B. GENERAL PATENTABILITY STANDARDS AND PROCEDURES

(h) Explain the standard used by your examining authority to determine whether an invention directed to a therapeutic application has industrial applicability or is useful.

The legal standard used to assess whether an invention directed to a therapeutic application is "useful" under US law is the same that applies to an invention in any field of technology. An invention will be considered "useful" in the meaning of 35 U.S.C. § 101 if the applicant for the patent can identify any "practical" utility for the invention. This standard has been explained by the US courts as follows:

> "Practical utility" is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public. *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

Certain issues have arisen in the context of applying this standard to inventions that depend for their utility on a specific method of therapeutic treatment of a human being. For example, in certain extremely rare situations, an applicant will identify a therapeutic utility for an invention that is not scientifically credible. In such a situation, and in the absence of any other scientifically credible utility, the invention would fail to satisfy 35 U.S.C. § 101.

Complete guidance on the application of the "useful invention" requirement of 35 U.S.C. § 101 is found in the PTO's Utility Examination Guidelines and supporting legal analysis. See, MPEP §§ 706.03(a)(1) and 2107-2107.02.

(i) Explain whether your examining authority has found recurring types of deficiencies related to industrial applicability/utility or sufficiency of disclosure in applications directed to the nucleic acid sequences where the characteristics or functions of protein(s) coded for by the sequence are not known and are not described by the applicant.

In general, PTO examiners have applied the patentability criteria of 35 U.S.C. § 101 (utility) and 35 U.S.C. § 112, first paragraph (enablement/description) to applications drawn to inventions as characterized in the question without significant difficulties. It should be noted at the outset that it is the experience of the PTO that applications in this fact pattern have not been frequently encountered.

Deficiencies that may be found in relation to the hypothetical fact pattern described in the question would likely arise under 35 U.S.C. § 112, first and second paragraphs (i.e., enablement, written description, claim definition). The general standard governing compliance with section 112, first paragraph (enablement) is described in question (s) below. As discussed below, the assessment for compliance with the enablement requirement of section 112, first paragraph, depends on an evaluation of several variables that affect the general question of whether the claimed invention can be practiced by a person skilled in the technical field of the invention without the exercise of "undue" experimentation. A simple answer to the generalized question, thus, cannot be provided in relation to section 112, but instead will depend on the facts presented in each application (i.e., the degree of disclosure and description provided in the application, the claims presented, the state of development of the technological field of the invention).

The question of whether deficiencies would exist in relation to the hypothetical fact pattern under 35 U.S.C. § 101would depend on indications made in the disclosure in relation to the utility of the various inventions claimed, as indicated in the preceding question. For example, if no indications were made in

the application as to the practical utility of a protein expressed by a particular nucleotide sequence, the claims directed to the protein would likely be deficient under section 101.

(j) Explain the test, if any, that your examining authority uses to determine whether a disclosure provides a sufficient basis to defeat the novelty of a claimed invention.

Under 35 U.S.C. § 102, an invention may not be patented if it is not novel. Where the basis for lack of novelty is a printed publication or patent, there is a requirement that the printed publication or patent contain a sufficiently complete disclosure of the claimed invention so as to place the claimed invention in the possession of the public.[7] The question of sufficient disclosure of an invention in the context of application of section 102 is not frequently encountered during the examination process.

(k) Inventive step/non-obviousness:

(i) Explain how the standard of inventive step/non-obviousness has been applied by your examining authority in determining whether biotechnological inventions are patentable;

The legal standard that governs whether a biotechnological invention is non-obvious over the prior art is the same as for inventions in any field of technology. The test derives from the language of 35 U.S.C. § 103 and was articulated by the Supreme Court in the seminal case of *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). The test has been frequently summarized by the Federal courts; a recent example was provided in the case of *In re Mayne*, 104 F.3d 1339, 41 USPQ2d 1451 (Fed. Cir. 1997), in which the Federal Circuit stated:

The legal determination under section 103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *In re O'Farrell,* 853 F.2d 894, 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art. *Graham v. John Deere Co.,* 383 U.S. at 17-18; *Miles Lab., Inc. v. Shandon Inc.,* 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993). Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness. *Stratoflex, Inc. v. Aeroquip Corp.,* 713 F.2d 1530, 1538, 218 U.S.P.Q. 231, 236 (Fed. Cir. 1983).

The PTO, during the examination process, evaluates each claimed invention to determine if it satisfies the requirement for non-obviousness. In order to impose a rejection of a claimed invention for failure to satisfy section 103, the PTO is required to establish a

[7] See, *In re John A. Donohue*, 766 F.2d 531; 533, 226 USPQ 619, 621 (Fed.Cir, 1985) ("It is well settled that prior art under 35 U.S.C. § 102 (b) must sufficiently describe the claimed invention to have placed the public in possession of it. *In re Sasse*, 629 F.2d 675, 681, 207 USPQ 107, 111 (CCPA 1980); *In re Samour*, 571 F.2d at 562, 197 USPQ at 4; see also *Reading & Bates Construction Co. v. Baker Energy Resources Corp.,* 748 F.2d 645, 651-52, 223 USPQ 1168, 1173 (Fed. Cir.1984). Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. See *In re LeGrice*, 301 F.2d at 939, 133 USPQ at 373-74. Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling. *In re Borst*, 345 F.2d 851, 855, 145 USPQ 554, 557 (1965), cert. denied, 382 U.S. 973 (1966). It is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.")

prima facie case of obviousness. The PTO has provided the following guidance to its examiners in relation to imposing such a rejection under section 103:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

See, *Manual of Patent Examining Procedure (MPEP)*, §706.02(j) ("Contents of a § 103 Rejection").

In addition to the general rule articulated above, current US law also provides for the possibility of a legal presumption of non-obviousness in certain situations involving applications drawn to biotechnological compositions of matter. This legal presumption was established in US law through amendments passed by Congress in 1995. The scenarios in which the legal presumption can be invoked are limited to situations where a novel and non-obvious biotechnological composition of matter (whether classified as a "starting material" or "end product") is used in conjunction with an otherwise conventional process. The effect of invocation of the legal presumption of section 103(b) is to treat the process claims as non-obvious due to its specific application involving the novel and non-obvious composition of matter. If properly invoked, section 103(b) precludes the PTO from rejecting process claims which involve the use or making of certain non-obvious biotechnological compositions of matter.

To successfully invoke section 103(b), the applicant must satisfy a number of conditions:

1. the biotechnological process and composition of matter must be contained in the same application or in separate applications that have the same effective filing date;

2. both the biotechnological process and composition of matter must be owned or subject to an assignment to the same person at the time the process was invented;

3. a patent issued on the process must also contain the claims to the composition of matter used in or made by the process, or, if the process and composition of matter are in different patents, the patents must expire on the same date (notwithstanding any extensions of patent term under 35 U.S.C. § 154);

4. the biotechnological process must fall within the definition set forth in 35 U.S.C. § 103(b); and

5. a timely election must be made to proceed under the provisions of 35 U.S.C. § 103(b). An election will normally be considered timely if it is made no later than the earlier of either (1) the payment of the issue fee, or (2) the filing of an appeal brief in an application which contains a composition of matter claim which has not been rejected under 35 U.S.C. § 102 or 103.

Since passage of the legislation, additional decisions from the Federal Circuit have clarified the law governing the determination of obviousness under 35 U.S.C. § 103 in situations analogous to those discussed above.[8] From these decisions, it is clear that the determination of whether an invention is non-obviousness requires a full examination of the specific facts found in each case. For example, in *In re Ochiai*, 71 F.3d 1565; 37 USPQ2d 1127 (Fed. Cir.1995), the Federal Circuit emphasized that it is improper to rely on "per se" rules for obviousness determinations, including in particular in situations where a well known process is applied to produce a new final product from a novel and non-obvious starting material, as such an approach fails to take account of all the relevant factors of the test for non-obviousness defined in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).[9] In view of the recent Federal Circuit decisions, it is anticipated that use of 35 U.S.C. § 103(b) will be rare.

(ii) Indicate whether application of this standard in the field of biotechnology has been discussed in any administrative or judicial decision. If so, please provide a summary of the issues and findings of such decisions;

Judicial review of the application of the non-obviousness requirement of section 103 in the context of applications related to biotechnological inventions has been fairly extensive. While this has provided useful precedent for application of the non-obviousness requirement in relation to biotechnological inventions, it should be noted that precedential cases concerning determinations of non-obviousness for inventions in any field of technology are part of the overall legal jurisprudence that governs application of 35 U.S.C. § 103 to inventions in the field of biotechnology.

The following provides a summary of several significant precedential cases involving inventions in the field of biotechnology that address questions under 35 U.S.C. § 103:

1. *Hybritech Incorporated v. Monoclonal Antibodies, Inc., 802 F.2d 1367; 231 U.S.P.Q. 81(Fed. Cir. 1986).*

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[8] See MPEP 2116.01 for a discussion of the Federal Circuit's decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996) which address the general issue of whether an otherwise conventional process could be patented if it were limited to making or using a non-obvious product. See also 1184 O G 86 (Comm'r Pat. 1996). See 35 U.S.C. § 282 for the effect of a determination of non-obviousness under 35 U.S.C. § 103(b)(1) on the presumption of validity.

[9] *In re Ochiai*, 71 F2d at 1572, 37 USPQ2d at 1133 ("The use of per se rules, while undoubtedly less laborious than a searching comparison of the claimed invention--including all its limitations--with the teachings of the prior art, flouts section 103 and the fundamental case law applying it. Per se rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient for PTO examiners and the Board. Indeed, they have been sanctioned by the Board as well. But reliance on per se rules of obviousness is legally incorrect and must cease. Any such administrative convenience is simply inconsistent with section 103, which, according to Graham and its progeny, entitles an applicant to issuance of an otherwise proper patent unless the PTO establishes that the invention as claimed in the application is obvious over cited prior art, based on the specific comparison of that prior art with claim limitations. We once again hold today that our precedents do not establish any per se rules of obviousness, just as those precedents themselves expressly declined to create such rules. Any conflicts as may be perceived to exist derive from an impermissible effort to extract per se rules from decisions that disavow precisely such extraction.")

The claimed invention was a method of using monoclonal antibodies to perform a sandwich immunoassay. Prior art teachings disclosed the general advance of hybridoma technology and monoclonal antibody production, and sandwich immunoassay methods that used polyclonal sera.

The Federal Circuit reversed a holding of invalidity by the District Court for reason of failure to satisfy non-obviousness requirement. A key basis of the reversal by the Federal Circuit was its finding that the District Court improperly relied on hindsight in evaluating the prior art references to conclude that it would have been obvious for a person of ordinary skill to try to practice the claimed immunoassay using a mixture of polyclonal antisera. The Federal Circuit also emphasized that secondary considerations of commercial success of monoclonal antibody sandwich immunoassay test kits had been improperly discounted in evaluating the non-obviousness of the claimed invention.

2. *In re O'Farrell, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988).*

The claimed invention was directed to a generic method of expressing a "predetermined" protein in bacteria, and to specific bacterial expression systems involving use of the beta-galactosidase gene.

The Federal Circuit upheld a finding that the claimed invention was obvious in view of prior art that disclosed the claimed process but for the specific exogenous proteins disclosed in the application. The prior art references included an extensive paper on the methodology of expression that was authored by two of the three inventors in the patent application. In challenging the conclusion of obviousness, the applicant asserted that a significant amount of unpredictability existed in the art at the time the application was filed, and on this basis, the predictive value of the prior art disclosure of the applicant's method should have little or no value. The court rejected this line of reasoning, stating:

Obviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious. *In re Merck & Co., 800 F.2d at 1098, 231 USPQ at 380; Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1461, 221 USPQ 481, 488 (Fed. Cir. 1984); In re Papesch, 315 F.2d 381, 386-87, 137 USPQ 43, 47-48 (CCPA 1963).* For obviousness under § 103, all that is required is a reasonable expectation of success. *In re Longi, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985); In re Clinton, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976).* The information in the Polisky reference, when combined with the Bahl reference provided such a reasonable expectation of success.

3. *In re Vaeck, 947 F.2d 488, 20 USPQ2D 1438 (Fed.Cir. 1991)*

The invention was generally directed to use of cyanobacteria to express the "bacillus" protein (an endotoxin that is effective in killing mosquito and black flies). The claims, among other things, covered a chimeric gene encoding the bacillus protein and a promoter region suitable for expression in any species of cyanobacteria, the transformed