reactions of scientists to the NIH filings. Scientists quoted in the popular and scientific press repeatedly expressed an

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[51] Examiner Martinell assumed otherwise in his second office action dated August 10, 1993, in which he noted that a DNA sequence covered by the claims may hybridize to more than one chromosome. If this is correct, then the disclosure is inadequate to enable use of the sequences for mapping and the utility of the sequences has not been established on this basis.

[52] 383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).

[53] 992 F.2d 1197, 26 U.S.P.Q.2d (BNA) 1600 (Fed. Cir. 1993).

operable for the described use without undue experimentation.[49] On the other hand, if a person with ordinary skill in the field would question the validity of the applicants' assertions of utility, the burden of proof shifts to the applicants to demonstrate their truth.[50]

Application of these principles is highly specific to the facts of particular cases. The requirement is harder to satisfy without actual data showing success in the laboratory in fields that exhibit greater unpredictability in experimental outcomes. Thus, patent examiners are typically more skeptical of asserted utilities based on prophetic examples for chemical inventions than for mechanical inventions. Examiners have shown particular skepticism toward unproven utilities for drugs and therapeutic inventions, although this attitude may be changing in light of the recent developments discussed above.

Returning to the Venter application with these general principles in mind, the disclosed utilities that are most vulnerable to challenge are those that either (1) do not indicate a specific purpose for which the inventions may be used, or (2) depend for their operability on the success of experiments that have not been performed and are not certain to work in the minds of other practitioners of ordinary skill in the field. The former category would seem to include the claimed utilities as diagnostic probes in genetic linkage analysis, as probes to locate gene regions associated with genetic disease, for regulation of gene expression through antisense and triple helix methods, and for differentiating tissue types. Even if these asserted utilities no longer trigger the heightened skepticism as to operability and enablement recently applied by the PTO to pharmaceutical and therapeutic inventions, they remain vulnerable to challenge on the ground that undue experimentation would be necessary in order to determine which if any diagnostic or therapeutic purposes any of the ESTs might serve. Yet each of these utilities is described in broad, general terms and in purely prophetic examples, unsupported by specific experimental

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[49] *See* Atlas Powder Co. v. E.I. DuPont Nemours, 750 F.2d 1569, 1577, 224 U.S.P.Q. (BNA) 409, 414 (Fed. Cir. 1984); Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737, 1775 (D. Mass. 1989).

[50] *See In re* Brana, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d (BNA) 1436, 1441 (Fed. Cir. 1995); *In re* Bundy, 642 F.2d 430, 433, 209 U.S.P.Q. (BNA) 48, 51 (C.C.P.A. 1981).

isolated through use of the EST probes, may be expressed in recombinant host cells to obtain their protein or polypeptide products. ESTs, or other sequences obtained through the use of ESTs, may be used as diagnostic probes, to detect the presence of a specific mRNA in a particular cell type, or in genetic linkage analysis, or to locate gene regions associated with genetic disease. ESTs may be used to regulate gene expression through triple helix formation or antisense methods. Panels of ESTs may be used for individual identification for forensic and other purposes, a use for which the estimated eighty-five percent of the ESTs that appear to come from noncoding regions are said to be particularly well suited because polymorphisms are more common in noncoding regions. Panels of ESTs specific to particular tissue types may also be used as reagents to identify tissue specimens by organ type or by species.

It is only necessary to show one practical utility for an invention in order to patent it.[47] Thus if any one of the utilities recited in the Venter applications amounts to a practical utility and is supported by an enabling disclosure, the sequences or panels of sequences that are shown in the specification to have this utility will pass the utility test. Moreover, the patent rights that could be obtained on the basis of such a disclosure of practical utility would not be limited to use of the sequences for the disclosed purposes, but would potentially extend to all uses of the sequences.

The patent examiner was unimpressed by the suggested utilities, and rejected the '195 appplication for lack of utility, among other grounds, in an Office Action dated August 20, 1992:

> The mere mention of general possible uses is not sufficient to establish a definite utility because the instant application does not disclose a patentable utility for the oligonucleotides or other nucleotides of the claimed inventions in their currently available form. Given what is disclosed in the instant application, it would be necessary for one to do further work in order to establish a utility for many of the nucleotides embraced by the

[47] 35 U.S.C. § 101 (1994).

The latest word from both the Federal Circuit and the PTO thus suggests that the utility standard for biotechnology inventions may be receding from its recent high-water mark.

Although proof of clinical efficacy may no longer be required to establish patentable utility, it bears emphasis that both the PTO and the Federal Circuit continue to require that, at least in cases where the invention does not have a well-established utility, the utility of a claimed invention be specifically identified in the patent application. Thus in its *Legal Analysis Supporting Utility Examination Guidelines*, the PTO observes that "a statement that a composition has an unspecified 'biological activity' or that does not explain why a composition with that activity is believed to be useful fails to set forth a 'specific assertion of utility.'"[39] And in *In re Brana* the Federal Circuit conceded that the PTO's argument that the application failed to disclose a specific disease that could be treated with the claimed compounds, thereby requiring undue experimentation before the invention could be put to use, was "not without merit."[40] In the end, however, the court was satisfied that comparisons made in the application between the effectiveness of the claimed compounds and prior art compounds implicitly asserted that the claimed compounds were useful against lymphocytic leukemia.

Another recent decision of the Federal Circuit, in a case not involving a pharmaceutical product, affirms that the utility requirement still operates to withhold patent protection from inventions that are too far removed from practical applications.[41] *In re Ziegler* involved an appeal from a rejection of a U.S. patent application claiming priority in the discovery of polypropylene on the basis of a German patent application filed in 1954.[42] The examiner rejected the claims at issue in part on the ground that the German

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[39] *Utility Examination Guidelines, supra* note 30, at 302.

[40] *Brana*, 51 F.3d at 1565, 34 U.S.P.Q.2d (BNA) at 1440.

[41] *In re* Ziegler, 992 F.2d 1197, 26 U.S.P.Q. 2d (BNA) 1600 (Fed. Cir. 1993).

[42] A U.S. patent application filed within one year of a foreign patent application is treated as if it had been filed on the foreign filing date for purposes of determining what counts as prior art, provided the foreign application satisfies the disclosure requirements of U.S. law. 35 U.S.C. § 119 (1994); Kawai v. Metlesics, 480 F.2d 880, 178 U.S.P.Q. (BNA) 158 (C.C.P.A. 1973).

demanding from patent applicants the sort of proof of clinical efficacy that the FDA requires prior to approval of a new drug application.[31] In announcing the proposed guidelines at a press conference, PTO Commissioner Bruce Lehman underscored his commitment to implementing the new guidelines through improved training of the examiners and supervisors and, if necessary, through changes in management practices or personnel.[32]

Second, the Court of Appeals for the Federal Circuit very recently reversed a PTO decision rejecting claims to a new pharmaceutical invention for lack of utility in *In re Brana*,[33] chiding the PTO that the issue of what an applicant must prove to establish the utility of such an invention "is one which we would have thought had been settled by case law years ago."[34] The patent claims in that case were directed toward new chemical compounds for use as antitumor substances. The prior art revealed that structurally similar compounds had shown *in vivo* activity against implanted murine lymphocytic leukemias, and the specification reflected greater *in vitro* activity against human tumor cells for the claimed compounds than for the prior art compounds. The examiner concluded that these tests were insufficient to establish the utility of the claimed compounds, and the Board affirmed.

The Federal Circuit reversed, indicating that the utility requirement was more than satisfied in this case. First, the court noted that disclosures of utility in the specification are presumptively correct unless manifestly based on implausible scientific principles, and that "treating cancer with chemical compounds does not suggest an inherently unbelievable

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[31] *See, e.g.*, Biotechnology Industry Organization, *Critical Synergy: The Biotechnology Industry and Intellectual Property Protection*, Presentations of the Intellectual Property Committee of the Biotechnology Industry Organization at the Hearing of the U.S. Patent and Trademark Office (October 17, 1994).

[32] *PTO Announces New Biotechnology Guidelines*, 49 Pat., Trademark and Copyright J. (BNA) 223, 224 (Jan. 5, 1995).

[33] 51 F.3d 1560, 1562, 34 U.S.P.Q.2d (BNA) 1436, 1437 (Fed. Cir. 1995).

[34] *Id.* at 1564, 34 U.S.P.Q.2d (BNA) at 1439.

In *Ex parte Balzarini*,[22] the Board affirmed a rejection for lack of utility of claims to pharmaceutical compositions in unit dosage form comprising one of two specified ingredients that had shown antiviral activity against HIV *in vitro*. The Board agreed with the examiner that those skilled in the art would regard the *in vitro* tests as a useful screening tool for selecting which compounds are appropriate candidates for further testing, but nonetheless held that the applicants had failed to satisfy their further burden of demonstrating that those skilled in the art would accept the *in vitro* test results as predictive of *in vivo* efficacy in treating humans who are HIV positive or suffering from AIDS. The Board was careful to note that it was not necessarily requiring clinical testing in humans to establish utility, although it could be that nothing short of human clinical trials would satisfy those skilled in this particular art that the claimed inventions would be effective *in vivo*.[23]

In *Ex parte Aggarwal*,[24] the Board affirmed the examiner's rejection of broad claims to a method of treatment of tumors in animals by administering a therapeutically effective amount of recombinantly produced lymphotoxin. The specification described preparation of recombinant lymphotoxin and demonstration of *in vivo* activity in mice as well as *in vitro* activity. The examiner took the position that given the unpredictability of the treatment of tumors at the time of the filing, the limited test data of record were insufficient to demonstrate utility across the broad range of the claims. In affirming, the Board conceded that "[t]here is no question that appellants have made an important discovery with regard to chemical compounds (proteins) which are the subject of serious scientific investigation but of unverified and speculative utility."[25] The applicant argued unsuccessfully that the public interest called for allowing the filing of a patent application on such an invention early rather than waiting for what may be a long period of experimentation. According to the Board, in light of *Brenner v. Manson* and subsequent caselaw, such an application is premature until the applicant "can provide evidence showing substantial activity in screening

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[22] 21 U.S.P.Q.2d (BNA) at 1892.

[23] *Id.* at 1897.

[24] 23 U.S.P.Q.2d (BNA) at 1334.

[25] *Id.* at 1339.

The Court explicitly rejected the view that the utility requirement is met by any invention that is not positively harmful to society.[13] Nor was utility established by showing that the invention yields products that are currently the subject of serious scientific investigation.[14] The court was particularly concerned that conferring patent rights in basic research discoveries could create "a monopoly of knowledge" and "confer power to block off whole areas of scientific development, without compensating benefit to the public."[15] The court concluded that patent protection was premature until the invention had been refined and developed to the point where "specific benefit exists in currently available form."[16] The majority opinion closed with the following passage: "A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. 'A patent system must be related to the world of commerce rather than to the realm of philosophy. . . .'"[17] One plausible reading of this opinion is that the utility requirement serves a timing function, leaving basic research discoveries in the public domain until they have yielded tangible benefits and have thereby left "the realm of philosophy" and entered "the world of commerce."

Whether or not there was a meaningful distinction to be drawn between the realm of philosophy and the world of commerce in the field of steroid chemistry in the 1960s, it is a very difficult distinction to maintain in biotechnology in the 1990s, with researchers in government and university laboratories seeking patent protection for their discoveries and with private firms developing research tools for commercial sale. In this environment, research discoveries that are the subject of serious scientific investigation may be sold commercially to researchers long before they have ripened into products for sale to the general public. How far must an inventor go to establish that such an invention offers a "specific benefit . . . in currently available form?"

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[13] *Id.* at 533, 148 U.S.P.Q. (BNA) at 695.

[14] *Id.* at 536, 148 U.S.P.Q. (BNA) at 696.

[15] *Id.* at 534, 148 U.S.P.Q. (BNA) at 695.

[16] *Id.* at 534-35, 148 U.S.P.Q. (BNA) at 695.

[17] *Id.* at 536, 148 U.S.P.Q. (BNA) at 696 (quoting *In re* Ruschig, 343 F.2d 965, 970, 145 U.S.P.Q. (BNA) 274, 279 (C.C.P.A. 1965)).

A. *Background And Applicable Law*

The U.S. Constitution authorizes Congress to provide patent protection for the express purpose of promoting progress in "the useful arts."[1] In keeping with this language, the U.S. patent statute limits patent protection to "useful" inventions[2] and requires patent applicants to disclose how to use their inventions.[3] The utility requirement has at least three interrelated dimensions to it, although the courts and the PTO are not always clear about which of these dimensions is at issue in a given case. First, an invention must serve a practical purpose.[4] Second, it must be "operable," or capable of use.[5] Third, the invention as claimed must be supported by a disclosure that is adequate to enable a skilled practitioner working in the field to use the invention with no more than routine experimentation.[6]

One source of difficulty in defining the content of the utility requirement is a lack of clarity as to its underlying purposes. In the early nineteenth century, Justice Story suggested that the standard of utility should be considered satisfied so long as an invention has some beneficial use and is not "frivolous or injurious to the well-being, good policy, or sound morals of society."[7] As long as the invention was not contrary to public morality and policy, Story saw no reason why the public should object to the patenting of an invention of very little utility: "If it be not extensively useful,

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[1] U.S. CONST. art. I, § 8, cl. 8.

[2] 35 U.S.C. § 101 (1988).

[3] 35 U.S.C. § 112 (1988).

[4] Anderson v. Natta, 480 F.2d 1392, 178 U.S.P.Q. (BNA) 458 (C.C.P.A.) 1973). *See* 1 W. ROBINSON, TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS (1890).

[5] Newmann v. Quigg, 877 F.2d 1575, 11 U.S.P.Q.2d (BNA) 1340 (Fed. Cir. 1989).

[6] 35 U.S.C. § 112 (1988).

[7] Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568).

I. INTRODUCTION

You have asked for our legal opinion on the patentability of inventions claimed in U.S. patent applications 07/716,831, filed June 21, 1991 (the '831 application, or "'831"), 07/837,195, filed September 25, 1992 ("'195"), and 07/952,911, filed February 12, 1993 ("'911"), all filed in the name of Craig Venter and others and assigned to the National Institutes of Health "(NIH)."

We understand that NIH has abandoned these patent applications and has no present intention of filing similar applications in the future, but that NIH remains interested in the patenting of human DNA sequences from a broader public policy perspective. We have therefore attempted to focus on issues that are likely to recur in other patent applications filed by other people and institutions involved in DNA sequencing rather than on questions that are peculiar to the facts of these particular applications. Nonetheless, we preface this opinion letter with the caution that the facts of each patent case are unique. We have before us for consideration only these three NIH filings, and we are not in a position to offer a definitive opinion on the patentability of other inventions that may be claimed by other parties and supported by different disclosures in different patent applications.

The expertise we bring to this issue is legal rather than scientific. Many issues of patent law turn on the understanding of skilled practitioners working in the field of the invention. We have identified these issues throughout this letter.

We begin with a brief description of the NIH patent applications and then turn to the patentability issues presented by these applications. In our view, the most significant of these issues concern the utility, nonobviousness, and disclosure requirements of the patent laws.

II. THE NIH cDNA PATENT APPLICATIONS

The three applications under review seek patent protection for inventions associated with the identification of approximately 6,800 partial cDNA sequences, called "expressed sequence tags" ("ESTs") in the applications, in the laboratory of Dr. Craig Venter at the National Institute of Neurological Disorders and Stroke prior to his departure from NIH in July 1992. These sequences, which are typically 150-400 base pairs in length, were obtained by partially sequencing randomly selected clones from human brain cDNA libraries enriched by removing ribosomal and other common

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