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Director of the U.S. Patent and Trademark Office  
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Attention: Mark Nagumo

This is Incyte Genomics, Inc.'s response to the Request for Comments by the U.S. Patent and Trademark Office ("PTO") on the Revised Utility Examination Guidelines (64 FR 71427), published December 21, 1999. Incyte submits these comments pursuant to the discussion on June 7, 2000 with the Director of the PTO during a meeting between representatives of Incyte and the PTO. Incyte sincerely appreciates this opportunity to supplement the comments already received by the PTO.

A pioneer in the genetic information industry, Incyte is dedicated to advancing greater and more meaningful understanding of the molecular basis of disease. Since its founding in 1991, Incyte has created the world's largest and most comprehensive collection of genomic information. Incyte's products and services assist pharmaceutical and biotechnology researchers with all phases of drug discovery and development including discovering new genes, understanding disease pathways, identifying new disease targets, and correlating gene sequence variation to disease.

Incyte applauds the PTO's efforts to revise its Patent Examination Guidelines in order to better comport with the "utility" requirement of 35 U.S.C. § 101. The Revised Guidelines themselves appear to accomplish this goal. Incyte is concerned, however, that portions of the PTO's corresponding statement as to how its Patent Examiners should implement these Guidelines, the Revised Interim Utility Guidelines Training Materials, may not be consistent with the law. It is Incyte's hope that the following comments will assist the PTO in identifying problems with the Training Materials as they now stand, and in crafting appropriate solutions.

The Revised Examination Guidelines take the general approach that every claimed invention must be supported by an asserted utility that “would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.” The Revised Guidelines themselves do not explain in detail, however, how a Patent Examiner should determine whether an asserted utility is “specific, substantial, and credible.” This task is left to the Training Materials.

Incyte submits that the Training Materials do not offer appropriate guidance to Patent Examiners in determining whether an asserted utility is sufficiently “specific.” Nor do they sufficiently address how such a utility should be proven. These and other problems, and potential solutions, are addressed below.

**I. A “specific utility” describes a beneficial use for the subject matter of the invention and need not be unique to the invention.**

In their present form, the Training Materials address the issue of specificity with reference to two kinds of asserted utilities: “specific” utilities which meet the statutory requirements, and “general” utilities which do not. The Training Materials define a “specific utility” as follows:

A [specific utility] is *specific* to the subject matter claimed. This contrasts to *general* utility that would be applicable to the broad class of invention. For example, a claim to a polynucleotide whose use is disclosed simply as “gene probe” or “chromosome marker” would not be considered to be specific in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

The Training Materials distinguish between “specific” and “general” utilities by assessing whether the asserted utility is sufficiently “particular,” *i.e.*, unique (Training Materials at p.52) as compared to the “broad class of invention.” (In this regard, the Training Materials appear to parallel the view set forth in Stephen G. Kunin, Written Description Guidelines and Utility Guidelines, 82 J.P.T.O.S. 77, 97 (Feb. 2000)(“With regard to the issue of specific utility the question to ask is whether or not a utility set forth in the specification is *particular* to the claimed invention.”)).

Such “unique” or “particular” utilities never have been required by the law. To meet the utility requirement, the invention must be “practically useful,” *Anderson v. Natta*, 480 F.2d 1392, 1397 (CCPA 1973) and confer a “specific benefit” on the public. *Brenner v. Manson*, 383 U.S. 519, 534 (1966). The threshold of utility under this standard is not high, and requires merely an “identifiable” benefit. *Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700 (Fed. Cir. 1999). In *Stiftung v. Renishaw*

*PLC*, 945 F.2d 1173, 1180 (Fed. Cir. 1991) the United States Court of Appeal for the Federal Circuit explained:

An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: “[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding lack of utility.” *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 762, 221 USPQ 473, 480 (Fed. Cir. 1984).

Thus “nebulous” uses which merely encourage further research on the invention itself do not meet this standard. *In re Kirk*, 376 F.2d 936, 940 (CCPA 1967)(“Appellants have not listed one specific use for their claimed steroids and as those skilled in the art know steroids are susceptible to hundreds of uses. What appellants are really saying to those in the art is take these steroids, experiment, and find what use they do have as medicines.”). Nor do incredible, “throwaway” utilities, such as trying to “patent a transgenic mouse by saying it makes great snake food.” Karen Hall, Genomic Warfare, *The American Lawyer* 68 (June 2000)(quoting John Doll, Chief of the Biotech Section of USPTO).

This does not preclude, however, a general utility. Practical real-world uses are not limited to uses that are unique to an invention. The law requires that the practical utility be “definite,” not particular. *Standard Oil Co. v. Montedison*, 664 F.2d 356, 375 (3d Cir. 1981). We are aware of no court that has rejected an assertion of utility on the grounds that it is not “particular” or “unique” to the specific invention. Where courts have found utility to be too “general,” it has been in those cases in which the asserted utility in the patent disclosure was not a practical use that conferred a specific benefit. That is, a person of ordinary skill in the art would have been left to guess as to how to benefit at all from the invention. In *Kirk*, for example, the CCPA held the assertion that a man-made steroid had “useful biological activity” was insufficient where there was no information in the specification as to how that biological activity could be practically used. *Kirk*, 376 F.2d at 941.

The fact that an invention can have a particular use does not provide a basis for requiring a particular use. See *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995)(disclosure describing a claimed antitumor compound as being homologous to an antitumor compound having activity against a “particular” type of cancer was determined to satisfy the specificity requirement). “Particularity” is not and never has been the *sine qua non* of utility; it is, at most, one of many factors to be considered.

Inventions that achieve a practical use that is also achieved by other inventions satisfy the utility requirement. Thus practical utilities can be directed to classes of

inventions, so long as a person of ordinary skill in the art would understand how to achieve a practical benefit from knowledge of the class. *Montedison*, 664 F.2d at 374-75. For example, many materials conduct electricity. Likewise, many different plastics can be used to form useful films. *Montedison*, 664 F.2d at 374-75; *Natta*, 480 F.2d at 1397. This is a general utility (practical films) that applies to a broad class of inventions (plastics) which satisfies the utility requirement of section 101.

This is not to say all broad classes of inventions are, by themselves, sufficient to inform a person of ordinary skill in the art of the practical utility for a member of the class. Some classes may indeed convey too little information to a person of ordinary skill in the art. These may include classes of inventions that include both useful and nonuseful members. *In re Ziegler*, 992 F.2d 1197, 1201 (Fed. Cir. 1993). In some of these cases, further experimentation would be required to determine whether or not a member of the class actually has a practical use. *Brenner*, 383 U.S. at 534-35.

The broad class of steroids identified in *Kirk* is just such a class. It includes natural steroids (concededly useful) and man-made steroids, some of which are useful and some of which are not. Indeed, only a small fraction of the members of this broad class of invention may be useful. Without additional information or further experimentation, a person of ordinary skill in the art would not know whether a member of the class falls into the useful category or not. This could also be the case for the broad class of “plastic-like” polypropylenes in *Ziegler*, which includes many -- perhaps predominately -- useless members.

The Training Materials fail to distinguish between broad classes that convey information of practical utility and those that do not, lumping all of them into the latter, unpatentable category of “general” utilities. As a result, the Training Materials paint with too broad a brush. Rigorously applied, they would render unpatentable whole categories of inventions heretofore considered to be patentable, and that have indisputably benefitted the public. For example, the PTO presumably would issue a patent on a novel and nonobvious fishing rod notwithstanding the lack of any disclosure of the particular fish it might be used to catch. The Training Materials would appear to warrant a rejection, however, on the grounds that the use of the fishing rod is applicable to the general class of devices used to catch fish.

The PTO must apply the same standard to the biotechnological arts that it applies to fields such as plastics and fishing equipment. *In re Gazave*, 379 F.2d 973, 977-78 (CCPA 1967) quoting *In re Chilowsky*, 299 F.2d 457, 461 (CCPA

1956)(“[T]he same principles should apply in determining operativeness and sufficiency of disclosure in applications relating to nuclear fission art as in other cases.”); see also *In re Alappat*, 33 F.3d 1526, 1566 (Fed. Cir. 1994)(Archer, C.J.,

concurring in part and dissenting in part)(“Discoveries and inventions in the field of digital electronics are analyzed according to the aforementioned principles [concerning patentable subject matter] as any other subject matter.”). Indeed, there are numerous classes of inventions in the biotechnological arts that satisfy the utility requirement.

Take, for example, the class of interleukins expressed in human cells of the immune system. Unlike the classes of steroids or plastic-like polypropylenes in *Kirk* and *Ziegler*, all of the members of this class have practical uses well beyond throwaway uses like snake food. All of them cause some physiological response (in cells of the immune system). All of the genes encoding them can be used for toxicology testing to generate information useful in activities such as drug development, even in cases where little is known as to how a particular interleukin works. No additional experimentation would be required, therefore, to determine whether an interleukin has a practical use. It is well-known to persons of ordinary skill in the art that there is no such thing as a useless interleukin.

Because all of the interleukins, as a class, convey practical benefit (much like the class of DNA ligases identified in the Training Materials), there is no need to provide additional information about them. A person of ordinary skill in the art need not guess whether any given interleukin conveys a practical benefit. Nor is it necessary to know how or why any given interleukin works. It is settled law that how or why any invention works is irrelevant to determining utility under 35 U.S.C. § 101: “[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works.” *In re Cortwright*, 165 F.3d 1353, 1359 (Fed. Cir. 1999)(quoting *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989). *See also Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570 (Fed. Cir. 1983)(“[I]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests.”).

Another example of a class that by itself conveys practical benefits is the G protein-coupled receptors (“GPCRs”). GPCRs are well-known as intracellular signaling mediators with diverse functions critical to complex organisms. They perform these functions by binding to and interacting with specific ligands. They are targets of many current drug treatments, including anti-depressants, anti-histamines, blood pressure regulators, and opiates.

Newly-identified GPCRs are used intensively in the real-world, even in cases where neither the specific ligand that binds to the GPCR or the precise biological function of the GPCR is known. Newly identified GPCRs are used, for example, as toxicity controls for drug candidates known to bind other GPCRs. Because a person of ordinary skill in the art would know how to use any GPCR to achieve a practical

benefit, even without any detailed or particular knowledge as to how it works, GPCRs as a class meet the utility requirement.

**II. The Training Materials fail to explain that only a “reasonable correlation” between a claimed invention and a product or method having known utility is required to demonstrate utility**

In addition to alleging a “specific” use for the claimed subject matter, a patent applicant must present proof that the claimed subject matter is in fact useful. *Brana*, 51 F.3d at 1565-66. The applicant need only prove a “substantial likelihood” of utility; certainty is not required. *Brenner*, 383 U.S. at 532.

The amount of evidence required to prove utility depends on the facts of each particular case. *In re Jolles*, 628 F.2d 1322, 1326 (CCPA 1980). “The character and amount of evidence may vary, depending on whether the alleged utility appears to accord with or to contravene established scientific principles and beliefs.” *Id.* Unless there is proof of “total incapacity,” or there is a “complete absence of data” to support the applicant’s assertion of utility, the utility requirement is met. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992); *Envirotech*, 730 F.2d at 762.

A patent applicant’s assertion of utility in the disclosure is presumed to be true and correct. *In re Cortwright*, 165 F.3d at 1356; *Brana*, 51 F.3d at 1566. If such an assertion is made, the Patent Office bears the burden in the first instance to demonstrate that a person of ordinary skill in the art would reasonably doubt that the asserted utility could be achieved. *Ids.* To do so, the PTO must provide evidence or sound scientific reasoning. *See In re Langer*, 503 F.2d 1380, 1391-92 (CCPA 1974). If and only if the Patent Office makes such a showing, the burden shifts to the applicant to provide rebuttal evidence that would convince the person of ordinary skill that there is sufficient proof of utility. *Brana*, 51 F.3d at 1566. The Revised Guidelines are in agreement with this procedure. *See Revised Guidelines at ¶¶ 3-4.*

The issue of proof often arises in the chemical and biotechnological arts when the patentee asserts a utility for a claimed chemical compound based on its homology or similarity to another compound having a known, established utility. In such cases, the applicant can demonstrate “substantial likelihood” of utility by demonstrating a

“reasonable correlation” between the utility of the known compound and the compound being claimed. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565 (Fed. Cir. 1996). Accordingly, under *Brana*, the Patent Office must accept the asserted utility unless it can show that a person of ordinary skill in the art would reasonably doubt that a “reasonable correlation” exists. If the Patent Office makes such a showing, however, the applicant may submit evidence in support of the correlation.

Though they imply that utility can indeed be established by correlation (*e.g.* p.35), the Training Materials largely ignore the “reasonable correlation” standard. Example 10 of the Training Materials addresses the topic of homology, but not the legal standard of “reasonable correlation” itself. By assuming a sufficient degree of homology to require a “well-established” utility, Example 10 assumes away any need to address the standard altogether. In fact, the degree of homology assumed -- 95% -- is sufficiently unrealistic that the example will have little bearing on the bulk of patent applications asserting utility by homology.

Example 10 also fails to illustrate how a Patent Examiner should proceed under the procedure established by *Brana* when confronted with a homology issue. Because Example 10 explicitly assumes a finding of a “well-established” utility, it does not address how the PTO should meet its *prima facie* case, or how the patentee might rebut it. It is not clear, however, that the PTO will consider lesser degrees of homologies (to useful polypeptides) to be “well-established.” In such cases, the Training Materials offer little assistance to the Patent Examiner. They fail to illustrate, for example, that the Patent Office bears the initial burden to prove that one of ordinary skill in the art would have reason to doubt the existence of a “reasonable correlation” between compounds that are claimed and those having some degree of homology with them. They also fail to illustrate many of the factors that can be relevant to determining whether a “reasonable correlation” exists.

By ignoring the “reasonable correlation” requirement and failing to illustrate the procedure established by *Brana*, Example 10 offers little guidance to Patent Examiners confronted with lesser degrees of homology. If, as we suspect, there are numerous patent applications asserting such lesser degrees of homology, and the factual circumstances surrounding the assertions differ from case to case, the potential for error may be significant.

**III. Materials to be used for research have a “substantial utility” unless further research would be required to determine a practical utility.**

In addition to conferring a specific benefit on the public, the benefit must also be “substantial”. *Brenner*, 383 U.S. at 534. A “substantial” utility is a practical, “real-world” utility. *Nelson v. Bowler*, 626 F.2d 853, 856 (CCPA 1980).

An asserted utility for a compound that merely invites further research to determine a practical utility is not substantial. In *Brenner*, for example, the U.S. Supreme Court held that a process for making a compound does not confer substantial benefit where the only known use of the compound was to be the object of further research. *Id.* at 535. Similarly, in *In re Kirk*, the CCPA held that compound would not confer substantial benefit on the public merely because it might be used to synthesize some other, unknown compound that would confer substantial benefit. *Kirk*, 376 F.2d at 945.

The Teaching Materials for the most part comport with this law, but may be subject to misapplication. They state:

Materials to be used for research, or methods of using those materials for research, raise issues of whether the utilities require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use.

To the extent it is possible to read this statement such that mere usefulness as a research tool is not a substantial utility, it states too much. The record is replete with examples of useful research tools, e.g., spectrophotometers. A material whose only use is as a tool in research may indeed be patentable. *Brenner* and *Kirk* exclude only those research purposes where the material itself is the subject of research. If *Brenner* and *Kirk* had held otherwise, any chemical material would, by virtue of its existence, be useful. Nowhere do those cases state or imply, however, that a material cannot be patentable if has some other beneficial use in research.

There are additional statements in the Training Materials that may similarly be subject to misapplication. The Training Materials state, for example, that substantial utilities do not include “Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.” Use of the term “such as” might imply to a Patent Examiner that there are “basic research” uses that have nothing to do with the properties of the material itself or its mechanisms of action. On the basis of this statement a Patent Examiner conceivably could reject a perfectly valid research utility, particularly where the material that is the subject of the

application could be used as a tool for research on subjects other than the material itself.



**IV. Objective evidence of specific benefit to the public, such as commercial success, is relevant to the determination of whether utility exists**

The Revised Guidelines state that a Patent Examiner should not reject an application for lack of utility if the asserted utility “would be considered specific, substantial, and credible by a person of ordinary skill in the art **in view of all of the evidence of record.**” Revised Guidelines at ¶ 4 (emphasis added). The Guidelines do not discuss, however, the kinds of evidence that an Examiner may consider to address the utility requirement.

There is in fact no restriction on the kinds of evidence a Patent Examiner may consider in determining whether a “real-world” utility exists. Indeed, “real-world” evidence, such as evidence showing actual use or commercial success of the invention, can demonstrate conclusive proof of utility. *Raytheon v. Roper*, 220 USPQ2d 592 (Fed. Cir. 1983); *Nestle v. Eugene*, 55 F.2d 854, 856 (6th Cir. 1932).

The Training Materials not only ignore the relevance of evidence of commercial success, they effectively negate it. They state, for example, that credible utilities for nucleic acids do not include “probes, chromosome markers, or forensic or diagnostic markers.” Training Materials at 5. Contrary to the Training Materials’ characterization of these types of uses as not being “credible” utilities, markets for each of them exist. There could be no better proof of their utilities. It stands to reason that patent applicants should be permitted to introduce evidence of commercial success or its likelihood.

**V. The Training Materials Can Be Modified To State the Appropriate Legal Standard for Specific Utility**

Incyte believes the following modifications of the Training Materials would address its concerns.

1. There is no legal requirement that utility be specific or unique to the claimed invention. Thus, the Training Materials should be revised to explain that specific utility is demonstrated by a practical use that confers a specific benefit. A utility that is specific to the subject matter claimed is one which a person of ordinary skill in the art would understand how to use the claimed subject matter to achieve a specific benefit. For example, a claim to a steroid whose use is disclosed simply as “having high biological activity” would not be considered specific in the absence of a

disclosure as to how a person of ordinary skill in the art could use the steroid to achieve some specific benefit. On the other hand, a claim to an anti-tumor compound structurally similar to another anti-tumor substance known to have antitumor activity against one type of cancer satisfies the utility requirement. In the latter case, the

disclosure is sufficiently specific to inform a person of ordinary skill in the art how to achieve a specific benefit from the invention.

Utilities can be directed to broad classes, without more, so long as the broad class does not include a sufficiently large subset of useless members that a person of ordinary skill in the art would have to do further experimentation or need additional information to determine whether some member of the class achieves a practical benefit. Broad classes that do not have a subset of useless members and are, therefore, sufficiently specific include, for example, plastics, interleukins, DNA ligases, and G protein-coupled receptors. Broad classes that have a sufficiently large subset of useless members that a person of ordinary skill in the art would have to perform further experimentation to determine whether any given member is useful and are, on the other hand, not sufficiently specific, include synthetic (i.e., non-naturally occurring) steroids and polypropylenes.

If the broad class does include a sufficiently large subset of useless members, the applicant can demonstrate utility nonetheless by establishing a “reasonable correlation” with another member of the class whose practical utility has been established or is well-known. See *infra*.

2. Revise or supplement Example 10 to address the “reasonable correlation” requirement when sequence homology is at issue. Example 10 should be rewritten or supplemented to illustrate situations in which the degree of homology is significantly less than 95%; for example, 40%. The Example should state that the asserted utility (that of a DNA ligase) is specific; accordingly, the Patent Office bears the burden of showing that 40% homology would not reasonably correlate with DNA ligase activity. The applicant need not provide evidence to the contrary unless and until the Patent Office makes such a showing.

The Example also should explain that there are additional factors that are relevant to the determination of “reasonable correlation” in addition to overall sequence homology. The degree of homology in some regions of the DNA fragment may bear on the correlation more than others. For example, an open reading frame showing only 10% overall homology with another one coding for a protein of known utility may nonetheless be sufficient to demonstrate a “reasonable correlation” if there is a much higher degree of homology in the portion of the DNA sequences known to code for the active site or other motif of the protein. Conversely, two open reading frames demonstrating a relatively high degree of overall homology may, in some cases, not be reasonably correlated with each other. The Example should be modified to address these kinds of problems.

3. Revise or supplement the definition of “substantial utility” to make explicit that research related utilities for materials ordinarily are substantial unless the subject of the

research is the material itself. The Examples could be supplemented to further clarify application of the substantiality requirement. If, for example, the full-length DNA of Example 10 were used as a probe for the purpose of determining the effect of a toxin on gene expression, it would have “substantial utility” because neither the probe itself nor its mechanism of action is the subject of the research. The DNA fragment is, in that case, a tool useful for performing research for an independent purpose having specific, practical benefit.

4. Include in the Examples, where relevant, an analysis of objective evidence of utility, such as commercial success. None of the examples includes facts relating to commercial success or any analysis of such facts. These could be included in the examples. Example 10, which relates to full-length (open reading frame) DNA sequences, could be supplemented or amended to include such evidence. It could include, for example, an assertion of utility as a chromosome marker. Since a market for chromosome markers exists, any evidence that the patent applicant has sold or could sell the subject DNA sequence should constitute conclusive proof of utility.

## **VI. Summary**

It is these concerns regarding the Training Materials guidance to the Examining Corps for implementing the Revised Utility Examination Guidelines that Incyte would like to bring to the attention of the PTO, and we ask that they be addressed before the Guidelines and Training Materials are finalized. Incyte is particularly concerned that in implementing the broad policy objectives of the PTO, the examiners may be over-interpreting the meaning of the term “specificity” found in *Brenner v. Manson*, and have lost sight of the underlying purpose of the utility requirement – that is, to determine whether one of ordinary skill in the art concretely knows how to use the invention in a real world context.



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Incyte would be very grateful if we were allowed to have our full comments entered in the record. The PTO's continuing efforts to establish appropriate guidelines for examination of patent applications are greatly appreciated by the entire industry, Incyte included, and we welcome the opportunity to participate in this process.

Sincerely yours,

Lee Bendekgey  
Executive Vice President, General Counsel